

Dear

You are receiving this request to complete an online questionnaire as a member of the Research Quality Association (RQA) or Institute of Clinical Research (ICR) with experience in GCP auditing or monitoring.

The purpose of this online questionnaire is to investigate the difference between auditing and monitoring in the pharmaceutical industry with a focus on quality management principles and techniques, as part of an independent research project for an MSc in Quality Management in Scientific Research and Development at Cranfield University, supported by the RQA.

Please respond to this questionnaire from the perspective of your current role (e.g. as a monitor, respond to the questions from a monitoring perspective).

This questionnaire has been designed to establish the key differences between auditing and monitoring, and has been divided into five main topics:

- Role and attributes of auditors/monitors within quality teams
- Principles and practices of research quality management in auditing/monitoring
- Quality practices of auditors/monitors
- Risk management in auditing/monitoring, and
- Quality improvement and CAPA management in auditing/monitoring

This questionnaire should take approximately 15 minutes, and comprises of 32 mainly multiple choice questions. The survey uses the Qualtrics electronic survey platform, through Cranfield University and can be accessed via the link below. The final date for responding is 31st March 2017.

Link: https://cranfielduniversity.eu.qualtrics.com/SE/?SID=SV_b1KOrX3X2pISIT3

By responding to this questionnaire you will be contributing to a final thesis titled: *An Investigation of Quality Management Principles and Techniques comparing the role of Auditor versus Monitor*. The research project is independent and not linked to any company or organisation. Results may be made available in future publications or forums.

The research project has been subject to ethics approval by Cranfield University. All responses are anonymous, confidential and will not be linked to you as an individual. You can withdraw your participation in this questionnaire at any time and whilst you are requested to respond to all questions, you may choose to skip particular questions, if you so wish.

Thank you for taking the time to participate in this research project, your input is greatly appreciated.

If you have any questions or queries please do not hesitate to contact me.

Kind Regards

Shaun Hastings

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