

# ICH Public Meeting

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# The Current State of Pharmaceutical Manufacturing

- Inability to predict effects of scale-up
- Lack of agility – usually takes years to bring up a new production site
- Operations fragmented around globe
- Inability to understand reasons for manufacturing failures

# Why A Harmonized Approach to A Comprehensive, Modern and Robust Quality System? (Why ICH Q10?)

- Improve quality of pharmaceutical products
- Improve CGMP compliance
- Facilitate continual improvement
- Necessary for implementation & effective utilization of:
  - Quality By Design (Q8 Pharmaceutical Development)
  - Risk Management (Q9 Pharmaceutical Risk Management)
  - Effective knowledge transfer
    - CAPA
    - Change control
    - Review and Inspection
  - Demonstrating state of control
    - Ability to manage movement within the design space

# ICH Q10

- Continuous Learning and Improvement
  - Much learning takes place through process experience
  - Our 21<sup>st</sup> Century Regulatory System will facilitate this improvement
  - Flexibility
  - Management and Performance based regulation

# ICH Q10 EWG Mission

- To establish a new tripartite guideline describing the model for an effective quality system needed to establish and maintain a state of control that can ensure the realisation of a quality drug product and facilitate continual improvement over the product life cycle.

# Q10 is Optional

- Q10 is intended to describe an approach to developing an effective quality system.
- A firm may choose to adopt certain elements of Q10, all of Q10 or an alternate approach to a quality system.
- The extent to which Q10 or any other quality system approach is adopted may depend on a firm's existing quality system as well as the size and complexity of operations.
- The design, implementation and demonstration of an effective Quality System can create a basis from flexible regulatory approaches.

## Q10 Scope

- Drug substance (small and large molecule) operations
- Drug product operations
- Throughout the product lifecycle, including pharmaceutical development, technology transfer and manufacturing.

# Q10 Basis

- Customer requirements
- Aligned with ISO, EU GMP, Q7A, FDA Quality Systems Guidance
- Bridges GMPs in various regions to a common approach for quality systems
- Prevent delays of introductions of new and stoppages of existing medicines
- Removes impediments to modernizing products and processes paralleling other industries which have made strides in quality culture and implementation

## Q10 Areas to Cover

- Common terminology
- Definition and maintenance of the Quality System
- The role of management including senior management
- Identification of performance indicators, management of trends to determine effects on processes and products
- Effective change control processes

# Quality System Elements

- Product Realization
  - Provide a manufacturing process capable of consistently producing a medicinal product of the quality required to meet customer requirements.
- Continual Improvement
  - Facilitate and control product quality improvements, process variability reduction, innovation, and quality system enhancements, thereby managing the risks related to product quality and the quality system.

# Continual Improvement

- Two Facets
  - **Product quality**
  - **Quality System effectiveness**

## Q10 and Q8

- Processes for pharmaceutical development (Q8 or equivalent) are key linkages to product realization within the Pharmaceutical Quality System.
- Q8 provides the process understanding that serves as the basis for continual improvement.

## Q10 and Q9

- The Quality System should encourage and facilitate the use of Quality Risk Management (Q9) approaches throughout the system.
- The design and application of processes within the Quality System should be based on appropriate risk management principles and methods

# Outsourcing

- The Quality System and management responsibilities should extend to the oversight, control and review of outsourced operations.
- The contract manufacturer or service provider may have an independent Quality System that links to a firm's Quality System
- The contract manufacturer or service provider may operate within a firm's Quality System.

# Expected Benefits

- Technical Innovation
- Post-approval changes that can be managed through internal change management processes.
- Design Space, Control Strategy and PAT
- New approaches to process validation that benefits from lifecycle improvements including Continuous Quality Verification where feasible
- Meaningful investigations
- Effective CAPA

# Work Plan

- Currently being drafted by Expert Working Group
- Hope to achieve Step 2 consensus in Spring 2007

# Conclusions

- An international harmonized approach to the manufacturing quality of pharmaceuticals
- Change control empowered to the manufacturer within design space and with a robust quality system
- More efficient manufacturing and regulatory processes.