

ICH M16 Structured Product Quality Submissions (SPQS) EWG Work Plan *7 August 2026*

Topic Adoption Date: *April 2025*

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Last Face-to-Face Meeting: *NA*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Oct, 2025</i>	<i>Concept Paper Outline</i>
<i>Feb, 2026</i>	<i>M16 SPQS Expert Working Group (EWG) Establishment</i>
<i>Aug, 2026</i>	<i>M16 SPQS Draft Concept Paper</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>NA</i>	<i>NA</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Sep, 2026	<i>M16 SPQS Concept Paper Endorsement</i>
Oct, 2026	<i>Initial Discussion with SPQS Relevant Supporting Organisations (RSO) (e.g., standards development organisations (SDOs) and vocabularies or dictionaries providing organisations); Draft Collaboration Plan</i>
Nov, 2026	<i>Face-to-face Meeting; Alignment of Key Content of the Core Guideline and Annex A</i>
Mar, 2027	<i>Draft SPQS Testing, including, but not limited to, testing concept for individual (Parts) Annexes and the full-fledged Step 2 for Testing, principles, scope, and procedures</i>
Jun, 2027	<i>Preliminary Draft M16 SPQS Core Guideline and Annex A (Part 1), ready for PWP and Stakeholder Consultation (may include testing) (Round 1)</i>
Sep, 2027	<i>Feedback/comments from PWP and Stakeholder Consultation</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Aug, 2026	Sep, 2026	<i>Conduct baseline analysis</i>	<i>The baseline analysis is to 1) identify gaps in data standards, 2) help prioritise the specific modules to be structured, and) inform collaboration priorities with RSOs to bridge gaps (if any).</i>
Aug, 2026	Oct, 2026	<i>Engage with SPQS RSOs</i>	<i>Establish and conduct the initial engagement with SPQS relevant supporting organisations (RSOs) to envision/draft a collaboration plan, supporting M16 development.</i>
Sep, 2026	Nov, 2026	<i>Develop two use cases</i>	<i>Two sub-working groups to develop two use cases (Description and Stability), respectively. These use cases are to 1) demonstrate how structured quality information can be assembled and rendered, and 2)</i>

			<i>subsequently, serve as a critical reference for the Annexes.</i>
Sep, 2026	<i>Nov, 2026</i>	<i>Draft key components of the Core Guideline</i> <i>Kick off the development of Annex A.</i>	<i>Focus on drafting the Framework (criteria for what and how to structure quality information), governance and lifecycle management of structured quality information and rendition paradigm.</i> <i>Establish a sub-working group and initiate the develop of Annex A (Part 1) by taking full advantage of the above outcomes.</i>
Nov, 2026	<i>Nov, 2026</i>	<i>Face-to-face meeting (Prague, Czech Republic)</i>	<i>Discuss and align components of the M16 SPQS Core Guideline and Annex A, and complete the two use cases to kick off the development of Annex A (Part 1).</i>