



M4Q(R2) CTD_品質に関する文書の 作成要領に関するガイドライン

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- マドリード会合前の状況
- マドリード会合での成果
 ✓ Step1合意
 ✓ 今後の作業についての議論
- ・ 今後の予定

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M4Q(R2)の概略





- Globally harmonized content and organization of quality information in Common Technical Document (CTD)/eCTD ✓ Module 2.3 Quality Overall Summary (QOS)
 - ✓ Module 3 Quality
- M4Q(R1) was a substantial improvement compared to the prior state with regional submission formats





The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

ICH The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality M4Q(R1) Quality overall Summary of Module 3, Module 3: Quality, September 2002



健やかに生きる世界を、ともに

M4Q(R2) Concept Paper



- Expand the scope of M4Q(R1) guideline to include all pharmaceutical drug substances and products (both chemical and biological).
 すべての医薬品に適用可能とする。
- Establish the role of M4Q(R2) as the main source of the structure and location of regulatory quality information.
 品質に係る薬事情報の、CTD上の構造及び場所を定める。
- Organize product and manufacturing information in a suitable format for easy access, analysis, and knowledge management.
 情報のフォーマットを定めることによりアクセス、分析、管理を容易にする。
- Incorporate concepts and data expectations presented in ICH Quality guidelines and aligning with currently recognized international standards and guidelines.
 現行のICHガイドライン等との整合。
- Better capture the pharmaceutical development and the proposed overall control strategy, which should be the backbone of the revised M4Q structure.
 開発の経緯、管理戦略をより理解しやくする。
- Enhance the Quality Module 2 to facilitate the efficiency and effectiveness of regulatory submissions and assessments.
 M2の利用による承認申請・審査の効率化。

Modified from M4Q(R2) concept paper https://www.ich.org/page/ctd



Modified from presentation slide for public consultation https://www.ich.org/page/ctd

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- ・ EWGで作成したガイドライン原案に対する、PWP/内部意見募集を実施。
- ・意見募集で寄せられたコメントへの対応をテレカン、中間会合にて検討。
- M4Q(R2)の施行に関連した懸念点を明確化、対応を検討。



マドリード会合での成果

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Step 1合意

- ガイドライン原案をline by lineで確認
- 全体の整合性の確認
- 2025年5月12日Step 1合意

THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE: QUALITY M4Q(R2)

ICH HARMONISED GUIDELINE

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

Draft version



Structure of M4Q(R2	2) PMDA
Module 2	健やかに生きる世界を、ともに
2.3.1 General Information	Essential product details, optionally supported by a schematic
2.3.2 Overall Development and Overall Control Strategy	High level summary of the development and overall control strategy, including the QTPP, CQAs, and how control elements ensure consistent quality
Module 2 2.3.3 Core Quality Quality overall summary Information (CQI)	Information needed to support a science- and risk-based review for product approval and ongoing lifecycle management
Quality Module 3 2.3.4 Development Summary and Justification (DSJ)	Scientific and risk-based rationale for development, including justifications for specifications and control strategies
2.3.5 Product Lifecycle Management	Strategy for managing post-approval changes, including a summary of changes, the PLCM, and any associated protocols or commitments
2.3.6 Product Quality Benefit Risk (Optional)	Optional summary of how quality-related risks are mitigated and justified in the context of the product's therapeutic benefits, especially relevant for expedited review pathways
Module 3 3.2 Body of Data	Detailed descriptions of methods, data, and other relevant quality information that supports Module 2.3

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各セクションの構成

- CQI、DSJ、Module 3について、右の 中から各materialのセクションを利用
- DMCSのセク 各 material の情報は、 ションを利用して格納
 - D : Description
 - M : Manufacture
 - C : Control
 - S : Storage

- Product Intermediate (PI)
 - Drug Substance (DS)





Packaged Medicinal Product for *multiconstituent products* (PM)





Medical Device (MD)

Facilities







健やかに生きる世界を、ともに

Reference Material (RS)

Raw Material (RM)

Starting / Source

Material (SM)

Excipient (EX)

Analytical Procedures





Figure from draft guideline https://www.ich.org/page/ctd

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今後の作業についての議論



- ・パブコメ用スライドの作成(ICH HP公表済み)
- ・R1 vs R2マッピング、CTDモックの作成
- 施行時の課題抽出
 - 13の規制当局にeCTDの導入状況をアンケート
 - ▶ 10/13の規制当局でeCTD導入済み
 - ▶ eCTD導入済みの10の規制当局で、eCTD 4.0導入済み/導入予定あり





Global Coordination:

Establish plans for implementation of eCTD 4.0, if not yet Align adoption timelines across ICH regions; allow optional early adoption eCTD 4.0の導入計画策定 各地域での施行タイムラインの協調

- **Adequate Transition Period**: Ensure sufficient time post-Step 4 for adapting systems, processes, and vendor-supported tools without disrupting regulatory operations 適切な移行期間の設定
- **Balanced Approach**: Aim to support digital advancement while minimizing disruption for industry and regulators デジタル化の促進⇒SPQS (ICH M16)との協力



https://www.ich.org/page/ctd





Expected future completion date	Milestone
2025年5月	ICH meeting in Madrid, Spain - Step 1 Expert sign off
	Step 2a Endorsement by Members of the Assembly
2025年5月	Step 2b Endorsement by Regulatory Members of the Assembly
	Release for public consultation
2025年8月頃	国内パブコメ開始予定(3カ月間程度)、JPMA/PMDA共催国内説明会予定
2025-2026年	Public workshops on introduction of M4Q(R2) Step 2
2026年3月	ICH 中間対面会合
2026年11月	Review and resolve public comments
2027年6月	Step 3 Sign-off and Step 4 Adoption of Final Guideline

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