Document Type Classification

Cortellis Regulatory Intelligence

A document type is assigned to each reference document released by regulatory authorities and organizations covered by Cortellis Regulatory Intelligence (CRI). The document type may be used as a filter in CRI

This glossary provides a meaningful definition of each type of document and which publications you can expect to find under such indexing term. Some of the terms are country specific, others may apply to several countries but with a different connotation or impact.

The CRI document type may not match the publication title in all situations. When they differ, the rationale for the selected indexing term is explained.

For example, an instruction (in title) can have a guideline or regulation as the indexing term because its definition corresponds to a guideline or regulation rather than an instruction.

Document Type	Description
510(k)	A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective (substantially equivalent) as a legally marketed device (section 513(i)(1)(A) Federal Food, Drug, & Cosmetic Act [FD&C]). Country specific: USA
Agreement	An agreement (or cooperative arrangement) includes international/bilateral agreements and letters of intent, protocol, memoranda of understanding, statements of cooperation, statements of intent, confidentiality commitments, etc. Documents in this category can be binding and non-binding.
Announcement	This document covers formal public statements published by regulatory agencies relating to changes in applications, new requests, reminders or clarification of points regarding legislative requirements, and updates and actions expected to be taken related to regulatory procedures. Different formats may be used by different organizations (e.g., notices, notifications, or informational notes). Announcements are not binding but they are recommended.
BLA	A Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). BLAs contain specific information about the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and medical effects of the biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the company to market the product. The two subcategories of BLAs are original approval-BLA and supplemental approval-BLA. Country specific: USA
CFR	The Code of Federal Regulations (CFR) is the legal codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the USA Federal Government. CFR is binding. Country specific: USA
Checklist	A checklist contains a comprehensive list (e.g.,, lists of required documents to be submitted with an application, lists of notified bodies, lists of bioequivalence centers, etc.).

CHMP Opinion	This document contains a Committee for Medicinal Products for Human Use (CHMP) adopted opinion on the marketing authorisation of a specific product. Region specific: EU
Circular	A circular provides non-statutory advice and guidance that expands on subjects referred to in law and regulations. Documents in this category (quasi-legislative) are generally not published in the official gazettes by the opposition.
Citizen Petition	A citizen petition is a document submitted to the FDA by an individual or a company (including a non-USA citizen) requesting that the FDA issue, amend, or revoke a regulation or order, or take/not take administrative action. A suitability petition is a type of citizen petition requesting that the FDA approve or disapprove a proposed change to a proposed generic drug. Country specific: USA
Code	A Code is a document that includes a system of principals, including: • Code of Conduct| A set of rules outlining the norms, rules, and responsibilities or proper practices of an individual party or organization. Businesses more commonly use their Code of Conduct as a self-regulatory tool rather than a legal instrument. • Code of Ethics | Written guidelines detailing the individual party or organization's primary values and ethical standards. The Code may be legally binding if a contract was formed.
Committees and Working Groups	This category of publications contains general information on committees and working groups such as charters of specific advisory committees and their official purposes, objectives, and scopes of activities as well as descriptions of their duties, estimated number and frequency of meetings, and other information.
Communication	This document contains news and information published by agencies that are not in press releases, including (but not limited to): • An agency's work • Legal regulations (i.e., to clarify/interpret further important legislation) • Requirements in the pharmaceutical and medical device sectors • International framework conditions • Official announcements about new authorizations of medicines, authorization withdrawals, amendments, etc.
Compliance Letter	A compliance letter is a notice of noncompliance that is given to manufacturers. Examples of compliance letters include: Close-out, Response, Notice of Opportunity for Hearing (NOOH), Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE), Notice of Intent to Revoke (NOIR), Restriction, and untitled, warning, and other similar letters.
Compliance Program Manual	This document refers to a compendium of Compliance Policy Guides (CPGs) that explain the FDA's policies regarding legal and regulatory issues. They include the strategy and policies to be applied when determining industry compliance by the FDA's field inspection, compliance, and industry staffs. Country specific: USA
Conflict of Interest	This document is a statement from an Advisory Committee member declaring no conflicts of interest.
Consultation	A consultation is a report published by an agency that solicits public comments on defined activities such as business processes and changes to regulatory requirements or practices that would allow the public to comment on a proposal. The comment's content formats vary to

	include proposals of changes or citations of sections for comments but are generally not drafted documents.
Curriculum Vitae	A curriculum vitae (CV) is a short account of a committee member's relevant education, training, career, and qualifications. EMA committee members include declarations of interest in their CVs.
Decision	This document contains binding decisions for those to whom they are addressed (e.g., an EU country or an individual company) and are directly applicable. Different types of decisions include [but are not limited to] Ministerial, Presidential, and Committee.
Decree	A decree is a legislative instrument issued to implement a law. A decree is a common form of regulation.
Directive	A directive is a legislative act that sets goals for all EU countries to achieve. It is the responsibility of the individual countries to devise their own laws on how to reach these goals. In some countries, directives can be guidelines or a form of regulation.
EPAR	A European Public Assessment Report (EPAR) is a document that provides public information on a medicine, including how it was assessed by the EMA. Article 13 (3) of Regulation (EC) No. 726/2004 requires the EMA to publish an EPAR for each centrally authorised medicine together with a public-friendly overview. EPARs include the product information published on the EMA's website. Region specific: EU
Evaluation Report	This document provides public information about a medicine, including how it was assessed by the country's medicines regulatory agency.
Evaluation Summary	This document provides a summary of public information on a medicine, including how it was assessed by the country's medicines regulatory agency.
Fact Sheet	A fact sheet presents data in a format that concisely emphasizes key points. Infographics, tables, and flow charts are included in fact sheets.
Federal Register Announcement	A Federal Register Announcement is a publication of the federal government that establishes new regulations or changes existing ones. Published by the Office of the Federal Register (OFR) of the National Archives and Records Administration (NARA) and the USA Government Publishing Office (GPO), the Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations as well as for executive orders and other presidential documents. Country specific: USA
Form	A form is a standard template to be filled in by an applicant for submission. Letters as templates are included in forms.
Guideline	A guideline is an administrative instrument meant to aid industry in complying with policies, governing statutes, and regulations. Although guidelines are not legally binding, by definition, they may have certain hard law characteristics as, for instance, if they impose obligations. The following publications are included in guidelines: • Guides, guidance, notices to applicants, and some directives, when applicable • Handbooks (topically organized books of reference on certain fields of knowledge) • Technical report series that include all guidelines adopted by the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations
Information Note	This category refers to the compilation of information taken from the official releasing authority's website that usually includes a description of regulatory procedures and provides valuable information not available elsewhere (e.g., regulations, guidelines, announcements, etc.).

Inspection Report	In the USA, an inspection report discloses the results of an investigation by the FDA. • Establishment Inspection Reports (EIR) | Detailed records of conducted inspections written by FDA inspectors. • FDA Form 483 | This is A summary of any violations of the Federal Food, Drug, & Cosmetic Act (FD&C) and related Acts found during an inspection that the company can address to bring themselves back into compliance. If no deficiencies are observed, no Form 483 is issued. • Correspondence | The company's response to the FDA Form 483. In the EU, an inspection report documents good manufacturing practices (GMP) noncompliance findings concerning manufacturers.
Instructions	Instructions are a series of detailed steps that define the way a procedure, application, etc. must be done. User manuals and all documents that fit this definition are included.
Judgment	This document discloses a decision of a legal court or judge (including judicial decisions, case law, and judgements).
Law	A law is a rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority. Primary legislation is the general term used to describe the main laws passed by legislative bodies. Acts, statutes, codes (a collection or compendium of laws such as the Code of Federal Regulation [CFR] in the USA and Code de la Santé Publique [CSP] in France), bills, and constitutions are all examples of laws.
Letter	A letter is a formal administrative document used by a regulatory authority to communicate with industry for a variety of purposes, mainly to complement or clarify certain aspects of authority decisions, rules, regulations, and guidelines. Letters include circular letters, letters to industry, and some communications to industry. Although letters are not legally binding, by definition, in some countries, letters are considered legal acts of authorized state bodies (Russia, Ukraine, etc.).
Meeting	This document refers to information about meetings (agenda, questions, work program, etc.) and records of meeting decisions or proceedings.
NDA	A New Drug Application (NDA) is the vehicle through which, pharmaceutical sponsors formally propose that the FDA approve a new drug for sale and marketing in the USA. When the sponsor of a new drug believes that enough evidence of the drug's safety and effectiveness has been obtained to meet the FDA's requirements for marketing approval, the sponsor submits an NDA to the FDA. The application must contain data from specific technical viewpoints for review, including chemical, pharmacological, medical, biopharmaceutical, and statistical. If the NDA is approved, the product may be marketed in the USA. For internal tracking purposes, all NDAs are assigned an NDA number. There are two subcategories of NDAs: original approval-NDA and supplemental approval-NDA. Country specific: USA
Newsletter	A newsletter is a regularly distributed publication that generally focuses on a single main topic of interest to its subscribers. Pharmacovigilance newsletters are called pharmacovigilance bulletins.
Notice of Compliance with Conditions	A Notice of Compliance with Conditions (NOC/c) is an authorization to market a drug (i.e., a Notice of Compliance [NOC]) with the condition that the sponsor undertake additional studies to verify its clinical benefit. The NOC, qualifying under the NOC/c policy, is issued under section C.08.004 of the Food and Drug Regulations.

	The NOC/c document exclusively records and incorporates the following files released by Health Canada into one comprehensive document: Notice of Compliance with Conditions-Qualifying Notice, Product Specific Fact Sheet, and Dear Health Care Professional letter. Country specific: Canada
Notification	This administrative document reflects the formal process of new subordinate legislation or procedures in public notices from departments and agencies.
Opinion	An opinion is an instrument that allows institutions to make statements in a non-binding fashion, in other words, without imposing any legal obligation on those to whom it is addressed. An opinion can be issued by the main EU institutions (Commission, Council, Parliament, etc.), the Committee of the Regions, and the European Economic and Social Committee. While laws are being considered, committees give their opinions drawn from their specific regional or economic and social viewpoint. Publications such as statements, conclusions, and proposals, are included in opinions, when applicable.
Order	An order is a common form of regulation. An order refers to a type of statutory instrument enacted via administrative power to implement a law.
Ordinance	An ordinance is a common form of regulation set forth by a governmental authority (specifically a municipal regulation).
Other Type	This term is used to describe documents that have no defined type.
PMA	A Premarket Approval (PMA) is any premarket approval application for a class III medical device, including all information submitted with, or incorporated by, a reference. PMAs include new drug applications for devices under section 520(l) of the Federal Food, Drug, & Cosmetic Act (FD&C). Original approval-PMA and supplemental approval-PMA are two subcategories of PMAs. Country specific: USA
Policy	A Policy is a document designed to regulate all major decisions, actions, and principles of an authority or organization.
Post-Authorizations Activity Table	A Post-Authorizations Activity Table (PAAT) is a document that includes brief summaries of activities, such as submissions for new uses of a product, and whether Health Canada's decision was negative, positive, or under NOC/c. PAATs are regularly updated with post-authorization activity throughout the product's life cycle. Country specific: Canada
Presentation	A presentation relates to meetings, conferences, and workshops that regulatory agency professionals participate in throughout the year. Presentations primarily appeal to the pharmaceutical industry and health care professionals, and topics vary.
Press Release	Press releases, news releases, media releases, and press statements are written communications directed at members of the news media for the purpose of announcing something ostensibly newsworthy.
Product Approval	A product approval package contains a distillation of the information provided to agencies during the new drug-, biologic-, or device-approval process.
Product Information	This document provides officially approved information about a medicine for health care professionals and patients. The product information includes the summary of product characteristics, package leaflet, and labelling.
Product Miscellaneous	The product miscellaneous category is comprised of diverse product-related documents (other than approvals and product information) that include [but are not limited to] certain paediatric and orphan designation decisions and specific paediatric studies.

Product Safety	A product safety document refers to safety, pharmacovigilance, and product-related information (other than periodic safety publications, pharmacovigilance bulletins, or punctual safety alerts).
Public Comment	A public comment document provides an overview of comments received from the public or industry related to a public consultation/drafted document.
Questions & Answers	This document provides answers to frequently asked questions from stakeholders.
Recommendation	A recommendation is issued by an institution to make its views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.
Referral	This document covers information on specific procedure-related referrals to the authorization of medicines at the EU level. Referrals are used to resolve disagreements between EU Member States on issues related to the authorization of medicines or to give an opinion on an issue of European-wide interest (such as safety). Region specific: EU
Regulation	This is a subordinate legislation created by persons or bodies (for example, Ministers, courts and tribunals, and public officials) using powers given to them by primary legislation (compare to Law). Subordinate legislation is used to further detail primary legislation, provide the flexibility necessary for updating laws when necessary, and respond to urgent situations. Examples of subordinate legislation referred to as “regulation” in the CRI Document Types list include (but are not limited to): executive regulations, notices, statutory instruments, norms, schemes, rules, directions, declarations, deliberations, dispositions, proclamations, determinations, specifications, and provisions. Irrespective of other jurisdictions, in the EU, a regulation is a binding legislative act. It must be applied in its entirety across the EU.
Regulatory Decision Summary	A regulatory decision summary (RDS) of a drug is a brief document that explains Health Canada's positive or negative decision for a larger scope of drugs seeking market authorization. It includes the purpose of the submission and the reason for the decision. The coverage concerns new drug submissions (prescription pharmaceuticals and biologics) and supplements to new drug submissions for new uses of prescription pharmaceuticals and biologics. An RDS for a device is a brief document that explains Health Canada's decision for certain health products seeking market authorization. It includes the purpose of the submission and the reason for the decision. The coverage concerns new class IV license applications for medical devices. Country specific: Canada
Report	A report is an official or formal statement of facts or proceedings written for a specific purpose or activity (e.g., annual activity report).
Resolution	A resolution is a European council publication used to express political positions on topics related to the EU's areas of activity - they are not foreseen in treaties and are, therefore, not legally binding. A resolution is a common form of subordinate legislation in Latin America, the Middle East, and North Africa.
Rules of Procedure	This document covers the [internal] regulations of a legislative body when conducting its business. They are the rules of order. This term, as applied to a law, ordinance, or rule of law, denotes its general purpose or tendency considered to be directed at the policy.
Pharmacovigilance Bulletin	This bulletin is a periodic safety newsletter that provides general safety insights.

Safety Alert	A safety alert is a document that provides product safety information (e.g., a Dear Doctor letter).
Speech	A speech is predominantly used in the USA by FDA commissioners or other FDA officials to communicate interventions.
Standard Operating Procedures	This publication documents the way an organization performs certain work activities and its compliance with current standards or legislation. It is developed by everyone involved in performing those activities.
Summary Basis of Decision	A summary basis of decision (SBD) outlines the scientific and benefit-/risk-based considerations that factor into Health Canada's decision to grant market authorization for a drug or medical device. The document summarizes Health Canada's risk/benefit analyses and includes regulatory, safety, efficacy, and quality considerations identified within Health Canada's regulatory review reports. Country specific: Canada
Testimony	A public hearing including testimony is a new procedure that enables agencies (such as the EMA) to engage with citizens regarding their views and experiences using a medication. Testimony is a non-binding instrument.
Untitled Letter	An untitled letter is a letter sent by the FDA, at the conclusion of an inspection, to the establishment or the individual inspected. They are issued in cases of serious violations of manufacturing controls or labeling that does not meet the threshold of regulatory significance for a warning letter. Untitled letters are used in circumstances where the agency needs to communicate with the inspected establishment but may not be prepared to enforce actions. Country specific: USA
Warning Letter	A warning letter may be issued by the FDA when the agency determines that a manufacturer has significantly violated FDA regulations. Warning letters are sent in cases of serious violations of regulatory significance. They identify the violation and require the company to correct it. The FDA then checks to ensure that the company’s corrections are adequate. If not, these violations may lead to enforcement actions. Warning letters do not always result from an inspection. They can also be sent directly to an establishment if the FDA observes significant violations (e.g., a website selling fraudulent health products, etc.). Country specific: USA
Withdrawn Application	This document details withdrawals and suspensions of applications.