



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

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Outline

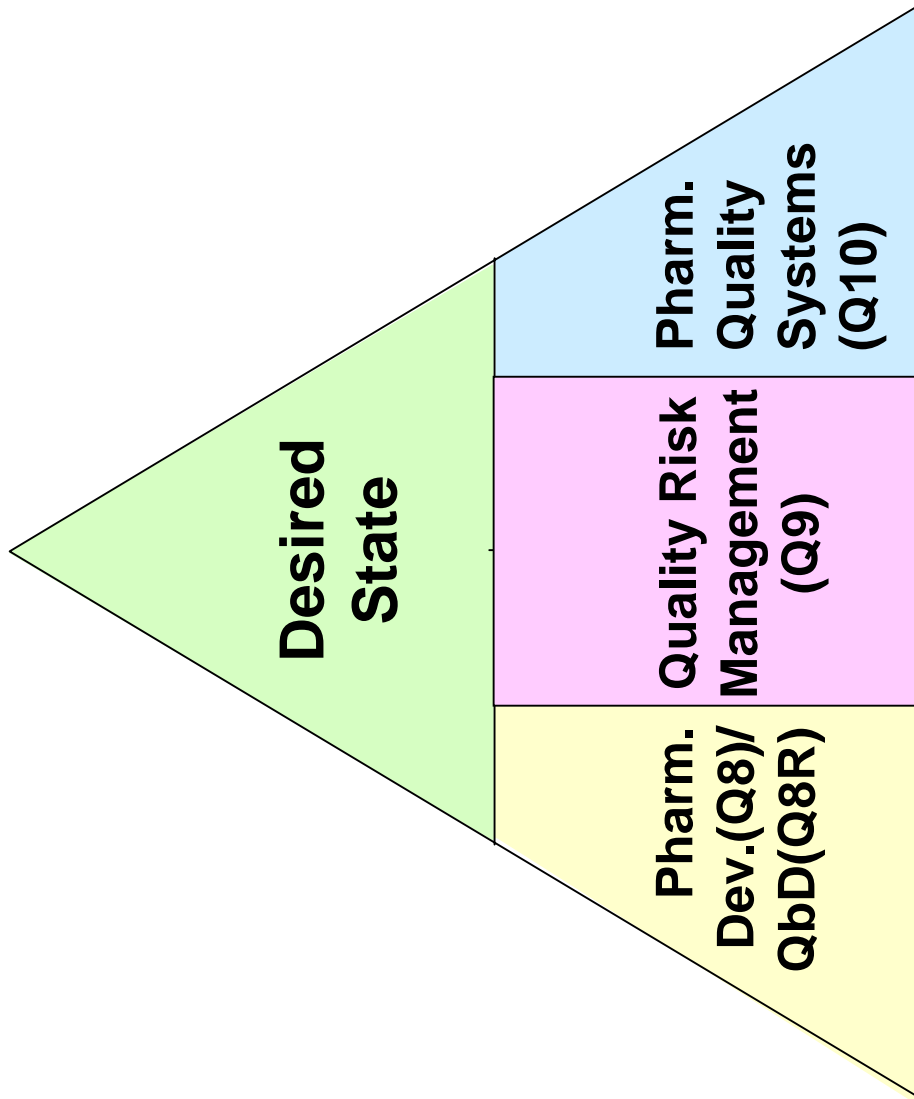
- General QbD principles
 - What is QbD/Design Space
 - Why use QbD for OINDPs?
- QbD applied to OINDPs
 - Product Design
 - Formulation Design
 - Container Closure System Design
 - Process Design (e.g. micronization)
 - Design and Setting Specifications in the Future
- Blinded case studies where QbD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

What is QbD?

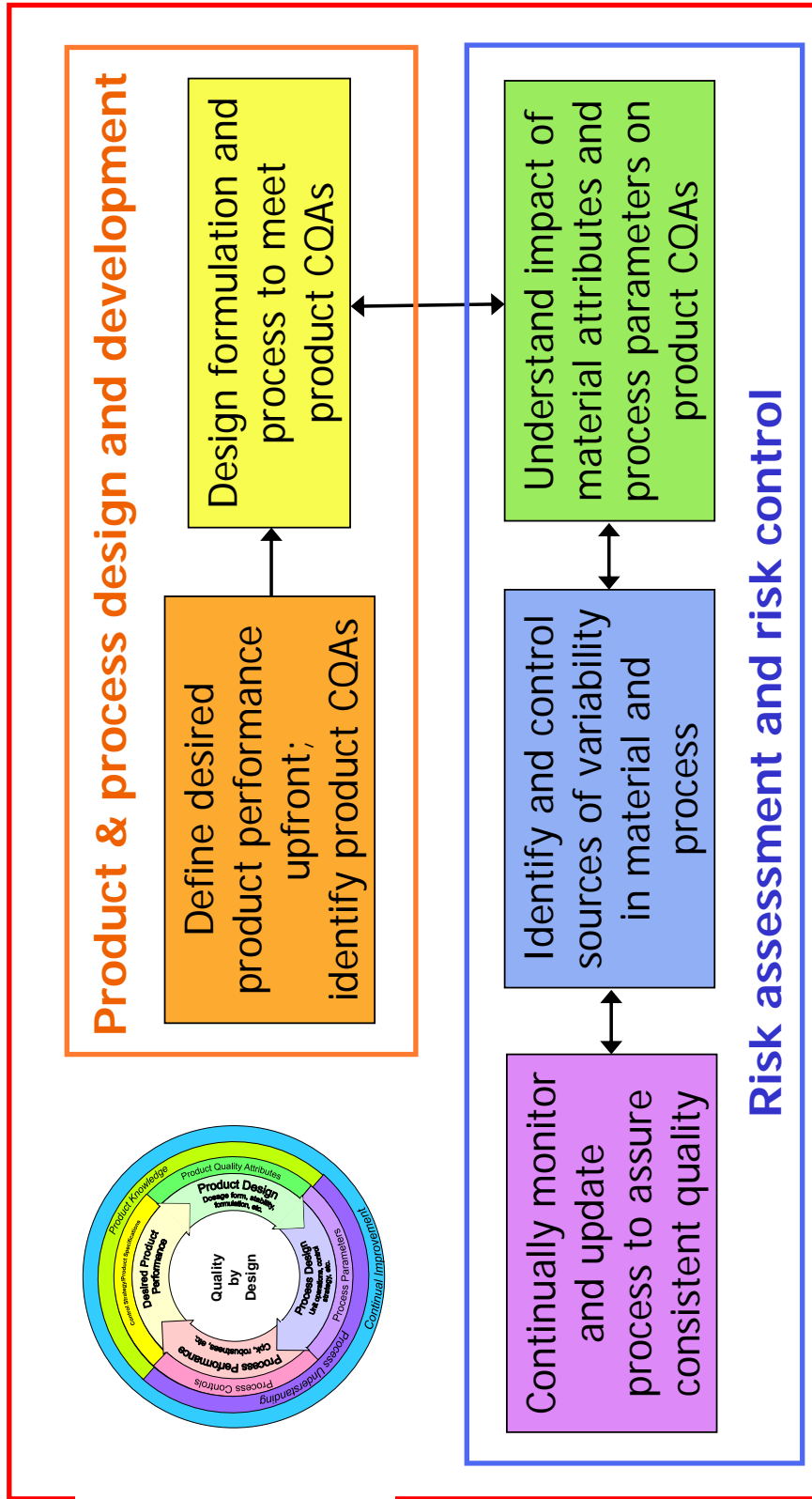
- Quality by Design is:
 - Scientific, risk-based, holistic and proactive approach to pharmaceutical development
 - Deliberate design effort from product conception through commercialization
 - Full understanding of how product attributes and process relate to product performance

QbD information and conclusions should be shared with FDA

ICH Quality Roadmap



ObD System



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