FIFARMA

Q&A – Webinar 2

Navigating the Guideline on the Common Technical Document on Quality: Key Changes and Impact for the LATAM

Pergunta	Resposta
Do you expect regulatory agencies to start using Module 2 from now on? In LATAM agencies, for synthetic products, Module 2 is usually not submitted; only Module 3 is. Do you think this will change? Will agencies also move toward an assessment based on Module 2?	This is one of the major objectives we aim to achieve with Revision 2 of the guideline. This module will contain all the information necessary for a regulator to make a decision. It will represent a true paradigm shift. Drawing a parallel, Module 2 for Quality would begin to be used in the same way it is currently applied for the assessment of safety and efficacy.
Ellen, from ANVISA's perspective, once M4Q(R2) is published and implemented, will it be possible to eliminate the need for additional documents such as the FIDR or the PATE, as well as specific statements currently requested in the registration and post-approval checklists for synthetic medicines? In other words, are we closer to avoiding the need to customize dossiers submitted in Brazil?	Yes. Considering the advances proposed in the CQI section of M4Q(R2), the expectation is that, under the new format, requests for additional documentation such as the FIDR, the PATE, and specific statements will be eliminated.
Will intermediates be considered Pharmaceutical Product After Transformation?	No. M4Q(R2) includes a specific section for Product Intermediates, where the relevant technical information should be provided when applicable. In turn, the Pharmaceutical Product After Transformation section refers to the final product obtained following a transformation step (according to the ISO definition). An example is a lyophilized powder for an injectable solution, where the transformed product is the solution ready for administration.
Regarding the use of the product for different "phases," device dossiers currently do not follow the CTD format. Are authorities expected to receive devices in this format?	M4Q(R2) addresses the format and organization of the Quality module but does not define the specific technical content to be submitted. This will continue to depend on the requirements established in each regulatory authority's legal framework.
Ellen, once M4Q(R2) is implemented, will CTD dossiers based on Revision 1 need to be adapted to comply with Revision 2? Or will this apply only to new marketing authorization applications submitted after publication of M4Q(R2)?	The implementation of M4Q(R2) is not the responsibility of the EWG. Following final adoption of the guideline (Step 4), the establishment of an Implementation Working Group (IWG) falls under the ICH Management Committee or the regulatory authorities themselves. In any case, the EWG recommends that migration of dossiers prepared according to Revision 1 should not be mandatory. However, the group considers that the possibility of submitting the Core Quality Information (CQI) within R1 dossiers could be explored, as this may facilitate and accelerate post-approval assessment.

What do you see as the main challenges in implementing the ICH-CTD guideline for companies with locally manufactured products?	One of the primary challenges for locally based manufacturers is aligning existing documentation and data management systems with the structured format required by the ICH-CTD, since many companies have historically relied on national templates or proprietary dossier structures. In addition, resource and training needs — both technical and regulatory — may be significant, particularly for small and medium-sized enterprises with limited experience in CTD-based submissions.
Has section 3.3 (Literature) been removed?	Yes. The former section 3.3 in M4Q(R1) has been removed in M4Q(R2). Relevant references should now be incorporated within the appropriate sections of the dossier rather than grouped into a separate section.
What challenges does ANVISA foresee in updating local regulations to adopt ICH M4Q(R2)?	In Brazil, adoption of ICH guidelines follows the framework established by ANVISA Ordinance No. 539/2024, which provides, in Chapter III, for the internalization of these directives through a specific Standard Operating Procedure. Therefore, implementation of M4Q(R2) will require updates to local regulations and procedures in line with this governance process. The main challenges include ensuring regulatory consistency between existing RDCs and technical standards, training both assessors and industry on the new structure and terminology, and upgrading electronic submission systems (eCTD) to handle the structured information introduced by M4Q(R2). Moreover, effective stakeholder engagement and phased implementation will be essential to facilitate a smooth transition without creating unnecessary regulatory burden for locally manufactured products.
Regarding regulatory harmonization among Latin American agencies, was there any intention to standardize local regulations based on ICH? Who is leading this process?	M4Q(R2) addresses the format and organization of the Quality module but does not define the specific technical content, which remains subject to the requirements established in each authority's regulatory framework.
For ANVISA/Ellen: What type of industry input do you believe would be most useful to ensure that Brazil's regulatory needs are considered and to facilitate international harmonization?	Industry contributions can be particularly valuable when focused on practical aspects of guideline implementation, taking into account the specific realities and challenges faced by the Brazilian pharmaceutical sector.
I am the Health Regulation Coordinator at ARCSA Ecuador. With whom at ICH could we coordinate for guidance on this guideline and country-specific modules, considering that we have just issued updated technical regulations for biologicals and synthetic medicines?	At this stage, the draft M4Q(R2) guideline remains under regional consultation, aimed at gathering feedback to support finalization of the document. Discussions related to implementation or country-specific guidance will therefore take place after Step 4, once the guideline has been formally adopted by ICH.
What tools have been developed to support adoption of the CTD by domestic companies?	ANVISA has already issued a detailed guidance document (Guidance No. 24/2019) to facilitate transition to the CTD format (Revision 1). Looking ahead, the forthcoming ICH M4Q(R2) guideline will introduce a more structured and harmonized framework, further supporting companies in improving clarity, digital readiness, and consistency in regulatory submissions.
Has ANVISA begun internal discussions regarding the timeline for regulatory impact analysis and the update of Guidance 24?	So far, ANVISA has not initiated formal internal discussions regarding the update of Guidance No. 24/2019. The current focus is the regional consultation on M4Q(R2), conducted in accordance with Ministerial Ordinance No. 539/2024. Once Step 4 is concluded at ICH, and based on the consultation outcomes, ANVISA will assess regulatory impacts and plan updates to local norms and guidance in alignment with the national strategy for regulatory harmonization.

Thank you for the presentation. Could you further explain how the changes will support reliance practices?	The introduction of the Core Quality Information (CQI) concept enables comparison of the central elements of a dossier and strengthens regulatory trust among agencies.
Regarding eCTD, could you elaborate on the importance of its implementation in a scenario where cloud-based submission tools are increasingly available? Will following the CTD format alone still be sufficient?	The eCTD was developed within the ICH framework and represents an international standard for structured electronic submissions, ensuring interoperability, traceability, version control, and data integrity between companies and regulatory authorities. Even as new cloud-based tools emerge, it is essential that they maintain the principles of structure, indexing, and navigability required under the new R2 format.
Question for Raphael: Several items in the "new" Module 2.3 and in Module 3 are linked to other regulatory tools that ANVISA has not yet implemented, such as ICH Q12 – Established Conditions. What is ANVISA's view on this and how will these tools be implemented?	Implementation of ICH Q12 will be discussed in the context of the revision of marketing authorization and post-approval regulations, as foreseen in the 2023–2025 Regulatory Agenda.
Is there any expectation of updating ANVISA's subject code checklists to incorporate the CTD modules?	So far, the focus has been the regional consultation on M4Q(R2), conducted in accordance with Ministerial Ordinance No. 539/2024, which defines the process for internalizing ICH guidelines in Brazil. Once Step 4 is completed at ICH, and based on the consultation results, ANVISA will assess regulatory impacts and plan updates to local regulations and guidance, aligned with the national regulatory harmonization strategy.
Once the guideline is implemented, will ANVISA require companies to convert product dossiers to the new format, or will R1 dossiers continue to be accepted even after R2 is in force?	The implementation of M4Q(R2) is not the responsibility of the EWG. Following final adoption (Step 4), the creation of an Implementation Working Group (IWG) falls under the ICH Management Committee or the regulatory authorities. In any case, the EWG recommends that migration from Revision 1 to Revision 2 should not be mandatory. However, the group believes that the option of submitting the Core Quality Information (CQI) within R1 dossiers could be considered, as this may facilitate and expedite post-approval assessment.
How is ANVISA preparing, or planning to prepare, its assessors to evaluate dossiers under this new format?	ANVISA recognizes that implementation of M4Q(R2) will require specific technical training for assessors. The current focus is on their active participation in the ICH working group, which has enabled the Agency to closely follow development of the guideline and anticipate internal training needs.