



QbD -- What is it ??

Quality by Design system :

- Begins with predefined objectives
- Systematic approach to development
- Appropriate control strategies are developed
- Based on sound science and quality risk management
- The product is designed to meet users needs and performance requirements
- The process is designed to consistently meet product critical quality attributes
- The impact of starting raw materials and process parameters on product quality is understood
- The process is evaluated and updated to allow for consistent quality over time
- Critical sources of process variability are identified and controlled

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QbD -- Why ?

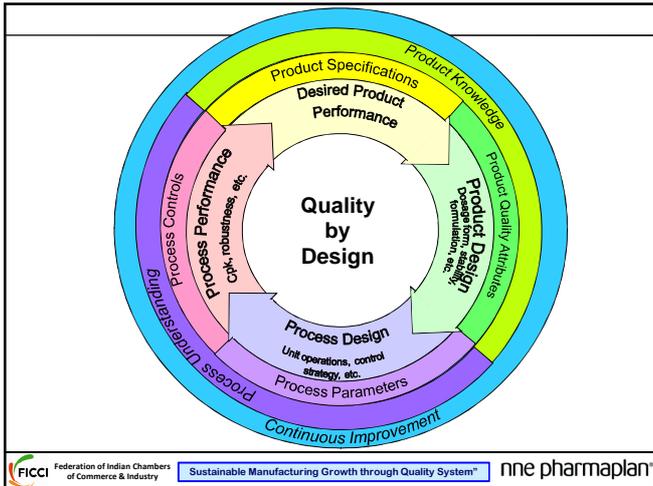
Higher level of assurance of product quality for user / consumer

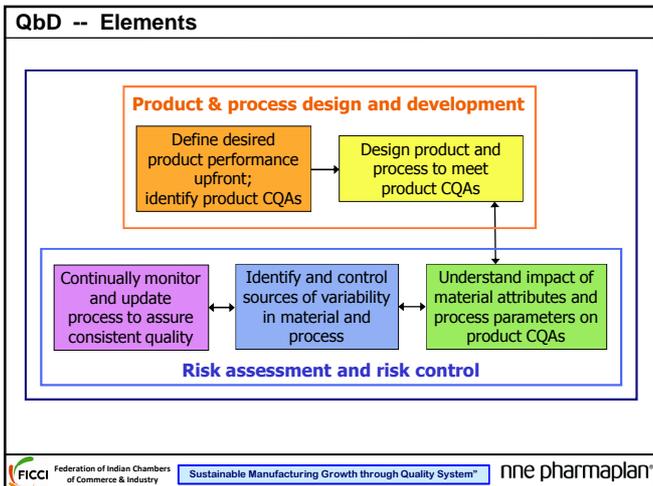
- Improved product and process design and understanding
- Quality risk management in manufacturing
- Monitoring, tracking and trending of product and process
- Continual improvement

Cost saving and efficiency for industry

- Increase efficiency of manufacturing process
- Minimize/eliminate potential compliance actions
- Provide opportunities for continual improvement
- Facilitate innovation

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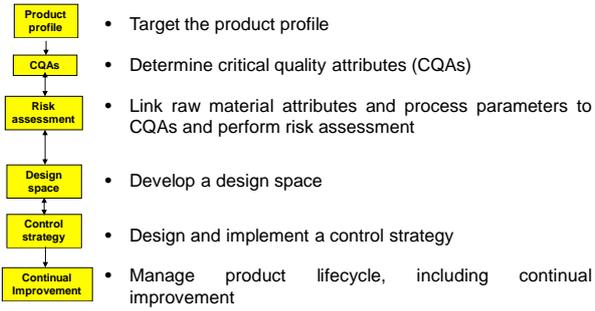


QbD -- Approach

Aspects	Current	QbD
Product Development	Empirical, Random, Focus on optimization	Systematic, Multivariate experiments, Focus on control strategy and robustness
Manufacturing Process	Fixed	Adjustable within design space, managed by company's quality systems
Process Control	Some in-process testing	PAT utilized, Process operations tracked and trended
Product Specification	Primary means of quality control, based on batch data	Part of the overall quality control strategy, based on desired product performance
Control Strategy	By testing and inspection	Risk-based control strategy , real-time release possible

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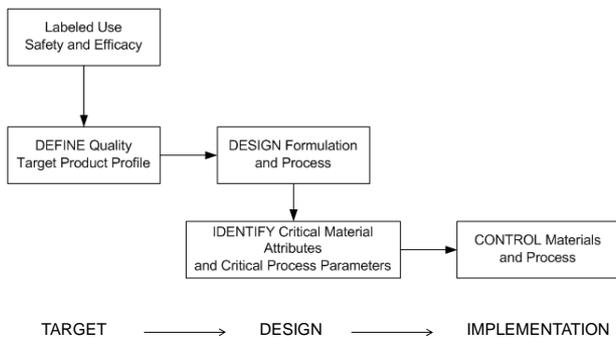
QbD -- Approach – example...



QbD -- Generic Approach

- Guides product and process development
- Promotes communication among different functions within the company
- Points to the need for good knowledge management systems
- Will and should improve technology transfer
- Move development activities upfront, more product and process understanding reduces risk of process scale-up
- Technical support and technical writers added.
- Understanding of manufacturing process
- Development report is now more product and process design focused.
- Deficiency questions are science-based and are used to re-direct R&D activity for future products

QbD -- Overview



QbD -- Manufacturing Process Development

- Start product design in early phases of development
- This may be an iterative/continuous process
- Base critical quality attributes on desired/targeted product performance requirements
- QbD is full understanding of product and process and implementation of that understanding
- QbD is more than traditional process and formulation optimization
- QbD is more than justification of CQAs and CPPs

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QbD -- Barriers

Culture challenges

- Move from prescriptive approach
- More sharing of scientific and risk information

Business Challenges

- Business justification
- Management Support
- Budgeting silos across business units

Implementation Challenges

- Collaboration between functions
- Experience with new concepts
- Workload and resource limitations

International harmonization

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QbD -- Barrier Break - Downs

New guidances on quality

- International participation

New review processes

- Greater information sharing in application
- Enhanced communication between developers and manufacturers
- Enhanced interactions between review and field investigation

Gain experience through working together

- Sponsored pilot programs
- Industry consortium, mock submission documents, etc.

Sharing information and experience

- Developers sharing with industry through meetings and conferences
- Sharing amongst industry through publications and presentations

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QbD -- Advantages

- Better innovation due to the ability to improve processes
- More efficient technology transfer to manufacturing
- Less batch failures
- Greater regulator confidence of robust products
- Risk-based approach and identification
- Innovative process validation approaches
- For the consumer, greater product consistency
- More product availability and less failures / rejections.
- Improved yields, lower cost, less investigations, reduced testing, etc.

Better Quality ...

QbD -- Golden Rule

- Get facility design right from the start
- Validate processes
- Write good procedures and follow them
- Identify Roles and Responsibilities
- Train and develop staff (including CAPA)
- Keep good records
- Maintain facilities and equipment
- Perform regular audits
- Build quality into the product lifecycle
- Practice good hygiene

QbD -- Key Concepts

- Build in quality versus test in quality
- Scientific-based knowledge of the products and processes
- Identify, understand, and control CQA's (Critical Quality Attributes) and CPP's (Critical Process Parameters)
- QrM (Quality Risk Management) approach (risk assessment, risk control, and risk review) ^[10]
- Design Space (DS) to identify acceptable limits of operation via DOE (Design of Experiments)
- Control Strategy to ensure production is maintained within the DS
- Use advanced statistical tools and technology such as PAT (Process Analytical Technology).
