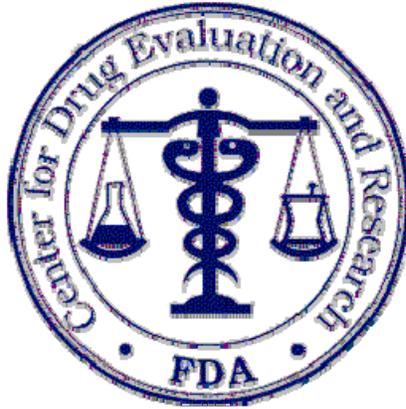


## **Disclaimer Statement**

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package might contain assessments and/or conclusions and recommendations written by individual FDA members. Such conclusions and recommendations do not necessarily represent the final position of the individual staff member, nor do they necessarily represent the final position of any FDA office or division. We have brought the agenda items to this Advisory Committee in order to gain the Committee's insights and opinions, and the background package may not include all issues relevant to any subsequent regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the advisory committee. The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all relevant internal activities have been finalized. Any final determination may be affected by issues not discussed at the advisory committee meeting.



Center for Drug Evaluation and Research

Advisory Committee for Pharmaceutical Science

and

Clinical Pharmacology

July 27, 2011

**Food and Drug Administration**  
**Meeting of the Advisory Committee for Pharmaceutical Science**  
**and**  
**Clinical Pharmacology**  
**July 27, 2011**

**BRIEFING INFORMATION**

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4. Presentation on QbD Implementation: *FDA Modernization -- Implementation of Quality by Design Progress, Challenges, Next Steps* (Helen Winkle, Director, OPS/CDER/FDA)
5. Presentation on QbD Implementation : *State of QbD Implementation: Adoption, Successes, and Challenges* (Ted Fuhr, McKinsey & Company)
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[This is an awareness topic – there will be no Advisory Committee discussion of this topic]
6. Background document for the Monograph Modernization Program Session

## MEMORANDUM

TO: Members, ACPS-CP

FROM: Helen Winkle  
Director, Office of Pharmaceutical Science, CDER, FDA

DATE: June 28, 2011

RE: ACPS-CP Meeting July 27, 2011

Dear Committee Members and Invited Guests,

We look forward to your participation in the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) meeting on July 27, 2011, a continuation of the meeting of the Committee on July 26<sup>th</sup>.

The meeting will focus on a number of important science issues currently being addressed in the Office of Pharmaceutical Science (OPS) in the Center for Drug Evaluation and Research (CDER). As you know, this office is mainly focused on the review of the quality of pharmaceutical products prior to market. This includes all pharmaceutical products – small molecule and proteins, and generic versions of these products. Through your participation and advice on the advisory committee, we are able to develop and finalize our standards for reviewing and approving products and set policy for regulatory decision-making.

We will continue our discussions with you on a topic that has been discussed at previous advisory committee meetings over the years. Additionally, since our last meeting, a number of new issues have surfaced in OPS that we will bring before the advisory committee for your awareness. Background materials for each of the proposed topics are attached.

Since our last meeting, the term for a number of members has expired and new members have been appointed. We look forward to welcoming the new members and to their scientific input into the topics being brought before the committee.

We look forward to a very productive meeting on July 27<sup>th</sup>. We value the opportunity to solicit your assistance in defining and solidifying OPS direction in developing sound, scientific responses to the emerging issues.

**July 27, 2011**

**Topic 1 – Implementation of Quality by Design (QbD) – Current Perspectives on Opportunities and Challenges**

With the successful incorporation of the completed ICH Guidelines for Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality System) into FDA *Guidances for Industry*, the focus of activity within the Office of Pharmaceutical Science is to implement the Quality by Design (QbD) principles and concepts of this new paradigm into the application (NDA and ANDA) CMC review centers of OPS. Our presentations to the Committee will focus on the opportunities and challenges of the QbD implementation, both from a regulatory perspective (FDA and the European Medicines Agency) and from an industry perspective (PhRMA and GPhA). At the conclusion of the presentations we will ask the Committee to discuss and make recommendation on the following questions:

**Draft Questions for Committee:**

1. Are there additional efforts the FDA should consider to facilitate the implementation of QbD?
2. How should we address the technical and regulatory gaps that have identified by the speakers?
3. Can QbD approaches be valuable for biotech product development, and if so, are there any potential scientific challenges that we should be aware of?

**Topic 2 - USP Interaction – Monograph Modernization Program and Other Initiatives**

This is a new topic for the Advisory Committee, and it will be presented as an ‘awareness’ topic. Accordingly, there will be no Committee discussion or recommendations following a series of presentations. Committee members will be permitted to address the speakers during their presentations for any clarifying questions specific to the presentation.

This awareness topic will update the Committee on an important program to both FDA and The United States Pharmacopeia (USP) to modernize the USP monographs. There is an identified group of existing USP monographs (APIs, products, excipients) that are not reflective of current technology, and/or are non-specific, non-stability indicating, or in need of additional process/degradation impurity tests. The presentations will provide awareness to the Committee as to the USP’s program to modernize the identified monographs, the importance to both organizations of the modernization effort in ensuring the quality and safety of all drug products, ongoing interactions between FDA, USP, and industry to modernize the monographs, and first steps already underway. We will also discuss other

points of interaction between FDA and USP in their efforts to ensure that quality products are on the market.

We are looking forward to a very stimulating discussion with the committee on the selected topics. The meeting will be held at the FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Room 1503), 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.



July 27, 2011

TOPIC 1:

*Implementation of Quality by  
Design (QbD) – Current  
Perspectives on Opportunities  
and Challenges*

**Background Information for the FDA Meeting of the Advisory Committee for  
Pharmaceutical Science and Clinical Pharmacology**

**July 27, 2011**

**Topic 1: *Implementation of Quality by Design (QbD) – Current Perspectives on Opportunities and Challenges***

This session will discuss progress made in the implementation of the new quality paradigm (ICH Q8, 9 &10). In addition, FDA and industry speakers will present opportunities and challenges related to the implementation of Quality by Design (QbD) in pharmaceutical development, manufacturing and associated regulatory processes.

To facilitate your preparation for the topic presentations, there are several pieces of information we are providing as background reading:

1. Link to the ICH Quality Guidelines:  
<http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
2. Link to the ICH Q8(R2) *Pharmaceutical Development* Guideline:  
[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q8\\_R1/Step4/Q8\\_R2\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q8_R1/Step4/Q8_R2_Guideline.pdf)
3. Link to the ICH Q9 *Quality Risk Management* Guideline:  
[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q9/Step4/Q9\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q9/Step4/Q9_Guideline.pdf)
4. Link to the ICH Q10 *Pharmaceutical Quality System* Guideline:  
[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q10/Step4/Q10\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q10/Step4/Q10_Guideline.pdf)
5. Link to ICH IWG Q8/Q9/Q10 *Questions and Answers*:  
[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Quality/Q8\\_9\\_10\\_QAs/Q-IWG\\_QAs\\_Step4/Q8\\_Q9\\_Q10\\_Question\\_and\\_Answer\\_R4\\_step\\_4\\_November\\_2010.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q8_9_10_QAs/Q-IWG_QAs_Step4/Q8_Q9_Q10_Question_and_Answer_R4_step_4_November_2010.pdf)
6. Link to ICH IWG Q8/Q9/Q10 *Workshop Training Materials*:  
<http://www.ich.org/products/guidelines/quality/training-programme-for-q8q9q10.html>
7. Two presentations on QbD Implementation:
  - a. *FDA Modernization -- Implementation of Quality by Design Progress, Challenges, Next Steps* (Helen Winkle, Director, OPS/CDER/FDA)
  - b. *State of QbD Implementation: Adoption, Successes, and Challenges* (Ted Fuhr, McKinsey & Company)



**46<sup>th</sup> DIA Annual Meeting**  
**Facilitating Innovation for Better Health Outcomes**  
Washington, DC  
June 16, 2010

**FDA Modernization**  
**Implementation of Quality by Design**  
**Progress, Challenges, Next Steps**

Helen N. Winkle  
Director, Office of Pharmaceutical Science  
Center for Drug Evaluation and Research  
Food and Drug Administration

# New Realities in Regulating Drug Quality

- Many more treatments available
- Sources of products and substances are worldwide
- Patterns of drug use and guiding information have shifted
- Patients and clinicians need more accurate, up-to-date and understandable information
- Greater dependency on generic drugs – 70% of all prescriptions are for generics
- New science and technologies promise accelerating product development and manufacturing capabilities
- Changing business models

# As a Result - FDA Has Had to Change to Keep Pace With Realities

- Emphasis on new sciences and technologies
- Need for changing methodologies to support regulatory decision-making (e.g., modern bioequivalence methods)
- Upgrade in skills base – including improving management processes and information systems
- More transparency and information on products needs to be made available
  - Better communication
- Globalization of drug development and manufacturing
- Modernization of regulation of product quality

# Regulation – Product Quality

- Pharmaceutical Quality Initiative for the 21<sup>st</sup> Century
  - Initiative began in 2002
  - Purpose of the initiative was to enhance and modernize the regulation of pharmaceutical manufacturing and product quality
  - Pertains to veterinary and human drugs and select human biological products such as vaccines
  - Guiding principles
    - Risk-based orientation
    - Science-based policies and standards
    - Integrated quality systems orientation
    - International cooperation
    - Strong public health protection
- Initiation of quality by design (QbD)

# Quality by Design

- “Building quality in”
- Objective is to ensure manufacturers are responsible for quality of products
- QbD is [in accordance with Q8(R2)]:
  - Systematic approach to development
  - Begins with predefined objectives
  - Emphasizes product and process understanding and process control
  - Based on sound science and quality risk management
- Change in how look at applications - assessment focused on critical quality attributes (chemistry, pharmaceutical formulation, and manufacturing processes) as relate to product performance

# Implementation - FDA

- Three offices in OPS focused on facilitating implementation of QbD
  - Office of New Drug Quality Assessment (ONDQA)
  - Office of Biotechnology Products (OBP)
  - Office of Generic Drugs (OGD)
- New paradigm for review – in some instances a new set of skills – implementing QbD involves using high quality pharmaceutical science and

# ONDQA's Pharmaceutical Assessment Program

- Pilot program
  - Opportunity for firms to submit CMC information which demonstrates QbD
  - Received 9 original and 3 supplemental NDAs
  - Common factors included design space, use of risk assessment and proposals for regulatory flexibility under the firm's quality system
- Applications containing QbD elements outside of pilot continue to increase
  - 12 NDAs, 18 INDs and 6 supplemental NDAs

# ONDQA, cont.

- ONDQA is accepting QbD applications
  - ONDQA is putting the staffing and systems in place to support QbD — new guidelines are in place or are being developed to facilitate implementation
  - Recent NDAs (both within and outside of the CMC pilot program) have provided opportunities for industry to implement QbD — provided opportunities for firms to meet and discuss
  - Continue to expand skills and knowledge - workshops, case studies, meeting with industry, research and internal training
- ONDQA encourages and accepts applications using QbD approaches

# OBP's Implementation Process

- Pilot program
  - Accepting applications to:
    - Consider QbD approaches to biotech unit operations
    - Explore the use of protocols as a regulatory approach to QbD
  - 5 BLAs and 4 post approval supplements received
  - Companies need to submit written and electronic requests to participate in pilot by September 30, 2010
- Holding meetings with sponsors
- Developing case studies – A-Mab: a Case Study in Bioprocess Development – available on ISPE Website
- Holding workshops and conducting internal training to enhance skills

# OBP cont.

- Specific challenges
  - Complexity of products requires additional considerations
  - Difficulty in identifying critical quality attributes
  - Biological characterization
  - Ensuring safety and efficacy
- Conducting research focused on biotechnology manufacturing science

# OGD – QbD: Moving Forward

- Developed a question-based review (QbR) for quality evaluation of generic drug applications
  - Based on QbD concepts and principles
  - Focused on product and process design and understanding
- 100% ANDA submissions are done in QbR format
- Currently evaluating the implementation of QbR and determining next steps to improve process
  - Several workshops held with goal of understanding QbD for generics
  - Agreed that emphasis needed to be on modified release products
  - Working groups established and meeting

# Implementation - Industry

- Important to determine how successful implementation of QbD has been across industry
- McKinsey Study – “Understanding Challenges to Quality by Design” – indicates industry “stepping up to the plate”
- Interest on part of industry for implementing QbD has continued to grow
- “QbD is evolving, gaining momentum and passion throughout the industry”
- A number of companies have actually adopted the concepts of QbD as the way they do business – others at different levels of maturity
- We have seen aspects of QbD in all our application processes

# Challenges Identified by McKinsey Report

- Inconsistency of treatment of QbD across FDA – individual buy-in
- Lack of tangible guidance for industry
- Regulators not prepared to handle QbD applications – different levels of understanding
- Unclear regulatory benefits
- Misalignment of international regulatory bodies – “one application does not fit all” – need for global harmonization
- Current interactions with companies not conducive to QbD

# Additional Implementation Challenges and Gaps at FDA

- Complications of merging new in with the old – changing from empirical to science-based standards
- Heavy workload and limited resources
- Gaps in interactions between review and cGMP
- Need better understanding of the linkage between quality, safety and efficacy
- Need for better utilization of modeling in pharmaceutical development and manufacturing

# Addressing Challenges

- McKinsey recommended three areas for next steps in effort to accelerate momentum around adoption of QbD:
  - FDA policy
  - Internal FDA change management
  - External change management
- OPS management met to determine next steps

# Next Steps – FDA Policy

- Define “design space” and other terminology and determining regulatory pathway for future
- Clarify regulatory flexibility and issue guidance
- Define and codify incentives
- Determine whether to require QbD through regulation
- Develop standards by which industry can apply QbD

# Next Steps – Internal Change Management

- Hire QbD manager to coordinate implementation of QbD across all OPS including developing a comprehensive plan for implementation
- Develop internal MAPP to integrate three ICH documents (Q8, Q9, Q10)
- Operationalize QMS for CMC
  - Consistent review process
  - Precedent system
  - Criteria for filing
- Develop tracking system for QbD applications
- Finalize and implement findings from NIPTE study – enhance training
- Implement team review of applications
- Further develop question-based review concept and consider relevance for other program areas

# Next Steps – Internal Change Management, cont.

- Utilize information learned from QbD for small molecules to support development of program in biotech
- Clarify links between quality and safety and efficacy
- Develop better relationship and training opportunities with ORA's Pharmaceutical Inspectorate – this will include more opportunities for reviewers on inspections
- Ensure better internal coordination where necessary with biopharm

# Next Steps – External Change Management

- Continued involvement in ICH
  - ICH workshops
- Develop additional case studies
  - Scientific case studies
  - Case studies on economic impact
  - Case studies which provide tangible examples of benefits
- Enhance communication with industry including:
  - Workshops
  - More one to one meetings on implementing QbD – informal – nothing binding in discussions
  - Part 15 hearing
  - Informational group available to discuss QbD and answer questions

# Summary

- FDA modernizing regulatory processes for product quality – quality by design
- FDA focused on implementation over last seven years
- All offices in OPS at some of stage of implementing QbD
- McKinsey report specified
  - Industry interested in implementing QbD
  - FDA has made progress in implementation
  - Identified continued challenges in implementation both for industry and FDA
- OPS taking steps to eliminate challenges and to better support industry in implementing QbD

# **State of QbD**

## Implementation: **Adoption, Successes, and Challenges**

**Ted Fuhr**

June 2010

McKinsey & Company

# Contents

- **Introduction**
- Summary of findings from QbD adoption project
  - State of adoption
  - Challenges
  - Business case
- Potential next steps

# We conducted a project to determine the state of QbD adoption in industry and the challenges and opportunities that companies are facing

## Scope

- Development of a consensus view on the state of QbD adoption including core issues, business case for implementation, and potential steps to catalyze adoption

## Discussion

- The program was designed to build an understanding of QbD adoption focused on a critical set of questions including
  - What is the spectrum of adoption across the industry?
  - What is the business case for QbD?
  - What are the challenges or barriers to adoption of QbD?
  - How can QbD adoption be catalyzed?
- In addition to exhaustive literature research, an extensive set of interviews with industry leaders was used to gauge the current understanding and level of QbD adoption, outline implementation issues, business drivers, and barriers to adoption for industry

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# QbD in industry has continued to evolve over the past years

## From...

- Familiarity with QbD terminology, but little idea how to actually implement
- Limited experimentation with concept
- Companies raise issue of inconsistent regulatory frameworks
- Skepticism about technical limitations

## ...To

- Increased maturity of what implementation of QbD means
- Increased acceptance and experimentation across the board as more companies see the value and take steps to implement
- With more experience comes more demands and expectations from regulators
- More companies recognizing they will do this regardless of any additional benefits/ clarity from FDA
- Continued skepticism on applicability of QbD to generics business case and biologics at the molecular level

# **We have heard a lot of enthusiasm for QbD across the industry**

**The value is clear,  
although it's hard to  
quantify – we would do  
this regardless of the FDA**

**Once people take time to  
understand what QbD is and  
how it actually works they  
become passionate**

**Our stated intent is for all  
products to be designed  
with QbD in mind**

**I don't understand  
why you wouldn't do  
this!**

**QbD really means  
doing good science**

**Our end game is to  
get every new drug  
submitted and rolled  
out with QbD**

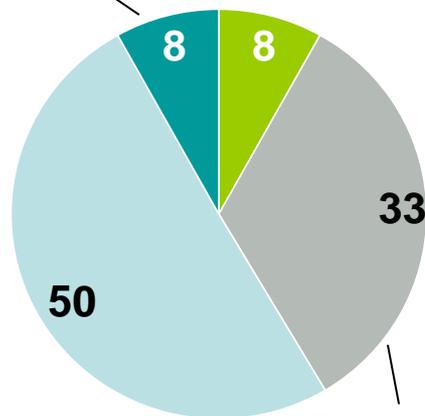
# Most believe that business case is strong but a large percentage are still skeptical

## Strength of QbD business case

Percent of interviewees, n = 15

Strong business case with year 1 payback

No viable business case



Strong business case with multi-year payback

Business case is uncertain/neutral

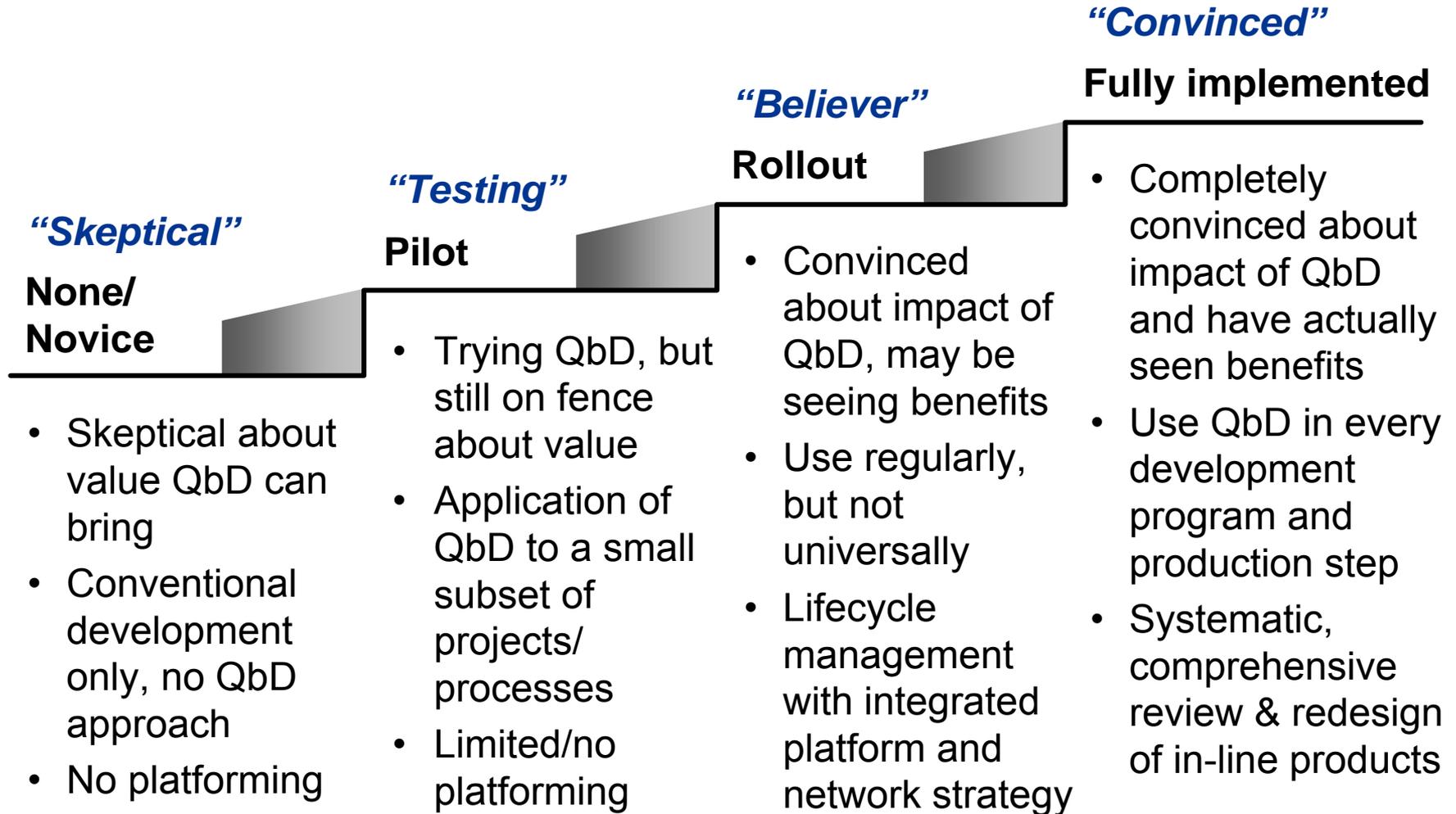
## Business case is strong

- “There is not more effort required for QbD”
- “The benefits are clear – speed, quality, and cost”
- “Once people saw that the upfront investment was more than balanced by savings – they really bought into it”
- “QbD and Lean are the core of our Operations strategy”

## But some people are still skeptical

- “I’m not sure QbD will have any benefits that will...change the safety or efficacy”
- “Since there is no global harmonization, why move away from traditional filing?”

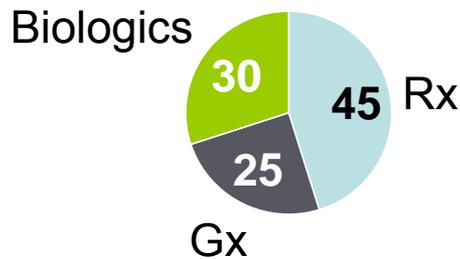
# Despite this momentum, there are distinct segments of where companies stand on QbD



# New drug segment is the most advanced along adoption continuum

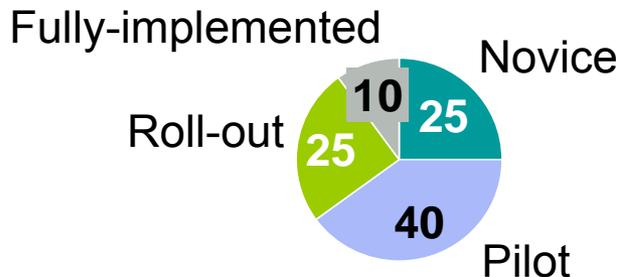
Total population by drug type

Percent



Total population by level of adoption

Percent



Level of adoption

Group	Novice	Pilot	Rollout	Fully implemented	Total
New Drug	22%	33%	22%	22%	100%
Gx	40%	20%	40%	--	100%
Biologics	17%	67%	17%	--	100%

I just don't see the business case  
– Novice Gx

QbD is a fundamental part of our operations strategy  
– Fully implemented New Drug

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# These are currently the top 10 issues related to QbD adoption

## Challenges within industry

- 1 Internal misalignment
- 2 Lack of belief in business case
- 3 Lack of technology to execute
- 4 Alignment with third parties

## Challenges within the FDA

- 5 Inconsistency of treatment of QbD across FDA
- 6 Lack of tangible guidance for industry
- 7 Regulators not prepared to handle QbD applications
- 8 The way promised regulatory benefits is currently being shared does not inspire confidence
- 9 Misalignment of international regulatory bodies
- 10 Current interaction with companies is not conducive to QbD

# Key challenges vary by industry segment...

 Key challenge

## Challenges to implementation

New Drug   Gx   Biologics

### 1 Internal misalignment

- “R&D is incentivized by shots on goal, not QbD”



### 2 Lack of technology to execute

- “We can’t prove the molecular parameters necessary in a QbD file since we don’t really understand what effects what”



### 3 Lack of belief in a business case

- “Generics is all about file first, figure out later”



### 7 Regulators not prepared to handle QbD applications

- “Huge amount of reviewer inconsistency”



### 9 Misalignment of international regulatory bodies

- “It takes more effort to file in other countries – they often take a while to ‘get it’”



SOURCE: Interviews

# Different challenges are highlighted by different stages of adoption

 Key challenge

Challenges to implementation		Novice	Pilot	Rollout	Fully Implemented
1	Internal misalignment	✓	✓		
2	Lack of technology to execute	✓	✓		
3	Lack of belief in business case	✓			
4	Alignment with third parties				✓
5	Inconsistency of treatment of QbD across FDA		✓		
6	Lack of tangible guidance for industry	✓	✓	✓	
7	Regulators not prepared to handle QbD applications			✓	✓
8	The way promised regulatory benefits is currently being shared does not inspire confidence (i.e., business case and regulatory benefits are not clear)	✓	✓	✓	
9	Misalignment of international regulatory bodies		✓	✓	
10	Current interaction with companies not conducive to QbD			✓	✓

SOURCE: Interviews

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# Interviews debunked two widely-held beliefs about QbD

**QbD is expensive and will drive costs up**

**FALSE**

- Most people believe QbD leads to a marginal increase during set up, but will have no marginal cost after
  - Initial marginal cost estimated to be <\$1 million
- In fact, some interviewees believe QbD drives development costs down in the long run

**QbD takes a long time and will require much more analysis**

**FALSE**

- QbD may add a negligible amount of time (~2 FTEs over 3 days) during initial clinical phase
- Does not effect amount of time spent in critical path, and reduces time to tech transfer and scale up

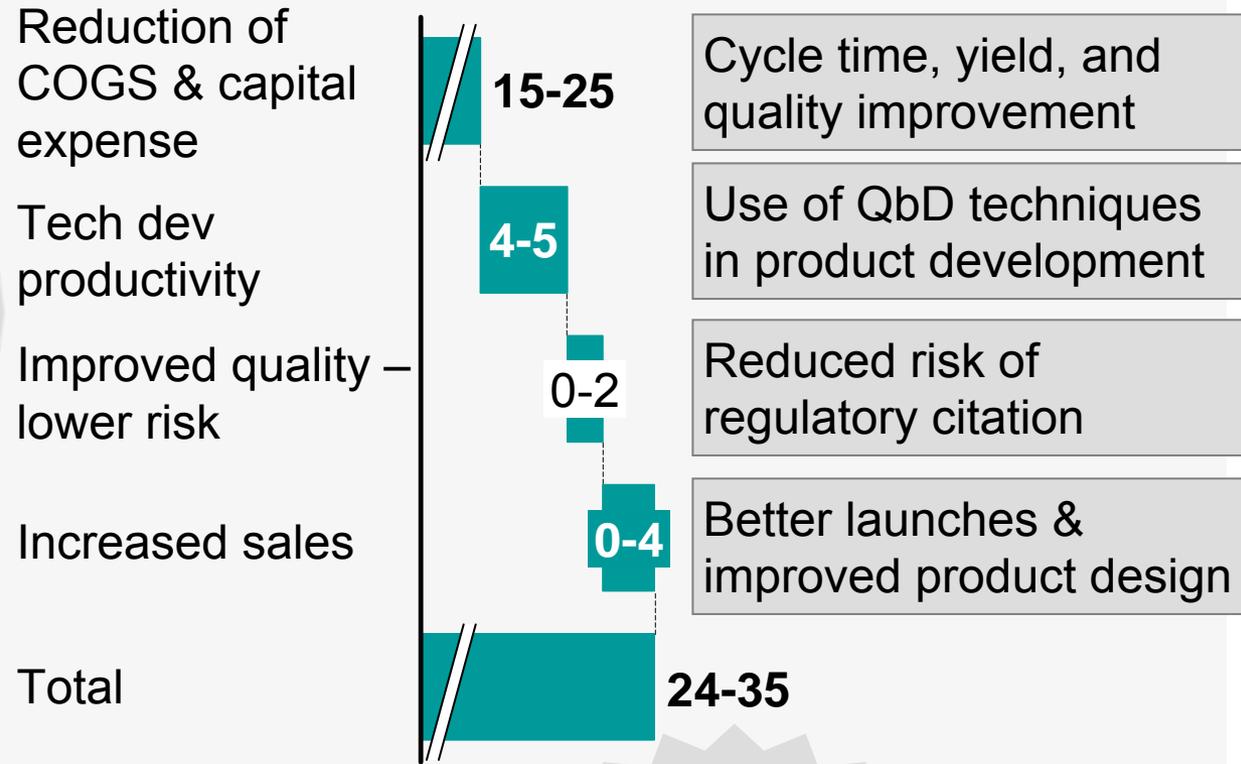
# Companies validated the source of value, which in our modeling translates to significant potential value for the industry

## Benefits from QbD

- “Lower COGS through... greater supply chain reliability and predictability”
- “We have reduced our development cost per program by 25% through QbD”
- “Our manufacturing site with QbD products has 30% lower quality staffing and cost”

## Potential sources of incremental profit from QbD<sup>1</sup>

USD billions



Potential to provide \$20-30 billion more profit to the industry

# More than half of interviewees saw a strong business case, however, two critical factors enable this potential

- **Alignment and change in the operating model**
  - Alignment from R&D through operations across processes, incentives, and platforms
  - Willingness to take out QC steps/costs
  - Culture/mindset of entire company QbD focused (from highest leadership to plant)
  - Real change in the way companies are thinking about manufacturing choice, network design, quality system designs
- **Enablers from FDA**
  - Delivery of promised FDA regulatory benefits
  - Reviewer upgrade and behavior changes
  - Stronger guidance and ground rules for QbD filings

# Within the company context, several things should be in place to better capture these benefits

## Leadership alignment

- “We have broad senior alignment – executive sponsorship is crucial to making this work since the business case is not 100% clear”

## Alignment between R&D and operations

- “What makes it work is changing commercialization, lifecycles, *and* manufacturing and quality systems to take advantage”

## The right talent/capabilities

- “You need people with the smarts, capabilities, motivation, and sponsorship to drive it forward”

## The right tools/processes to execute

- “Adoption is ensured by a rigorous framework”
- “You need standardized – development hardware/process and commercial hardware/processes”

## Culture aligned to continuous improvement

- “It requires a culture of continuous improvement without the need for regulatory intervention to approve changes”
- “QbD has become part of our culture”

# There is a correlation between supporting mechanisms and levels of adoption

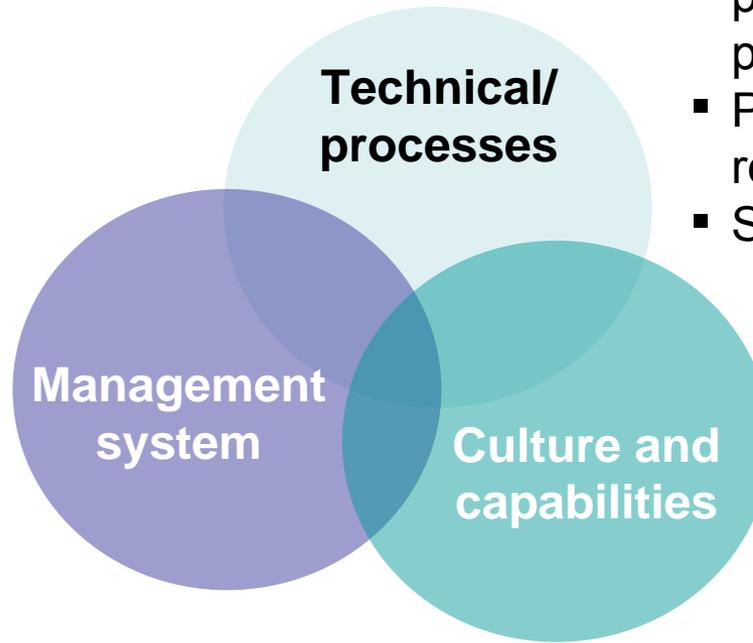
 Implemented  
 Somewhat implemented

Mechanisms to support QbD	Novice	Pilot	Rollout	Fully implemented
Formal QbD pilot program/organization/special project				
Standard development processes built upon QbD principles				
QbD principles "built in" to our regular regulatory CMC processes				
Stage-gate process for CMC program review				
Incentive alignment amongst development & manufacturing				
Talent acquisition and management				
Participation in industry/regulatory groups				
Capability/training programs for personnel				
Standardized equipment				

SOURCE: Interviews

# Companies that are experiencing the largest business benefits are utilizing mechanisms across the 3 elements of operations to facilitate QbD

- Strong leadership across top and middle management
- Alignment of incentives and/or organization to support a connected operating model



- Standard development processes built upon QbD principles
- Participation in industry/regulatory groups
- Standardized equipment
- Talent acquisition/management with the purpose of supporting QbD
- Capability/training programs for personnel

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  - Business case
- **Potential path forward**

# Findings provoked a set of questions around what next steps to take

- How to best address the major challenges to adoption?
- What types of actions should be considered?
- Should the approach be tailored across New Drugs, Generics, and Biologics?
- How to undertake change management across industry segments? And the FDA?
- Would a different model for engagement between industry and FDA deliver superior results?
- What should the expectations be for global regulatory alignment?

# Acknowledgements

- Katy George
- Navjot Singh
- Elisabeth Hill

July 27, 2011

TOPIC 2:

*USP Interaction –  
Monograph Modernization  
Program and Other  
Initiatives*

**Background Information for the FDA Meeting of the Advisory Committee for  
Pharmaceutical Science and Clinical Pharmacology**

**July 27, 2011**

**Topic 2: *USP Interaction – Monograph Modernization (MM) Program and Other Initiatives***

This is a new topic for the Advisory Committee, and it will be presented as an “awareness” topic. Accordingly, there will be no Committee discussion or recommendations following a series of presentations. Committee members will be permitted to address the speakers during their presentations for any clarifying questions specific to the presentation.

The United States Pharmacopeia is a non-governmental body that establishes official public standards for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. It achieves this in the form of a vast collection of monographs for drug substances, drug products, and inactive pharmaceutical ingredients (i.e., excipients), known as the United States Pharmacopeia – National Formulary (USP-NF). With the advancements in science and technology, and the evolution of a global drug supply, there is a need for modernization of many of the monographs published in the USP-NF.

For some time, FDA, through an active Task Group, has been assisting USP in prioritizing its monographs for modernization. At the Advisory Committee meeting, we plan to give an overview of the Task Group’s work, including (1) historical background, (2) previous examples of monograph modernization, and (3) current focus. Invited experts, including those from the USP, will also present information regarding their respective organization’s involvement and perspectives on the modernization effort. The topic will conclude with additional updates on USP-FDA interactions and potential future challenges.

Further background information pertaining to USP’s Monograph Modernization Program is available online at USP’s website: <http://www.usp.org/hottopics/monographs.html> .