Quality, Quo Vadis?

Research Quality Association
Annual conference
The Grand Hotel, Brighton
12-14 November 2014
Dear Delegate,

On behalf of the 2014 Conference Programme Committee, I would like to welcome you to the RQA 2014 Annual Conference in Brighton with the theme *Quality, Quo vadis?*

Vibrant, colourful, and fun, Brighton offers the energy of the city and freedom of the sea. From the stunning heritage of the Royal Pavilion, Regency architecture and Victorian aquariums to the seaside fun of Brighton Pier, the Brighton Wheel and the famous pebble beach, Brighton offers something for every walk of life. Brighton is famous for shopping with the lifestyle shops of The Lanes to the unique shops of Hove; the retro chic of the North Laine to the big-name stores of Churchill Square and Brighton Marina, shopping in Brighton really is retail paradise.

As the title says, this conference is about looking forward and the Programme Committee have enjoyed planning and implementing a programme that fits this brief. We hope that the variety of topics covered will provide for an interesting, instructive, interactive and inspiring conference and are very grateful to all the speakers who have risen to the challenge of delivering this theme.

Your feedback on the conference is vital for future events and to continually improve them and I would encourage you to complete the delegate feedback form.

Should you have any questions, problems or concerns whilst at the conference please contact myself, a member of the RQA Conference Team or any member of the Programme Committee, who will assist you in any way they can.

Wishing you an enjoyable and informative conference.

Nichola Stevens  
*Conference Programme Chair*
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### Speakers abstracts, biographies and presentations

**Wednesday 12 November**

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Programme

Wednesday
12 November 2014

Session 1: Quality, Quo vadis?
Chair: Louise Handy, RQA Chair
09.20 Opening address
Louise Handy, RQA Chair
09.30 Great success but where’s the assurance?
An overview of a quality improvement initiative in a research environment
Alexander Prisco, Defence Science and Technology Laboratory
10.30 Refreshment break

Session 2: Quality, Quo vadis?
Chair: Yasser Farooq, Dstl
11.00 The future of QA
Marcus Benton, Consultant
11.45 Smart risk/risk management decision making
Roger Chapman, Chapman QA Ltd
12.30 Lunch

Session 3: Quality, Quo vadis?
Chair: Allison Jack, GlaxoSmithKline
13.30 Pro-active QA using Quality by Design principles – A new journey
Nicky Dodsworth, Premier Research
14.15 Pro-active quality – Are we ready for it?
Lena Vågberg, AstraZeneca
15.00 Refreshment break

Session 4: Ipsum Influxum
Chair: Rhona McAteer, TMQA
15.30 Cloud computing – panacea or poison pill?
Keith Williams, Formpipe
16.15 Social media and pharma: What can we do?
Paul Woods, Paul Woods Compliance Ltd
17.00 RQA AGM
17.45 Meet the delegates drinks reception

Thursday
13 November 2014

Stream A

Good Clinical Practice
Session 1: Per aspera ad astra
Chair: Angelika Tillmann, Theorem Clinical Research
09.00 Electronic working – MHRA GCP inspection findings
Kathleen Meely, MHRA
09.45 Protocol design and development: Integration of Risk Assessment and Categorisation Tool (RACT) to improve the quality of clinical trials
Sabine Glibert, BMS
10.30 Refreshment break

Session 2: Per aspera ad astra
Chair: Angelika Tillmann, Theorem Clinical Research
11.00 Lean Six Sigma and its applications in clinical research
Pramod Wable, Daiichi Sankyo Development Ltd, UK
11.45 Quality Risk Management and risk based auditing
Robrecht Tistaert, PPD
12.30 Lunch

Session 3: Per aspera ad astra
Chair: Angelika Tillmann, Theorem Clinical Research
13.30 Quality partnerships and oversight in clinical trials
Nicky Dodsworth, Premier Research
14.15 Evolving role of the clinical quality professional
Simon Molloy, Gilead Sciences International Limited
15.00 Refreshment break

Session 4: GCP QA clinic
Chair: Chris Shepherd, GlaxoSmithKline
15.30 GCP QA clinic
19.00 Drinks reception
19.30 Gala dinner
Stream B

Good Laboratory Practice

Session 1: GLP: A changing environment
Chair: Vanessa Grant, Huntingdon Life Sciences
09.00 Case Study: Failures of data integrity and resultant prosecution
Andrew Gray, MHRA
09.45 GLP principles in ATMPs (Advanced Therapy Medicinal Products): A new challenge
Patrizia Cristofori, GlaxoSmithKline
10.30 Refreshment break

Session 2: The blurring GLP boundaries
Chair: Paul Davidson, Headway Quality Evolution
11.00 Blurring the boundaries
Lee Monk, UCB
11.20 GLP Requirements in medical device submissions
Alan Dench, Clinical Compliance Services
11.45 Why is there no little ‘c’ in GLP?
Ian Kennedy, Covance
12.05 GCLP: A clinical perspective
Hilary Tinsley, Covance
12.30 Lunch

Session 3: Embracing the challenges
Chair: Jane Elliston, Battelle UK Ltd
13.30 The challenges of operator exposure studies
Sven Buckingham, Buckingham QA Consultancy Ltd
14.15 Skills for the next generation of auditors
Andrew Waddell, TMQA
15.00 Refreshment break

Session 4: GLP QA clinic
Chair: Paul Davidson, Headway Quality Evolution
15.30 GLP QA clinic
19.00 Drinks reception
19.30 Gala dinner

Stream C

Good Pharmacovigilance Practice

Session 1: The journey begins with me (us)
Chair: Ron Ward, Support in Pharmacovigilance Ltd
09.00 QA and the PV department: A true collaboration
Laura Trower, Allergan Ltd
09.45 How does drug safety/PV see QA
Sarah Hall, Takeda UK Ltd
10.30 Refreshment break

Session 2: The journey begins with me (us)
Chair: Ron Ward, Support in Pharmacovigilance Ltd
11.00 A regulator’s perspective on assessing risk in the PV system and the PV quality system
Kiernan Trevett, MHRA
11.45 Value added auditing
Ana Maria Aguirre Arteta, Novartis Pharma AG
12.30 Lunch

Session 3: Marketing partner workshop
Chair: Allison Jack, GlaxoSmithKline
13.30 Marketing partner workshop
Ana Maria Aguirre Arteta, Novartis Pharma AG
15.00 Refreshment break

Session 4: All things change
Chair: Allison Jack, GlaxoSmithKline
15.30 The new European Cosmeceuticals requirements – challenges of performing vigilance audits [from the perspective of a Pharmacovigilance auditor]
Lindsay Watt, GlaxoSmithKline
16.00 GPVP QA clinic
Allison Jack, GlaxoSmithKline
19.00 Drinks reception
19.30 Gala dinner
Thursday
13 November 2014

Stream D
Good Manufacturing Practice

Session 1: Novum et vetus medicinae
Chair: Matilda Street
09.00  GMP and the QP – where have we been and how did we get here?
  Sue Mann, Sue Mann Consultancy Ltd
09.45  Cell therapy regulation and clinical development
  Jacqueline Barry, Cell Therapy Catapult
10.30  Refreshment break

Session 2: Novitas
Chair: Gordon MacDonald, Thermo Fisher
11.00  Selection of biological raw materials for use in the manufacture of Advanced Therapy Medicinal Products
  Patrick Ginty, Cell Therapy Catapult
11.45  MHRA Support for innovation
  Ian Rees, MHRA
12.30  Lunch

Session 3: Et ipsum compositum ex genere
Chair: Julian Reeves, Cogent QA Limited
13.30  Differences in regulatory pathways for combination products and the risk impact in post market surveillance
  Henny Koch, QIMP Management Systems Ltd
13.50  Drug device combinations – What the QP does and does not need to know and when!
  Ulrike Feurstein, AbbVie Deutschland GmbH & Co. KG
14.15  Generic quality
  Roy Baxendale, Sandoz International GmbH
15.00  Refreshment break

Session 4: GMP QA clinic and workshop
Chair: Gordon MacDonald, Thermo Fisher and Rhona McAteer, TMQA
15.30  GMP QA clinic
16.15  Drug/device products – a secret combination – workshop
  Peer Schmidt, AbbVie Deutschland GmbH & Co. KG
19.00  Drinks reception
19.30  Gala dinner

Stream E
Medical Devices

Session 1: Is it a medical device – Quid deinde?
Chair: Alan Dench, Clinical Compliance Services
09.00  The medical devices in healthcare
  Fraser Smith, PPD
09.45  Management review: Obligations, benefits and expectations
  Henny Koch, QIMP Management Systems Ltd
10.30  Refreshment break

Session 2: Is it a medical device – Quid deinde?
Chair: Fraser Smith, PPD
11.00  The proposals for the medical device regulations
  Kath Clarke, Namsa Medvance
11.45  Investigator initiated medical device investigations – points and considerations
  Yvonne Enever, PHARMexcel Ltd
12.30  Lunch

Session 3: Is it a medical device – Quid deinde?
Chair: Alan Dench, Clinical Compliance Services
13.30  Medical devices regulation and the joint action programme including unannounced audits
  Neil Adams, BSI Group
14.15  Medical Device Regulation – quid futurum tenet?
  Graeme Tunbridge, MHRA
15.00  Refreshment break

Session 4: Medical devices QA clinic
Chair: Alan Dench, Clinical Compliance Services
15.30  Medical devices QA clinic
19.00  Drinks reception
19.30  Gala dinner
Programme

Stream F

IS/IT

Session 1: Reaching for the cloud
Chair: Matthew Davies, BIOVIA
09.00 Contracting in the cloud
Andy Tyrrell, Covance
09.45 Does the clouded vision obscure the view of data privacy?
Trev Simmons, ZigZag Associates Ltd
10.30 Refreshment break

Session 2: Reaching for the cloud
Chair: Matthew Davies, BIOVIA
11.00 The cloud, infrastructure, compliance and security
Keith Williams, Formpipe
11.45 How do cloud systems fit in an integrated laboratory environment
Tony Davies, AkzoNobel
12.30 Lunch

Session 3: Software in the regulated environment
Chair: Matthew Davies, BIOVIA
13.30 Agile software development in life sciences
Donal O’Brien and Ryan O’Sullivan, QUMAS
14.15 Achieving the business and regulatory benefits of Quality by Design (QbD) using an operations intelligence solution
Justin Neway, Accelrys Ltd
15.00 Refreshment break

Session 4: IS/IT QA clinic
Chair: Matthew Davies, BIOVIA
15.30 IS/IT QA clinic
19.00 Drinks reception
19.30 Gala dinner

Stream G

Outreach

Session 1: Qualitas potential nostra
Chair: Kerry Bunyan, Clintec International
09.45 Promoting compliance in the non-regulated laboratory
Shirley Hallam, Hallam Pharma Consulting
10.30 Refreshment break

Session 2: Qualitas potential nostra
Chair: Kerry Bunyan, Clintec International
11.00 Implementing a Quality Management System (QMS) in a non-commercial organisation
Melanie Boulter, Nottingham University Hospitals NHS Trust
11.45 Update from the Health Research Authority (HRA)
Janet Messer, HRA
12.30 Lunch

Session 3: Outreach QA clinic
Chair: David Butler, new RQA Chair
13.30 Outreach QA clinic
15.00 Refreshment break

Animal health

Session 4: Automation and IT in Animal Health studies
Chair: Iain McPhee, Novartis
15.30 Auditing animal health electronic data capture (EDC) studies
Janice Sarasola, Ondax Scientific
16.15 Animal Health QA clinic
19.00 Drinks reception
19.30 Gala dinner
Programme

Friday
14 November 2014

Session 1: What’s the future for the industry?
Chair: David Butler, LGC
09.30 Commercial strategy driving the Life Sciences vision
   Chris Evans, Gael Ltd
10.15 Refreshment break

Session 2: What’s the future for the industry?
Chair: David Butler, New RQA chair
11.00 Tomorrow’s health – a better and safer world
   Judith Hann, ex. presenter
   “Tomorrow’s World” – Government advisor
11.45 JSQA Update
   Teiki Iwaoka, JSQA
12.20 Closing address
   David Butler, new RQA Chair
12.30 End of conference
Faculty

Neil Adams  
BSI Group

Ana Maria Aguirre Arteta  
Novartis Pharma AG

Jacqueline Barry  
Cell Therapy Catapult

Roy Baxendale  
Sandoz International GmbH

Marcus Benton  
Consultant

Melanie Boulter  
Nottingham University Hospitals NHS Trust

Sven Buckingham  
Buckingham QA Consultancy Ltd

Kerry Bunyan  
Clintec International

David Butler  
LGC Ltd

Roger Chapman  
Chapman QA Ltd

Kath Clarke  
Namsa Medvance

Rosemarie Corrigan  
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Matthew Davies  
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Tony Davies  
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Nicky Dodsworth  
Premier Research

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Yvanne Enever  
PHARMexcel Ltd

Chris Evans  
Gael Ltd

Yasser Farooq  
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Patrick Ginty  
Cell Therapy Catapult

Sabine Gilbert  
BMS

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Huntingdon Life Sciences

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Judith Hann  
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JSQA

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GlaxoSmithKline

Ian Kennedy  
Covance

Henny Koch  
QIMP Management Systems Ltd

Gordon MacDonald  
Thermo Fisher

Sue Mann  
Sue Mann Consultancy Ltd

Rhona McAteer  
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Iain McPhee  
Novartis Pharma AG

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MHRA

Janet Messer  
Health Research Authority

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Gilead Sciences International Limited

Lee Monk  
UCB

Justin Neway  
Accelrys Ltd

Donal O’Brien  
Qumas

Ryan O’Sullivan  
Qumas

Alexander Prisco  
Defence Science and Technology Laboratory

Ian Rees  
MHRA

Julian Reeves  
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Chris Shepherd  
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PPD

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Matilda Street  
Theorem Clinical Research

Hilary Tinsley  
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Kiernan Trevett  
MHRA

Laura Trower  
Allergan Ltd

Graeme Tunbridge  
MHRA

Andy Tyrrell  
Covance

Lena Vågberg  
AstraZeneca

Pramod Wable  
Daiichi Sankyo Development Ltd, UK

Andrew Waddell  
TMQA

Ron Ward  
Support in Pharmacovigilance Ltd

Lindsay Watt  
GlaxoSmithKline

Keith Williams  
Formpipe

Paul Woods  
Paul Woods Compliance Ltd
Acknowledgements

Acknowledgements from RQA

RQA would like to thank all the members of the 2014 Conference Programme Committee for their hard work, commitment and valuable time which they have given in order to produce such an informative, interactive and challenging programme with the theme Quality, Quo vadis?

Particular thanks go to Nichola Stevens, Programme Committee Chair.

Acknowledgements from the Programme Committee chair

I would like to offer my personal thanks to all members of the Programme Committee, who have worked extremely hard since the first ‘brainstorming’ meeting in November 2013. I hope you will agree that they have produced a very interesting, informative and thought provoking programme focused on the needs of the RQA membership. This is by no means an easy task with all of them having ‘day jobs’ along with many other responsibilities.

Thanks are also due to the RQA office staff for their support ensuring that all milestones along the way were achieved.

2014 Conference Programme Committee members

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<tr>
<td>Nichola Stevens</td>
<td>Programme Chair</td>
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<tr>
<td>Kerry Bunyon</td>
<td>Deputy Programme Chair &amp; Outreach Representative</td>
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<tr>
<td>Colin Wilsher</td>
<td>RQA Board Representative</td>
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<tr>
<td>Angelika Tillmann</td>
<td>Good Clinical Practice</td>
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<td>Rosemarie Corrigan</td>
<td>Good Clinical Practice</td>
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<td>Jane Elliston</td>
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<td>Paul Davidson</td>
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<td>Iain McPhee</td>
<td>Animal Health</td>
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<td>Matthew Davies</td>
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<tr>
<td>Yasser Farooq</td>
<td>Education &amp; Training</td>
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<td>Alan Dench</td>
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Sponsorship

Thanks go to the following sponsors:

- Delegate Bag: BIOVIA
- Delegate Handbook: BIOVIA
- Meet the Delegates: Rescop Ltd
- Pre-dinner Drinks Reception: BIOVIA

RQA Conference staff

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<tr>
<td>Association Manager</td>
<td>Anthony Wilkinson</td>
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<td>Staff</td>
<td>Jane Moulster</td>
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Exhibitors floor plan

A big thank you to all the exhibitors at the conference, your support is greatly appreciated.

See the following pages for details on this year’s exhibitors.

Stand 1  Next Docs
Stand 2  TMQA
Stand 3  Hays Life Sciences
Stand 4  MasterControl Global Ltd
Stand 5  Quality Context
Stand 6  Formpipe
Stand 7  ZigZag Associates Ltd
Stand 8  The CQA Company
Stand 9  Barrington James
Stand 10  ADAMAS Consulting Limited

Stand 11  Sparta Systems
Stand 12  Quology Ltd
Stand 13  Phlexglobal Ltd
Stand 14  Qumas Ltd
Stand 15  JSQA
Stand 16  RQA

17 Consultant’s table
Rescop Ltd
Falcon Consulting Group
Advancing the Science of Compliance

Today, pharma – and the clinical trials they manage – are under tremendous pressure. Every day. Every dollar. Every resource. Every process counts. Meaning that taking every opportunity to add speed, efficiency and cost savings is essential. Or avoid delays, misfiled and missing documents, and quality issues.

NextDocs is the leader in compliance innovation. Helping our clients bring life-enhancing therapies to market faster, safer and more efficiently. We are advancing compliance through INNOVATION: building the PRIME compliance solution on the #1 Collaboration Platform for the Enterprise. Open. End-to-end. Robust. Through EXPERIENCE: forward-looking experts in compliance process and workflows who have supported thousands of studies. And PERFORMANCE: a total focus on measurable client success. Speed. Lower audit risk. Lower costs. All backed by real-time tracking and reporting, including performance metrics.

NextDocs provides an innovative enterprise content management system including eTMF, SOP management and quality management systems. These solutions enable highly regulated industries to achieve compliance with the EMEA and other regulatory agencies. NextDocs solutions are 100% browser-based and can be deployed on premise or in the cloud.

NextDocs is the partner you need to help you speed your cycle of innovation.
TMQA (Tower Mains Quality Assurance) is a specialist Research Quality Assurance organisation providing audit, training and consultancy support across all the “Good Practice” standards including preparation for regulatory authority inspections.

TMQA’s expertise covers the full spectrum of “GxPs” including Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Pharmacovigilance Practice (GVP), Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). Additionally we have experience of related ISO standards including ISO 9001, ISO 15189, ISO 13485, ISO 14155 and ISO 17025.

Established in 2001 and headed up by international QA expert, Dr Andrew Waddell, TMQA has an unrivalled reputation for its flexibility and professionalism. We have world-wide audit experience and our European presence has been enhanced by the opening of TMQA’s Central Europe office earlier this year.

All our services are delivered by TMQA’s own staff and we are not dependent on the availability of contractors. This enables us to offer scheduling flexibility and ensures we maintain full control of service standards. Working with TMQA is a transparent process and our fixed fee pricing structure means no surprises for your budget. The content of audits and the reporting mechanisms are agreed and documented in advance to ensure you know exactly what we will be doing on your behalf.

Our portfolio of services includes:
- Audits for all “GxPs” (GCP, GLP, GMP, GVP, GDP)
- Regulatory Documentation Audits
- Inspection preparation including mock inspections and interview training
- Clinical Trial Manufacturing Support
- Development of Quality Management Systems
- Non-regulated Research support
- Training for all GxPs.

The TMQA Team are delighted to be involved in several elements of this year’s RQA Annual Conference. As well as exhibiting at stand 2 during the conference, TMQA’s Managing Director Dr Andrew Waddell, will be presenting on “Skills for the next generation of GLP auditors” during session 3 of the GLP stream. Rhona McAteer, our GMP subject matter expert, will be chairing session 4 on day one and co-chairing session 4 of the GMP stream. We will also have strong representation from our GCP Team with Karen Martin, Katarina Eghan and Charlotte Bishop all attending.

To find out more about TMQA please speak to one of the team on stand 2 or visit www.tmqa.co.uk

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Quality Assurance and Validation – Hays Life Sciences

Hays Life Sciences has a specified QA function, which specialises in Quality Assurance recruitment across all GXP’s within the UK and Ireland. Offering permanent and interim solutions, Hays Life Sciences have successfully recruited junior to senior level QA professionals.

Hays Life Sciences has a membership within the RQA and work in partnership with the RQA when arranging certain seminars and events.

Quality Assurance Focus Areas

• GCP Quality Assurance
• GMP Quality Assurance including Qualified Persons (QP’s)
• GDP Quality Assurance including Responsible Persons (RP’s)
• PVG Quality Assurance
• GXP Quality Assurance
• CSV Quality Assurance
• Validation

Quality Assurance Solutions

• Permanent Contingency
• Contract and Temp Contingency
• Executive Search / Retained Search
• Recruitment Process Outsource – Mass Permanent Recruitment
• Master Service Provider – Mass Contract Recruitment
• Digital Solutions

Example of recent permanent and contract hires include

• Senior Inspection Readiness Associate – (GCP) – Global CRO
• Quality Assurance Manager (GCP) – Global Japanese Pharmaceutical Company
• Associate Director, Quality Assurance (GMP) – Large Biopharmaceutical Company
• Senior QA Manager (GCP) – Global Japanese Pharmaceutical Company
• Qualified Person – Large Global Pharmaceutical Company
• Validation Manager – Speciality Pharmaceutical Company
• QA Manager (GDP) – Global Pharmaceutical Company
• CSV Contract Specialist – Global Pharmaceutical Company
• Quality Regulatory Compliance Associate Interim Specialist – Global Pharmaceutical Company
• Quality Specialist – GMP / GDP – Global Pharma
• Validation Specialist – Global Medical Device and Pharmaceutical Company

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MasterControl – Compliance Accelerated

Purchasing a quality management system (QMS) is a major investment that will affect your organisation for years to come. That’s why it is so important to choose a QMS provider who can support you beyond implementation. For more than 750 regulated companies worldwide, MasterControl is the preferred provider of QMS solutions and services that accelerate time-to-market and maintain compliance while improving efficiencies and reducing costs.

For more than 20 years, companies of all sizes and in a wide range of regulated industries – from pharmaceuticals and blood centres to medical devices and general manufacturing – have relied on us to automate, streamline and effectively manage their quality and compliance processes. MasterControl combines industry best practices with applications customised to each company’s unique needs, and we securely manage our customers’ critical information throughout the entire product lifecycle. Our software is easy to implement, easy to validate and easy to use.

MasterControl solutions include clinical management, quality management, audit management, document management/control, product lifecycle management, training management, bill of materials, supplier management and much more.

Supported by a host of services based on industry best practices, MasterControl offers an end-to-end software suite that accelerates product delivery while maintaining regulatory compliance.

Achieve higher ROI with MasterControl solutions

MasterControl software helps companies achieve a high return on investment through a number of ways, including: reducing costs related to paper-based quality management processes; increasing revenue by streamlining critical processes, improving product quality and accelerating product delivery; and reducing risk by enhancing and enforcing quality standards across the entire organisation.

Get the support you need with our global services

While our eQMS software solutions are the mainstay of our business, MasterControl also provides a wide range of comprehensive services to ensure customers maximise their software investment, including software and implementation services. Implementation support services are also available, including project management support, validation support, technical support and integration support.

Tap into our expertise with quality and compliance consulting

MasterControl offers quality and compliance consulting services tailored to the compliance, regulatory and quality needs of customers and noncustomers alike. Our consultants can provide assistance to noncustomers regardless of their eQMS solution, and our thought leaders offer workshops, conferences and coaching services related to all core quality processes, including CAPA and audit management.

For more information, visit http://uk.mastercontrol.com/ or call +44 (0) 1256 325 949 (Europe); 800 825 9117 (U.S.); or 81 (3) 5422 6665 (Asia).
Quality Context Ltd is a national provider of Quality Management Services and Analytical Services to the pharmaceutical and healthcare industries. We are a trusted provider of services to a broad range of small, large and global companies including:

- Advice on Quality Management Systems
- Bespoke training solutions
- Audit management services
- Project management
- Qualified person and responsible person services
- Full range of analytical services.

Our clients tell us they appreciate our up-to-date industry insights, impartial and practical advice and close attention to detail.

We enjoy sustained working relationships with clients who rely on our expertise, benefit from our experience and appreciate our attention to detail.

We work with our clients to improve efficiencies in key systems and processes to help reduce their business and regulatory risk whilst saving them time and money.

All of our clients benefit from our:

- Expert advice
- Dedicated support
- Cost effective solutions.

Our team would be delighted to help you identify the right solution. Please feel free to get in touch to discuss your requirements or to chat about any quality management issues you are dealing with. If we don’t feel we can help, we will point you in the direction of some of our trusted partners.

Alternatively come and chat to our Clinical Manager, Mark Graham and Marketing Executive, Becky Wilsdon at stand number 5.
Formpipe

Formpipe.GxP simplify complex process and technology environments to help Life Science organisations achieve their compliance goals. We deliver pragmatic advice and regulatory support to fulfil clients’ unique requirements in a Simply Compliant way. We achieve this through a combination of Solutions and Compliance Consultancy (Audit, Computer System Validations, Quality Systems, Remediation and Training).

Our clients’ value our knowledge, experience and skills, that guides them through their journey. The Solutions and Consulting we provide are consistently reviewed by external regulatory and internal auditors as an integral part of their quality systems. Our team is often asked to be directly involved with supporting our customers through these inspections to demonstrate GxP compliance to ‘Get Compliant’ and ‘Stay Compliant.’

Formpipe.GxP has worked with over 50 Life Science organisations as well as developing and supporting companies new to compliance. We have successfully delivered over 350 compliance based projects within the US and EU regulatory landscape and we work with 12 of the 20 leading global businesses to help them ‘Stay Compliant.’

Stand personnel

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ZigZag

Our role at ZigZag is to navigate the complex route to fulfil your quality targets. Our experienced team provides a full range of Quality Assurance (QA) services. With a completely flexible approach, we provide you with the right resource, wherever and whenever you need it.

**Services**

We provide a complete range of QA services with particular strengths in Pharmacovigilance and Good Clinical Practice. We recognise that each of our clients has individual needs. With our tailor-made services, we have a broad range of expertise to meet your requirements. So much so, it would be difficult to list everything we do. So here is a brief snapshot of our main services within GCP, GVP, GMP, GLP, CSV, GDP and PV:

- auditing, including management of audit programmes
- building PV systems for drug development and marketed products
- training
- inspection readiness and post-inspection support
- gap analysis
- quality management system development
- standard operating procedure writing and review
- corrective action and preventative action management
- in-house support
- general consultancy.

**Global reach**

Whether you require a single audit or a team to manage a global programme, we have the people, expertise and the experience to provide you with the support you need. Our global QA team has worked in over 60 countries across all major continents.

**Why choose ZigZag?**

- reliable
- flexible
- open communicators
- experienced global team

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Stand personnel

Julie Beal  
Peter Knapp  
Nick Rodopoulos  
Mark Brennan  
Trevor Simmons

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The CQA Company™

The CQA Company™ is the backbone of the international TCTC Group, originally formed as The Clinical Trial Company Ltd. in 2002. In common with all TCTC Group companies, its corporate structure facilitates optimum commercial efficiency in helping bring clients’ products to market. Its Quality Assurance function originally operated solely as an internal resource for its TCTC Group, sister companies but since 2004 has expanded to be accessible externally for clients with time and budget pressures.

The CQA Company™ maintains the Group’s quality management system, audits internal operations and external suppliers, manages documentation, ensures compliance, provides internal QA training and implements current ISO accreditation management.

Most client companies have a quality team of staff as traditionally, it has proved culturally awkward to import assistance from the outside.

The difference with The CQA Company™ is that clients are able to access a live QA function rather than a theoretical consultancy. In effect, clients “borrow” fully operational personnel with the flexibility they would expect from their own staff. The TCTC Group operates its sister company, The CRA Company™ in the same way. Staff demonstrate a comprehensive understanding as a result of experience gained working with a wide range of clients in a variety of sectors.

The CQA Company operates under the guidance of a Qualified Person (IMP) and experienced QA professionals from all areas of the pharmaceutical industry including GCP, GMP, GLP, GPvP, and GDP.

The founders of TCTC Group realised there was an opportunity in the CRO sector for a company which targeted medium size clinical trials and novel products which lacked a classical road map to the market. Large CROs prioritise studies from the big pharma companies, for good business reasons. However, this approach can sometimes disadvantage their smaller clients who are equally keen to complete their clinical trials quickly.

The company’s Directors and experienced management team offer comprehensive client-side experience to global players. This offering appeals to people unhappy with delays caused by conventional off-the-shelf approval strategies which ignore the unique nature of each product and market.

The Clinical Trial Company Limited is headquartered in Knutsford in Cheshire, UK with regional offices in Stirling, Berlin, Copenhagen, California, Montreal and Sydney, Australia. TCTC has operating divisions covering all aspects of drug development including The CRA Company™, The Regulatory Affairs Company™, The CNS Company™, The Clinical Training Company™ and The CQA Company™.
Barrington James are a global specialist recruitment consultancy working across the Healthcare sector. Our structure, with separate divisions and dedicated consultants for the markets we serve ensures a thorough, professional and intelligent approach in both permanent and interim solutions. Our tailored methodologies include contingency database search and executive search.

With offices in the USA, Europe and Singapore we have developed an unrivalled reputation and built an extensive global network, whilst delivering quality results to our clients. The markets we serve include; Clinical Research, Medics, Regulatory Affairs, Quality Assurance, Commercial, Drug Safety, HEOR, Market Access, Pricing and Reimbursement and Epidemiology.

Our specialist team of consultants, who have experience in both the pharmaceutical and recruitment industry will be available throughout the event and welcoming our existing network to our exhibition stand, along with making new connections and building relationships in person with those we have spoken with over the past year. We will also be scheduling face to face appointments that will provide you with the opportunity to discuss your specific requirements regarding recruitment solutions for your department/team if applicable, market intelligence and of course your own goals and career aspirations.
Do you need support with your Clinical Auditing requirements, or other areas of Quality Assurance?

ADAMAS provides high quality, professional quality assurance and quality management services to the healthcare industry. Our objective is to present the ‘Human Face of Auditing;’ not to find fault but to offer positive support and practical solutions to quality problems.

ADAMAS employs its own Consultants, ensuring and maintaining the highest professional standards. The ADAMAS consultancy team are highly experienced and dedicated professionals, with backgrounds ranging from national regulatory inspectors to senior managers within the Quality Assurance environment. They understand the need for quality, and are motivated to work with integrity and to the highest possible standards. The Consultants have over 300 years of cumulative experience with a wide range of language capabilities. They are considered to be standard setters for the pharma and biotech marketplace.

ADAMAS is a privately owned Clinical Quality Assurance group, established in 1997, with offices in United States, United Kingdom and India. ADAMAS provides a comprehensive range of Clinical Quality Assurance services, consultancy and training and has successfully delivered projects to over 250 clients, including most of the leading pharma and biotech companies, in over 60 countries. ADAMAS is not affiliated to any other company and does not have involvement in any aspect of clinical trials.

ADAMAS provides a full range of independent services that include:

- GCP, GVP, GLP GDP and GMP quality assurance audits,
- Clinical study and process audits
- Regulatory Mock Inspections
- Computer systems validation
- Mock Inspections
- Training
- SOP Development
- Quality Management Consultancy services, helping clients to design, develop and improve their quality processes.

Studies, service providers and systems are audited against international and national standards, including FDA 21 CFR, ICH-GCP, and the EU Directives.

Our flexibility enables us to respond quickly and efficiently to client requirements to:

- bolster existing resources
- provide skill sets that do not exist within the client organisation
- provide third party oversight to establish suitable procedures or validate existing ones.

Our clients tell us that our reports are the best in the sector, ‘I can always tell an ADAMAS report – they stand out from the rest.’ Our reports have been described as “succinct, pragmatic, successfully identifying and prioritising the key issues.”
Sparta Systems, an industry pioneer and global leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise.

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Qualogy Ltd

Qualogy was founded in 1995, as an Independent consultancy company, specialising in providing expertise to organisations that are required to implement the requirements of Good Laboratory Practice and Good Clinical Practice.

The company was founded by Tim Stiles, who has worked within the regulatory arena since the inception of FDA GLPs in 1978, including working as the Director of Quality Assurance within a large Contract Research Organisation (CRO).

Regulatory archive

Qualogy’s Contract Regulatory Archive facilities were established in 2000 under the management of a qualified regulatory Archivist. A fast growing secure archive, providing high quality archive services. The facilities are operated to the exacting standards required by the Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) Regulations.

Working with our clients, we offer a personal service with knowledge and expertise.

- Centralising your material with Qualogy could prove to be more cost effective, enabling your company to make significant savings. We can advise and liaise with clients and sites to assist in the logistics of moving material from across Europe.

We pride ourselves on having a high level of security and preventative measures in place including intruder and fire monitoring and alarms, fire suppression system, CCTV, temperature and humidity control and continuous monitoring.

With separate buildings on one site we are able to archive Investigator Site Files (ISF’s) and Trial Master Files (TMF’s) independently.

Our systems have been inspected by the UK GLP Regularity Authority (MHRA).

GCLP accreditation scheme

Tim Stiles Director of Qualogy is the co author of the Good Clinical Laboratory Practice (GCLP) Guidance document (ISBN 978-1-904610-00-7) and also operates a GCLP accreditation scheme.

The scheme is aimed at those laboratories who wish to demonstrate to sponsors of clinical trials and government agencies worldwide that their clinical laboratory operates to a standard that assures subjects rights and confidentiality as well as the reliability, quality and integrity of the work and results generated.

Training and consultancy

In addition to the accreditation scheme Qualogy runs an extensive number of Training courses for Good Clinical Laboratory Practice (GCLP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP).

Qualogy offers consultancy services to assist and ensure compliance with the regulations.

We can offer guidance and expertise in the implementation and operation with Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Clinical Laboratory Practice (GCLP).
Phlexglobal are the Trial Master File (TMF) Experts, and pioneers in the provision of innovative, flexible and technology-enabled TMF solutions and services.

Phlexglobal is a specialist provider of technology-enabled, electronic Trial Master File (eTMF) solutions and other support services to the global clinical research market. We offer a unique combination of technology, quality and services that deliver a range of flexible, targeted to the life science industry.

From our establishment in 1997, we have worked with both commercial and non-commercial organisations, Pharmaceutical/Biotech companies and full service CROs to promote the importance of excellence in clinical trial administration, with a focus on efficient management of clinical trial documentation, paper or electronic. Our work has spanned across large and small organisations globally giving us a detailed understanding of the importance of an accurate and complete Trial Master File (TMF) to enable the evaluation of a clinical trial.

Phlexglobal supports companies with predominantly paper TMFs that are looking to move to an eTMF system, by providing standardisation of filing, security of filing in dedicated TMF rooms, quality control of content, TMF consolidation and archiving to ensure regulatory compliance.

Phlexglobal is unique in that we offer both our own best of breed eTMF system, PhlexEview, and the associated business processing and quality services. This enables the production of a regulatory compliant eTMF in accordance with 21 CFR part 11. PhlexEview has been presented to Regulatory Inspectors as the primary TMF for our clients.

Taking a consultative approach, Phlexglobal is able to assess existing guidelines, processes and TMF structures and identify where process and productivity improvements can be made. We advise and assist clients in implementing changes to their TMF structures and processes where necessary. Phlexglobal can provide the expertise and operational support to ensure the successful implementation of complete TMF management outsourcing. Working with either PhlexEview or client-chosen systems and associated processes, we help to implement the most efficient TMF management processes and workflows whilst maintaining service levels for internal customers and reducing risk for the client.

Quality is an integral part of our work ethos and our quality management system ensures the appropriate policies, processes and procedures are in place to comply with relevant industry and government regulations. Training, through our dedicated department, underpins our delivery.

What our customers say about us...

“There are CROs that have the capability to do it, some do have the electronic systems, but there isn’t anybody I know who provides as good a solution as Phlexglobal.”

Senior Director in Clinical Operations, top 20 global pharma

“The fact that TMF is their core business makes them very attractive. This drove our selection of them for our remediation projects.”

TMF Owner, top 5 global pharma
QUMAS, now part of BIOVIA from Dassault Systèmes, is the leader in Regulatory, Quality and Compliance Management Solutions with more than 280 global customer deployments and two decades of experience helping companies in highly regulated industries. QUMAS is a Gold Microsoft Partner, and provides the QUMAS Compliance Platform on SharePoint, EMC Documentum, Oracle or SQL.

QUMAS Quality Management solutions provide Electronic Document Management (SOPs, QA documents), Electronic Process Management (CAPA, Deviation, Change Control and Audit) and GMP Compliance Management. QUMAS Regulatory Affairs solutions provide content and Submission Management including eCTD authoring templates, collaborative review, full integration with leading publishing solutions, scanning, and automated import of paper documents.

All QUMAS software solutions provide built-in electronic signatures and audit trail (FDA 21 CFR Part 11), role-based permissions, migration of documents from legacy systems, and controlled access to all content and processes.

For more information visit www.qumas.com or email info@qumas.com

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JSQA

About JSQA

The Japan Society of Quality Assurance (JSQA) incorporated is a non-profit organisation founded in 1992. JSQA consists of three divisions, the GLP, GCP, and GQP/QVP/GPSP divisions. Currently, we have around 1,400 members from 430 companies.

The vision and mission statements of JSQA are as follows:

Vision statement:
The Japan Society of Quality Assurance contributes to the improvement of the health and welfare of people by transmitting relevant information, developing human resources, and presenting appropriate suggestions on specialised information concerning the quality assurance of pharmaceuticals, medical devices, regenerative medical products, pesticides, and chemical substances, etc.

Mission statement:

1. To examine quality assurance relating to pharmaceuticals, medical devices, regenerative medical products, pesticides, chemical substances, etc., and present the study reports.

2. To provide opportunities for in-depth study and training necessary for the development of human resources involved in quality assurance.

3. To make proposals to the Japanese and overseas industries, academia, and regulatory authorities, from the viewpoint of quality assurance specialists, utilising trust and co-operation.

Our stand

At the JSQA stand, we are going to provide you with information on our current activities. The information on Japanese regulations and GxP is also available. Please stop by at our stand. Brochures and various kinds of goods and souvenirs will be prepared!

Please answer our questionnaire

We are planning to conduct a brief questionnaire survey during the RQA Annual Meeting. The questionnaire has been put into your delegate bag. We should be most grateful if you would cooperate with the survey. Upon completing the questionnaire, we will be glad to present you with a gift.

Stand personnel

Makiko Azuma

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RQA

RQA is an Association dedicated to informing and advancing its members, we provide status and visibility for individuals concerned with the quality of research in pharmaceuticals, agrochemicals, chemicals and medical devices. Since its beginnings in 1977, the Association has grown and developed to reflect regulatory changes, the impact of regulatory inspection and the changing structure and needs of industry. RQA's purpose is to drive quality and integrity in scientific research and development.

Vision
Driving quality and integrity in scientific research and development.

Mission
1. To develop and promote quality standards in scientific research and development.
2. To facilitate knowledge sharing and transfer through:
   - Discussion
   - Training
   - Seminars and Forums
   - Conferences
   - Publications and webcasts
   - Partnership and co-operation.
3. To liaise with regulatory agencies in the development and interpretation of regulations and guidance.

Our Constituency
Quality professionals including managers, scientists, auditors and other practitioners worldwide.
Those concerned with the quality and compliance of research and development with a particular focus upon the safety and efficacy of pharmaceuticals, biologicals, devices, agrochemicals and chemicals in man, animals and the environment.
Those working in regulated or non-regulated, commercial or non-commercial environments.
Visit the website at www.the rqa.com for information on all our products and services.
Poster 1

Problem definition through CAPA effectiveness: Across GxPs

Rebecca Noss, Noss Research Consulting LLC

Root Cause Analysis (RCA):
Is a structured problem solving process used to:
- Systematically find causes and test for logic
- Find and address core causes rather than reacting to symptoms
- Provide documented evidence and defensible investigations
- Establish causal relationships between the root cause and the defined problem
- Enable fact-based decision making

The Outcome of an effective Root Cause Analysis will support sustainable corrective and/or preventive actions and is a key component of effective process improvement.

Six (6) Steps Approach to Corrective Action Preventive Action Plan (CAPA):

1. Identify and select the problem(s).
2. Define the problem – a comprehensive and thorough definition.
3. Investigate the problem, gather objective/factual data/evidence.
4. Analyse the problem – identify the causal relationships (those things that have an impact) associated with the defined problem; identify all influences.
5. Solve the problem – choose appropriate tools to identify effective solutions that prevent recurrence and implement appropriate actions.
6. Confirm the results – observe the recommended solutions to ensure effectiveness.
   - When thinking of an effective CAPA programme using the 6-step, the focus must be on the root cause
   - Effective implementation of corrective action (immediate fix) and preventive action (prevention of recurrence) must be focused on root cause(s)
   - If not, problems will recur (systemic issue).

Poster 2

Quality in drug discovery data reporting: A mission impossible

Tom Lavrijssen, David Gallacher and Hans Molls, Janssen Research & Development division of Janssen Pharmaceutica NV.
David Malwitz and Malini Dasgupta, Janssen Research & Development, LLC

The growing number of publications on poor reproducibility of results in preclinical research is concerning and impacts more and more the way pharmaceutical companies work with their contractors and collaborators to improve reliability of externally generated data. One can think of many reasons for reproducibility issues, such as poor documentation or technical limitations of the methods used. However, more and more published cases are brought up involving biasing, fabrication or falsification of data. It goes without saying that these fraudulent cases are not only undermining the credibility of scientists, but they are also incentivising teams in the pharmaceutical industry, such as our team at Janssen Research & Development (JRD), to look for ways to minimise and detect data integrity issues in our own labs as well as in contract labs that generate data that are used in our programmes.

JRD, as a research driven pharmaceutical company, strives towards leadership in setting data quality standards within its research community. We not only aim to bring innovative molecules to the clinic, but we also want to ensure that these are supported by high quality, sound and reliable experimental evidence as well. To help in reaching this goal, our team has spearheaded a quality maintenance programme for our global discovery organisation, which is built on close partnership between discovery scientists and the QA organisation.

Retaining the vital creative spirit of our discovery organisation while requiring thorough and accurate documentation of research data is often challenging, but our team is convinced that our quality maintenance programme will help the organisation achieve its data integrity goal and contribute to the success of development decisions for many compounds in the future.
**Poster 3**

**Process Based Inspection: Strategies and a Practical approach**

Dr. Labhu. U. Sanghani and Smit J. Patel, Jai Research Foundation

As per OECD GLP, process based inspections (PBI) can be performed for studies/processes which are of a routine and repetitive nature. For e.g., a particular toxicology study carried out a few times per six months, can be ‘ROUTINE’ but a lapse of months between studies makes it ‘NON REPETITIVE.’ Conversely, processes for the analysis of a number of samples become ‘REPETITIVE’ but a novel study is not ‘ROUTINE.’ So planned as a rolling programme, PBI is appropriate only when the study type is routine and repetitive. PBI are performed independently of specific studies, but they relate to the processes of multiple studies of the same type. It is advisable to conduct PBI for particular processes once in three months. Relevant processes which are not directly involved in a study but conducted to support a study can be covered under PBI.

Standard operating process for conducting process based inspections should cover all relevant aspects viz., type of process to be audited, decision criteria for type of inspection, maximum credential time for one cycle of PBI, scheduling mechanism, performance, way of reporting, QA statement, method of verification of corrective action.

The most important tools for scheduling PBI are Master Schedule, identification of associated processes for each type of study, historical observations and risk involved in each process.

Observations during PBI should be reported to Test Facility Management and concerned SD/auditees for corrective action. For a type of study which is monitored exclusively by means of PBI, all relevant process inspections (i.e., those concurrent with, or close to, the critical phase of the concerned study) must be detailed in QA statement.

**Poster 4**

**Significance of effective QA Auditing and Reporting System in a GLP Test Facility**

Dr. Labhu. U. Sanghani and Smit J. Patel, Jai Research Foundation

Effective auditing of GLP studies and processes are essential requirements for monitoring of GLP compliance. Along with effective auditing, it is also highly important to report the audit observations in a timely and effective manner to concerned Study Directors and Test Facility Management. Jai Research Foundation’s Quality Assurance Audit Management Programme (AMP) is an in-house developed, validated database management system, compatible to Window 9x operating system. The AMP includes the scheduling of audits, audits performed and QA observations, classification of QA observations in different categories and status of corrective action for completed audits. Types of inspections/audits include study plans, critical phases, processes, raw data & reports and facilities & functions.

For Study Director: The AMP generate QA statements for individual studies with a list indicating details of audits performed including critical phase(s) covered, dates reporting to Study Director and Facility Management. The QA statement also includes the details of process based inspections, if applicable for the type of study.

For QA: The AMP provides the information which is subjected to regular trend analysis for identification of the correction pathway. JRF QA monitors the audit observations in various activities, regulatory areas and GLP aspects, in conformity with the latest GLP requirements.

For Test Facility Management: The AMP provides a daily QA audit summary report with details of audits performed, audit observations, deviations from study plan, GLP and SOP along with list of critical observations requiring immediate action.
Posters

Poster 5

Audit challenges of EDC in VICH GCP Animal Health studies

Donna Taylor, Triveritas Ltd

Electronic Data Capture (EDC) is becoming the data collection method of choice in Animal Health studies conducted to VICH GCP. One reason being the promise of a faster turnaround of the Final Study Report after data collection is complete. EDC confers many advantages in this advancing electronic world, but also numerous new challenges to be faced by the auditor.

EDC studies require more technical expertise and training beforehand and upfront planning is therefore essential. A hybrid system of electronic and paper-based data capture is usually required due to the nature of Animal Health studies, requiring flexibility of auditing procedures. There are several systems available providing different data flow set-ups and validation requirements. EDC systems capture more information due to time stamping and therefore require additional checks. Changes are seen within the scope of audits; when and what to audit. Challenges and the impact and changes to the auditor’s role are assessed.

Overall EDC studies allow greater quality oversight. However, the Animal Health Industry needs to consistently interpret and apply the same guidelines to stay on a compliant path going forward. The limited guidance available for the Animal Health Industry conducting EDC studies will be discussed and how the auditor can assure data integrity and compliance with VICH GCP.

Poster 6

A pragmatic process to help evaluate the quality of outsourced, non-GxP research projects

Sandrine Bongiovanni, Marc Mason & Steve Volsen, Novartis Pharma AG

Within todays Pharmaceutical Industry, global research networks drive the business. Innovation is no longer an “Inside Job,” and experimental programmes, which harness both internal and external expertise, are the norm. However, in order for the science to “Stand the Test of Time,” robust research process is required across the entire value chain. Within the regulated arena, Quality Assurance oversight of outsourced projects is mandatory but within non-GxP research, where no such statute exists, effective third party oversight is a matter of some concern. We describe here a pragmatic QA process developed to help address this growing business challenge. It is hoped that components of the system may be of assistance in your area of research QA.

Poster 7

How much research do routine UK labs support and to what Quality Standards do they work?

Darren Ames, St Helens and Knowsley NHS Teaching Trust

Every NHS Trust and also every sizeable Private Hospitals will have a Pathology laboratory performing diagnostic healthcare testing. They will all on occasion have a role in supporting Clinical Research interests. This can vary from one Doctor’s personal interest to assistance with Large Formal Clinical Trials.

This poster will describe the methodology and results of a comprehensive UK wide survey to be issued in the late Summer of 2014.

It is expected that the Survey will show how much research is being supported by UK routine labs. It also aims to identify what type of research is facilitated from “pure” blue sky Clinical Research and Trials to Clinical Audit. It will assess the additional demand and burden that this places on laboratories. There will be an assessment of the comparative resource supplied to labs to facilitate Research.

In addition it aims to identify any Quality Gaps. This is to cover what the MHRA expect in terms of laboratory performance for facilitating Research. It will also consider how MHRA and Good Laboratory Practice relate to ISO 15189 requirements (the accreditation standard for Pathology Laboratories).

Poster 8

Remotely conducting vendor audits

Dr Annie Chen, Consultant and Chris Pierce, ADAMAS Consulting

Description: The traditional manner of conducting vendor audits is to perform audits “on-site.” This poster will identify which remotely conducted vendor audits may be advantageous in replacing the traditional “on-site” approach, for specific types of vendor audits. This will be determined by:

• Completing a risk assessment questionnaire that is scored according to pre-set criteria; this risk assessment includes considering the different types of vendor audits and evaluating geographical, social and environmental situations; and

• Interviewing auditing consultants experienced in remote vendor audits.

Learning objectives include identifying a new approach to conducting vendor audits; evaluating cost and time management benefits of remotely conducting vendor audits; and introducing new auditing efficiencies to the industry, based on assessed risk factors.
In any industry there is a risk that the perceived value of “quality assurance” and of continual quality improvement activities decreases over time if there are no significant identified or suspected issues. In challenging economic circumstances the desire to improve efficiency will often lead to look at what activities and effort can be streamlined to effect the same outcome but with less expense; and additionally, too often “quality” is only addressed after an issue has been identified or realised. The cumulative effect of these mean that if quality is not afforded the respect, time or effort it deserves then any output is likely to suffer at a sooner or later stage. The consequence of this in terms of risk to human and environmental health and safety, or to a business in economic terms, is naturally dependant on the nature of the output.

Using poignant lessons learnt from the defence industry, this talk will explain why and how Dstl adopted a proactive approach to maintaining and improving quality against a backdrop of challenges; together with a brief introduction to the work that Dstl does.

**Alexander Prisco**

Alex has over 14 years experience within both the human and veterinary pharmaceutical industries. Alex has had a number of technical and management roles in quality control, pharmaceutical product development, and technical operations. Recently Alex has been responsible for the leadership and management of Dstl’s GXP capability and responsible for delivery of the initiative to improve quality assurance in research areas.

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**The future of QA**

**Marcus Benton, Consultant**

Where is “Quality” going?
- Obvious future trends & less obvious leaps
- What do we need to get there?
- How shall we go about it?
- Will we need auditors?

Will one size QA fit all?
- The role of the QA function
- Do our differences “make a difference” that matters.

Canvassing of several key opinion leaders
- Crystal-ball gazing from industry luminaries, as well as from those that “hide their light under a bushel.”

**Marcus Benton**

Marcus is an MBA-qualified QA Professional with extensive knowledge and 30 years GXP expertise in Quality Management Systems within the European, Asian & US pharmaceutical sectors (Research, Manufacturing & PVI). He has hosted over a dozen inspections by regulatory agencies. Marcus has been freelance for the last eight years.
Smart risk/risk management decision making

Roger Chapman, Chapman QA Ltd

‘Smart Risk’ is thankfully not yet another new buzzword or acronym in the world of ‘Risk’ – its just a sensible, pragmatic approach to risk acceptance. This presentation will look at how Risk is now reaching into the heart of National GxP compliance monitoring programmes and QA Audit programmes alike. Nothing technical, not much text-book . . . just an independent and realistic view of what’s going on in our Industry right now.

The type of risks to consider – and those you might accept – will be discussed, and some thoughts on assessing probability and impact will be shared. Practical applications of risk-based thinking will be described in terms of applying the concept to QA audit programmes, and some components necessary to enable dynamic maintenance of those programmes will be suggested.

Finally, this presentation will look at the drivers for moving to a risk-based audit programme, and consider balancing those drivers with a company’s appetite for risk in the wider sense . . . is moving to a risk-based audit programme a risk in itself?

Roger Chapman

Roger is a former Director of Quality Assurance at Huntingdon Life Sciences UK, where he worked in the Contract Research Industry for over 33 years. He is a recognised expert in the pragmatic interpretation and application of OECD GLP to the full spectrum of regulatory studies, both in the laboratory and in the field. Roger also has extensive experience of GCP in the laboratory (GCLP), GMP in the QC laboratory environment, Archives management, SOP management, project management and Computer Systems QA/validation. He is a regular conference speaker and established trainer/facilitator. A highly experienced risk-based QA audit and CAPA programme manager, Roger has led and participated in some 70 regulatory inspections.

Roger is a Fellow, and former Director, Board member and Treasurer of the Research Quality Association (RQA). He is now Director of Chapman QA Ltd, an independent GxP Consultancy based in the UK.
Pro-active QA using Quality by Design principles – A new journey

Nicky Dodsworth, Premier Research

Quality by Design (QbD) has emerged as an important concept because its approach has potential advantages to every industry stakeholder. QbD has evolved though GMP but has been more recently adapted to clinical trials with the aim of delivering a product or a service that is reproducible and consistent. According to Wikipedia – ‘quality problems relate to how quality was planned’ and ‘QbD is a successor to quality by quality control (QC) or quality after design’.

However, implementing QbD is complex and challenging. Many of the concepts, frameworks, and tools are still new to pharma. Decisions are made at various levels on the basis of knowledge founded on data, each decision will only be as good as the processes used to collect, analyse, interpret and report. As in any operational transformation, adopting QbD requires a cohesive set of technical tools, management infrastructure (such as steering groups and key performance indicators), and new mindsets and capabilities, including well delivered timely training, a knowledge base, and a high-performance operating culture. But unlike lean programmes, which pay off fairly quickly, the benefits of QbD may take three to five years to appear because it takes so long for pharma products to reach the market. These challenges are going to be of great interest to QA.

We may now understand how QbD concepts can be applied to manufacturing and running clinical trials but have we considered this impact on the QA groups and can we also apply these QbD principles to our daily activities? This presentation will look at how QbD may be applied to Quality Assurance groups with the anticipation of QA being more proactive, so we can better assist in helping our organisations improve their quality and perhaps avoid repeated errors. We take a top level view of the principles of QbD, why change is necessary and focus on the importance of quality metrics and risk assessment. The role of QA in the past is considered before taking a more detail review of QA’s new journey, from what we need to consider at the start and how this will evolve in the future.

Nicky Dodsworth

Nicky is Vice President, Global Quality Assurance for Premier Research, a Contract Research Organisation that assists biopharmaceutical and medical device companies develop their therapies and devices especially in the areas of paediatric medicine and rare diseases. She has over 20 years of experience in global clinical trials mainly in the development, maintenance and oversight of quality management systems.

As an active member of the European Forum for Good Clinical Practice (EFGCP), she was appointed Chair of the Education Working Party in 2011. Nicky runs an accredited European Medical Writers Association (EMWA) Workshop on Quality Awareness in Clinical Study Report Development. She is Co-Chair of the GCP Forum for the Institute of Clinical Research (ICR) and a member of the editorial board of the CRfocus journal. Nicky is also a member of the Research Quality Association, West & Wales Regional Forum Group which promotes information exchange at a regional level.
Quality, Quo vadis?

Pro-active quality – Are we ready for it?
Lena Vågberg, AstraZeneca

In this session I will build on the Quality by Design principles. We will look back to the journey on how quality principles have developed during the years, and where we in the different GXP areas are now. Other types of industry have implemented quality principles more into the daily operations – and there will be some examples discussed. There are barriers, principle barriers, as well as human related barriers. How can these be overcome?

The issuing of ICH Q8, 9 and 10 will help in making quality a more integrated concept, but is this going to be enough?

Examples and my future thoughts on quality, on quality assurance and how to improve the efficiency will be covered.

Lena Vågberg

Lena holds a MSc degree in Chemical Engineering from Royal Institute of Technology in Sweden, Stockholm. After having worked at a Lab CRO, leading implementation of a quality system, and implementing ISO 9001 certification at AQA Gas, Lena moved into the Pharmaceutical industry and worked in the Pharmaceutical/Analytical R&D at Pharmacia (and later Pharmacia & Upjohn) for about three years. As Fresenius Kabi was formed from a split of Nutrition business from Pharmacia & Upjohn, Lena took on the task of heading up the Global Regulatory Affairs function, which she did for four years. After spending two years, rebuilding the QA/QC function within the manufacturing unit at Fresenius Kabi, Lena joined AstraZeneca in Södertälje as VP Regulatory Affairs at the Nordic/Baltic Marketing company. In this role she gained deeper experience from Regulatory Affairs, Pharmacovigilance, GDP and Crisis Management. Currently Lena is leading the global QA function within the Science Units at AstraZeneca, and covers the areas of GCP, GVP, GLP and Research Quality as well as Good Regulatory Practices quality.

Lena is also engaged in the pharmaceutical trade association in Sweden, and currently chairing the patient safety strategic committees reporting to the LIF board.

Ipsum Influxum

Cloud computing – panacea or poison pill?
Keith Williams, Formpipe

• What is cloud computing?
• What does it offer?
• How is it constructed?
• What are the regulatory risks?
• How can we mitigate these risks?
• Once compliant, how do we keep it there?

Keith Williams

An entrepreneur, director, and business manager with UK, European and US experience. Keith brings over 25 years of Life Sciences experience, particularly in a pragmatic approach to getting computerised systems compliant and keeping them compliant. He has worked in a manufacturing, laboratory and clinical environment and has more recently focused this experience to build compliant set of configurable SharePoint products for content and document management. He has a BSc in Microbiology and an MSc (Eng) in Biochemical Engineering.
Social media and pharma: What can we do?

Paul Woods, Paul Woods Compliance Ltd

This presentation will introduce the complex jigsaw of regulations and codes that apply to pharmaceutical companies’ social media activities. The current regulatory situation applying to providing information on prescription medicines to the public will be described and the difficult question of ‘what constitutes advertising’ will be explored. Reflecting on lessons learned from the unsuccessful attempts to initiate consistent European directive controls on medicines information to patients leads to an understanding of the underlying concerns about the role of commercial interests. Taken with the limited existing guidance on the use of social media for Pharma communications the presenter will outline ‘Ten Top Tips’ which can form a practical basis for evaluating what is and isn’t acceptable for Pharma companies to do with social media.

Paul Woods

After 23 years working in international compliance roles for a large pharmaceutical company Paul became a consultant in 2011 specialising in marketing, sales and patient communications ethics and compliance. He currently works with pharmaceutical companies, industry code bodies, professional organisations and medical societies. He draws on his experience of worldwide compliance policies, promotional regulatory standards, international training initiatives and promotion ‘Nominated Signatory’ work.

Paul was a member of the committees that oversee and draft both the International and European codes of practice and led various initiatives for them. He has contributed to industry and company internet and social media compliance policies and also has a special interest in the regulation of Pharma-patient communications. Until January 2011 he was co-chair of the EFPIA Informed Patient Task Force leading the industry position on proposals to change European legislation on patient communications.

Paul qualified as a pharmacist then worked in medical information, clinical research and medical affairs roles in the pharmaceutical industry. He worked for Squibb, and then ICI/Zeneca/AstraZeneca. He has been awarded a Master of Arts degree in Medical Ethics and Law that included an ethical analysis of European law relating to information on prescription medicines for patients.
Electronic working – MHRA GCP inspection findings

Kathleen Meely, MHRA

Electronic systems that are used in clinical trials in the creation/capture of electronic clinical data may include the following:

- Electronic Case Report Forms (eCRFs) – to collect source data or transcribed data from other sources
- Electronic patient data capture devices used to collect Patient Reported Outcome (PRO) data – used to record observations, ratings scales, IMP use etc.
- Instruments supplied to investigators for recording clinical data such as biometric measures e.g. BP, ECG etc.
- Instrumentation or electronic systems to capture, generate, manipulate or store data in an environment where analysis, tests, scans etc. are performed in the support of clinical trials
- IVRS/IWRS – can be used to register patients, manage IMP and unblind subjects if required
- Electronic Health Records.

Introduction of such systems is understandable for Global/multi-centre clinical trials.

Centralised data capture systems ensure consistency and standardisation of data capture. However electronic systems present additional challenges in providing an adequate level of confidence in the data.

The basic concept of source data (electronic or otherwise) is that it permits not only reporting and analysis but also verification at various steps in the process for the purposes of confirmation, quality control, audit or inspection.

Taking into account the above, I hope to present where the GCP Inspectorate have findings due to failures in the control of electronic systems used in clinical trials.

Kathleen Meely

Kath joined the MHRA in July 2005 as a Good Clinical Practice Inspector. Since joining the inspectorate she has been promoted to Senior GCP Inspector in 2008. Whilst at the Agency she has been involved in performing a variety of National as well as EMA inspections. Kath attends the EMA GCP IWG meetings and has sat on sub-group with respect to GCP Findings and the benefit-risk balance. Kath studied Pharmacology at Liverpool University and has over 13 years of experience in clinical research, within the pharmaceutical industry holding positions in monitoring and Project Management before joining the MHRA.
Protocol design and development: Integration of Risk Assessment and Categorisation Tool (RACT) to improve the quality of clinical trials

Sabine Glibert, BMS

The implementation of the quality by design (QbD) and risk based approach in the clinical trial environment is a positive adaptation of the health Authorities and Industries to the increased complexity of the studies leading to difficult and cost effective operational implementation and making the “standard” quality management difficult to implement.

During this presentation, you will learn how to use the QbD philosophy and the risk based approach in clinical trials. Examples will be given to illustrate how the Risk Assessment and Categorization Tool (RACT) is helping study teams at BMS to consistently evaluate risk, define primary end points and critical processes. We will also discuss how the Quality Assurance is adapting the auditing approach to this risk-based approach.

Sabine Glibert

With bio-engineer university background from the Belgian Catholic University of Louvain-la-Neuve, Sabine joined the Pharma industry in 1998 as a CRA in early clinical phase at Eli Lilly and Company where she stayed for almost 10 years in various Operations and Quality functions.

In 2007, with three partners, she created Aepodia, a small CRO dedicated to early clinical trials, this has been a unique opportunity to build a entire quality system.

In 2011, she joined ICON as Director Quality Compliance Clinical Operations to develop, and manage the global quality associate group.

Since May 2013, she is the European Regional Quality Operations Lead at Bristol Myers Squibb, managing European Quality Managers. She is also the Global CRO quality liaison partner to ensure adequate quality Oversight of BMS outsourced activities.

These roles have been each time a unique opportunity to apply two of my key principles: Keep it Simple & Quality embedded in scientific innovation.
Lean Six Sigma and its applications in clinical research

Pramod Wable, Daiichi Sankyo Development Ltd, UK

Lean Six Sigma is a process improvement programme that combines two ideas: Lean – a collection of techniques for reducing the time needed to provide processes, products or services, and Six Sigma – a collection of techniques for improving process, quality of products and services, substantially contributing to increased customer satisfaction. By combining the two, Lean Six Sigma is a proven business management strategy that helps organisations to operate more efficiently. According to many business analysts and quality improvement experts, Lean Six Sigma is the most popular business performance methodology in the history of corporate development.

In exponentially growing clinical research industry, turnaround time, data accuracy and quality are critical. The cost of a one-day delay in a drug being brought to the market can be in millions. It is essential; therefore, that all stakeholders in clinical trials take steps forward to improve efficiency, accuracy and quality of the clinical research. Doing so requires that organisations look beyond symptoms to uncover the true causes of errors in quality and delays. Additionally, new processes must be implemented in such a way as to become part of institutional culture, ensuring the consistent, on-going success of future efforts.

This presentation focuses on use of combined techniques such as Six Sigma and Lean together in clinical research to evolve stable and robust Process, Products, Services and Quality Management Systems.

Pramod Wable

Pramod is Manager, QA GCP/GLP at Daiichi Sankyo Development in Gerrards Cross, UK. He has been working in clinical quality assurance for past eight years. Previous, he worked at ICON Clinical Research UK as a Senior CQA Auditor. This has involved working with global clinical QA team to develop a harmonised audit process and procedures to support global clinical trials. Prior to this, Pramod has also worked for INC Research, UK (legacy Kendle International Inc) as a Quality Assurance Auditor where he was responsible for auditing, QA project support and assuring compliance with regulations and Good Clinical Practice.

Pramod holds a Bachelor degree of Pharmacy from University of Pune, India and a Masters in Pharmaceutical Science from Kingston University, UK. Pramod has published articles within index journals and conferences on different subjects relevant to GCP.

Pramod is a trained Six Sigma Black Belt and has taken initiatives in improving and developing robust, sustainable processes and quality management systems in GXP.
Quality Risk Management and risk based auditing

Robrecht Tistaert, PPD

Setting the scene by describing briefly current understanding of Quality Risk Management and agreeing on a few keywords.

Quality Risk Management (QRM) within Clinical Research has resulted in a number of innovative approaches, such as risk based monitoring with as many variations as we have companies attending the conference.

But with the implementation of the operational QRM initiatives, is our audit strategy adapted or better do we need to adapt our audit strategy? Where do we go from here?

How can auditors assess the effectiveness of risk-based strategies, tools and centralised statistical data analysis models for data monitoring. Do we need to become statistical sophisticated or can we, as GCP auditor, simply ignore the statistical output and apply a traditional approach, knowing that the regulatory environment may not be that risk tolerant?

Maybe Risk Based Auditing should not exist, if only our clinical programmes were better designed (Quality by Design), if only we were collecting critical to quality data points and did not have to worry about ancillary, often redundant, information.

With some basic examples we try to describe PPD’s journey how we give a meaning to risk based auditing, it is a demonstration of the GCP stream’s title: through hardship to the stars.

We certainly can demonstrate the rough road we are at, and hopefully you recognise some challenges, maybe we offer you something practical to think about. But whether we have reached the stars, the Q&A session at the end may provide the answer.

Robrecht Tistaert

After some years of biotechnological research Robrecht joined the pharmaceutical industry as international clinical project coordinator for The Upjohn Company. Succumbing to Merger and Acquisitions fever in 1996, Robrecht joined the Quality Assurance department of Covance, travelling around the globe, performing audits, preaching GCP and process improvement.

In 2003 moved to a small Clinical Trial Logistics company, where he was responsible for the QA department. With his broadened GxP experience Robrecht decided to become a consultant for PricewaterhouseCoopers. However, missing the delights of Clinical Research and Auditing, returned in 2006 back to CRO joining the CQA department at PPD.

Robrecht previously headed the group of auditors that cover Europe, Middle East, Africa, currently he is the global head of Issue Management within PPD’s Global Quality and Compliance department, looking after QA consultancy, Regulatory Inspection support, misconduct investigations and corporate CAPA.

Since 2013 Robrecht has been a member of the RQA GCP Committee.
Outsourcing of clinical trials has increased significantly over the last 20 years along with a greater need for cost effective solutions along with improved strategic relationships and timely operational delivery. It is now therefore, even more important to strengthen the relationship between the sponsor/ Pharma company and the Clinical Research Organisation (CRO). This is the view from the CRO perspective.

Have we considered the role of the Quality Unit in helping to enhance this partnership? Quality Units have a unique view across their organisations with access to company-wide performance and compliance issues. Our role is not simply to measure and ensure compliance issues are adequately addressed, we can assist in many other ways. The quality governance structure is important in policy setting, strategy and defining overall quality goals. Our appetite for risk is low but important decisions need to be made by sponsors and CROs collaborating together to review risks and how best to address them. Quality Agreements are on the rise and these help play a part in how quality units from Pharma and the CRO effectively engage thus enhancing the overall relationship. Metrics are a ‘must’ but there can be pitfalls. What kind of metrics should we be sharing to ensure there is robust oversight and governance? Responsiveness and delivery performance can be measured in many ways.

The remainder of the presentation focusses on how to get it right when partnering. Starting with a clearly defined contract and a full understanding of customer needs and expectations. The ongoing guidance, feedback and support process during the management of the clinical trial along with the importance of mutual trust and timely communication on both-sides. The CRO has to perform to a different level than we did 20 years ago, now we have to be more aligned with sponsor values, sharing risks and far greater transparency. Quality is ultimately judged by our customers.

Nicky Dodsworth

Nicky is Vice President, Global Quality Assurance for Premier Research, a Contract Research Organisation that assists biopharmaceutical and medical device companies develop their therapies and devices especially in the areas of paediatric medicine and rare diseases. She has over 20 years of experience in global clinical trials mainly in the development, maintenance and oversight of quality management systems.

As an active member of the European Forum for Good Clinical Practice (EFGCP), she was appointed Chair of the Education Working Party in 2011. Nicky runs an accredited European Medical Writers Association (EMWA) Workshop on Quality Awareness in Clinical Study Report Development. She is Co-Chair of the GCP Forum for the Institute of Clinical Research (ICR) and a member of the editorial board of the CRfocus journal. Nicky is also a member of the Research Quality Association, West & Wales Regional Forum Group which promotes information exchange at a regional level.
Evolving role of the clinical quality professional

Simon Molloy, Gilead Sciences International Limited

The aim of this session will be to look at whether the role of the clinical quality professional has changed by asking a number of questions related to key activities that are typically undertaken by clinical QA groups.

• Is the skillset required by the modern clinical quality professional any different to what it was 15-20 years ago?
  – Is the role of clinical QA to investigate or verify, e.g. is involvement in Quality Control (QC) activities a thing of the past?
  – Risk-based auditing is not new but how much reliance is still placed on study verses internal system/process audits?
  – Is there more of a need for specialist knowledge in certain areas, such as electronic systems (eCRF, e-source, eTMF, etc.) or laboratory compliance? Do we need generalists or specialists or both? What is the impact of not getting the balance right?

• Beyond auditing – what other activities are clinical quality professionals likely to be involved with and do these sit within the clinical QA function?
  – Early input into Quality Risk Management (QRM), including Quality by Design (QbD): planning (including failure mode analysis, risk management plans and risk mitigation strategies), management (risk tolerance, quality dashboards, audit and other control strategies), improvement (trending/metrics, analysis of performance/outcome).
  – CAPA management (including investigation and root cause analysis and continuous process improvement initiatives).
  – Vendor quality partnership and oversight: where does one end and the other begin?

• How is the vision of a modern clinical quality professional achieved?
  – Strategic influence from operational stakeholders and clinical quality management.
  – Clinical quality professional skill-set: champion concepts of risk management and prioritising what matters; investigate, analyse and present complex data and issues; collaborate, facilitate and educate across functional and company boundaries; acquire and manage knowledge.

Simon Molloy

Simon is a Director of Clinical Compliance, belonging to the global Regulatory Compliance department within Gilead Sciences.

He holds an honours degree in Applied Chemistry and a Diploma in Industrial Studies from Nottingham-Trent University, and the RQA Diploma in Research Quality Assurance from Anglia-Ruskin University.

After graduating from college, he worked in an analytical chemistry laboratory at Napp Pharmaceuticals Limited for six years before transitioning to a Clinical Compliance role within the same company. In this latter role he established systems for auditing, training and managing SOPs. In 1999 he moved to Amgen Limited working as part of the clinical QA team, where one of his first tasks was to establish a documented process for auditing the documentation and processes associated with the submission of a licence application. While at Amgen he assumed responsibility for a small team of specialist auditors, which was responsible for system and vendor audits. Simon moved to Gilead Sciences in 2005 where he is responsible for the International (ex-US) clinical study (GCP), and global pharmacovigilance (GPvP) and Medical Information compliance audit programmes.

Simon joined RQA in 1997 and has been an active member of the GCP committee for the last 12 years. He is responsible for maintaining the GCP Q&A database, presented at the 2007 conference on audit related CAPAs and has helped organise a number of one day meetings.
Case Study: Failures of data integrity and resultant prosecution

Andrew Gray, MHRA

In April 2013 the MHRA’s Press Office announced the first successful prosecution under the Good Laboratory Practice Regulations which resulted in the defendant receiving a three month prison sentence for generating a number of false Good Laboratory Practice Instruments.

The case revolved around the manipulation of analytical data which was generated in a GLP compliant facility and used to support clinical trial applications and marketing authorisations. This presentation will examine how the data anomalies were identified and investigated. Additionally, the presentation will explore strategies for the prevention and early detection of data fraud which have been considered as a result of this case.

Finally, the presentation will look at what was required to secure a successful GLP prosecution in a court of law.

Andrew Gray

Andrew joined the MHRA in January 2003 as a GLP inspector. In 2004 Andrew was appointed Operations Manager for the Good Laboratory Practise and Good Distribution Practise Groups. In May 2006 Andrew took on the role of Head of the United Kingdom Good Laboratory Monitoring Authority. Most recently in September 2014 Andrew was appointed Inspectorate Unit manager for the GLP/GCP/GDP teams.

In Andrew’s capacity as Head GLPMA he is a member of the OECD, EC & EMA GLP working groups and has contributed to a number of national and international guidance documents. Andrew has been involved in the training of GLP inspectors from monitoring authorities around the world and regularly speaks at international conferences on the maintenance of GLP compliance. Andrew is currently the Chair of the OECD GLP Working Group.

Prior to joining the MHRA, Andrew worked in both academia and the pharmaceutical industry where he was primarily involved in the early development of drugs designed to treat cardiovascular disease. During this time Andrew regularly published peer reviewed papers in the scientific press.
GLP principles in ATMPs (Advanced Therapy Medicinal Products): A new challenge

Patrizia Cristofori, GlaxoSmithKline and San Raffaele-Telethon Institute for Gene Therapy (HSR-TIGET)

Several gene therapy clinical trials using gene-modified hematopoietic stem cells have shown therapeutic efficacy in multiple disease areas. As this therapeutic strategy is applied to an increasing number of monogenic diseases, rigorous studies in appropriate non-clinical models are needed to assess the risk/benefit ratio and fulfill the requirements for future market registration. In the EU, advanced therapy medicinal products including gene therapy (GTMP), go through a centralised marketing authorisation procedure of the EMA. However, due to the novelty and complexity of these products, fulfilment of regulatory expectations with regard to demonstration of pre-clinical safety is an evolving area and can present formidable technical and quality challenges. The fact that GTMP development is often in rare diseases with limited opportunity for financial return and also often sponsored by academia, charities and small companies with limited resources or regulatory experience, further complicates this process.

In order to address some of the challenges of conducting high quality pre-clinical safety testing, the Alliance of GSK with San Raffaele-Telethon Institute for Gene Therapy has established a GLP compliant Test Facility. This Test Facility aims to perform validation, biodistribution and tumorigenicity/toxicity studies to support the regulatory review process for gene therapy medicinal products.

This presentation will cover the challenges around studies on GTMPs including the nature and characterization of the test item, nature of the animal model and the complexity of analyses/examinations. Evaluating the biosafety of GTMPs in accordance with GLP, provides data of high regulatory standard and with assurance of scientific integrity/reliability.

Patrizia Cristofori

After graduation in Biological Sciences at University of Padova Patrizia joined the Endocrinology Department at Verona University. She did her PhD in experimental pathology at the University of London.

She joined Glaxo R&D as a toxicology pathologist in Safety Assessment in Verona, and in 1990 she became Head of Pathology where she had the responsibility for quality of safety evaluation and GLP compliance of Pathology and Clinical Pathology Laboratories.

In 2010, Patrizia joined the Department of Safety Assessment at GSK, UK, as Director of where she started her interest in Gene Therapy. She worked with TIGET, the Academic Institution partner of GSK, in promoting the development of gene therapy for the treatment of genetic inherited diseases. She set up a GLP certified Test Facilities at TIGET in Milan working closely with Prof. Luigi Naldini, leading expert in Gene Therapy. Currently, she is Safety Assessment Therapy Area Lead for GSK’s gene therapy products and she is also part of the Management of the TIGET Test Facilities.

Patrizia was founder and President of the Italian Society of toxicology Pathology (SIPTS) and is member of various international societies of toxicology pathology. She has been supervisor of PhD student and is Professor in the PhD programme of Nanosciences and Advanced Technologies, at the University of Verona.
**The blurring GLP boundaries**

**BL**
**SESSION 2**

**THURSDAY**

**11.00**

**Blurring the boundaries**

Lee Monk, UCB

In this presentation, we contemplate the benefits and pitfalls of running non-regulated studies alongside regulated studies in a GLP-compliant laboratory. We consider if ‘dual standards’ can work in a GLP-compliant facility, or if one standard (ie GLP) is the only way forward. Opinions tend to be divided . . . will your sentiments be revised after listening to this deliberation?

Lee Monk

With twenty two years in the drug-development industry, Lee has extensive experience in Good Laboratory Practice (15 years) gained both in the CRO and Sponsor environments. Equipped with a Microbiology decree from University College London (UCL), she worked in the field of microbiology and Genetic Toxicology before moving into Quality Assurance. Other than GLP, Lee has worked for six years in non-regulated research QA introducing ISO 17025 accreditation and Good research Practice Quality Systems in the field of tobacco scientific research. Lee has been a member of the RQA Education & Training Committee since 2006, with recognised teacher status at Cranfield University as lecturer and module adviser for the MSc in Quality Management in Scientific Research and Development.

**11.20**

**GLP Requirements in medical device submissions**

Alan Dench, Clinical Compliance Services

In August 2013 the FDA issued draft guidance on the applicability of Good Laboratory Practice in Medical Device submissions for marketing authorisations in the USA. The guidance was issued in response to frequently asked questions.

During the presentation the nature of medical devices as understood within the regulatory regimes of the USA and the EU will be explained. The regulations within these marketing territories will also be described, together with the framework and supporting standards. The registration requirements in the USA and EU to demonstrate safety and effectiveness of a device will be explained within the structure of the respective regulatory regimes.

The scope, objectives and content of the draft guidance will be presented.

The aim of the talk will be to familiarise participants with those aspects of medical device component design and development which may require input and testing, validation and verification using GLP principles of non-clinical laboratory testing.

Alan Dench

Alan manages an independent quality management consultancy, Clinical Compliance Services. Previously he was the Quality Assurance and Regulatory Affairs Manager for Wesley Coe, a sub-contract manufacturer to the medical device industry. He has several years experience in the pharmaceutical and medical device businesses in R&D, project management, quality and regulatory roles. His quality management experience covers GLP, GCP, cGLP, GMP, as well as the application of International Standards in both public and private sector organisations.
Why is there no little ‘c’ in GLP?

Ian Kennedy, Covance

GMP and GLP are both regulations imposed by regulatory authorities on healthcare product manufacturers and must be complied with before a product can be marketed. Both share the ultimate objective of protecting the health interests of end consumers, and yet they differ so much.

Why is it that GMP, has moved forward with advanced thinking on topics like quality risk management, CAPA, management review, continual improvement, etc, whilst many GLP organisations are still fire-fighting issues with individual studies. This presentation will touch upon the key differences between GMP and GLP and highlight some opportunities to adopt a more proactive approach to quality and GLP compliance.

Ian Kennedy

Ian is the Global Head of GMP Quality Assurance in Covance Laboratories, Early Development Business, responsible for sites in UK, France and US. Ian is also a Qualified Person (QP) named on Covance’s Alnwick facility manufacturing authorisation.

Before joining Covance, he was the Validation Manager for sanofi-aventis, where he developed and implemented global methodologies for the validation of facilities, utilities, equipment and computer systems.

Ian has a BSc (Hons) in Applied Biology, a MSc in Analytical Chemistry, a MSc in Pharmaceutical Quality Assurance and a Professional Diploma in Management. He also holds chartered status with the Society of Biology and Chartered Quality Institute.

GCLP: A clinical perspective

Hilary Tinsley, Covance

The UK MHRA ‘Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples’ and EMA ‘Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples’ describe the quality system applicable to laboratories involved in the analysis of clinical trial samples. Their purpose is to provide facilities with information to assist them with developing and maintaining quality systems which will comply with the GCP regulations.

This presentation will look at specific aspects of the guidance documents; the procedures implemented locally to address the GCP requirements and the understanding of why these requirements exist to comply with GCP.

Hilary Tinsley

Hilary is a QA Staff Associate for Covance Laboratories, in Harrogate, with current responsibility for facilitating all client and regulatory GLP and GCP QA on-site inspections.

In her role, Hilary has co-hosted numerous GLP and GCP regulatory inspections and she receives upwards of 50 Sponsor QA inspections annually. She is therefore ideally placed to review GCP regulatory expectations and the reasons for implementing local procedures to comply with GCP requirements.

Hilary started her career as an auditor with ICI, now Syngenta, and joined Covance in March 1997. She has held various positions in Quality Assurance and has experience in developing and managing audit programmes, preparation of in-house GLP and GCP regulatory training modules and harmonisation of global QA procedures.
The challenges of operator exposure studies

Sven Buckingham, Buckingham QA Consultancy Ltd

For both agricultural chemicals and veterinary products there is a risk that people will be exposed to the chemicals before, during and after their use in the field or on animals.

There is therefore a requirement to assess the potential exposure to workers, either as operator exposure studies (pre and during application) or as worker re-entry (post application) studies and determine the risk that the exposure poses to human health. Such studies must be conducted to GLP and are, as far as I know, the only GLP study types where man is the test system. Such studies may be supplemented with bystander studies.

In this presentation I shall focus on the operator exposure and worker re-entry studies, examining the potential issues around the design and conduct of these studies, together with some thoughts on best practices. The interface between the field and laboratory activities will be discussed, as will the role of QA in such studies.

Sven Buckingham

Sven is a QA consultant, working for a range of companies involved in the developing and testing of human and veterinary pharmaceuticals and biologics and agricultural chemicals. He has also been involved in implementing minimum standards in non-regulated research. He has audited a range of operator exposure studies over the last eight years.

He started life as an auditor in 1990 at Life Science Research (later Pharmaco-LSR) in Eye. In 1995 he moved to Mallinckrodt Veterinary (later Schering-Plough Animal Health) as QA manager. After being made redundant in 1998, Sven became a consultant.

He joined RQA (formerly QAG/BARQA) in 1990 and has been a member of the Animal Health Committee since 1996 and is currently committee chair. He has presented at various RQA meetings and seminars and has lectured on the Veterinary GCP short course. He was awarded the Diploma in Research QA in 1997 and was elected a Fellow in 2014.
Skills for the next generation of auditors

Andrew Waddell, TMQA

‘Audit’ is a very simple concept. You establish your expectations, you measure reality against the expectation and you create a finding which is either that the reality meets the expectation – or it does not.

Effective training of auditors never loses sight of this concept. The material that is being audited may be complex but the outcome of the audit should be simple.

During this presentation we will examine the components of the auditor’s skill set and how these can be developed. These include:

- Clarity of expectations
- Accuracy of observation
- Objectivity of finding.

We will discuss the content of effective audit reports and how to create findings that encourage improvement (and discourage argument).

Audit is an important element of Quality Assurance but its value is often underestimated. Training and development of auditors should include the skills to deliver effective audits that promote the value of Quality and Quality Assurance.

Andrew Waddell

Andrew holds a doctorate in Pathology from the University of Edinburgh Medical School where he was part of the team that performed the early work on apoptosis. Following a period as the Government’s Professional Advisor on Health Education Policy he moved to Inveresk Research (now part of Charles River Laboratories) where he worked as the Head of Quality and Training for nearly twenty years.

Andrew is the Director of Tower Mains Quality Assurance (TMQA), a company he founded in 2001 which is based in Edinburgh and has a new office in Slovakia. He currently sits on the Board of the Scottish Lifesciences Association and the Professional Game Board of the Scottish Football Association.

He is a past Chairman of the RQA and is its longest serving currently-active member, having joined the then QA Group in 1980. During his membership he has been involved continuously in training since his participation in the design and delivery of the first ever training course. He has been the Course Principal of the Auditing Course since it was first delivered and believes that audit is simple – it’s just the people that make it complicated.
QA and the PV department: A true collaboration

Laura Trower, Allergan Ltd

The relationship between the QA department and the PV department has the potential to influence the effectiveness of an audit, the observations made and subsequently the CAPAs implemented. With European legislation requiring auditors to verify the PV system, while remaining independent, a collaborative balance must be maintained with the PV department.

The presentation will consider the different roles of the auditor and how we can best work alongside the PV department during the following activities:

- Audit phases – preparation, conduct and report writing
- CAPA development
- CAPA verification
- PSMF maintenance
- Consultation
- Regulatory Inspection Support.

The key legislative requirements will also be reviewed along with a summary of ideas for how we, as auditors, can best work towards a collaboration with our safety colleagues.

Laura Trower

Laura is currently a PV audit manager at Allergan based in Marlow primarily conducting PV system and subsidiary audits. Laura is responsible for the PV risk tool and works with the business on CAPA management and inspection support.

Prior to joining Allergan, Laura worked at Johnson & Johnson in the Pharmacovigilance Quality Assurance (PVQA) department where she conducted system and subsidiary PV audits, assisted in company CAPA management, PSMF maintenance, audit risk methodologies and inspection support.

Laura’s Pharmacovigilance background also includes case processing and management and she was an integral part of a team responsible for setting up a Centre of Excellence for literature review.

Laura was a Registered Adult Nurse specialising in Urology, Orthopaedics and Ophthalmic surgery before moving into industry.
Each Marketing Authorisation Holder (MAH) must operate a Pharmacovigilance (PV) system that allows them to perform their legal duties with regards to PV. QA is responsible for ‘policing’ implementation of a company’s PV System checking that appropriate processes and measures are in place. PV audits should allow companies to identify where they need to make improvements. If issues can be identified and addressed within the company there shouldn’t be any surprises when the inspectors arrive. In order to help achieve that goal there needs to be good communication and understanding between PV and QA.

The presentation will discuss interactions between PV and QA including:

- Audits from the point of view of PV
- PV pre-audit discussions and preparation
- Helpful and unhelpful auditor styles
- How to work towards better safety systems/processes whilst maintaining auditor independence.

The talk is just one opinion based on a lot of inspection and audit experience. At the very least, it aims to give PV auditors an idea of how the audit feels from the point of view of the auditee. Hopefully it will also help auditors see where QA and PV can work together to ensure that PV audits are a constructive experience for both parties.

**Sarah Hall**

Sarah Hall is the Head of Medical Information and Pharmacovigilance at Takeda UK Limited covering both the UK and Ireland. She has been in Pharmacovigilance for over 15 years and during that time has been involved in many inspections (GPvP, GMP, GDP, GCP) by a number of Regulatory Agencies. She has also been involved in many audits both as an auditee and accompanying auditors.

Sarah is a member of the ABPI Pharmacovigilance Expert Network and IPHA Pharmacovigilance Advisory Forum. She is also a member of the PIPA Committee and is a lecturer on the Uni of Herts and EU2P Pharmacovigilance Msc courses.

Sarah has a BSc in Biochemistry from King’s College, London and a PhD from the Royal Postgraduate Medical School, London and spent a number of years in medical research within the NHS before moving into the pharmaceutical industry. Since joining the pharmaceutical industry she has worked for both small and large pharmaceutical and biotech companies in different areas of Pharmacovigilance and has worked in a joint Medical Information and Pharmacovigilance role for the last eight years.
A regulator’s perspective on assessing risk in the PV system and the PV quality system

Kiernan Trevett, MHRA

The revised EU pharmacovigilance legislation introduced the legal basis for marketing authorisation holders to establish and use quality systems for the performance of pharmacovigilance activities. These quality systems should provide for the effective monitoring of the pharmacovigilance system, with an emphasis on a risk-based approach to quality system review and audit.

The presentation will provide an overview of the applicable legislation and guidance that establish the minimum requirements for these quality systems. It will cover key aspects of performance monitoring and the use of key performance indicators to continuously monitor the good performance of pharmacovigilance activities. The principles for the risk-based approach to audit are also covered, including potential risk factors and risk assessment methodologies for the strategic, tactical and operational planning of pharmacovigilance audits.

The presentation will conclude by highlighting the role of the pharmacovigilance system master file with respect to the quality system underpinning pharmacovigilance activities.

Kiernan Trevett

Kiernan has worked as a GPvP Inspector at the Medicines and Healthcare products Regulatory Agency since April 2012. She has contributed to the development of the EU Good Pharmacovigilance Practices (GVP) and has had a role in the training of GPvP Inspectors in other EU Member States.

Before joining the MHRA, Kiernan worked as a certified Quality Assurance auditor for a central laboratory that provided services for Phase I-III pharmaceutical clinical trials.

Kiernan has a Master of Biomedical Sciences degree from the University of Southampton.
Value added auditing

Ana Maria Aguirre Arteta, Novartis Pharma AG

Business owners and organisations might regard the annual audit as a cost or a “necessary evil” that adds little or no value to the business. The audit team needs to know that the partner expects them to understand the business and to add value to the business by identifying areas where the auditee can improve. Added value to the audit does not happen by accident, there must be a communication, a two-way exchange of ideas between auditor and auditee. Audit findings impact patient safety as they might lead to changes in the summary of Product Characteristics (SmPC) which can consequently lead to changes in the patient information leaflet (PIL). Audit findings can also help to improve a specific system/process based on evidence and/or experience (audit).

The world of Pharmacovigilance is comprising several disciplines and functional departments which can have an impact on the safety profile of a product. It is essential to work before, during and after the audit with business to provide support to target the issues and to be a partner not an adversary (e.g. licensing knows well what is not working with the license partner).

In summary by having the same aims, working together, understanding the business and the products all these lead to safe products and safe patients.

Ana Maria Aguirre Arteta

Ana Maria is “Global Head Pharmacovigilance (PVI Audit)” in Pharma Auditing & Compliance Quality Assurance at Novartis Pharma AG in Basel, Switzerland.

Prior to joining Novartis in 2012, Ana Maria has held different positions in German Headquarters in several companies:

1  “Head Global Drug Safety Governance” Grünenthal GmbH
2  “Senior Group Leader” ALTANA Pharma AG
3  “Scientific Laboratory Director” Bayer AG
4  “Scientific Guide” Gläsernes Labor

Ana Maria started her career in the GLP world designing animal models for testing different pharmaceutical products in the viral environment of HIV, PPVO and CMV. From here she moved to the other GxP areas (PV, GCP, GMP) in the subsequent years.

She has trained teams for PV inspections and been inspected herself by different local authorities globally. During her various roles she has worked cross functional with many different departments such as Regulatory Affairs, Development, Marketing, Legal, etc. In her actual role she is responsible for a PV audit team and for establishing the audit strategy for all global PV activities.

Ana Maria holds the following qualifications:

1  PhD in Molecular Biology from Humboldt University
2  Masters in Medical Science/Oncology from the University of KwaZulu-Natal
3  Masters in Technical Biology from Universidad del Pais Vasco.

She has also studied Business Administration in Bayer AG.
Marketing partner workshop

Ana Maria Aguirre Arteta, Novartis Pharma AG

The Marketing Authorisation Holder (MAH) needs to ensure that formal contracts exist with all third parties that could form part of their Pharmacovigilance (PV) System, particularly third parties performing a function that may expose them to safety data. Even if PV responsibilities are mentioned in the contracts, questions might arise:

1. Are the safety contracts covered in sufficient detail to allow the MAH to be compliant with current legislation and guidelines?
2. Are the safety contacts identified between the companies?
3. How old are these agreements?
4. Do they reflect the current activities, the correct product list, the territories etc?

Audits at Marketing Partners focus not only in the activities conducted by the partner company, but it is also a mechanism of oversight for the MAH. The different contracts with third parties are also reflected in the Pharmacovigilance System Master File (PSMF).

During this Marketing Partner Workshop you will learn more about some of the risks for ranking license partners, different approaches to auditing the partners, how the PSMF can be used in an audit, topics to consider in an audit and how to build an agenda. You will also have the opportunity to discuss with peers your ideas and challenges and increase your network.

Ana Maria Aguirre Arteta

Ana Maria is “Global Head Pharmacovigilance (PV) Audit” in Pharma Auditing & Compliance Quality Assurance at Novartis Pharma AG in Basel, Switzerland.

Prior to joining Novartis in 2012, Ana Maria has held different positions in German Headquarters in several companies:

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Ana Maria holds the following qualifications:

1. PhD in Molecular Biology from Humboldt University
2. Masters in Medical Science/Oncology from the University of KwaZulu-Natal

She has also studied Business Administration in Bayer AG.
The new European Cosmetovigilance requirements – challenges of performing vigilance audits (from the perspective of a Pharmacovigilance auditor)

Lindsay Watt, GlaxoSmithKline

This presentation summarises current European cosmetovigilance requirements outlined in the legislation and guidance. In doing so the presentation includes important definitions and concepts, identifies key players, and provides some thoughts about how these requirements could be audited.

The presentation is written from the perspective of a specialist/dedicated Pharmacovigilance Auditor with extensive experience in the vigilance arena (human, veterinary, medical devices and cosmetics) and will be of interest to colleagues who already perform vigilance audits in one or more of these areas or are about to do so.

Lindsay Watt

Lindsay started her career at GlaxoWellcome in Pharmacovigilance Operations. In 2003 she joined MHRA to work as a Pharmacovigilance Inspector and was appointed as the GCP Inspectorate Operations Manager in 2007. After leaving the MHRA, Lindsay worked as a Pharmacovigilance Auditor at MSD for 4.5 years. Lindsay re-joined GlaxoSmithKline in May 2013 as Pharmacovigilance Auditor.

Lindsay has performed vigilance audits in USA, Europe, Latin America, Africa and Asia Pacific and has experience of auditing vigilance activities for medicinal products (human and veterinary), medical devices and cosmetics.

Lindsay has a BSc (Hons) in Pharmacology, an MSc in Clinical Pharmacology and a Post-graduate Diploma in Pharmacovigilance.
GMP and the QP – where have we been and how did we get here?

Sue Mann, Sue Mann Consultancy Ltd

This talk will open Stream D of the annual RQA conference by asking these questions. The GMPs are undergoing an unprecedented amount of change at this time and there is a lot of turmoil in the industry. This is happening in many areas of the world; however, there is a real focus on Europe and the EU at present. A significant proportion of the Chapters and Annexes in the EU GMP guide have either just been updated or are currently undergoing revision.

The talk will take a brief look at history and the development of the GMPs as this helps us understand why the legislation and guidelines have been written in such a way that emphasises certain requirements and expectations.

It will go on to review the principal legislation and guidance which we use on a daily basis whilst operating in the EU; focussing specifically on those which are of particular interest to the Investigational Medicinal product (IMP) Qualified Person (QP).

Time only permits a brief look at the numerous issues and challenges that face the industry (and Regulators) as 2014 draws to a close. The talk will look at a few of these; including the so-called Falsified Medicines Directive and more recent issues regarding data integrity. It will also seek to explain why there is an increased emphasis and interest in how investigations are performed, how the root cause of the issue is identified and then what corrections and corrective actions are proposed and how all of this is documented on each occasion. This applies to all types of deviations (non-conformances), complaints, out of specification (OOS) and out of trend (OOT) or anomalous results investigations amongst others.

The talk will conclude with a look at the ever increasing challenges for IMP manufacturing operations and the QPs who are legally responsible for certifying batches for supply to a clinical trial.

Sue Mann

Sue has extensive experience in the Pharmaceutical industry, spanning over 30 years, principally in Quality Management; also in Clinical Trials supply, Technical Management and Production Support. Sue has knowledge and experience in most major dosage forms, both in R&D and commercial operations.

Sue has worked for many types of company, including international, national, contract manufacturing, Japanese and virtual; latterly as Vice President of International Quality Assurance at Shire Pharmaceuticals. Here she managed all quality and GMP aspects for both development and commercial products (100+ third party companies).

Sue has also spent over 15 years as a consultant, providing Quality Systems support, Quality, GMP and technical training, Regulatory Inspection support and auditing around the world. During this time, she has presented at hundreds of training courses and conferences.

Sue is a Pharmacist, a Qualified Person (EU Directive 2001/83/EC), member of the Chartered Quality Institute and the Research Quality Association (GMP Committee member).

She is also a QP Assessor, working on behalf of the UK MHRA, representing the Royal Pharmaceutical Society.
The field of ATMP is a rapidly evolving field with new and unique challenges for QA and regulatory affairs professionals.

The presentation will cover:

- What is an ATMP?
- The regulations applicable to Blood, Tissues and ATMPs
- Challenges for the manufacture, testing and release of Advanced Therapy Medicinal Products
- The role of QA in meeting these challenges.

Jacqueline Barry

Jacqueline is Head of Regulatory for Cell Therapy Catapult, an independent, not for profit, company founded as part of the Technology Strategy Board/BIS Catapult programme. Prior to this she worked at the Scottish National Blood Transfusion Service in a number of senior quality and regulatory positions, including acting as Responsible Person and Qualified Person. Before that she held a number of academic posts studying neuromuscular regeneration. She has experience in the development, translation, clinical trial and approval of cell based medicinal products and therapies in the UK and EU.
Selection of biological raw materials for use in the manufacture of Advanced Therapy Medicinal Products

Patrick Ginty, Cell Therapy Catapult

The manufacture of cellular therapies for clinical application frequently requires the use of raw materials of biological origin during key process steps. The use of such biological raw materials can pose a risk to product quality/safety if they themselves are not manufactured to quality and traceability standards that make them suitable for human use. In the April 2013 meeting with the European Directorate for the Quality of Medicines and Healthcare (EDQM) in Strasbourg, the European Medicines Agency (EMA) revealed that the insufficient assessment of raw materials impact on final product quality was one of the most common quality objections at the Market Authorisation stage. The vast majority of biological materials used in ATMP manufacture are non-compendial and if only research grade materials are available to developers, demonstrating the appropriate level of quality at the licensing stage remains challenging. The EDQM and the EMA clearly understand the need for intervention, as they have set up a task force with the aim of harmonising the quality standards for raw materials via the European Pharmacopeia. However, there is still value in a practical guidance document that will aid developers in selecting raw materials and the potential impact they will have on product quality. This document will cover both the EU and US regulatory requirements related to raw materials, providing an explanation of key differences between the regulatory approach and terminologies used in both territories, along with a comprehensive list of the appropriate legislation and guidance. To achieve this, Cell Therapy Catapult and the British Standards Institution have brought together a team of experts in the field of cell therapy manufacture and regulation to compile and publish publically available specification (PAS) 157, aimed primarily at early stage developers, to both fill the current void and complement the longer-term objectives of the EDQM and EMA.

Patrick Ginty

Patrick started his career working in a hospital pathology laboratory before a short spell as a researcher for Boots Healthcare. Patrick received his Master’s degree in Biomolecular Technology in 2002 followed by a PhD in tissue engineering and drug delivery in 2005, both from the University of Nottingham. He has since worked in both industry and academia pursuing a career in the regulation of cellular therapies and medical devices. During this time, he has received a certification from the Regulatory Affairs Professionals Society (RAPS), has worked on over 20 different cell therapy products, and gained over 20 publications/patents in regenerative medicine and cellular therapy. Patrick is currently working as the Regulatory Affairs Manager at the Cell Therapy Catapult Ltd in London, where he provides regulatory support to the growing cell therapy industry.

MHRA Support for innovation

Ian Rees, MHRA

The MHRA has as one of its five corporate objectives 'Bringing innovation safety to market.' This presentation will explore this in the context of an enlarged Agency with the Innovation Office which opened in March 2013, the UK’s growth agenda, EU legislation and guidelines and increasing global convergence.

Ian Rees

Biography unavailable at time of printing.
Differences in regulatory pathways for combination products and the risk impact in post market surveillance

Henny Koch, QIMP Management Services Ltd

Within Europe, regulatory compliance for Medical Devices is organised in Medical Device directive 93/42/EC. This directive specifies that the requirements of the ISO 13485:2012 Standard is in place for Quality Management Systems following the format including reference to ISO 14971:2012 for Quality Risk Management.

The revised ISO Standard 14155:2011 is intended to direct Clinical Investigations of Medical Devices for Human Subjects. Important consequences of this Standard are:

- Presence of a Clinical Investigation Plan to cover medical device aspects including application of device risk analysis and requires risk assessment in accordance with ISO Standard 14971:2007
- Documentation and reporting /reviews of (serious) adverse device effects including monitoring and auditing thereof
- Assure correct registration and timely handling of actions related to adverse device effects.

In 2013, the FDA issued regulations 21CFR Part 4, Current Good Manufacturing Practice Requirements for Combination Products. Implementing these regulations, additional compliance processes become in place for combination products consisting of medicinal products and medical devices.

In Europe, potential combination products are often being registered as a medicinal product, following the regulations laid down in directive 2003/94/EC for medicinal products for human use and Directive 91/412/EEC for veterinary use.

There is unawareness with direct risk impact within the medicinal compliance GxP arena that the Medical Devices Directive 93/42/EC, Article 1 (Definitions, scope), paragraphs 3 and 4. state that, not only the regulations for medicinal products are applicable but also medical device Directive 93/42/EC remains applicable.

Comparing GCP and medical device requirements, essential differences in the set up and control of clinical investigations may lead to unawareness in the applicability of Investigational Medicinal Products increasing the potential patient risk in post market surveillance. Regulatory differences and their liability risk impact is explained.

Henny Koch

Henny is Managing Director of Qimp Management Systems Ltd. With a track record of 39 years in pharmaceutical industry covering 18 years in R&D, seven years in manufacturing, 10 years in Global Quality & Compliance and three years as independent consultant.

Being qualified in Quality Management, his major focus is on the setup and implementation of Quality Management Systems and as lead auditor on GxP compliance and ISO systems. The major goal is to support companies striving for efficient and effective quality processes. Creating the Transformative Deming Cycle as part of Total Process Quality Improvement (TPQI), a QA management approach has been developed to achieve operational excellence and leading to business optimisation, cost effective health care products and improved patient safety.

The main focus for Qimp Management Systems Ltd. (founded 2011) is on Quality Systems consultancy and the guidance of regulatory processes for medicinal products and medical devices. Within the RQA, he is committee member for Medical Devices.
With the 21 CFR Part 4 “Current Good Manufacturing Practice for Combination Products,” FDA has issued a streamlined approach to GMP for drug device combinations and highlighted the need to meet both sets of GMP regulations for such combination products. However, definitions and intrinsic regulations for drugs and devices have been in place for a long time.

This presentation will provide a framework of drug and device regulations in the EU and US and explain how they apply to Investigational Medicinal Products. The Qualified Person should have a good understanding of product classification and the applicable regulatory framework.

The presentation will outline aspects for consideration by the QP when releasing drug device combination products for clinical use and highlight differences compared to certification of investigational drugs, comprising:

- Design Control
- Material Control
- Supplier Control
- Quality System
- Non-medical Complaints
- Human Factors.

Ulrike Feurstein

Ulrike has nine years practical experience as Lead Qualified Person for Investigational Medicinal Products in global organisations. Before becoming a QP she was lab manager in an Analytical R&D department. Until 2013 she was in a Regulatory Change Management function in R&D QA Compliance. Within this role she has led the implementation of FDA’s Combination Product regulations for the Abbott/AbbVie R&D QA organisation. She recently moved into her current position in CMC Submission Management being responsible to compile CMC dossiers for clinical and marketing applications for AbbVie products, comprising drug device combination products.

Ulrike is a Licensed Pharmacist and holds a PhD in Pharmaceutical Biology from University of Regensburg, Germany.

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company’s mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world’s most complex and serious diseases. AbbVie employs approximately 25,000 people worldwide and markets medicines in more than 170 countries.
Generic quality
Roy Baxendale, Sandoz International GmbH

The presentation will cover the following:

- Comparison of innovator and generic drug/device development, the reality
- What are the challenges of generics from a QA perspective?
- What is generics impact on originators, regulators and quality and vice versa?

Roy Baxendale

Roy is currently Head of QA Development Operations for Sandoz International GmbH in Germany. He has global responsibility for GMP operations in the development of small molecule generic medicines for human use. Roy holds a physics degree and MSc in Quality Management. Previous appointments have included Head of quality and Risk Management in GSKs External QA Department, responsible for external early phase manufacturing facilities, Head of Quality at GSKs Clinical Imaging Centre in London and QA roles at HLS and Delta Biotechnology, a small biotech manufacturing company.

Roy is a previous Board member of RQA and is frequently seen presenting at conferences and seminars.

15.30 GMP QA clinic
Rhona McAteer, TMQA
Driven by FDA, there is increasing awareness of drug/device combination products in the pharmaceutical industry. In fact, many medicinal products considered drugs in the US and EU actually comprise device constituent parts. The same applies to typical drug kit packages. Consequently, it is recommended to take a close look at local regulations to ensure compliance. Elaborate supply chains with multiple parties involved add further complexity to legal responsibilities across the product life-cycle.

In this session, we will:

- Review examples of combination products
- Identify what determines the classification of combination products in major markets
- Highlight device-specific requirements applicable to drug/device combination products
- Explain the process and stakeholders involved in the registration of European medical devices
- Identify critical items for management of device developers
- Take a look at the changing landscape of medical device regulation in Europe.

The presentation will include a short quiz to further clarify the topic and to allow a check of understanding.

Peer Schmidt

Peer has 10+ years of experience in both pharmaceutical and medical device manufacturing with Abbott/AbbVie. As Senior Manager Device QA, Peer supports AbbVie’s global quality system for combination products. As EU Authorised Representative, he is responsible for liaison with European Competent Authorities on AbbVie medical devices. He is a member of the AbbVie Centre of Excellence for Risk Management.

Before joining AbbVie, Peer performed research on pre-clinical high-throughput screening and was responsible for programme management in the in-vitro diagnostics start-up arena. Formerly, he was Head of QA for Abbott Biotechnology Deutschland.

Peer studied Biology at the Universities of Bonn and Munich, Germany, and Edinburgh, Scotland. He holds a Ph.D. in Molecular Biology from the Max-Planck-Institute for Psychiatry in Munich, Germany.
The medical devices in healthcare
Fraser Smith, PPD

Medical devices play a key role in health care, vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimising risks of adverse events. Unless medical devices are managed proactively, the same types of mistakes, errors and adverse incidents happen repeatedly. This session introduces the diversity and range of medical device products, looks at the innovativeness of the sector, the EU’s involvement and references good medical device management practices that may help identify and potentially assist in reducing their potential for harm.

Fraser Smith

Dr Fraser Smith serves as executive director and QP within PPD’s global quality assurance organisation. His responsibilities include leading the GMP quality solutions function and quality assurance activities for Phase I, government operations and information systems programmes. Prior to his current PPD role, Fraser was head of global clinical quality assurance and also previously served as leader of PPD’s U.K. pharmacovigilance department. He is a seasoned health care professional with a diverse industry background that includes QA leadership roles at Johnson & Johnson Medical, Systagenix Wound Management and Ethicon. Fraser is a trained U.K. pharmacist, holds a master’s degree in information technology, a doctorate in medical business administration, is a certified ISO 9001 Quality Management systems lead auditor and also achieved Chartered IT Professional Fellowship status with the British Computer Society.
Management review: Obligations, benefits and expectations

Henny Koch, QIMP Management Systems Ltd

The ISO 13485:2012 Standard is in place for Quality Management Systems (QMS) of Medical Devices. For the Management Review in Clause 5.6.1 it is stated: ‘Top management shall review the organisation's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.’

But what does this include? Is this just a compliance burden or can it and how will it be beneficial for the company and our business?

The Management Review is the routine evaluation of whether the QMS is performing as intended and effectively produces the desired outcome. As such it is the ‘learning experience’ of our processes leading to products that meet demands and expectations. The value add of a QMS becomes clear during unexpected calamities. Establishing and maintaining the effectiveness of the QMS is a prerequisite for survival in industry. It is not only there to achieve compliance across the complex and sometimes chaotic regulatory arena but it improves the productivity of our business processes. This is why it is so important that top management is directly involved in the ongoing activities to analyse performance, to identify potential improvements and to assure that required changes are effectuated. The choice of performance measurements as well as the validity and correct evaluation of metrics is crucial not only for product realisation but even more for effective business processes. Well defined inputs as well as adhering decisions and actions including regular review of follow through and progress should be priority driven.

To create awareness and to get away from experienced management snares it would be good to adapt from the wording in ISO 13485 that top management shall review the organisation’s Quality Management System and realise that in practice top management shall review the organisation’s “Business Impact System.” At least than stakeholders and shareholders would improvingly show interest in a well-functioning Management Review.

Henny Koch

Henny is Managing Director of Qimp Management Systems Ltd. With a track record of 39 years in pharmaceutical industry covering 18 years in R&D, 7 years in manufacturing, 10 years in Global Quality & Compliance and three years as independent consultant.

Being qualified in Quality Management, his major focus is on the setup and implementation of Quality Management Systems and as lead auditor on GxP compliance and ISO systems. The major goal is to support companies striving for efficient and effective quality processes. Creating the Transformative Deming Cycle as part of Total Process Quality Improvement (TPQI), a QA management approach has been developed to achieve operational excellence and leading to business optimization, cost effective health care products and improved patient safety.

The main focus for Qimp Management Systems Ltd. (founded 2011) is on Quality Systems consultancy and the guidance of regulatory processes for medicinal products and medical devices. Within the RQA, he is committee member for Medical Devices.
The Medical Device Directives are undergoing a major revamp and will be issued as Regulations. The Medical Device Directive, 93/42/EEC and the Active Implantable Directive 90/385/EEC will both be incorporated into a single Regulation, whilst the In-vitro Diagnostic Directive, 98/79/EC will be governed by a separate Regulation. Unlike Directives, Regulations are not transposed into the national laws of each member state of Europe and are accepted as law as written. This will go a long way towards ensuring that the differences in the interpretation of the Medical Device Directives which currently exist, between different member states, will no longer occur.

There are many changes within the current proposal for the new Medical Device Regulations; the scope of the Regulation, the approach to clinical investigations, the role of the Notified Bodies and Competent Authorities, the requirements for vigilance and market surveillance and a scrutiny procedure to name but a few.

The aim of this presentation is to give an overview of some of the proposed key changes associated with the Regulation which is to incorporate the Medical Device Directive and the Active Implantable Directive.

Kath Clarke

Kath Clarke is the Regulatory Affairs and Quality Assurance Manager at NAMSA Medvance, who are a Medical Research Organisation.

Kath has a BSc in Chemistry and is a professional member of RQA (Research Quality Association) and TOPRA (The Organisation for Professionals in Regulatory Affairs). Kath sits on RQA’s Medical Device Committee and also resides on two BSI Committees concerning Healthcare Standards.

Kath started her career in the Medical Device Industry more than 25 years ago, working for Smith & Nephew. During her time at Smith & Nephew she held a variety of QA and RA roles in numerous divisions covering various therapeutic areas. After 20 years Kath moved to Tissue Science Laboratories, where she held the position of Regulatory Affairs Manager, her responsibilities being many and varied; including CE marking and product registration in global markets.

Kath moved to NAMSA Medvance in 2010, where she continues to specialise in Regulatory Affairs.
Investigator initiated medical device investigations – points and considerations

Yvanne Enever, PHARMexcel Ltd

This presentation discusses when and how to set up a clinical investigation with a focus on Investigator Initiated studies. The key aspects of the presentation covers:

- What is a medical device?
- Standards for conducting a clinical investigation
- Roles and Responsibilities under ISO 14155
- CIP planning
- CIP development
- Approvals
- Study Conduct and Close-out
- Publication.

Yvanne Enever

Yvanne is founder and Managing Director of PHARMExcel Ltd a small research consultancy supporting academic and commercial research of both medicines and devices.

She has over 18 years experience developing extensive knowledge of the clinical trial and device regulations. She is a member of the Research Quality Association (RQA), The organisation for professionals in Regulatory Affairs (TOPRA), sits on the sub committee of the ICR Freelancers Forum and is an active member and secretary for the RQA Medical Devices Committee.

She has recently been involved in the development of the RQA medical devices regulatory road map and the RQA medical devices seminar on clinical investigations.
Medical devices regulation and the joint action programme including unannounced audits

Neil Adams, BSI Group

This presentation reviews the impact on Notified Bodies of the European Joint Action Plan on medical devices that arose from Commissioner Dalli Initiative published as a response to PIP scandal of 2012. It discusses the key requirements of Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices, which directs Competent Authorities how to control Notified Bodies. It will then consider the consequent impact of these requirements on manufacturers, now and going forward.

The requirements of Commission Recommendation (2013/473/EU) of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices, which directs Notified Bodies how to audit Manufacturers, will be reviewed. Finally we will consider progress on implementing these requirements and the impact these will have on manufacturers.

Neil Adams

Neil is a Regulatory Affairs professional with over thirty years’ experience. After ten years as a regulator and policy maker in UK Government, Neil has spent over twenty years working in industry and the regulatory service sector. He has been leading BSI’s medical device certification effort for six years; currently as Director Operations and Delivery, Medical Devices. He is responsible for operational and regulatory affairs aspects of the BSI medical technology organisation, including its Notified Bodies: NB 0086 in the UK and NB 0535 in Germany.

Before joining BSI Neil was European Regulatory Affairs Manager for STERIS Corporation, working on the regulatory freedom to operate of Active and Non-active Medical Devices, Disinfectants, Detergents and Cleaners, Cosmetics and other consumable products and capital equipment.

He is a member of the TOPRA Medical Technology SPIN Steering Committee, and a Vice Chairman of the Association of British Healthcare Industries (ABHI) Technical Policy Group. Neil represents BSI in negotiations with the UK Government on all aspects of medical devices regulations. The current focus is on the navigation of the proposed medical device regulation and in vitro diagnostic device regulations through the European Commission, Council of Ministers and European Parliament.
Get right up to date with the latest developments in the negotiations on new legislation on medical devices and in vitro diagnostic devices. Following a refresher on how European legislation is agreed, the presentation will give a general overview of the new legislation and pick out some of the key changes that are likely to be included in new legislation for further explanation. These include changes to the pre-market assessment of devices, controls on the ‘in-house’ manufacture and use of devices by health institutions, requirements for clinical evidence, the introduction of unique device identification and changes to the requirements around the reprocessing of single-use devices. The presentation will also explain the likely timescales for agreement and implementation of the new legislation.

Graeme Tunbridge

Graeme is Head of Medical Devices EU Policy at the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. He is responsible for leading the UK Government’s input into negotiations on the revision of legislation on medical devices.

Prior to joining the MHRA in 2011, Graeme had extensive experience in the UK Department of Health, working in policy roles in areas including tobacco regulation, clinical commissioning and healthcare associated infections. He also spent 18 months as Private Secretary to the Secretary of State for Health and headed up the Department’s Freedom of Information team.

Graeme has a Master’s Degree in Biochemistry from the University of Oxford.
Contracting in the cloud

Andy Tyrrell, Covance

What challenges do companies face when considering using Cloud providers for the first time?
Is dealing with Cloud suppliers any different to dealing with any other supplier of technology services?
Are there any challenges unique to our industry?
What steps can companies take to mitigate these concerns?

These are all legitimate questions which face the key decision makers within any organisation, when considering embarking on a relationship with a Cloud supplier for the first time.

This presentation will aim to address these questions and more, and will focus on the following topics:

• Selecting the right cloud provider
• Using the RFI to address cloud concerns
• Setting expectations of your cloud provider
• Key contractual considerations

The presentation will conclude by summarising the key points that that need to be considered when Contracting in the Cloud, and will provide a tool kit and resource guide which can be used back in the workplace.

Andy Tyrrell

Andy is a Senior Manager within Covance’s Global IT Risk and Compliance Group. Based in the UK, his responsibilities include representing IT within Client Audits and Regulatory Inspections, in addition to leading the effort to develop an IT Global Control Framework across Covance. In the past year he has also developed comprehensive audit metrics to provide visibility to senior management on key audit trends within the IT space.

Before joining Covance, Andy worked as an IT Advisory Manager within KPMG’s Risk Consulting Practice, where he worked on various client assignments including leading the Compliance and Control workstream for an Oracle Implementation project for an international Telecommunications company. Prior to that, Andy has held a number of positions within Technology Risk Management, Internal Audit and External Audit.

Andy has a BSc in Business Operation and Control from the University of Salford. He is also a qualified Chartered Accountant (ACA) and holds the CISA and CISSP certifications.
The cloud, infrastructure, compliance and security

Keith Williams, Formpipe

- Annex 11 how do we achieve compliance?
- How do we ensure our CSP’s adherence to the regulations?
- Web services, can we control them?
- How safe is our data?

Keith Williams

An entrepreneur, director, and business manager with UK, European and US experience. Keith brings over 25 years of Life Sciences experience, particularly in a pragmatic approach to getting computerised systems compliant and keeping them compliant. He has worked in a manufacturing, laboratory and clinical environment and has more recently focused this experience to build compliant set of configurable SharePoint products for content and document management. He has a BSc in Microbiology and an MSc (Eng) in Biochemical Engineering.

How do cloud systems fit in an integrated laboratory environment

Tony Davies, AkzoNobel

While there are many thousands of words written about the need for and delivery of integrated laboratory solutions the reality is that most deployments are a mixture of systems of various levels of antiquity, often displaying poor interoperability, deployed at different levels of complexity and often operated to a fraction of their actual potential. This talk will look at the dilemma from the point of view of the various players in this scenario from the long-suffering laboratory analyst and their managers through the IT and IP manager’s influences to their business managers’ commercial imperatives. At the end of the day we all need to be aware of their influences and bottom lines when we approach the thorny issue of moving to Cloud-based systems and their additional integration burden. It may well be a case of *perfer et abdura; dolor hic tibi proderit olim*. Unfortunately, the current position of a significant number of our decision makers in many areas could well be summed up as *cras credemus, hodie nihil*. The final answer may well lie in why a conference which is at the forefront of Quality thinking is so plagued by Latin quotations!

Tony Davies

Tony Davies is Lead Scientist at AkzoNobel in the Strategic Research Group – Measurement and Analytical Science in Deventer, The Netherlands. Tony has worked in both regulated and non-regulated industry where he has managed several global analytical IT project rollouts as well as academia and government research in Germany, the UK and now the Netherlands. As Chairman of the International Union of Pure and Applied Chemistry, Subcommittee on Electronic Data Standards he has been responsible for coordinating and authoring many of the current vendor independent electronic data standards to be found in the analytical laboratory. Tony acts as a director of two SME’s and continues to teach advanced analytical chemistry at degree and higher levels. He jointly edits the Tony Davies Column on spectroscopic data handling in the journal Spectroscopy Europe.
Agile software development in life sciences

Donal O’Brien and Ryan O’Sullivan, QUMAS

- Understand why more than 80% of organisations now report using an agile approach
- How to successfully implement agile across large teams and distributed contexts
- Implementing an agile approach to safety-critical systems in a regulated environment
- Ensuring continuous compliance and living traceability

Donal O’Brien

Vice President of Development & Support, QUMAS.

Donal is responsible for leading and managing all aspects of the QUMAS product development and product support activities.

Over twenty years experience in the development and implementation of software systems, in a number of industry sectors including Life Sciences and Financial Services.

Certified Scrum master and Certified Product Owner.

Holds a BSc in Computer Science and a Masters in Business Administration.

Ryan O’Sullivan

Senior Development Manager, Scrum Master.

Ryan has over fifteen years experience in product development across a number of technology sectors.

Certified Scrum master and Certified Product Owner.

Worked across all technologies within QUMAS over the last 13 years.

Responsible for Implementing a Regulated Scrum development model within QUMAS.

Holds a BSc in Biological Sciences and a Higher Diploma in Computer Science.
Achieving the business and regulatory benefits of Quality by Design (QbD) using an operations intelligence solution

Justin Neway, Accelrys Ltd

The process and quality data stored in systems like Paper Records, LIMS, LES, EBR, ELN, Historians, ERP, etc., is organised differently in each system to serve the needs of specialised users who focus on different portions of pharmaceutical production processes. This creates problems for Quality and Process users who need to perform monitoring, data analysis and reporting on the process as a whole, to understand the sources of variability and implement initiatives like Quality by Design (QbD). These users need an automated way to access, aggregate and contextualise all types of process-related data in a validated environment for analysis and reporting outside of the disparate source systems without resorting to labor intensive, error prone spreadsheet methods. This includes on-line data from PAT instruments. This presentation will describe how pharmaceutical companies have overcome these problems by using a Manufacturing Informatics solution that provides a validated environment for self-service, on-demand access and automated contextualisation of data located in disparate source systems without making any alterations to those change-controlled sources systems.

Attendees will hear about:
- How to provide self-service access and aggregation of process and quality data
- The importance of automated data contextualisation for analysis and reporting
- Implementing automated process and analytical method monitoring and review-by-exception in the same validated environment as follow-up investigations
- Automating Annual Product Reviews (APR’s) and Periodic Quality Reviews (PQR’s).

Justin Neway

Justin O. Neway, Ph.D., BIOVIA Vice President and General Manager, Operations Intelligence, and Senior Fellow, BIOVIA Science Council, at Dassault Systèmes, has over 30 years of experience in biotechnology and pharmaceutical process development and manufacturing, and in the application of software solutions to operational issues and quality compliance in biotechnology and pharmaceutical manufacturing. He received his B.Sc. (Microbiology, 1975) and M.Sc. (Biochemistry, 1977) from the University of Calgary (Canada) and his Ph.D. in Biochemistry from the University of Illinois (USA) in 1982. Dr. Neway founded Aegis Analytical Corporation in 1997, and was its Vice President and Chief Science Officer at the time of its acquisition by Accelrys in 2012. Accelrys was subsequently acquired by Dassault Systèmes in 2014 to become its BIOVIA division. Before Aegis, he held various Process Development and Manufacturing leadership positions at Wyeth BioSciences, Novartis Vaccines and Baxter BioSciences.

IS/IT QA clinic

Matthew Davies, BIOVIA

15.30
Implementing a Quality Management System (QMS) in a non-commercial organisation

Melanie Boulter, Nottingham University Hospitals NHS Trust

Developing, implementing and controlling a quality management system can be a substantial task, whether creating a system from scratch or renewing and improving an existing system.

Nottingham University Hospitals NHS Trust (NUH) is a large acute teaching hospital that hosts and sponsors an extensive portfolio of research studies and has worked with a number of commercial and non-commercial organisations for many years.

As sponsor of a variety of different studies types NUH has experience of implementing and maintaining a quality management system. In this session NUH will share those experiences and provide the audience with an insight into the history of NUH’s quality management system through three MHRA inspections. NUH will discuss the challenges of maintaining their quality management system, how those challenges are overcome and the future plans for their quality management system.

Melanie Boulter

Melanie recently joined the Research and Innovation department at Nottingham University Hospitals NHS Trust as a QA Auditor following a career as a Biomedical Scientist for nearly 13 years. Melanie graduated in 2002 with a degree in Biomedical Science and went on to complete a Masters in Pathological Sciences whilst working as a Biomedical Scientist in Clinical Chemistry.

Prior to taking up her existing position Melanie fulfilled the role of Laboratory Lead for the Bowel Cancer Screening Eastern Hub in 2010 and went on to become Deputy Quality Manager in 2012, where she was involved in implementing the Quality Management System in the department in order to gain stand alone Clinical Pathology Accreditation.

Having worked in a laboratory for eight years Melanie can relate the quality culture to both the laboratory and management side of her QA Auditor role.

Promoting compliance in the non-regulated laboratory

Shirley Hallam, Hallam Pharma Consulting

Collaboration between a commercial sponsor and a non-regulated laboratory can be a mutually rewarding experience. Most academic laboratories welcome involvement with clinical trial sponsors and work well to cooperate to understand the sponsors’ needs. They are receptive to quality systems support if given in the right manner and with mutual understanding and respect of the needs of both parties.

This presentation contains advice for the development of contracts, guidance on audit and oversight, and an outline of the documentary evidence required by laboratory and sponsor. The roles and limits of quality systems, and preparation for regulatory inspection are also included.

Shirley Hallam

After obtaining a degree in philosophy, Shirley decided to do something more practical, and trained as a registered nurse. She worked for two years in general surgery before moving into public health research. She began her pharmaceutical career as a Clinical Research Associate, and worked for 10 years in clinical trial monitoring and project management before moving into GCP Quality Assurance in 2000. She currently works as an independent GCP auditor and consultant, working for commercial and non-commercial sponsors.
Update from the Health Research Authority (HRA)
Janet Messer, HRA

The Health Research Authority was established three years ago to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research.

We provide patients and the public with confidence in the quality of health research in the UK through an efficient and effective regulatory system. That means that people can feel confident about taking part in research, and we can all feel confident about the results of research in the UK.

We are making it easier to do good research by streamlining the regulatory system, providing guidance and advice, encouraging a learning culture, and developing templates and tools. We use our leadership, influence and collaborative approach to embed proportionate standards across the research community.

Janet Messer

Janet is Director of Systems & Development at the Health Research Authority, and Programme Director for HRA Approval, implementing a new integrated system for approval of health research in England over the next two years. She also works collaboratively with a wide range of partner organisations to fulfil the HRA’s aims to make it easier to do good quality ethical research in the UK. Prior to working at the HRA she was Head of Research Management and Governance at the NIHR Clinical Research Network, where she was responsible for a major change programme to improve the NIHR Coordinated System for gaining NHS Permission. She has a PhD in biochemistry from University of Cambridge and a Masters in Medical Law, along with many years’ experience of clinical research in the pharmaceutical industry and working with NHS R&D.

Outreach QA clinic
David Butler, new RQA Chair
Over recent years Animal Health has steadily embraced EDC technology for VICH GCP studies. The impact of EDC affects many study roles including the Investigator, Monitor, Data Manager and Quality Assurance (QA). In addition, EDC also impacts on a wide range of procedures that are performed by both Data Management (DM) and Clinical departments. Any auditing procedures adopted will require modification according to the changes brought by EDC implementation.

One of the major impacts of EDC studies for the study personnel involved in designing, validating and auditing EDC studies is the shift in the timelines for related activities in relation to the key clinical study milestones. The main changes are related to the development of the study database that will capture the study data as it is generated at the study sites.

Traditionally the study specific database was designed and built during the ongoing clinical phase. Completion required only prior to data entry usually following animal completion in the study. Any relevant Study Protocol Amendments arising during the study could be incorporated into the database build and subsequent validation steps. The timing of the database build and validation had no impact on the data that was being collected in paper CRFs.

In sharp contrast, the timelines for designing, building, validating and subsequent audit procedures for an EDC database have potentially a major impact on the study data. Any errors not picked up prior to the EDC database going live may have direct impact on the future study data to be collected. From an auditing perspective our efforts need to focus on these pre-study database related activities to ensure the integrity of the future study data.

The presentation will look at the following areas:

- EDC activities versus study roles
- Timelines of the study milestones
- Quality Assurance (QA) activities in EDC studies
- EDC specific issues.

**Janice Sarasola**

Janice graduated with a BSc. in Biology followed by a PhD in Veterinary Medicine at Glasgow University (1993). Janice continued her post doctoral research at Glasgow University in swine infectious diseases. On completion of her postdoctoral studies Janice joined Pfizer Research and Development at Sandwich where she held different positions within Human Clinical Development (R&D) involved mainly in European Phase III anti-infective clinical trials.

Following her career in the pharmaceutical industry, Janice jointly set-up ONDAX Scientific, a Contract Research Organisation (CRO) located in the UK and Northern Spain. Since the year 2000, ONDAX Scientific has been providing clinical development services to the pharmaceutical and biotechnology industries focussing mainly on all areas related to multinational VICH GCP clinical trials in livestock and companion animals. ONDAX Scientific main activities include set-up and monitoring of veterinary clinical trials, Data Management, Statistics, Quality Assurance and training in VICH GCP.

Janice is responsible for the Quality Assurance department within ONDAX Scientific whose activities include the auditing of VICH GCP clinical trials and related Data Management activities. These activities have focussed over the last few years on the development of all quality systems, validation and auditing activities required by the new EDC Data Management activities. In particular they have involved system selection, installation and validation, SOP/procedures development and training within ONDAX and quality input on database design and validation audits for both paper and Electronic Data Capture (EDC) database systems.

Janice has been a member of RQA since 2000, becoming a member of the Animal Health Committee in 2008.
What’s the future for the industry?

Commercial strategy driving the Life Sciences vision

Chris Evans, Gael Ltd

Creating a new product, a new technology, a new solution doesn’t necessarily mean it will be a success. Unless people and industry use it, it will never be a success and most importantly it will never drive the industry forward.

The presentation will look at:

- Commercial strategy for success
- Life science – Where are we?
- Maturity journey and can we fly?
- Collaboration and collective oversight
- Realising the vision.

We all have our own vision of what the future will hold for the Life Science industry . . . the reality of what we will actually see depends on what will be needed, what will bring benefit and value, and how demand will drive this vision.

Chris Evans

Chris has over 20 years’ experience of working within GLP, GMP and ISO regulated organisations. He is responsible for the life science strategy at Gael Ltd., a provider of Quality, Safety and Risk management solutions and services. He has delivered Q-Pulse projects all over the world within Medical Device, and Pharmaceutical organisations, as well as Healthcare, Manufacturing and Aviation sectors.

Having held Operational, Quality Assurance and Project Management positions within NHSBT and global life science organisations, including Quintiles and Sigma Aldrich, Chris has an understanding of the commercial and regulatory compliance challenges faced by global organisations.
What’s the future for the industry?

FRIDAY

11.00

Tomorrow’s health – A better and safer world

Judith Hann, Key note speaker, ex. presenter ‘Tomorrow’s World’ – Government Advisor

I will talk about healthcare of the past half century, the major innovations I have seen, and what breakthroughs I hope and expect over the next 50 years.

Medicine owes so much to the discovery of the structure of DNA by Crick and Watson and the genetic modification that eventually became possible. The human genome project then led to greater understanding, which made it possible this summer for centres in the UK to sequence the genetic codes of people with cancer and rare diseases. The first genome was sequenced on 30 May, with the aim of reaching the 1,000 genome mark by the end of this year.

This increased genetic knowledge has also affected IVF and its developments, which I explained regularly on Tomorrow’s World and wrote a book about research in this area of medicine. The latest debate is about changing the law to allow three-person IVF, with the aim of eliminating human mitochondrial diseases. The nucleus of a cell would be transferred from one woman’s egg to another woman’s egg that has had its nucleus removed. The result would be a child with DNA from two women and one man. This could be done because mitochondria have their own separate DNA. Children normally inherit this DNA only from their mother, so if her mitochondria are faulty the child can develop serious illness.

Another medical area which is advancing rapidly involves stem cell research. If current projects are successful it will bring a revolution to healthcare, giving doctors a new set of tools to treat diseases like cancer and repair damaged organs, like the brain, the heart and the eye.

Crick and Watson’s discovery will also lead to more personalised medicine as we begin to understand what causes patients to have different responses to drugs. And by understanding the genetic make-up of diseases, scientists will be able to target them more accurately. Pharmaceutical companies will benefit from personalised medicine with fewer abandoned products and expensive lawsuits. And health providers like the NHS will be able to buy more effective treatments.

Judith Hann

Judith is one of Britain’s leading science journalists, known to millions for presenting BBC’s Tomorrow’s World for 20 years as well as programmes on technology, health, food and the environment. After graduating from Durham University with a degree in zoology and botany, she trained as a newspaper journalist and twice won the Glaxo Award for science writing.

For five years she was a member of the AEBC, the Biotechnology Commission, helping to write reports, organise debates and give advice to the Government on new areas of scientific development which could affect farming and the environment. She has written seven books and the latest, How Science Works, has been translated into twenty languages and sold over one million copies worldwide.

Judith is a self-confessed herb fanatic and has planted a garden with over 150 different types of edible herbs at her home in the Cotswolds where she runs a very successful herb cookery school. She cooked for Rick Stein on his Food Heroes series and has made other TV programmes on food as well as writing two books on the subject.

With her husband, the television news journalist, John Exelby, she runs a media training and communications skills company. The Royal Society is one of their main clients and over the past six years they have trained hundreds of the world’s leading scientists. In 2009 Durham University awarded Judith an Honorary Doctorate of Civil Law for what the citation described as her “outstanding contribution to science journalism.”
Japanese Society Quality Assurance (JSQA) has moved to a “Corporate Organisation” this spring, 1 April 2014, which benefited us in various aspects, especially in secure intellectual properties and accountings. Internal organisation was not changed though and we keep the same activities as before.

Japanese pharmaceutical regulation was changed and new regulation will come into effect this autumn (25 November 2014). Japanese Pharmaceutical Affairs Law (PAL) is now changed into “Pharmaceuticals and Medical Devices Law”. In accordance with this movement, many Implementing Regulations and Ministry Ordinances were or will be revised. Japanese GCP, GVP and GPSP Ordinances which may affect our activities were updated. The presentation will cover such regulation changes/updates and to what extent they will affect us, Quality Assurance personnel.

Teiki Iwaoka

Dr. Teiki Iwaoka has 33 years of experience working for Sankyo Co. Ltd and 10 years for CAC Corporation (now CAC Exicare). During the work in Sankyo, he managed the QA group from GLP to GMP. He was a member of JSQA and RQA as well in this period. He was invited to give the speech at the SQA Annual Conference.

Moving to drug safety and pharmacovigilance field, he served as ICH E2B IWG and the chair of ICH E2D, ending up the Chair of ICH 6. ICH E2D step 4 document was his true baby.

After retirement from Sankyo, he was invited to CAC Corporation enabling him to work as internationally well-known colleague as an ex-ICH expert. The FDA Award in 2006 was for his contribution for his explanation of Japanese regulations to US colleagues. In 2007 he came back to JSQA (and RQA) and started again to serve Quality Assurance. This year he gave a presentation in 4th Global QA Conference.

Closing address

David Butler, New RQA Chair
Dear Delegate,

On behalf of the 2014 Conference Programme Committee, I would like to welcome you to the RQA 2014 Annual Conference in Brighton with the theme *Quality, Quo vadis?*

Vibrant, colourful, and fun, Brighton offers the energy of the city and freedom of the sea. From the stunning heritage of the Royal Pavilion, Regency architecture and Victorian aquariums to the seaside fun of Brighton Pier, the Brighton Wheel and the famous pebble beach, Brighton offers something for every walk of life. Brighton is famous for shopping with the lifestyle shops of The Lanes to the unique shops of Hove; the retro chic of the North Laine to the big-name stores of Churchill Square and Brighton Marina, shopping in Brighton really is retail paradise.

As the title says, this conference is about looking forward and the Programme Committee have enjoyed planning and implementing a programme that fits this brief. We hope that the variety of topics covered will provide for an interesting, instructive, interactive and inspiring conference and are very grateful to all the speakers who have risen to the challenge of delivering this theme.

Your feedback on the conference is vital for future events and to continually improve them and I would encourage you to complete the delegate feedback form.

Should you have any questions, problems or concerns whilst at the conference please contact myself, a member of the RQA Conference Team or any member of the Programme Committee, who will assist you in any way they can.

Wishing you an enjoyable and informative conference.

Nichola Stevens
Conference Programme Chair
Quality, Quo Vadis?

Research Quality Association
Annual conference
The Grand Hotel, Brighton
12 -14 November 2014