Updates on ICH Quality Guidelines and Implications

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Disclosures

- I am currently an employee of Pfizer, Inc. I am Executive Director, Global CMC.
- I worked at the U.S. Food and Drug Administration (FDA) in 1986-2008. I was Deputy Director, Office of New Drug Quality Assessment, CDER.
- The following are my views and not necessarily the views of the Food and Drug Administration Alumni Association, or FDA, or Pfizer.
- Expenses for travel, lodging, and per diem are being paid by Pfizer.
Introduction
ICH Q8, Q9, Q10 – A New Quality Paradigm*

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* Reference: Robert Baum (Pfizer), JCCT Workshop on “Implementation of ICH Q8, Q9, and Q10,” Beijing, China, Dec. 2008

- Q1A-E Stability
- Q2 Method Validation
- Q3A-C Impurities
- Q5A-E Biotechnology
- Q6A-B Specifications
- Q7A GMP for APIs
- M4Q CTD for Quality
ICH Q: The second decade
(2002 …)

- Q8  Pharmaceutical Development
- Q9  Quality Risk Management
- Q10 Pharmaceutical Quality System
- Q11 Development and Manufacture of Drug Substances (under development)
## Differences between Early and Recent ICH Quality Guidelines

<table>
<thead>
<tr>
<th>Early Guidelines (Q1-Q7 &amp; M4Q)</th>
<th>Recent Guidelines (Q8, Q9, Q10)</th>
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<tbody>
<tr>
<td>Scientific (Q1/2/3/5/6) or systems (Q7A, M4Q/CTD-Q) oriented</td>
<td>Both scientific and systems oriented</td>
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<tr>
<td>Based on many years of extensive industry and regulator experience</td>
<td>Little industry or regulator experience</td>
</tr>
<tr>
<td>Numerous published regulatory guidelines available in each region</td>
<td>Few published regulatory guidelines available in any region</td>
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<tr>
<td>Looked at past experiences to reach consensus</td>
<td>Focused on future aspirations and visions</td>
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Differences between Early and Recent ICH Quality Guidelines (2)

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<td>Primary focus on development activities leading to product registration (Q1/2/3/5/6); addressed R&amp;D and manufacturing phases (Q7A, CTD-Q)</td>
<td>Applicable throughout the product life cycle</td>
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<td>Established minimum or baseline expectations (prescriptive)</td>
<td>Optional; encourages QbD, innovation, continual improvement; potential for transformational changes to achieve the “new quality paradigm”</td>
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Drivers for Change

- EU guideline on parametric release
- FDA 21st Century Pharmaceutical Quality Initiative
- Pharmaceutical Affairs Law in Japan
- Increased interest in PAT → QbD
- More licensing and mergers and acquisitions than ever before
- More focus on biologics and devices (not just tablets and capsules)
ICH Quality Vision

- “Develop a harmonized pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to risk management and science” – ICH Quality EWG July 2003 (Brussels)

- Product lifecycle includes the following technical activities:
  - Pharmaceutical development (R&D)
  - Technology transfer
  - Manufacturing
  - Product discontinuation
The ICH Vision & Opportunity

**Pharmaceutical Development** (Q8) + **Quality Risk Management** (Q9) + **Pharmaceutical Quality Systems** (Q10)

**A New Quality Paradigm**

- Science and risk-based approaches to product development, dossier submission, review, inspection, and post-approval change management
- Manufactures empowered to effect continuous improvement and technical innovation throughout the product lifecycle
- Efficient and consistent regulatory oversight across/between regions