

ICH E2B(R3) EWG/IWG Work Plan

January 28, 2022

Topic Adoption date: July 2013

Rapporteur: Dr. Takashi Mitsu - MHLW/PMDA, Japan

Regulatory Chair: Mr. Ta-Jen Chen - FDA, United States

Last Face-to-Face Meeting: Amsterdam, Netherlands, June 2019

1. Key milestones

1.a. Current status of key milestones

| Past completion date | Milestone |
|----------------------|--|
| <i>Jun. 2019</i> | <i>Complete the Training Material Module I¹</i> |
| <i>Sep. 2019</i> | <i>Complete the Service Level Understanding (SLU) document with M2</i> |
| <i>Jul. 2020</i> | <i>Complete the revision of the EDQM User Guide incorporating the mapping table for RoA between ICH and EDQM terms</i> |
| <i>Dec. 2020</i> | <i>Completed the Training Material Module II¹</i> |
| <i>Jun. 2021</i> | <i>Published the information paper regarding ISO IDMP use in E2B(R3) messages</i> |
| <i>Dec. 2021</i> | <i>Finalised the revision of Appendix I (B) Backwards and Forwards Compatibility Recommendations</i> |

¹Note: Deliverables have been completed by the WG, but have not yet been circulated for approval/publication outside of the WG.

1.b. Future anticipated key milestones

| Expected future completion date | Milestone |
|---------------------------------|--|
| <i>Jun. 2022</i> | <i>Finalise contents of the Training Material Module III²</i> |
| <i>Jun. 2022</i> | <i>Finalise the “voice over” presentation for Module I²</i> |

| | |
|------------------|--|
| Jun. 2022 | <i>Process and update Q&As as needed</i> |
| Jun. 2022 | <i>Revise Appendix I (G) Technical Information</i> |

²*Timeline for circulation outside of WG to be determined.*

2. Timeline for specific tasks

| Beginning date | End date | Task / Activity | Details |
|-----------------------|------------------|--|--|
| Jun. 2019 | <i>Jun. 2022</i> | <i>Process and update Q&As as needed</i> | <ul style="list-style-type: none"> ➤ <i>Monitor and discuss any comments submitted to the ICH mail box and/or from E2B experts</i> ➤ <i>Add new Q&As to the document if applicable</i> |
| Jun. 2019 | <i>Jun. 2022</i> | <i>Finalise contents of the Training Material Module III</i> | <ul style="list-style-type: none"> ➤ <i>Create contents by each subsection: Regulatory section, Industry section and Technical section</i> ➤ <i>Finalise the subsections</i> |
| Sep. 2019 | <i>Jun. 2022</i> | <i>Finalise the “voice over” presentation for Module I</i> | <ul style="list-style-type: none"> ➤ <i>Add scripts and restructure the contents of Module I</i> |
| Dec. 2020 | <i>Jun. 2022</i> | <i>Revise Appendix I (G) Technical Information</i> | <ul style="list-style-type: none"> ➤ <i>Correct the language regarding “Total Dosage” expression</i> ➤ <i>Xpath for “Total Dosage” is going to be corrected</i> |