

ICH Topics on Quality

FDA Public Meeting for November 2008,
Brussels, Belgium ICH Meeting
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Current Events in ICH Q

- Guideline on Pharmaceutical Development (Q8R1)
- Guideline on Pharmacopoeial Texts Harmonization (Q4B)
- Quality Implementation Working Group
- Development and Manufacture of Drug Substances (Q11)

Pharmaceutical Development (Q8R1)

- Pharmaceutical Development Revision 1 (Q8R1)
- “further clarification of key concepts outlined in the core guideline [and] principles of quality by design (QbD)”
- Draft finished in Yokohama
 - FDA version dated October 2008
 - <http://www.fda.gov/cder/guidance/8084dft.pdf>

Pharmaceutical Development (Q8R1)

- Public comments are being discussed
- May reach step 4 in Brussels

Pharmacopoeial Texts (Q4B)

- Evaluation and Recommendation of Pharmacopoeial Texts for Use in the [ICH] Regions
- “...process for the evaluation and recommendation by the Q4B Expert Working Group (EWG) of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions”
- Final core document in Yokohama
 - Final ICH dated November 2007
 - <http://www.fda.gov/cder/guidance/8078fnl.pdf>
- Final annex for Residue on Ignition/Sulphated Ash
 - <http://www.fda.gov/cder/guidance/8078fnl.pdf>

Pharmacopoeial Texts (Q4B)

- Draft annexes may reach step 4
 - Extractable Volume of Parenteral Preparations
 - <http://www.fda.gov/cder/guidance/8080dft.pdf>
 - Particulate Contamination: Subvisible Particles
 - <http://www.fda.gov/cder/guidance/8081dft.pdf>
- Additional Efforts for discussion
 - Microbiological testing
 - 3 annexes
 - Uniformity of dosage unit testing
 - Scope of Q4B
 - Working Group Status

Pharmacopoeial Texts (Q4B)

■ Residue on Ignition	5
■ Extractable Volume	5
■ Particulate Matter	5
■ Microbiological Tests (a,b,c)	2
■ Disintegration	2
■ Uniformity of Dosage Units	1
■ Dissolution	1
■ Sterility	1 going 2
■ Endotoxins	0
■ Color	0

Quality IWG

- Quality Implementation Working Group
- “will concentrate on responding to questions from the stakeholders and developing training materials to enhance implementation”
- Group formed in Yokohama
- Strategy session in Portland
- Brussels
 - Q and A document discussions

Drug Substances (Q11)

- Development and Manufacture of Drug Substances
- Brussels
 - Discussion of proposals for a draft guidance

End

- Say what you do
- Do what you say