ICH Q3D(R3) EWG Work Plan
January 31, 2025

Topic Adoption date: *October 2009 (Maintenance procedure for incorporation of PDEs for new elemental impurities (EI)/routes of administration & revision of PDEs for EIs as new toxicological information becomes available – November 2022)*

Rapporteur: *Dr. Roland Froetschl (EC, Europe)*

Regulatory Chair: *n/a*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Apr. 2022	*Step 4 of ICH Q3D(R2) 26 April 2022*

1.b. Key Deliverables

Approval Date	Deliverable
Ongoing	*Respond to relevant Q3D(R3) EWG queries when submitted*
Ongoing	*Consider new data and proposals*

1.c. Future anticipated key milestones

Expected future completion date	Milestone
n/a	*n/a*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2025	*Nov. 2025*	*respond to queries*	*respond to queries received via the ICH secretariat from public channels, when submitted*

Jan. 2025	*Nov. 2025*	*Consider new data and proposals*	*consider new data and/or proposals pertaining to the revision of the Q3D guideline with supporting information, if submitted by any ICH member party*