GLPs and Quality Management Systems

The Potential to Increase Compliance

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Agenda

- What is a Quality Management System (QMS)?
- Different Types of QMS
- Similarities and Differences between GLP and ISO 9001 QMS (International Organization for Standardization)
- Benefits of ISO QMS to the GLPs
- Summary

What is a QMS?

Collective policies, plans, practices, and the supporting infrastructure that enables an organization to identify, measure, control and improve the various core business processes that will ultimately lead to improved business.

Types of QMS

- General
  - ISO 9001 – Quality Management System Requirement
- Industry and Product Specific
  - TL 9000 – telecommunications
  - API-Q1 – petroleum, petrochemical and natural gas
- Process Specific
  - GLP (FDA, EPA...) – conduct of non-clinical laboratory studies
  - ISO 17025 – general requirements for the competence of testing and calibration laboratories

QMS Requirements: GLP and ISO 9001

GLP

- Test System
- Master Schedule
- Study Workflow
- Study Director
- Archivist
- QAU

Shared

- Equipment
- Procedures
- Records
- Management
- QC
- Training*
- Audit*
- Corrective actions*

ISO 9001

- Customer Feedback
- Continuous Improvement
- Procurement
- Preventative Actions
- Management Review
- Metrics

*Different implementation of shared requirements

Differences in Implementing Shared Requirements

	GLP	ISO 9001
Training	Understanding SOP	Understanding SOP Competency training
Audit	Independent of study conduct	Part of the process
Corrective actions	Address issues for the study	Root cause analysis

Potential Benefits of Adding ISO 9001 Requirements to GLPs

- Drives implementation of permanent solutions to entire organization
- Increase organizational effectiveness
- Imbeds continuous improvement into the culture

Drives Implementation of Permanent Solutions

Management of Non-Compliance

GLP

- Study/Facility issues are assessed for impact to study integrity
- QA identifies non-compliance, reports findings and ensures findings are addressed

ISO 9001

- Study/Facility issues are assessed for impact to product (study) and **process** integrity
- Issues (non-conformities) documented in a CAPA process
- Preventative Actions and Opportunities for Improvement identified and tracked (CARs ⟶ PARs, OFIs)

Increases Organizational Effectiveness

Communication to Management on Quality

GLP

- QA communicates all issues to Study Director and Management via audit report
  - Reports can be seen as punitive

ISO 9001

- Teams discuss all issues and overall quality status during Management Review Meetings
  - Open dialogue, management support, shared ownership

Imbeds Continuous Improvement Into the Culture

Continuous Improvement

GLP

- Each study is treated independently, not built into system

ISO 9001

- Continuous improvement built into the system
- Effectiveness, efficiencies and their interactions are measured and tracked

Summary

GLP – minimum requirement that we must meet to ensure data integrity

- It's the Law!

ISO 9001 – May enhance GLP compliance

- Additional aspects of Training, Corrective Actions
- Select QMS Specific requirements (Continuous Improvement, identifying and implementing permanent solutions to the issues)

Thank you!

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