



**QUALITY BY DESIGN (QbD)  
APPROACHES FOR ORALLY INHALED  
AND NASAL DRUG PRODUCTS  
(OINDPs) IN THE USA**

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# Outline

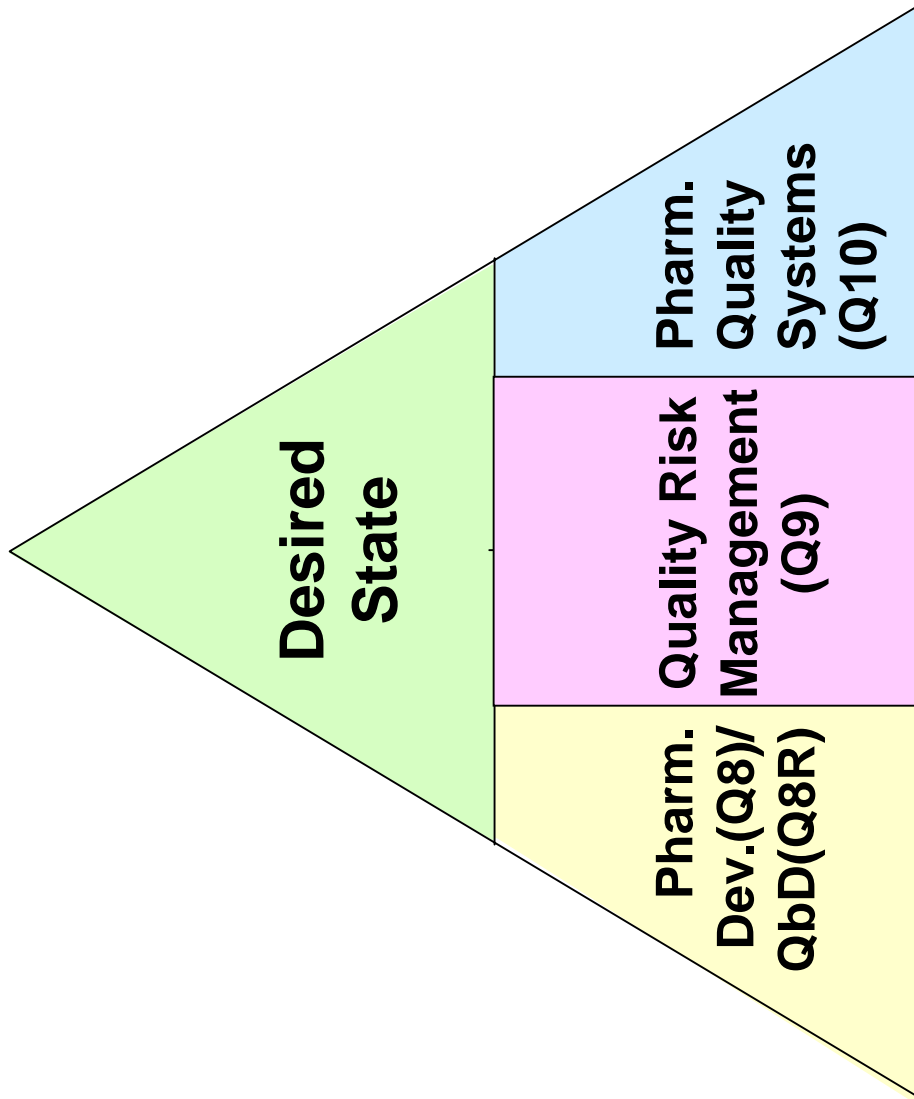
- General QbD principles
  - What is QbD/Design Space
  - Why use QbD for OINDPs?
- QbD applied to OINDPs
  - Product Design
  - Formulation Design
  - Container Closure System Design
  - Process Design (e.g. micronization)
  - Design and Setting Specifications in the Future
- Blinded case studies where QbD could have helped shorten approval time

# What is QbD?

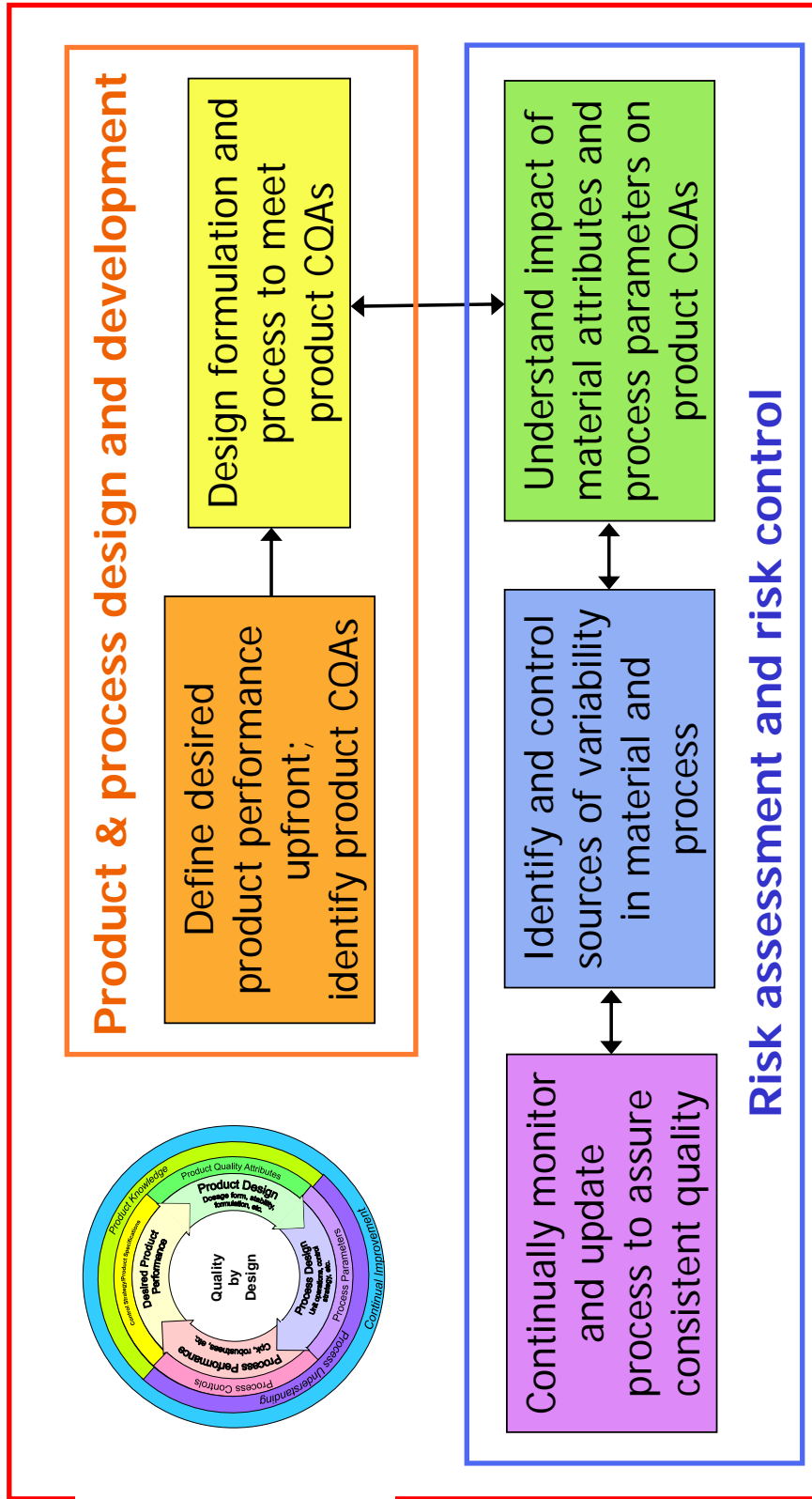
- Quality by Design is:
  - Scientific, risk-based, holistic and proactive approach to pharmaceutical development
  - Deliberate design effort from product conception through commercialization
  - Full understanding of how product attributes and process relate to product performance

QbD information and conclusions should be shared with FDA

# ICH Quality Roadmap



# ObD System



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