



Need answers fast? Ask the new Cortellis Regulatory AI Assistant

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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 AI 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 AI 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 AI

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 AI platform
expertise**

Fast, accurate and hassle-free:

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



Live Demo Cortellis Regulatory AI 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**

Hi Beth, what is your regulatory question?


Let me find answers from our high-quality, comprehensive, and verified regulatory data

→


You can currently ask me to... [Question tips](#)

**Understand a requirement**

For example: "What is the requirement for retaining records in clinical trials in the US?"

**Find a document**

For example: "Find me a document about the distribution of drug samples in Canada"

**Summarize a document**

For example: "Briefly summarize the FDA's press release announcing completion of the first AI-assisted scientific review"

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 ¹
- **Supporting Legislation:** The regulatory framework for Disposition 7729/11, which detail the requirements and products, including the need for comprehensive documents should be presented in the CTD format. ² ³
- **Documentation Requirements:** For biosimilars and other pharmaceutical, and biological information, as well as evidence of quality, safety, and efficacy, in line with ANMAT

Source documents

- 1 [Application Format, Content and Submission](#)
Expert Report • Cortellis • Argentina • Last updated 23-Sep-2025 • More info
- 2 [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

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What sources are used to generate answers?

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

The screenshot shows a web browser displaying a regulatory summary report. The browser's address bar shows '1 of 21' and '100%'. The report is titled 'Regulatory Summary' with the Clarivate logo and the tagline 'Continuously monitored and updated'. The main heading is 'Application Format, Content and Submission (Argentina)'. Below this is a table with two columns: 'Reason for update' and 'Date'. The table contains two rows of updates. The first row is dated 2025-09-23 and mentions 'Decree 150/92'. The second row is dated 2025-06-10 and mentions 'Disposition 3752/25'. Below the table, the section 'Q1 Application Format and Content' is expanded, showing questions Q1.1 through Q1.6. Q1.1 asks about ICH CTD format requirements, Q1.2 asks about the legal basis, Q1.3 asks about local application format, Q1.4 asks about the legal basis for local format, Q1.5 asks about Module 1 content requirements, and Q1.6 asks about other content requirements. The answer for Q1.1 is provided, mentioning 'Circular 11/2019' and 'ANMAT'. The answer for Q1.2 is also provided, mentioning 'Circular 11/2019'. The answer for Q1.3 is provided, mentioning 'Format of Applications - New chemical entities; New pharmaceutical form(s) and/or concentration(s) (Synthetic and semi-synthetic drug products)'.

Regulatory Summary
Continuously monitored and updated

Application Format, Content and Submission (Argentina)

Reason for update	Date	Reason for update description
Content Update	2025-09-23	The regulatory summary has been updated to add to Decree 150/92 (IDRAC 27330) to Q2.1.3 and link in Q1.6 as a result of a comprehensive validation. Also, obsolete information about paper submission is removed from sections Q1.3, Q1.6, Q2.2.1-Q2.2.3.
Content Update	2025-06-10	The regulatory summary has been revised to add the information in the section Q1.3 and to update information in the section Q1.6 as per Disposition 3752/25 (IDRAC 408127).

Q1 Application Format and Content

Q1.1 Is ICH CTD format required/accepted in the country/region? For which type of application?

With the issuance of [Circular 11/2019](#) (IDRAC 303508) ANMAT implemented the CTD format for the Biologics, Vaccines and Radiopharmaceutical submissions.

For small molecules submissions, although ANMAT implemented an electronic submission system, it does not follow CTD format.

Q1.2 What is the legal basis and regulatory framework for ICH CTD implementation in the country/region?

[Circular 11/2019](#) (IDRAC 303508)

Q1.3 If a local application format/non-ICH standard applies in the country/region, what are its structure and content requirements?

A) Format of Applications - New chemical entities; New pharmaceutical form(s) and/or concentration(s) (Synthetic and semi-synthetic drug products)

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

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

Circular 11: Registration procedure for Biological and Radiopharmaceutical Medicinal Products and Vaccines, 03-Dec-2019

Valid

303508

Argentina

Reference Document

Circular

Translation: Machine Translation

Drugs and Biologics

Dossier Format and Submission

CMC



BOLETÍN OFICIAL

de la República Argentina

Machine Translated by Google



BOLETÍN OFICIAL

de la República Argentina

1. Summary

2. Document

3. Reason For Update

4. Mentioned Documents

5. Mentioned By

Summary

Abstract

This document establishes that all the electronic management system with a view to the implementation of the

It outdates the Circulars [007/2012](#) and [008/2012](#)

Previous version

[Circular 008/2012: Flow Chart for the Review of Biologics \(Biosimilars\), 01-Aug-2012](#)
[Circular 007/2012: Flow Chart for the Review of Biologics \(Biosimilars\), 01-Aug-2012](#)

Last Updated Date

Added Date

16-Aug-2025

10-Dec-2019

ADMINISTRACIÓN NACIONAL DE MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA

CIRCULAR 11

Proceso de Inscripción en el Registro de Especialidades Medicinales de medicamentos de vacunas y radiofármacos.

Visto el Plan Estratégico ANMAT establecido por esta Administración para el periodo 2016-2019, el Plan Estratégico ANMAT y que una de las líneas prioritarias establecidas en el año 2016 es el Objetivo estratégico 6. Objetivo 6.1 "Mejorar en forma continua la Gestión de Administración de Medicamentos, Alimentos y Tecnología Médica (MAT) atinente a la desburocratización, simplificación de procesos y digitalización de trámites relacionados con las funciones reguladoras esenciales definidas por la Organización Mundial de la Salud.

Que la implementación de una plataforma o sistema electrónico para gestionar todas las actividades relacionadas con el ciclo de vida de los productos biológicos, vacunas y radiofármacos de la Administración de Medicamentos, Alimentos y Tecnología Médica (MAT), la posterior autorización efectiva de comercialización, las variaciones post registro (modificaciones, extensiones) hasta las renovaciones de las autorizaciones de comercialización (reinscripción) contribuya al cumplimiento de los objetivos principales.

Qué, asimismo, tal como fuera previsto y anunciado al inicio del año 2016, una de las líneas prioritarias de la Administración de Medicamentos, Alimentos y Tecnología Médica (MAT) es la adopción del formato del Documento Técnico Común o CTD (Common Technical Document) de la Organización Internacional de Armonización (ICH- International Conference Harmonization)

NATIONAL ADMINISTRATION OF MEDICINES, FOOD AND MEDICAL TECHNOLOGY

CIRCULAR 11

Registration Process in the Register of Specialized Medicines of vaccines and radiopharmaceuticals.

Considering the ANMAT Strategic Plan 2016-2019 and that one of the priority lines established in the year 2016 is Objective 6.1 "Continuously improve the management of Medicines, Food and Medical Technology (MAT) through the simplification of processes and digitalization of procedures related to the essential regulatory functions defined by the World Health Organization (WHO).

That the implementation of an electronic platform or system to manage all the activities related to the cycle of biological products, vaccines and radiopharmaceuticals of the National Administration of Medicines, Food and Medical Technology (MAT), the effective marketing authorization, the post-registration variations (modifications, extensions) up to the renewals of the marketing authorizations (re-registration) contribute to the fulfillment of the main objectives.

That, likewise, as was foreseen and announced at the beginning of the year 2016, one of the priority lines of the National Administration of Medicines, Food and Medical Technology (MAT) is the adoption of the Common Technical Document (CTD) format of the International Conference on Harmonization (ICH- International Conference Harmonization)

 **BOLETÍN OFICIAL**
de la República Argentina

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

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 AI-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!

AI Regulatory Assistant Vision and roadmap (video)

Harnessing generative AI to fuel your regulatory strategy and compliance

AI 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 cross-country 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?

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About Clarivate

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