GLPs and Quality Management Systems
The Potential to Increase Compliance

Milica Vogt
Quality Assurance Team Lead
Monsanto Company

NAICC 2015 Annual Meeting
1/22/2015
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

<table>
<thead>
<tr>
<th></th>
<th>GLP</th>
<th>ISO 9001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training</td>
<td>Understanding SOP</td>
<td>Understanding SOP Competency training</td>
</tr>
<tr>
<td>Audit</td>
<td>Independent of study conduct</td>
<td>Part of the process</td>
</tr>
<tr>
<td>Corrective actions</td>
<td>Address issues for the study</td>
<td>Root cause analysis</td>
</tr>
</tbody>
</table>
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!