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

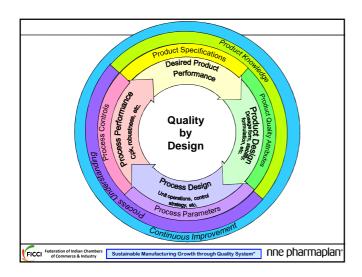
- Improved product and process design and understanding
- Quality risk management in manufacturing
- Monitoring, tracking and trending of product and process
- Continual improvement

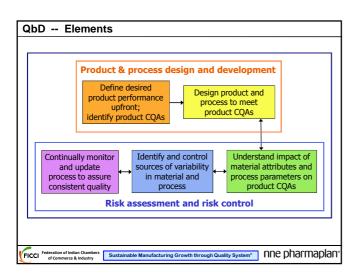
Cost saving and efficiency for industry

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

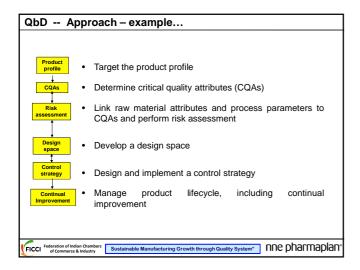
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QbD Approach			
Aspects	Current	QbD	
Product Development	Empirical, Random, Focus on optimization	Systematic, Multivariate experiments, Focus on control strategy and robustness	
Manufacturing Process	Fixed	Adjustable within design space, managed by 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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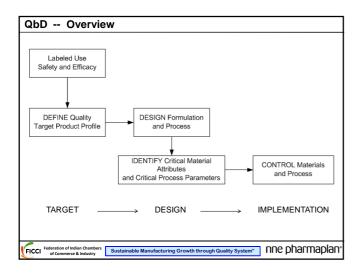
QbD -- Generic Approach

- · 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

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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 nne pharmaplan[®] 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 FICCI Federation of Indian Chambers of Commerce & Industry Sustainable Manufacturing Growth through Quality System" NNE pharmaplan* 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 nne pharmaplan FICCI Federation of Indian Chambers Sustainable Man

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.	
Rosson Quality	
Better Quality	
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or Commerce & industry	
QbD Golden Rule	
Get facility design right from the start	
Validate processes	
Write good procedures and follow them	
Identify Roles and Responsibilities	
identity 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	
Tractice good hygiene	-
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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). 	
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QbD -- Take Home Message

- · QbD is different in different industry
- QbD philosophy leads to
 - Stronger linkage between departments within companies
 - Improved success in product approval
 - More robust, efficient commercial operations.
 - Decreased production failures
 - Decreased regulatory burden
 - Improved relationship with regulatory bodies
 - Science driven compliance

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QbD -- Conclusion

Quality by Design

- Define quality target product profile
- Design and develop product and process to meet target product quality profile
- · Identify critical raw material attributes, process parameters, and sources of variability
- Control raw materials and process to produce consistent quality over time

PAT, DoE, and Risk Assessment are tools to facilitate the implementation of QbD

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Thank you for your attention

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