ISPE Product Show
Quality Systems in the 21st Century

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7 October 2015
3:30 pm – 4:30 pm

Agenda

• Introductions
• What Schools are here today?
• What Majors?
• Overview of Quality Systems
Quality System

- Pharmaceutical Development
- Technology Transfer
- Commercial Manufacturing
- Product Discontinuation

GMP

Management Responsibilities

Quality System Elements
- Process Performance & Product Quality Monitoring System
- Corrective Action/Preventive Action (CAPA) System
- Change Management System
- Management Review

Enablers
- Knowledge Management
- Quality Risk Management

Quality Systems

- **Achieve Product Realization**
  - Deliver products with quality attributes to meet the needs of patients and agencies

- **Establish and Maintain a state of control**
  - Effective monitoring systems for process performance and product quality... Quality Risk Management (QRM) can be useful

- **Facilitate Continual Improvement**
  - Knowledge Management and QRM
Quality Systems

- **Document Control**
  - Good Documentation Practices
    - Blue or Black Indelible Ink
    - No White Out
    - Corrections – Comments
    - Documented at time of performance
    - Recreate activity based on records

BDS = Bulk Drug Substance
POR = Plan of Record
• Careers in Quality? Let's Review the Process
  • Raw Material Receipt
  • Media Prep
  • Growing Cells in Bioreactors
  • Environmental Monitoring
  • Control Room – Automation
  • Process Monitoring
  • Buffer Prep for Purification of Cells
  • Suitable Equipment
  • Calibration

Workplace Organization
Housekeeping—
Everyone’s Responsibility

- Manage responsibilities of housekeeping using visual aids and standard work practices.

Change Management System

- Risk Based approach to ensure proposed changes have impact to marketing authorization
- Proactive . . . driven by data
  - Data Driven Decisions ...
  - Outputs from monitoring, trending,
  - Evaluate to assure no unintended consequences
  - Evaluate Effectiveness of Changes
Quality Systems

- **Quality Records**
  - Must be able to provide evidence of completed records for:
    - Employee Training
    - Management Review Meetings
    - Supplier Qualification Records
    - Inspection of products conducted by employees (QC)
    - Batch Records, Job Travelers, Recipes
    - Laboratory Tests

Quality Risk Management (QRM)

- QRM begins in Product Development and continues in Manufacturing as part of its life cycle management

- Knowledge gained during development is foundational to a process and the manufacturing history builds on that knowledge base
The Basic Structure of Design Control

- Planning
- Input
- Output
- Verification & Validation
- Design Transfer
- Design Change
- Design Review
- Design History File (DHF)

Design Control Success

- Establish a team culture
  - Design wants to make it work.
  - Quality wants to prevent failure.
  - Regulatory wants to make it legal.
  - *All three are needed. None is sufficient by itself.*
Review

• Quality System Elements and Management Responsibilities
  – Encourage use of Science and Risk Based Approaches
  – Promote Continuous Improvement
  – Enablers
    • Knowledge Management
    • Quality Risk Management
**Sequence and Interaction of Processes**

**Quality Management System**

- Customers → Management Responsibility → Satisfaction
- Resource Management → Measurement, analysis and improvement → Product
- Requirements → Product Realization → Product

**Management Commitment**

- Effective Quality System is in place to achieve quality objectives
- Roles Responsibilities defined
Internal Communication

• Appropriate communications processes
  – All levels of company
  – SharePoint
  – Huddles
  – GEMBA (lit. the “real” or “actual” place)
  – Bulletin Boards
  – Newsletters

• Escalation of product quality as needed...
  – Notification to Management

Management Review

• Senior Management Governance
  – Suitable Adequate Effective

• Product Quality and Process Performance

• Quality System Performance

Note: 21 CFR 820
Outsourced Activities and Purchased Materials

- Quality System and Management Responsibilities extend to control and review of any outsourced activities and purchased materials
- Process must be in place:
  - Assess suitability of outsourced operations and material suppliers
  - Ensure use of qualified suppliers and approved supply chains
    - Audits, questionnaires
  - Define responsibilities and communication processes
    - Quality agreements

Product Quality

- Measured at various stages before, during and after manufacturing process
- Annual Product Reviews (APR)
Continual Improvement of Quality System

- Measurement of achievement of Objectives
  - Key Performance Indicators (KPI)
    - Performance Indicators to monitor effectiveness
    - Audits, CAPA, complaints, recalls—internal
    - Emerging regulations
    - New technology
    - Change in business strategy
  - Outcomes of Review and Monitoring
    - Improvement to Pharmaceutical Quality System (PQS) and Processes
    - Revision to Quality Policy and Objectives
    - Allocation and Reallocation of Resources

Quality Systems Today

- Globalization and complex supply chains
- Increased Outsourcing
- Cost Reduction
- Reduction In Force (RIF)
## Manufacturing Control Systems

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<thead>
<tr>
<th>210/211 (cGMP)</th>
<th>820 (QS)</th>
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<tbody>
<tr>
<td>211.84 Testing and Approval or rejection of components, drug product containers, and closures</td>
<td>820.30 Design Controls</td>
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<tr>
<td>211.103 Calculation of yield</td>
<td>820.50 Purchasing Controls</td>
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<td>211.137 Expiration dating</td>
<td>820.100 Corrective and Preventive Action</td>
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<td>211.165 Testing and release for distribution</td>
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**Thank you!**

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