China-Japan ICH Regional Joint Open Conference

Q2(R2)/Q14 EWG representing IFPMA from PhiRDA

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Q2(R2)/Q14: Revision of Q2(R1) Analytical Validation and Analytical Procedure Development

Q2(R2)/Q14 Concept Paper/Business Plan

Nov-2018:

Concept paper/Business plan endorsement

Formal EWG

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Q2-2019:

First intra-constituent review

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Q1-2021:

Second intra-constituent review

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Nov.2021: Step 1 sign off

Dec.2021: Step2a/b endorsement

Jan-Jun.2022: Public consultation

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Step3

Step4

Original impression based on Q2(R1):

Analytical Procedure Development

Multivariate statistical analyses

State-to-the-art techniques

Independent documents

Industry easy to follow

Q2(R2)/Q14 Drafting

Nov-2018:

Concept paper/Business plan endorsement

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Step3

Step4

Content drafting:

Two documents (Q2, Q14, Glossary, linkage)

Alignment with the other Q guidances

Q6-Pharmacopial procedures
Q8-Q11 – QMS，knowledge/risk management
Q12-lifecycle management, EC, MODR…
Q13-Multivariate procedure, RTRT

ATP

Traditional (minimal)/hybrid/advanced approaches

Analytical Procedure Control Strategy

Regulatory submission

TAE

Q2(R2)/Q14 Implementation

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Step3

Step4

Considerations on implementation:

Dependent documents

Premises on Q2(R2)/Q14 good implementation –

- Good implementation of the other Q guidances

Comprehensive and exemplified training materials

Leading industry to follow –

- Incentives to industry from regulatory flexible environment

Thank You!