

# Clinical Laboratory Standards – Expectations and Statutory Inspections from a UK perspective

Louise Handy

Brisbane 2008

## Introduction

- History & relevance of GCP, GLP & GCLP
- MHRA meeting
- Inspections
- Expectations

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## Regulatory background

- GLP regulations predate GCP by many years
- GLP is specifically for non-clinical health and environmental safety studies
- UK/EU – spate of legislation around GCP from 2001 to 2006

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## So what about clinical labs?

- GCP primarily about patient safety/rights
- 
- Only 3 references in GCP to labs – no detail
  - GCLP published by BARQA to address the identified need in 2003

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## MHRA

- Understanding of role of labs
- Guidance expected for some while
- Meeting held 5<sup>th</sup> March 2008
- 5 Inspectors and the Director, Inspection & Standards
- Attendees from pharma, CROs, industry bodies, universities, hospitals



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## MHRA

- Guidance document promised for this Autumn
- Already a legal basis for inspections of labs under EU directive 2001/20/EE
- 5 inspectors in MHRA conducting lab inspections – cross trained GLP/GMP, GCP/GPvP, GLP/GCP

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## Inspections

- Developing database of labs
- Inspections approx every 2yrs but risk based approach
- No plans to send inspection schedule
- Emphasis on GCP patient related issues not relevant to GLP studies
- Findings categorised – critical, major, other

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## Expectations - contracts

- List of studies
- Heavy emphasis on contracts & agreements & SOPs to drive them
- Recognise MSAs but expect periodic routine review – common deficiency
- Require enough detail re key elements
- In place before study start



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## Expectations – study conduct

- Expect work plans in place before study start
- SOPs, policies etc to be authorised by appropriate staff - senior level
- On inspection, expect documentation to verify instructions have been complied with
- Expect documentation to explain missing samples, short samples etc

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## Expectations – study conduct

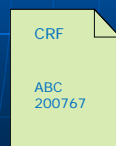
- Expect SOPs to cover safety issue as well as lab procedures, e.g. patient confidentiality, blinding etc
- Subcontractors to be clearly agreed & assessed for compliance and ability
- Findings include
  - Use of lab manual by clinical staff
  - Storage conditions not supported by stability
  - No explanation of missing/erroneous samples
  - Computer systems not validated/insecure
  - Problems with patient confidentiality

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## Expectations – confidentiality & patient awareness

- Identifiers
- Consent – no extra tests – rights extend to how samples are taken, processed & reported
- Blinding
- Expedited reporting

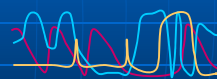


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## Expectations – lab practice

- LIMS validation
- Kit preparation
- Sample collection & tracking
- Method validation
- Repeat analysis
- Storage & archiving



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## Expectations – staff & training

- Roles & responsibilities clear
- No conflict of interest re reviewing data
- Expect training in relevant aspects of GCP
- Staff should be technically competent
- Verifiable

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## Expectations – quality systems

- QA – planned, systematic, independent
- QC – operational techniques & activities
- Document control
- Staff training



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## Clinical Laboratory Standards

- Recognise lack of guidance in legislation, but seen as a positive
- Key areas of interest
- Mostly similar to BARQA GCLP guidelines but with defined:
  - Emphasis on the patient – GCP
  - Emphasis on contracts

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