

## Implementation of a Modern Risk-based Approach

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### Breakout Session D: Implementation of Quality Systems: Opportunities and Challenges

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## Breakout Session Outline

- Issues Discussed
- Shared Understanding & Agreements
- Remaining Challenges
- Recommendations
  - Strategies to implement agreed-upon issues
  - Proposals to resolve remaining challenges

## Issues Discussed

- Quality system – role in QbD
- Knowledge Management – integration with the quality system
- Change Management
  - Within design space
  - Outside the design space
- Risk Management

## Quality System - general

- Shared understanding
  - Role & support of management is key
  - Firm needs an overarching approach to quality system, but individual sites will implement locally
- Remaining challenges
  - Transition from a compliance/checklist approach to quality system/knowledge based approach
  - Integrating quality systems as business structures change (e.g. multi-site, mergers)
  - Regulatory requirements for quality systems vary globally
- Recommendations
  - System must involve all areas of firm, not just the quality unit
  - Management expectations and support should be included in the quality system
  - Evaluate effectiveness of quality system periodically and implement continuous improvements
  - Continue to support global harmonization of guidance
  - Education is needed for all parts of organization – industry & regulatory bodies

## Knowledge Management

- Shared understanding
  - Common understanding of importance
  - Knowledge of both failure & success
  - Knowledge needs to flow in both directions between development and manufacturing
- Remaining challenges
  - Format knowledge is captured in and shared with regulator & within company
  - Converting data & experience to knowledge
  - Inconsistent interpretation of PAT in Quality by design
- Recommendations
  - Balance written reports with interpersonal meetings
  - Use of product history file, Risk assessments as an approach
  - Utilize existing quality system processes where possible e.g. APR
  - Technical report: focus on conclusions / knowledge gained
  - Quality system processes should include expectations to use existing knowledge and capture new knowledge
  - Need for further discussion of role of PAT in Quality by Design

## Risk Management

- Shared understanding
  - Should be used to manage product/process controls not to justify position
  - Risk management: good tool to focus data management
- Remaining challenges
  - Common understanding for concept and use
  - Lack of common understanding and use of term 'critical'
- Recommendations
  - Engage diverse inputs to risk management
  - Quality system processes should be designed to focus efforts & resources on areas of highest risk
  - Focus on how risk is controlled rather than definition of critical.
  - Manage to agreed acceptable risk – not necessarily zero

## Change Management

- Shared understanding
  - All changes need to be managed irrespective of regulatory process requirements
  - Change management system must include evaluation of risk
- Remaining challenges
  - Understanding the regulatory commitments with respect to the design space
  - Change management system needs to include evaluation of existing design space knowledge and further data needs (e.g. scale –up)
  - Evaluating change proposals for clinical relevance
  - Reluctant to change due to perceived regulatory repercussions
- Recommendations
  - Cumulative impact of multiple changes needs to be monitored
  - Continue to evolve interaction between review and field
  - Clarify change management expectations (e.g. Q10, CFR 314.70)