

Final Concept Paper

M16 EWG: Structured Product Quality Submissions (SPQS)

Endorsed by the Management Committee on 18 August 2026

1. Background to the proposal and statement of the perceived problem

This Guideline addresses the critical need to modernise regulatory quality information management within the Common Technical Document (CTD) framework. While the M4Q Guideline establishes the overall structure and location of quality information in Modules 2 and 3, it does not identify what information is most appropriate to provide as structured information, nor how structured information can be optimally integrated with relevant non-structured information contained within the application. This gap results in significant variability across regions and applicants. There is a need for data standardisation and interoperability for quality information to enable the efficient use and reuse of data, and adoption of modern information technologies for essential functions such as marketing authorisation assessment and lifecycle management. The absence of interoperability creates business and technical barriers preventing effective information exchange among stakeholders and hindering regulators from efficiently sharing assessment knowledge and leveraging reliance/collaboration mechanisms. Although multiple independent regional efforts are underway, a lack of coordination may create significant risk of disharmony and extra burden.

With the above identified challenges and needs, this Guideline is intended to define harmonised standards for the representation of product quality information in structured formats considering controlled vocabularies and dictionaries, in accordance with applicable legal and regulatory frameworks. It does not redefine the established CTD structure or content locations defined in M4Q but rather specifies how selected quality information may be represented and exchanged as structured information. The adoption of this Guideline is envisioned to promote global harmonisation, eliminate legacy format inefficiencies, enable real-time assessment and risk detection, and improve decision-making efficiency for both industry and regulatory authorities, and where applicable, facilitate timely patient access to medicines.

2. Type of harmonisation action proposed

New Guideline

3. Issues to be resolved and expected deliverable(s)

Main issues to be resolved:

- High volume of unstructured quality information (e.g., free text in PDF) in current submissions, limiting efficient analysis, review, retrieval, and lifecycle management.
- Existence of multiple formats for the same quality information, creating inconsistency, duplication of effort, and increased risk of misinterpretation.

- Absence of comprehensive data standards, controlled vocabularies and/or dictionaries for submissible quality information, and harmonised guidance and governance for the adoption of such standards.
- Lack of an agreed transport (exchange) format for packaging and transmitting structured quality information, with a requirement to accommodate varying organisational digital readiness and to function beyond constraints of current eCTD versions.
- Lack of data interoperability constraining reuse, aggregation, and automated processing of quality information.
- Limited ability to enable easy access, analysis, and management of quality information, including support for cross-domain data reuse (e.g., quality with clinical, non-clinical/safety, supply chain, and regional/M1 application information), and usage across the entire lifecycle of medicinal products from concept development through post-market surveillance.

Scope of the issues to be resolved:

M16 Guideline focuses on data (content) standards in structuring key product quality information in Modules 2.3 and 3, in accordance with the M4Q (R2) framework, across various submission types - including those referring to or consisting of master files - and is applicable to initial marketing authorisations and corresponding post-approval submissions. The outcomes can be applied to assemble structured quality information in other submission types (e.g., IND, IMPD), as applicable within the regional regulatory frameworks. This Guideline is intended to support the implementation and integration of existing, relevant data standards, and controlled vocabularies and dictionaries, across all medicinal product modalities and components. Where suitable standards or vocabularies or dictionaries do not yet exist, collaborative engagement with relevant stakeholders – such as standards development organisations (SDOs) – would support the development or extension of fit-for-purpose standards.

M16 is not intended to change the underlying scientific or quality requirements; rather, it introduces new expectations for the provision of product quality information in a structured, standardised, and reusable data format.

Deliverables:

The envisioned deliverables include:

- A Core Guideline providing
 - a framework for structured quality information;
 - principles for the governance and use of data standards, controlled vocabularies and dictionaries
 - a data lifecycle management (DLM) framework defining, including but not limited to, auditing, traceability, validation, and associated business rules;
 - foundational concepts and high-level requirements for rendering structured quality information.
- Annexes containing data and technical specifications leveraging existing relevant standards (e.g., ISO IDMP, HL7 FHIR and IEC 61512-1:2026), controlled vocabularies (e.g., MedDRA) and dictionaries (e.g. SPOR OMS) as applicable. Under appropriate governance mechanism, these specifications would support interoperability, data consistency, and machine-readable exchange of structured data. They would encompass, where appropriate, common semantics and data models, standardised data elements and identifiers, data-centric business rules, and exchange mechanisms. Where suitable standards and vocabularies or dictionaries do not yet exist, collaboration would be undertaken with relevant supporting organisations (RSOs) to develop or extend them.

- Delivery of a staggered approach for the development of structured quality information, collectively covered through two Annexes, considering all medicinal product modalities, based on a defined set of priorities aligned with the M4Q(R2) framework.
- Implementation recommendations that account for varying levels of digital readiness, legacy submissions, and potential transition periods.
- Training and presentation materials, together with mock-up example(s), as applicable.

4. Planning

4.1. Resources and Expertise

Development of this Guideline requires subject matter experts from regulatory authorities and industry with innovative thinking and adequate expertise and experience in 1) technical and regulatory issues associated with the product quality parts of regulatory submissions, 2) data standards, and 3) information technology and data exchange standardisation. Input and expertise may also be obtained from SDO observers.

4.2. Planned Interactions/Data Generation

Developing and implementing this Guideline will require interactions and consultation with ICH Experts Working Groups (e.g., M2, M4Q(R2) and M8), and pertinent SDOs and other harmonisation forums (e.g., ISO, HL7, ISA, MedDRA and IMDRF). It is anticipated that such interactions will happen throughout the development of this Guideline.

4.3. Stakeholder Engagement and Impact

To successfully develop this Guideline, it is important to engage with SDOs and relevant supporting organisations providing data standards, controlled vocabularies and dictionaries. Additionally, ICH would need to reach agreement(s) with certain organisations supporting the development and adoption of this Guideline.

4.4. Timeframe and Key Milestones

A Staggered Approach for Guideline Development:

Considering its broad scope and complexity, the M16 Guideline is envisioned to include two Annexes, in addition to the Core Guideline. Each Annex addresses a distinct sub-part of the quality data domain: Annex A intends to focus on Module 2.3.1 General Information and 2.3.3 Core Quality Information (CQI) as defined by M4Q(R2), Annex B will cover the remaining quality-related Modules. To maximise development efficiency, Annex A is organised into three parts; the scope and priority of each part are determined by the value of the use cases achieved and dependencies between data domains, while considering maturity of existing standards. One round of Plenary Working Party (PWP) and stakeholder consultation is envisaged for each part of Annex A and Annex B. Accordingly, a staggered development approach will be used to consider practical requirements through scope definition, stakeholder consultation, ensuring early validation of interpretation and applicability across product modalities and regions, within an approximately four-year window. Adoption of the Guideline is envisioned following the completion of *Step 4*.

Planned completion timeline for key milestones:

Planned Completion Timeline	Milestone	Planned Scope
June 2027*	Core Guideline	A framework for structured quality submissions, governance for data standards and controlled vocabularies/dictionaries, data lifecycle management framework, and foundational concepts and high-level requirements for rendering structured quality information.
	Annex A (Part 1)	2.3.1 General Information 2.3.3 Core Quality Information (CQI) • D. Description • S. Storage through all elements 2.3.3. FA Facilities
Nov 2027*	Annex A (Part 2)	2.3.3 CQI • C. Control through all elements 2.3.3 AP. Analytical Procedures
	Annex A (Part 3)	2.3.3 CQI • M. Manufacture through all elements
Jun 2028*	Annex B	2.3.2 Overall Development and Overall Control Strategy 2.3.4 Development Summary and Justification (DSJ) 2.3.5 Product Lifecycle Management (PLCM) 2.3.6 Product Quality Benefit Risk 3.2 Body of Data
Nov 2028	Step 1 Technical Document	
	Step 2a Assembly endorsement	
Nov 2029**	Step 2 for Testing, including addressing comments and EWG consensus**	
Dec 2029	Step 2b Regulatory endorsement	
Nov 2030	Step 3 Public consultation, including addressing comments and EWG consensus	
	Step 4 Adoption	

* PWP and stakeholder consultation will follow after each draft is completed. The EWG will then review and address the comments received and revise the corresponding deliverable(s) accordingly, while adhering to the overall timeline.

** In accordance with Section 2.1.3 *Step 2 for Testing* of the Standard Operating Procedure of the ICH Working Groups (Version 13.1), the EWG intends to conduct a testing phase during which the proposed standards will be tested by ICH Members and appropriate external parties/vendors to confirm technical adequacy.

5. Impacts of the project

Envisioned impact of the Guideline include:

- Supporting data interoperability and machine readability, enabling automation, data reuse, and the application of advanced analytics across development, regulatory assessment, and lifecycle management.

- Enhancing the ability to locate, assess, and reuse quality information, improving the efficiency and effectiveness of regulatory assessment, and enabling cross-domain integration with clinical and non-clinical data.
- Increasing efficiency of dossier creation and lifecycle management by reducing variability, local customisation and duplication in product quality submissions
- Enabling structured rendering of quality data into human readable formats aligned with M4Q framework, supporting broader global applicability.
- Ultimately, contributing to realise critical downstream benefits such as stronger data integrity, more effective drug shortage mitigation and pharmacovigilance, greater supply chain agility, enhanced regulatory reliance, and lower operational cost for both industry and regulators.