ISPE Product Show

Quality Systems in the 21st Century

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Connecting a World of Pharmaceutical Knowledge

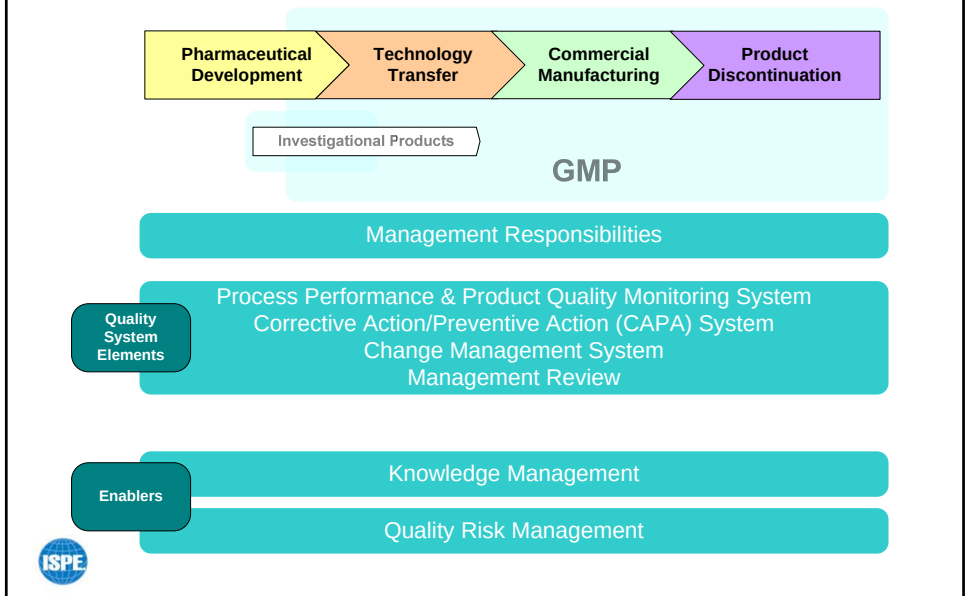
7 October 2015
3:30 pm – 4:30 pm

Agenda

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

Slide 2

Quality System



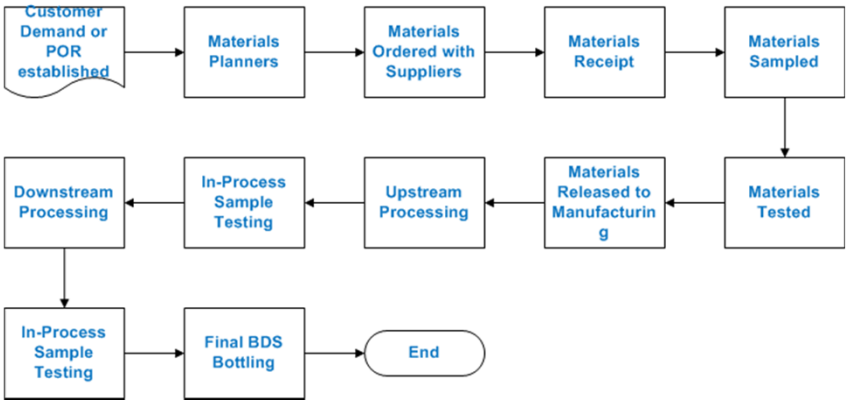
Slide 3

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

Slide 4

BioTech



BDS = Bulk Drug Substance
POR =Plan of Record

Slide 5

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

Slide 6

- Careers in Quality? Lets 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**

Slide 7

Workplace Organization

Slide 8

Housekeeping—Everyone's Responsibility

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

Slide 9

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

Slide 10

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

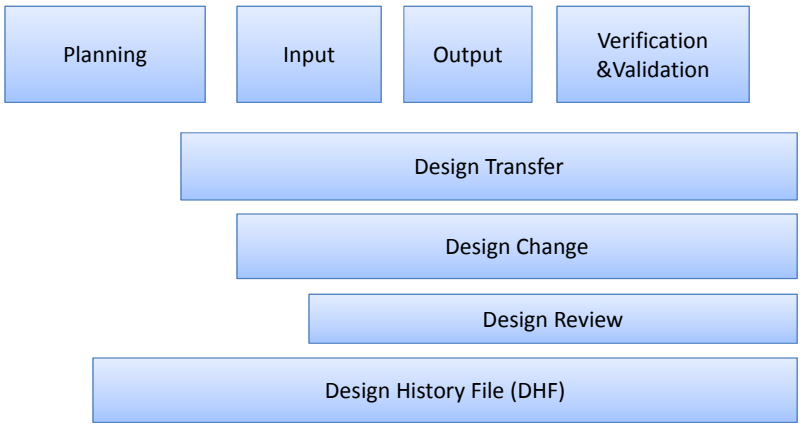
Slide 11

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

Slide 12

The Basic Structure of Design Control



Slide 13

Design Control Success

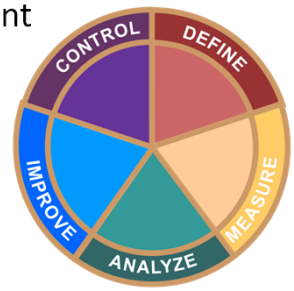
- **Establish a team culture**
  - Design wants to make it work.
  - Quality wants to prevent failure.
  - Regulatory wants to make it legal.
  - ***All three are needed. None is sufficient by itself.***

Slide 14

Slide 15

Review

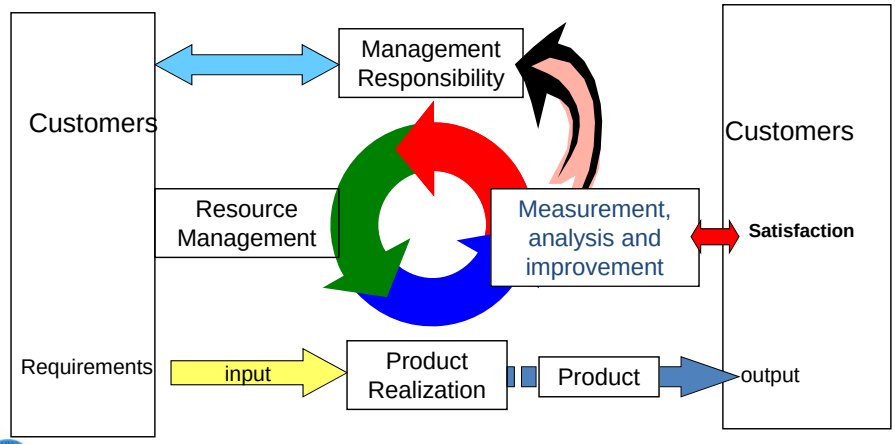
- Quality System Elements and Management Responsibilities
  - Encourage use of Science and Risk Based Approaches
  - Promote Continuous Improvement
  - Enablers
    - Knowledge Management
    - Quality Risk Management



Slide 16

Sequence and Interaction of Processes

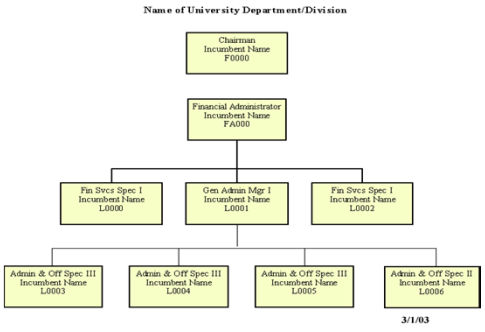
Quality Management System



Slide 17

Management Commitment

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



Slide 18

Internal Communication

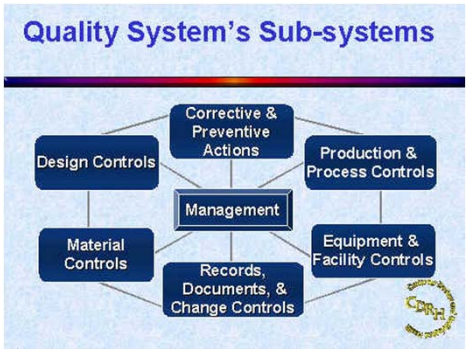
- Appropriate communications processes
  - All levels of company
  - SharePoint
  - Huddles
  - GEMBA (lit. the “real” or “actual” place)
  - Bulletin Boards
  - Newsletters
- Escalation of product quality as needed…
  - Notification to Management

Slide 19

Management Review

- Senior Management Governance
  - Suitable Adequate Effective
- Product Quality and Process Performance
- Quality System Performance

Note: 21 CFR 820



Slide 20

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

Slide 21

Product Quality

- Measured at various stages before, during and after manufacturing process
- Annual Product Reviews (APR)

Slide 22

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

Slide 23

Quality Systems Today

- Globalization and complex supply chains
- Increased Outsourcing
- Cost Reduction
- Reduction In Force(RIF)

Slide 24

Manufacturing Control Systems

210/211 (cGMP)	820 (QS)
211.84 Testing and Approval or rejection of components, drug product containers, and closures	820.30 Design Controls
211.103 Calculation of yield	820.50 Purchasing Controls
211.137 Expiration dating	820.100 Corrective and Preventive Action
211.165 Testing and release for distribution	
211.166 Stability Testing	
211.167 Special Testing Requirements	
211.170 Reserve Samples	

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45th Annual Boscon:

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Thank you!

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