

Agenda

- What is Cortellis Regulatory Intelligence?
- Overview Cortellis Regulatory Assistant
- Live demo
- Roadmap Cortellis Regulatory Assistant
- Q&A and Feedback



What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities:



300K+ official documents



8K+ Value-add regulatory reports, analyses and global comparisons



English translations for all native language documents



81 countries and regions
Drugs & Biologic and
75 Medical Devices & IVDs



Updated daily



Regulatory experts & local consultants



A transformative AI partner you can trust

Proven and trusted Al rolled out across Clarivate industry-leading solutions (including Web of Science and Proquest), used by:

- 3,050+ institutions and life sciences companies
- 1.85M+ queries submitted

"We are so pleased to be a part of the beta testing for the new Al Regulatory assistant.

This tool will save us significant time and resources compared to searching manually and we are already seeing how this will speed up internal enquiries and intelligence work.

We have been impressed with how the team is actively engaging clients in the development process by seeking out and acting upon our feedback to continually improve the product. They are dedicated to building a useful tool that meets our needs while ensuring that it is also accurate and user-friendly."

Collaborative Partner Programm Testimonial

Director, Regulatory Intelligence & External Engagement



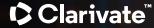
Delivering value specific to the needs of regulatory teams

Our unique combination:

Depth and breadth of content

Deep domain expertise

Proven enterprise-level Al





How does the Regulatory Assistant work?

Understand user intent & context Plan path to execution Collect data from sources Execute Validate & enhance outputs Iterate & refine



Trusted Cortellis human curated content & original sources

Clarivate expert regulatory knowledge

Clarivate Al platform expertise

Fast, accurate and hassle-free:

- Full conversational experience
- Smooth entry point to Cortellis Regulatory Intelligence
- Search support for nonfrequent users
- Ability to answer questions based on trusted sources - and refer back to them

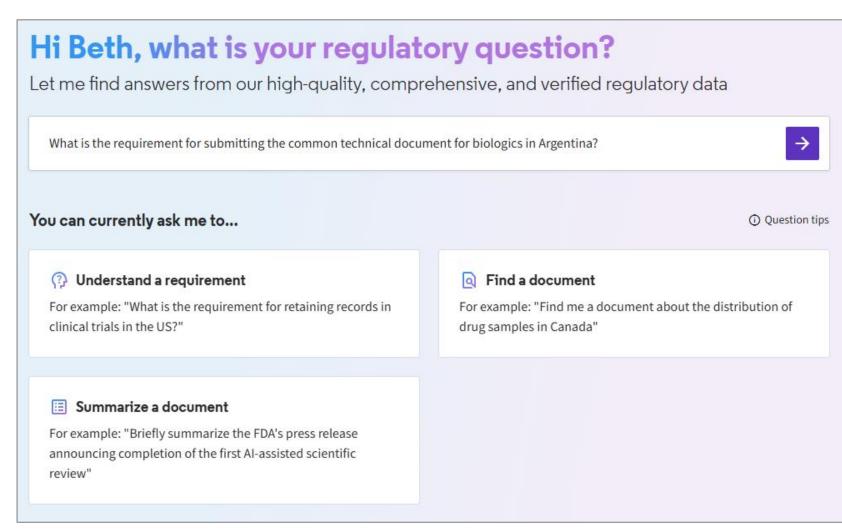


Live Demo Cortellis Regulatory Al Assistant

Cortellis Regulatory Assistant to simplify your access to regulatory information

Three use cases available now:

- Understand a requirement
- Find a document
- Summarize a document





Cortellis Regulatory Assistant to simplify your access to regulatory information

 Answers provided in text format

 Direct links to Source **Documents**

Feedback rating

Copy/paste icon

What is the requirement for submitting the common technical document for biologics in Argentina?



Answer

How was this generated? ▼

The requirement for submitting the Common Technical Document (CTD) for biologics in Argentina is established by ANMAT through Circular 11/2019, which implemented the CTD format specifically for Biologics, Vaccines, and Radiopharmaceutical submissions. This means that any application for registration of these products must follow the CTD structure when submitting dossiers to ANMAT. 1

- CTD Format Implementation: Biologics, vaccines, and radiopharmaceuticals must be submitted in the CTD format as per Circular 11/2019. This requirement does not apply to small molecule submissions, which use a different electronic system. 1
- Regulatory Basis: The CTD format is required for the registration process and is referenced in the regulatory summary for Argentina, ensuring harmonization with
- Supporting Legislation: The regulatory framework for Disposition 7729/11, which detail the requirements an products, including the need for comprehensive docu should be presented in the CTD format. 2 3
- Documentation Requirements: For biosimilars and ot pharmaceutical, and biological information, as well as evidence of quality, safety, and efficacy, in line with AN

Source documents

1 Application Format, Content and Submission

Expert Report . Cortellis . Argentina . Last updated 23-Sep-2025 . More info

Disposition 7729/2011: Sets up the Requirements for the Marketing Authorization of Medicinal Products of Biological Origin Similar to Other Medicinal Products of Biological Origin Already Registered, 14-Nov-2011 (Official Consolidated Version up to Amendments Brought by Disposition 101/2012 of 04-Jan-2013)

Regulation • CC BY 4.0 • Argentina • Last updated 07-Jan-2024 • More info • 🖫 Summarize

3 Regulation 1741/2025: Establishes the "Requirements, Guidelines, and Criteria for the Comparability Exercise of Biosimilar Medicinal Products", 14-Mar-2025

Regulation • BORA • Argentina • Last updated 17-Mar-2025 • More info • 🔳 Summarize

4 Guidelines: Vaccines Batch Releases and Request to Export (FORM LVAC 1.1) (Version 2.0), Feb-2024

Guideline • CC BY 4.0 • Argentina • Last updated 25-Aug-2025 • More info • 🔳 Summarize



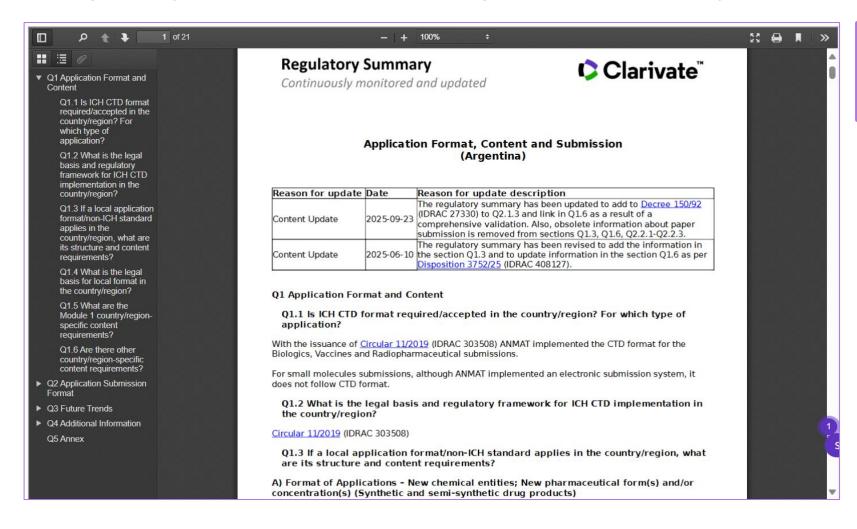






What sources are used to generate answers?

Regulatory Summaries: Consistent guidance on 50+ topics across the Regulatory policy spectrum

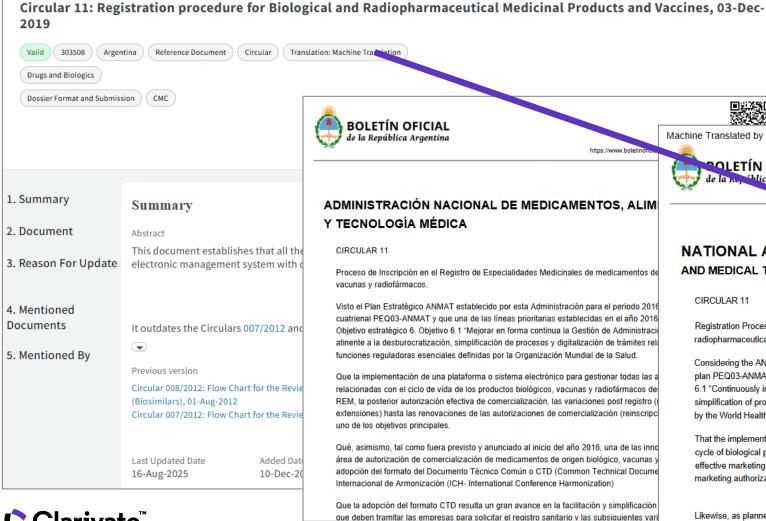


Expertly created report from Cortellis experts and our external network of global consultants



What sources are used to generate answers?

Source Documents: updated daily from up to 80+ countries/regions all in one searchable platform



Access the native language versions and English translations without having to leave Cortellis

Machine Translated by Google





https://www.boletinoficial.gob.ar/#!DetalleNorma/222604/20191203

NATIONAL ADMINISTRATION OF DRUG, FOOD AND MEDICAL TECHNOLOGY

CIRCULAR 11

Registration Process in the Registry of Medicinal Specialties for medicines of biological origin, vaccines and radiopharmaceuticals.

Considering the ANMAT Strategic Plan established by this Administration for the period 2016-2019: Four-year institutional plan PEQ03-ANMAT and that one of the priority lines established in 2016 related to Strategic Objective 6. Objective 6.1 "Continuously improve Management of Administration", was to deepen matters related to debureaucratization, simplification of processes and digitalization of procedures related to the essential regulatory functions defined by the World Health Organization.

That the implementation of an electronic platform or system to manage all authorizations related to the life cycle of biological products, vaccines and radiopharmaceuticals from their registration in the REM, the subsequent effective marketing authorization, post-registration variations (modifications and extensions) until renewals of marketing authorizations (re-registrations) was considered one of the main objectives.

Likewise, as planned and announced at the beginning of 2016, one of the innovations planned in the area of marketing authorization of medicines of biological origin, vaccines and radiopharmaceuticals has been the adoption of the Common Technical Document or CTD format (Common Technical Document) of the Conference International Conference Harmonization (ICH)



Key Features of the Cortellis Regulatory Assistant

- **Conversational Interface**: Ask regulatory questions naturally and receive relevant, curated responses. Ask follow-up questions to dig deeper.
- ❖ Narrative Answers with Citations: Understand regulatory requirements with Al-generated summaries linked to source documents.
- ❖ Document Discovery: Quickly locate the top 3 most relevant documents or specific IDRAC numbers.
- **Summarization**: Digest lengthy source documents with one-click summarization.
- ❖ Multi-Language Support: Ask questions and receive answers in your preferred language.
- **Chat History**: Access up to 500 recent conversations.
- Question tips Icon: Gives tips to craft well-structured questions.
- **FAQ document**: Covers usage, languages, benefits, limitations, access, privacy, sources, accuracy, transparency, sustainability etc.



Considerations

related to Cortellis Regulatory Assistant's 1st release (Sep 2025)

- ➤ **Content Scope**: Responses are limited to our best-in-class content within Cortellis Regulatory Intelligence, and subject to your license.
- "Understand a requirement" questions covering Product Approvals and Compliance & Inspection domains are currently excluded.
- Asking the same question again might provide answers with different wording due to the nature of large language model searching.
- ➤ **Document Versions**: Answers to "Understand a requirement' questions only cite final, valid versions; draft versions are excluded. All answers exclude outdated documents.
- ➤ **Unsupported Use Cases**: Comparing requirements across countries/ regions, document version comparisons like draft vs. final, and queries requiring answer aggregation from many (6+) sources. Comparisons options planned for 2026.
- > **Section-Specific Citations**: If documents are unstructured, section-specific citations and source text excerpts may be unavailable.





Coming soon!

Al Regulatory Assistant Vision and roadmap (video)

Harnessing generative AI to fuel your regulatory strategy and compliance

Al Assistant launch (Sept 30)



Your questions, answered accurately

- Search intuitively, using natural language
- Guided enquiry and exploration
- Enriched experience with narrated answers
- References and links to relevant sections
- Interact with the assistant in preferred language

Easily digest documents

Quick, comprehensive document analysis and summarization

2026 enhancements



Multi-document analysis and crosscountry comparison

- Easily compare document versions, e.g. differences between final and draft guidance
- Compare requirements across multiple countries.
- Simply ask a question and get an instant analysis drawn from multiple documents, e.g. summarize product X's approval history across markets.

Product vision



Track the regulatory changes that matter to you

- Personalized recommendations
- Easily change alerts preferences
- Contextual experience

Assess the impact of regulatory changes

- Understand the broader context of regulatory changes with impact assessment
- Empower decision-making with recommended actions

CLARIVATE ARTIFICIAL INTELLIGENCE PLATFORM

FOUNDATION - Trusted regulatory intelligence and expertise





Thank you! Questions?

Claudia Haas and Beth Wise Claudia.Haas@Clarivate.com and Beth.Wise@Clarivate.com

About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com

© 2025 Clarivate

Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license.