



MHRA Inspections from the perspective of a Pharmaceutical company

**ACDM/BARQA MHRA Inspections, 9th June 2009
Wyeth, Taplow, Maidenhead**

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Agenda

- Preparation for MHRA Inspection
- Business Contact role versus Regulatory Compliance
- Activities during audit
- What went well
 - Inspectors feedback
 - GSK feedback
- How could we do better next time?
- Audit finding – CDM
- Summary
 - Observations, a personal perspective

Preparing for MHRA inspection

- MHRA GCP audit conducted at GSK sites, January 2007
- The process that was followed by the MHRA was in relation to UK Statutory Instrument [SI 2004 No.1031] and ICH GCP
- GSK Clinical Compliance group convened a number of meetings with business support representatives to “prepare for audit”
- Business support representatives in conjunction with Clinical Compliance identified expected targeted groups from the audit plan supplied by MHRA
 - Supplied information to identify likely inspection targets and the all important “who” would be interviewed
 - which business areas would be inspected
- Training on the audit process was provided

Business Contacts role in supporting the business

Regulatory Compliance

- **Scope**

Provide management with a snapshot in time of identified risks to be mitigated

Business Contacts role in supporting the business

Business Contact

● Remit

Ensure quality through consultancy in providing education to ensure regulatory compliance through proactive / reactive risk mitigations

Ensure support by providing resource where required (e.g. audits, process improvement, training)

Key role in audit preparation and focus

Groups supported by Business Contacts

- Provide consultancy and assistance prior to and during regulatory audit to the following groups:
 - Statistical Sciences
 - Clinical Data Management
 - Integrated Systems Support (ISS) - system owners
 - Epidemiology
 - Regulatory Compliance

During the audit

- What happened during the audit, who was involved, what was expected by the auditors.....
 - GSK Regulatory Compliance group hosted the auditors, coordinated inspection and ran a tight ship for interviews and document retrieval following requests.
 - Business Contacts employed as runners (myself included)
 - Audit conduct and schedule was as per the inspection plan.
 - Each days activities summarised by the auditors verbally
 - Final day closed with an overall summary feedback
 - No unexpected issues occurred during audit

What went well.... According to the Inspectors

- Document retrieval (speed of provision)
- Response to queries
 - part resolution relating to a verbal finding commenced immediately
- Iron Mountain and destruction of clinical trial records
 - GSK proactive in identifying lost records
 - GSK initiated a for-cause audit of Iron Mountain
- Notification to MHRA of urgent safety measures for a trial was prompt (study terminated due to side effects), with good supporting records of action taken.

What went well.... From a GSK Perspective

- Business Contacts
 - Supported the Inspection Co-ordinators
 - Developed (& shared) action plans
 - Prepared own functional areas
 - Made time/ prioritised inspection-related work
 - Identified key contacts (back ups, runners etc)

What went well.... From a GSK Perspective

- Control Room
 - Useful to have manager from the functional area present
 - Use of Instant Messenger
 - Anticipate document requests
 - Emerging issues
 - Organisation of documents
 - Overview

What went well.... From a GSK Perspective

- Everyone contributed
 - Business Contacts
 - Runners
 - Interviewees
 - Others too!
 - Reception
 - Security
 - Cleaning staff
 - Facilities management
 - Admins

How can we do better next time?

- Face to face meeting with the inspectors prior to the inspection
 - Inspectors to gain better understanding of how GSK is organised
 - Agree areas for focus
 - More discussion over scope
 - Determine appropriate personnel in advance

How can we do better next time?

- Determine rationale for requesting certain documents
 - Documentation provided may not address inspectors concerns
- Runners/ Back ups need to be contactable
- Ensure systems are up to date (and clean)
- Follow up on findings from this (and other) inspections

Audit findings

Data Management

- Investigator does not have original copy of the CRF, which is **independent** of the sponsor at the end of a study
- Data management have little input into the QC of eCRF data
 - reliance on monitors at site doing SDV, Data Management has no input into Source Data Verification strategy
 - QC concentrates on mechanistic, automated, programmed checks
- Lack of clarity regarding the QC process with respect to extracting data from Data Management System to SAS

Summary

Business Contacts role is a plus

- Provide guidance to functional areas on next steps
- Liaise with identified responders to findings as appropriate
- 'Calming effect' on functional area
- Provide updates to functional areas as necessary
- Worked with the business to work on mitigation strategies
- Provided input to the audit report for GSK responses

Audit report – Final

- All responses accepted by MHRA

Personal observations following audit

- Auditors chose studies which being managed in an EDM system but..... Came in with a “paper” mentality on the process.
- GSK started working on responses following verbal feedback provided during inspection closeout meeting.
 - Working on verbal findings not included in the audit report is a risk but..... a risk worth taking as this enabled GSK to be prepared when the report was delivered by the MHRA (especially as we did not receive this until 6 months after inspection).
- You cannot prepare enough, audit preparedness not only demonstrated compliance with our own process but makes for a less stressful time.

Questions?



GlaxoSmithKline