



GLP 30 Years On: Challenges for Industry

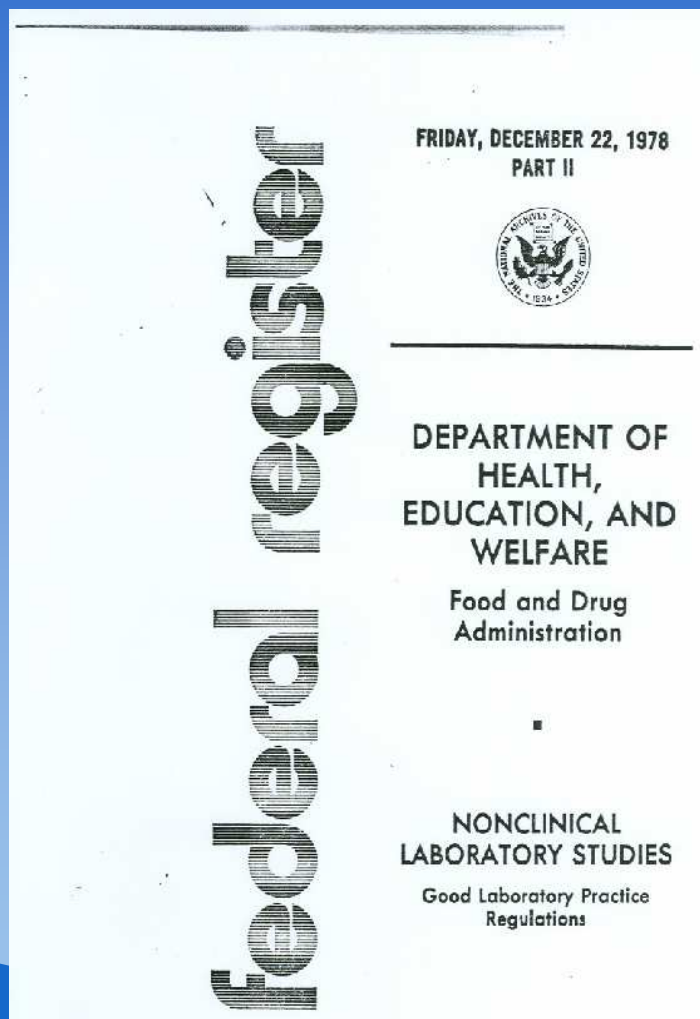
Mark Goodwin

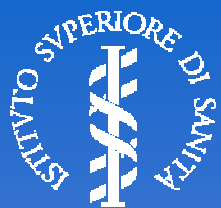
BARQA

11 April 2008

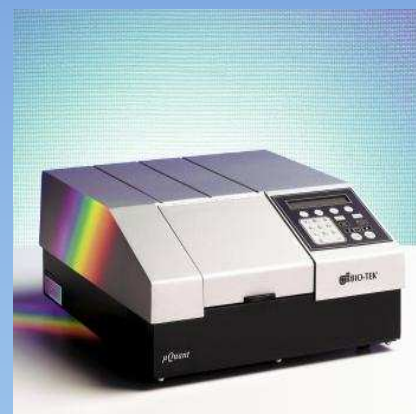
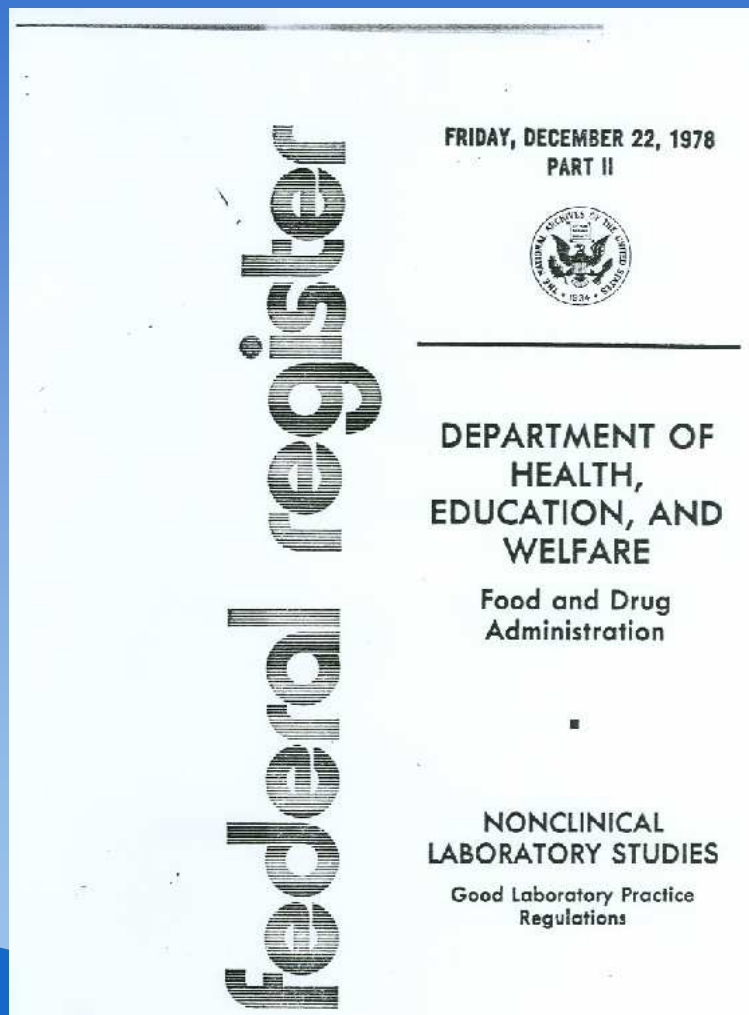


Status in 1978





Status in 2008





Industry Challenges

- Applying GLP Regulations in the modern day working environment
- Globalisation / harmonisation – national monitoring authorities interpretations
- Multi-site studies
- Independent QA v partnering with the business; relationship of industry with monitoring authority
- Scope of GLP



Applying GLP Regulations in the modern day working environment

- Scientific advancement
 - Replacing “accepted” techniques with novel approaches
 - New methodologies; ability to measure new parameters
 - Sensitive assays – contamination
 - Increasing interest in biological entities



Applying GLP Regulations in the modern day working environment

- Advances in technology
 - computerisation
 - automation
 - communications
- Risk management principles



Globalisation / harmonisation

- Organisations operate on a global basis rather than as separate national entities
 - National monitoring authorities differing GLP interpretations



Globalisation / harmonisation

National monitoring authorities differing GLP interpretations

- Scientists contribution reports v scientist signing fully integrated final report
- Definition of Pathologists raw data
- Information on QA statements
- Listing computer systems in protocols



Globalisation / harmonisation

National monitoring authorities differing GLP interpretations

- Test item characterisation to GLP (exceptions in compliance statement)
- Characterisation and stability of test item; different views on standard.
- Data cannot be removed from archive once lodged
- Data has to be paginated before archiving



Globalisation / harmonisation

National monitoring authorities differing GLP interpretations

- Terminated studies with no human exposure; final report, summary report or no report
- Critical phase inspections on every study
- Independent review of QA
- Test site to retain a photocopy of all study data if being returned to SD



Globalisation / harmonisation

- Streamlined organisation
 - Global management
 - Harmonisation of processes / procedures
 - Minimal duplication of functions
- Resource management
 - Secondments; short-term sharing of staff
 - Global training / meetings
- Multi-site studies



Multi-site Studies

- Numerous permutations relating to number, types and compliance status of test sites
- Different interpretations of management of multi-site studies
- Protocol input, distribution and PI acceptance of responsibilities



Multi-site Studies

- Clear understanding of ‘rule of ones’
- Effective QA monitoring of entire study and communicating findings to SD
- Demonstrating communication between remote parties



Maintaining QA Independence

- QA and auditees work for the same company; common goal - products to market or provision of quality contract service
- QA considered partner rather than police force; QA provide GLP training, advice and consultation.
- QA must maintain independence



Relationship of Industry with Monitoring Authority (MA)

- Industry must maintain compliance; MA must independently monitor industry for compliance – to protect public health
- Good proactive interactions satisfy both needs
- MA gain understanding of the business
- Industry made aware of issues – CAPA
- MA to make less findings; minimise repeat findings; minimise risk to public health



Scope of GLP

- Interpretation of ‘non-clinical safety study’
- New study types
- ‘Investigative studies’
- Use of non-GLP facilities
- Predictive software (modelling)
- Validation
- Archiving



Summary

- The test facility environment has changed and is forever changing
- The GLP principles, although a little dated, are still fundamentally sound
- Test facilities, Monitoring Authorities and Receiving Authorities must embrace a compliance approach fit for the 21st century.