Cortellis Regulatory Intelligence Topics

What is Topic Tagging in Cortellis Regulatory Intelligence

Cortellis Regulatory Intelligence uses a methodical approach to organizing and categorizing regulatory content through **topic tagging**. Topic tagging enables more relevant, contextual, and filterable search results across the Cortellis Regulatory Intelligence platform enabling a **significantly augmented search experience.**

As of **Q3 2025**, Cortellis Regulatory Intelligence has transitioned from manual editorial categorization to a **language model–based tagging system** powered by a data science tool. Editorial expertise is now used to train and **will** continuously refine the model, ensuring high-quality topic assignments,

Key Improvements for users

- **Enhanced Consistency**: Standardized logic minimizes human variability, ensuring uniform topic tagging across all content.
- **Contextual Accuracy**: The model analyzes full-document context, improving the precision of topic identification beyond rule-based methods.
- **Human Oversight:** Final validation by experts ensures quality control and allows for nuanced adjustments when needed.

This evolution streamlines the indexing workflow while maintaining Cortellis Regulatory Intelligence's high standards of **accuracy, relevance**, and **user-centric searchability.**

What are Cortellis Regulatory Intelligence Topic terms and their definitions

Topics terms are defined using a dual approach:

- Structured metadata for automation: Keywords , synonyms, and boundary conditions help the tool identify relevant content.

- Conceptual clarity for human validation: Each topic includes a clear description, scope, and examples for reviewers.

This table includes:

- **Topic term**
- **Description**
- **Key words and synonyms** for both **Drugs/Biologics** and **Medical Devices/IVDs** where applicable

Notes

- **Most topics apply to both product types.** Check *one asterisk ()** for topics that apply **only to Drugs and Biologics**, and *two asterisks () for topics that apply **only to Medical Devices (MD) and In Vitro Diagnostics (IVDs).**
- The term **"Other Topic"** should be used **only when none of the listed terms are applicable.**
- A document may be associated with **more than one topic.**

Topic	Description	Key words Terms (Non-exhaustive list)
Active pharmaceutical ingredient*	A chemical/biological substance used in the manufacturing of a finished drug or biologic that produces the intended pharmacological effect. This includes both existing and new active ingredients and may be supported by documentation such as Active Substance Master Files (ASMF) or Drug Master Files (DMF).	Active Pharmaceutical Ingredient, ASMF, DMF, New Active Ingredient
Advertising and promotion	Activities and materials used to market or promote drugs, biologics, or medical devices, including advertisements, and promotional communications.	advertising, promotion, promotional material
Authorities and organizations	International, national, regional Regulatory bodies and organizations responsible for oversight, approval, and monitoring of drugs, biologics, and medical devices/IVD.	competent authority, regulatory authority, health authority, notified bodies

	Includes health authorities, ministries, agencies, and frameworks for transparency and cooperation.	
Clinical research	Activities related to clinical trials and research studies involving human subjects to evaluate the safety, efficacy, and performance of drugs, biologics, or medical devices.	Clinical trial, clinical study, informed consent, sponsor, investigator, ethics committee, good clinical practice, clinical trial application, investigational medicinal product, investigational device, clinical data, clinical evaluation
CMC*	Chemistry, Manufacturing, and Controls (CMC) refers to the regulatory requirements and guidelines that address the quality-related aspects of medicinal products and biologic development, including composition, manufacturing processes, and quality control standards. Although most CMC information is structured within Module 3 of the Common Technical Document (CTD), Cortellis Regulatory Intelligence primarily emphasizes general guidance, and compliance expectations and practical guidance rather than exhaustive technical specifications. These requirements are typically embedded in regulatory documents for Marketing Authorization Applications (MAA) and Clinical Trial Applications (CTA), ensuring that investigational and commercial products meet established standards for safety, efficacy, and quality.	Active Pharmaceutical Ingredient, batch records, biologics, biosimilars, container closure system, GMP, manufacturing, quality control/assurance, stability, shelf-life, validation
Compliance and inspection	Processes and activities to ensure regulatory compliance through	Inspection, audit, certification, conformity assessment, standards

	inspections, audits, and certifications.	
Device classification**	Categorization of medical devices and IVDs based on risk and intended use, determining regulatory requirements.	Medical Device Classification, Class I, Class II, Class III, In Vitro Diagnostic
Distribution	Processes and regulations related to the supply and distribution of drugs, biologics, and medical devices.	distributor, supply chain, shortage, Good Distribution Practice
Dossier format and submission	Standardized formats and procedures for submitting regulatory documentation for product approval.	Common technical document (CTD), eCTD, Marketing Authorization Application, application submission, technical documentation, CE mark, 510(k), Premarket Approval (PMA), New Drug Application (NDA), Biologics License Application (BLA)
eHealth	Use of digital technologies in healthcare, including data collection, patient monitoring, and software-based medical devices.	cybersecurity, mobile medical apps, artificial intelligence, machine learning, telehealth, telemedicine, electronic health records, software as a medical device
Environment	Environmental considerations and controls in the pharmaceutical and medical device industries.	environmental protection, environmental impact, waste management, bio-hazardous materials
Fees	Regulatory fees associated with product registration, lifecycle, and services.	fee, annual fee, product fee, user fee, taxes
Generics and biosimilars*	Drugs that are equivalent to brand-name products in dosage, safety, strength, and intended use, including biosimilars. interchangeability, reference products, and regulatory pathways for approval of Medicinal products developed to be equivalent or highly similar to an approved reference product, including generic drugs and biosimilar biologics.	generic, biosimilar product, reference medicinal product, bioequivalence, interchangeability

Geriatrics	Medical considerations and regulatory aspects related to the elderly population.	geriatrics
GCP	Good Clinical Practice (GCP) refers to an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human subjects.	Good Clinical Practice, clinical trial standards, GCP compliance
GDP	Good Distribution Practice (GDP) outlines the minimum standards for the proper distribution of medicinal products for human use.	Good Distribution Practice, distribution standards, GDP compliance
GLP	Good Laboratory Practice (GLP) is a set of principles intended to ensure the quality and integrity of non-clinical laboratory studies.	Good Laboratory Practice, non-clinical study standards, GLP compliance
GMP	Good Manufacturing Practice (GMP) ensures that products are consistently produced and controlled according to quality standards.	Good Manufacturing Practice, manufacturing standards, GMP compliance
GVP	Good Pharmacovigilance Practice (GVP) refers to measures and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.	Good Pharmacovigilance Practice, pharmacovigilance standards, GVP compliance
GXP	GxP is a general term for Good practices documents used in Cortellis Regulatory Intelligence to categorize other than GCP, GLP, GMP, GDP, and GVP (ex. Good Regulatory Practice, Good review Practice, etc.)	Good Practices, GxP standards, Good Regulatory Practice, Good Review Practice
Import and Export	Regulatory requirements and procedures for importing and exporting medicinal products and medical devices.	import, export, import license, export license, authorized representative
Legislative Framework	The legal and regulatory foundation governing the development, approval, and oversight of medicinal products	drug laws, legislative proposals, legal basis, decrees, ordinances

	and medical devices. Used to tag core legal documents that establish the basis for regulatory requirements.	
Manufacturing and Control	Processes and systems involved in the production and quality control of medicinal products and medical devices.	manufacturing process, quality defect, batch release, batch control, production, validation
Non-Clinical Studies	Studies conducted in vitro or in vivo to assess the safety and performance of medicinal products and medical devices before clinical trials.	pharmacokinetics, pharmacodynamics, preclinical research, toxicology, genotoxicity, carcinogenicity, biocompatibility
Orphan Products*	Medicinal products intended for the diagnosis, prevention, or treatment of rare diseases or conditions.	orphan drug, rare disease, orphan designation
Packaging and Labelling	Requirements and standards for the packaging and labeling of medicinal products and medical devices.	labeling, packaging, Summary of Product Characteristics, product information, leaflet, instructions for use, serialization, traceability, mock up
Pediatrics	Regulatory requirements and studies related to the development and use of medicinal products in pediatric populations.	Pediatrics, Pediatric Investigation Plan, Pediatric Study
Pharmacovigilance / Technovigilance - Risk Management	Activities related to the monitoring and managing the safety of medicinal products and medical devices, pre and post marketing.	pharmacovigilance, risk management plan, adverse event, adverse reaction, Periodic Summary Reporting / Periodic safety update report (PSUR), Qualified person for pharmacovigilance (QPPV), Individual Case Safety Report (ICSR), recalls, post-market surveillance, medication error, drug safety, Development Safety Update Report (DSUR), Post-Authorisation Safety Study (PASS), Field Safety Corrective Action (FCSA)
Post-Authorisation Studies	Studies conducted after product approval to monitor safety, efficacy, or usage in real-world settings.	Post-Authorisation Safety Study (PASS), epidemiological Study, observational Study

Prescription Requirements	Regulations governing the prescription, dispensing, and sale of medicinal products and medical devices.	prescription, dispensing, over-the-counter, internet sales
Pricing Reimbursement / HTAs	Processes and policies related to the pricing and reimbursement of medicinal products and medical devices.	pricing, reimbursement, health technology assessment (HTA), Pharmacoeconomics
Product Assessment	Evaluation of medicinal products and medical devices for approval, including benefit-risk analysis and regulatory decisions.	Evaluation report, European public assessment report (EPAR), product approval,
Regulatory Procedures	Administrative and scientific processes for the approval, variation, and lifecycle management of medicinal products and medical devices.	post approval changes, priority review, accelerated approval, renewal, withdrawal, marketing authorization, licensing, submission, CE marking, orphan drugs, advanced therapy medicinal product

Disclaimer

This list of terms is provided for reference purposes only and is non-exhaustive. The regulatory, scientific, and technological landscape for pharmaceuticals, biologics, and medical devices evolves continuously due to updates in international guidelines, jurisdiction-specific requirements, and emerging innovations. Consequently, additional terms, concepts, and practices may apply depending on context, region, or future developments.

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