

# China-Japan ICH Regional Joint Open Conference

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**Q2(R2)/Q14 EWG representing IFPMA from PhiRDA**

**Jufang Xu, Ph.D**

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

# Q2(R2)/Q14 Concept Paper/Business Plan

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**Nov-2018:**

**Concept paper/Business plan endorsement**

**Formal EWG**

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**Q2-2019:**

**First intra-constituent review**

...

**Q1-2021:**

**Second intra-constituent review**

...

**Nov.2021: Step 1 sign off**

**Dec.2021: Step2a/b endorsement**

**Jan-Jun.2022: Public consultation**

...

**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

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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!***

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