

ICH Q3C(R10) EWG Work Plan

25 July 2026

Topic Adoption Date: 14 March 1994 (Maintenance procedure for incorporation of PDEs for new residual solvents & revision of PDEs for residual solvents as new toxicological information becomes available – November 2021)

Rapporteur/s: Dr. Roland Froetschl (EC, Europe)

Regulatory Chair N/A

Last Face-to-Face Meeting N/A

1 Key Milestones

1.1 Current Status of Key Milestones

- List key **past milestones** in the table for context.
- Key Milestones Include:
 - Concept Paper endorsement,
 - Completion of PWP Consultation (if applicable)
 - ICH *Step sign-off* (Guidelines, Q&As, Implementation Packages)
 - Completion of *Step 3* Public Consultation,
 - *Step 2* and *Step 4* Presentations
 - Stakeholder Engagement Activities
 - Training materials developed.
- **Choose only the most relevant achievements.**

Completion date	Milestone
Jan, 2025	Concept Paper for ICH Q3C(R10) endorsed
Month, Year	
Month, Year	
Month, Year	
Month, Year	
Month, Year	

1.2 ICH MC Key Deliverables

- The table records **all deliverables** that the ICH MC has approved for development, either:
 - those listed in the **Concept Paper**, or
 - additional deliverables **approved later** by the MC.
- **“Approval Date”** = the date the MC **approved starting work** on that deliverable (either the **Concept Paper approval date** or a **later time point based on MC approval**).

MC Approval Date	Deliverable
Jul, 2026	Step 1 sign off for revision of monographs for Dimethylformamide (DMF), Dichloromethane (DCM) and Ethyleneglycol (EtG). Step 1 sign off for revised table in core guideline
Aug, 2026	Step 2 a/b endorsement of document and release to public consultation
Sep, 2026	Step 1 sign off for restructured support document
Mar, 2027	Step 3 sign off for revision of monographs for Dimethylformamide (DMF), Dichloromethane (DCM) and Ethyleneglycol (EtG). Step 3 sign off for revised table in core guideline Step 3 sign off for restructured support document
Mar, 2027	Step 4 adoption

1.3 Future Anticipated Milestones

Please provide in the table below the **main deliverable(s) to be achieved in the next year(s)**:

Dates or expected timeline (e.g. Q1 2026 etc.) should be provided for:

- PWP engagement (if applicable) ahead of Step 1 and Step 3 Sign off
- Step 1 sign-off and Step 2a/b endorsement and delivery of the Step 2 Presentation
- Step 3 sign-off and Step 4 adoption and delivery of the Step 4 Presentation
- Any other relevant high-level deliverables (finalised documents, public consultation period, special actions to advance the topic through ICH, e.g. stakeholder engagement or training, etc.)

Expected future completion date	Milestone
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Jul. 2026	<i>Step 1 sign off for revision of monographs for Dimethylformamide (DMF), Dichloromethane (DCM) and Ethyleneglycol (EtG). Step 1 sign off of revised table in core guideline</i>
Aug. 2026	<i>Step 2 a/b endorsement of document and release to public consultation</i>
Sep, 2026	<i>Step 1 sign off for restructured support document</i>
Dec. 2026	<i>Step 3 public consultation phase</i>
Mar. 2027	<i>Step 3 document and sign off</i>
Mar. 2027	<i>Step 4 adoption</i>

2. Timeline for Specific Tasks

*Please provide in the table below short-term high-level specific tasks for work to be done within the Working Group **between now and the next ICH meeting** (recommended 4 – 10 tasks).*

Beginning date	End date	Task / Activity	Details
May. 2026	<i>Jul. 2026</i>	<i>Finalise revised monographs for step 1 sign off</i>	<i>Finalise revised monographs for Step 1 sign off by EWG and Step 2 adoption, prepare Step 2 presentation</i>
Sep. 2026	<i>Dec. 2026</i>	<i>Public commenting phase</i>	<i>Collect public comments</i>
Dec. 2026	<i>Mar. 2027</i>	<i>final Step 3 documents for sign off</i>	<i>Discuss public comments on relevance, implement where relevant and prepare Step 3 documents for sign off</i>