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REVIEW ON REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRY

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INTRODUCTION

Regulatory Affairs (RA), sometimes known as Government Affairs, is a job in regulated sectors including pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics, and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialized departments of regulatory affairs professionals.[1-3]

The modern pharmaceutical industry is well-organized, methodical, and adheres to worldwide regulatory requirements for the production of chemical and biological pharmaceuticals for human and veterinary use, as well as medical equipment, traditional herbal items, and cosmetics. Blood and its derivatives are subject to strict GMPs, as is regulated production for Traditional Herbal Medicines, Cosmetics, Food, and Dietary Products, which was not the case a century ago. This has led to the methodical production and marketing of safe, effective, and high-quality medications. With the rise of industry, the regulation from each region has gotten increasingly complicated, creating a demand for regulatory specialists. To understand the chronological development of the modern era of pharmaceutical industry and regulatory framework, we will glance through the historical evolution of regulations in USA, Europe and India.[4-6]

• The role of the regulatory professional

Regulatory professionals are responsible for.

1. Keeping track of the ever-changing legislation in all the regions in which a company wishes to distribute its products
2. Advising on legal and scientific requirements
3. Collecting and evaluating scientific data
4. Presenting registration documents to regulatory agencies and carrying out any subsequent negotiations necessary to obtain or maintain marketing authorisation for the products concerned
5. Giving strategic and technical advice at the highest level in their companies, making an important contribution both commercially and scientifically to the success of a development programme and the company as a whole
6. Helping the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data.

• IMPORTANCE OF DRUG REGULATORY AFFAIRS

The value of regulatory affairs for drugs A product's ability to reach the market faster is a vital parameter in the current global competitive climate, and the company's success depends on this. In today's competitive world, reducing the time it takes to reach the market is vital to the success of a product and, by extension, a company. As a result, the firm places a high value on the correct execution of its regulatory affairs operations. Inadequate data reporting can preclude a prompt positive evaluation of a marketing application. A new medication may have cost millions of euros, dollars, or pounds to develop, and even a three-month delay in bringing it to market has significant financial implications. Further, a product recall may be necessary as a result of incomplete reporting of every relevant information or the introduction of a product with incorrect labeling.[7-9]

• The role of the regulatory affairs department

The regulatory affairs (RA) department of a pharmaceutical company is responsible for obtaining approval for new pharmaceutical products and ensuring that approval is maintained for as long as the company wants to keep the product on the market.

It is the responsibility of RA to keep abreast of current legislation, guidelines and other regulatory intelligence. Such rules and guidelines often allow some flexibility, and the regulatory authorities expect companies to take responsibility for deciding how they should be interpreted. The RA department plays an important role

in giving advice to the project team on how best to interpret the rules. The RA department reviews all documentation from a regulatory perspective, ensuring that it is clear, consistent and complete. The documentation includes clinical trials applications, as well as regulatory applications for new products and adjustments to existing ones. The RA has a key proactive job of providing input when legislative changes are being debated and proposed.[12]

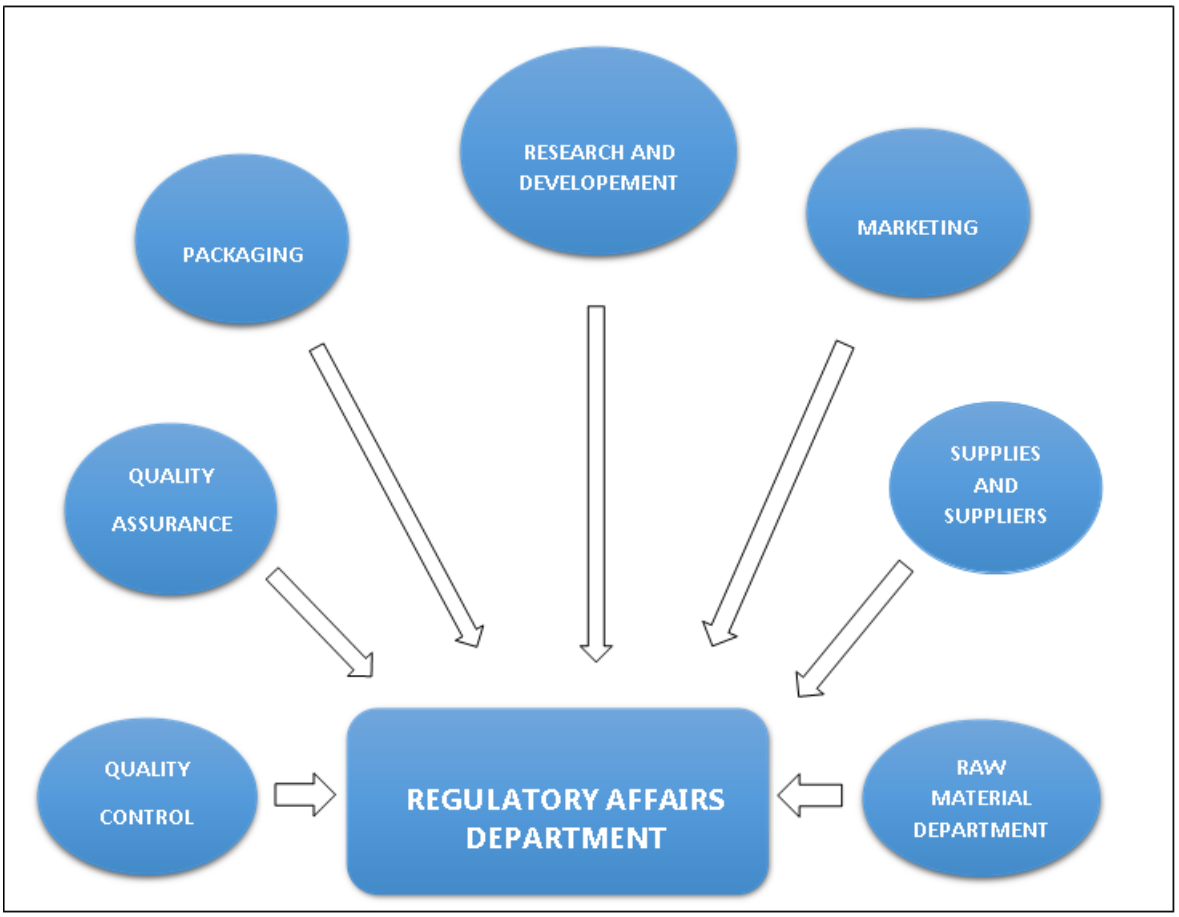

Figure 1 Roles of Regulatory affair department.

• Need of Regulatory Affairs in Pharmacy curriculum

Pharmaceutical biotechnology and medical device research and development are two of the world's most tightly regulated sectors. India will continue to develop. In order to fulfil the present needs of companies to compete on a worldwide basis, regulatory relations specialists are in great demand in the pharmaceutical sector. Regulatory affairs professionals operate as a link between the pharmaceutical sector and international regulatory agencies.

The curricula of pharmacy schools should prepare students to give the most up-to-date knowledge to industry. The purpose of this study is to discuss the significance of regulatory education. India's pharmaceutical sector is growing at a rapid pace, and regulatory affairs professionals are in high demand to help firms compete worldwide. Regulatory affairs professionals operate as a link between the pharmaceutical sector and international regulatory agencies. There is an increasing need to integrate existing pharmaceutical industry standards into pharmacy college standard curriculum to train students for the latest technologies to support the industries.[10]

• Regulatory affairs in R & D

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags. Adaptive clinical trial strategies, quick regulatory approval, and avoiding procedural hazards will all assist to accelerate the introduction of new medications while decreasing costly errors and time delays. [11,19]

•Regulatory affairs in Clinical Trials

Regulatory affairs professionals act as the primary contact between an organization and worldwide

regulatory organization's such as official bodies (US FDA, CDSCO, MCCA, TGA, etc.). Their role is to offer quick evaluations of new data gathered during trials and to help in the approval of new medications as necessary by local regulatory bodies in their respective states. The RA team devises strategies to prevent delays and communicates clinical trial data to regulatory authorities in order to gain quick approval and reduce the time it takes for novel compounds to be authorised. Regulatory authorities, medical and educational services, and the general public. RA's operational tasks include ensuring that all parties are aware of and comply with government requirements, market-driven needs, and developing research conventions.[13,14]

•Regulatory affairs in Product management

Drug goods are tightly regulated in compared to other channels. These rules are usually maintained and managed by regulatory bodies; these bodies generally guide substance formulation based on IND/NDA standards until the approval phase is complete; once the approval process is complete, these bodies focus on the medication post-market properties as well as the Pharmacovigilance characteristics of the drug product. The entire job of Regulatory Affairs goes beyond substance registration; they also give strategic and technology guidance to firms at the highest levels. They play a significant role in everything from product development to promotion and post-marketing efforts. Their guidance at all stages of the development process, both in terms of regulatory and technological requirements, saves time and money for enterprises.[15]

• REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRY

Regulatory affairs are developed by the government to protect the health of the public by ensuring the efficacy and safety of the products including pharmaceutical products, fertilizers, pesticides, medical gadgets, veterinary medicines, agrochemicals and cosmetics. The manufactured product should satisfy the need of public and ensure their health. The finished products are tested and evaluated according to the guidelines or legislation. It is the company's responsibility to discover, manufacture, test and market the products and should contribute for the welfare of people. The regulatory affairs department should know the legislation requirement in all the company's export markets.[16,17]

• Regulatory Agencies of few Countries[18]

Country	Authority	Full Form
USA	USFDA	United States food and drug administration
UK	MHRA	Medicines and health care products regulatory agency
India	CDSCO	Central drug standard control organization
Canada	HEALTH CANADA	Health Canada
Australia	TGA	A Therapeutic goods administration
South Africa	MCC	Medicine control council
Brazil	ANVISA	Agencia Nicional de vigilancia sanitaria
European Union	EMEA	Europe, the middle East and Africa
China	SFDA	Saudi food and drug authority
New Zealand	MEDSAFE	New Zealand medicines and medical devices safety authority
Japan	MHLW	Ministry of health,labour and welfare
Korea	KFDA	Korean medical device regulator
Sri Lanka	MOH	Ministry of health

• The Central Drug Standard Control Organisation (CDSCO)

The Central Drug Control Organisation (CDSCO) carries out responsibilities delegated to the Central Government under the Drugs and Cosmetics Act. Six zonal offices, four sub-zonal offices, thirteen port offices, and seven laboratories are under the management of CDSCO. Federal and state regulators now have particular responsibilities for the regulation of pharmaceuticals and cosmetics thanks to the 1940 Drugs & Cosmetics Act and the 1945 Guidelines. By regulating the use of medications and cosmetics, it intends to consistently apply the Act's and its Rules' requirements to safeguard patients' safety, rights, and well-being. CDSCO is constantly working to improve transparency, accountability, and standardization in its services to guarantee the safety, efficacy, and quality of the medical products produced, imported, and distributed in the country.[20] According to the Drugs and Cosmetics Act, CDSCO is responsible for approving drugs, carrying out clinical trials, establishing drug standards, checking the quality of drugs imported into the country, and coordinating the work of state drug control organizations. CDSCO also provides expert guidance to ensure that the Drugs and Cosmetics Act is applied consistently across the board.[21]

- Vision: To protect and promote India's public health.
- Mission: To ensure the Safety, Effectiveness, and efficiency of medicines, Cosmetics and Medical devices in order to protect and Improve public health.

• CDSCO's Key Responsibilities include

Drug imports, approval of new products and clinical trials, meetings of the Drugs Consultative Committee (DCC) and drug Technical Advisory Board (DTAB), and approval of such licences as the central License Approving Authority are all regulated by the CDSCO headquarters.[22]

• Functions of CDSCO

Sr No.	Functions
1	Approval of new drugs and clinical trials.
2	Amendment of D & C Act and Rules.
3	Import Registration and Licensing.
5	License approving of blood banks, LVPs vaccines, r-DNA products, and some medicinal devices (CLAA scheme).
6	Banning of Drugs and Cosmetics.
7	Testing of new drugs.
8	Oversight and market Surveillance through inspectorate of center over and above the State Authority

• Drug Approval Process in India

The Drug and Cosmetic Act 1940 and Rules 1945 were proclaimed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (DCGI) was established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure. When a company in India wants to manufacture/ import a new drug it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945.[23] In order to prove its efficacy and safety in Indian population it has to conduct clinical trials in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in specified format.[24]

When a business in India wants to develop or import a new medicine, it must fill out Form 44 and transmit the data needed under Schedule Y of the Drugs and Cosmetics Act 1940 and Rules 1945 to the licencing body (DCGI). It must conduct clinical trials in accordance with the standards specified in Schedule Y and use the results of those trials in the manner outlined in Schedule Y to show its efficacy and safety in the Indian community.[25]

Clinical study approval in India typically takes three months. Clinical trials can be filed with the Clinical Studies Registry of India (CTRI), which keeps track of both the trials and the people who take part in them. The Drugs and Cosmetics laws of 1945 provide the following guidelines.

The below are the provisions of the 1945 Drugs and Cosmetics Rules

- Rule 122 – A: Request for New Drug Import Approval.
- Rule 122-B: application for permission to import a new medication that is not on Schedule C or C. (1).
- Permission to import or export fixed dosage combinations (Rule 122-D).
- Rule 122 – DA: Request for approval to perform clinical trials for a new drug or an investigational new drug.
- DAB: Compensation in the event of injuries or death during clinical trials (Rule 122).
- The Drugs and Cosmetics Act has been amended to include definitions for Phase I-IV trials as well as specific obligations for inspectors and sponsors. In 2006, the clinical trials were further split into two groups. Clinical studies can be performed in other markets with qualified and advanced regulatory regimes in one category (category A), while the others fall under another category (category B) Other than A. Clinical trials in category A (approved in the United States, The United Kingdom, Switzerland, Australia, Canada, Germany, South Africa, Japan, and the European Union) are eligible for quick tracking in India, with approval expected within eight weeks.

Class B clinical trials are scrutinized more closely and are approved in 16 to 18 weeks. DCGI should be contacted for an application to perform clinical trials in India, as well as data on chemistry, processing, monitoring, and animal tests. Add The trial protocol date, investigator brochures, and informed consent documents. The ethical committee must have a document, and clinical trials will only begin after DCGI and the ethical committee have given their consent.[22]

- **Stages of Approval**
- The submission of a Clinical Trial proposal for the purpose of determining the safety and effectiveness of a product.

- Conditions for the clearance of new medicines.
- Improvements in biological products after approval: cost, protection, and effectiveness records.
- Preparation of high-quality data for new drug submission approval of a medication. The CTD format has been adopted by the vast majority of nations. As a result, CDSCO has agreed to use the CTD format for technical specifications for prescription product registration for human use.

- **U. S. FDA (United States Food and Drug Administration)**

The U.S. Food and Drug Administration (FDA or USFDA) is a regulatory agency within in the U. S. department of health and human services, one of the united states federal executive departments. Headquarter Silver Spring, Maryland, united states. Established-24 june 1938. The USFDA is responsible for protecting and promoting public health through the regulation supervision of food safety, tobacco products, dietary supplements, prescription and over-thecounter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products and cosmetics.[26]

- **FOOD AND DRUG ADMINISTRATION (FDA)**

The United States Food and Drug Administration (FDA or US FDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and overthe-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED). Cosmetics, animal foods & feed and veterinary products. The FDA's primary focus is enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C). Robert Califf is the current commissioner, as of 17 February 2022.The FDA has its headquarters in unincorporated White Oak, Maryland The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008, the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.[27]

• Drug approval process in USA

In the USA, all the food, drugs, cosmetics and medical devices for both humans and animals are regulated under the authority of the United States Food and Drug Administration (USFDA).Vaccines for individuals, including blood and blood derivatives, cellular and gene therapy products, and allergens in tissues and organs The United States has some of the world's strictest drug approval standards. Drug approval criteria in the United States are stringent. Many individuals consider nations to be the most difficult in the world. The adoption of the United States Drug Act in 1820 marked the start of a new era in drug regulation in the United States. It was decided to construct the United States Pharmacopoeia. Congress approved the first Food and Drug Act in 1906, mandating medications to satisfy official strength and purity requirements. Create products. However, due to the great depression in 1937, the Federal food, Drug, ad Cosmetics Act (of 1938) and Sulfanilamide Tragedy was enacted, which included new requirement for the approval of new drugs (medicines).Demonstrated to be safe before marketing. The FDA's new medication approval procedure includes two stages: United Clinical Trials (CT) and New Drug Application (NDA) approval. A new drug application regulates the new medication product. NDA (Non-disclosure Agreement) (National Defense Authorization Act). Such applications have been accepted for analysis in eCTD at this time. The approval procedure begins once an investigational new drug (IND) application is submitted to the FDA. The Food and Drugs Act (1906) is a major landmark in the history of US drug law. It stipulates that drugs must satisfy certain criteria. Food, Drug, and Cosmetics Acts of 1938: After that, it was enacted. To demonstrate the safety of a medication before it is approved, the sulfanilamide tragedy occurred it has been advertised.

There are several changes to the FDA Modernization Act of 1997 (FDAMA). The Food, Drug, and Cosmetics Act governs the manufacturing and distribution of food, medicines, and cosmetics. User fees are being calculated, and the approval process is being accelerated.[28]

• Investigational New Drug Application (INDA)

There are several kinds and varieties of IND. Individual sponsor-investigators will be classed as Research INDs.[The other type is called Bcommercial IND.] The FDA classifies IND applications as Bcommercial if the sponsor is a business enterprise or one of the National Institutes of Health, or if the medication has the potential for commercialization. The FDA has provided several guidance's for submitting an IND. 80% of the Guidance's target at industry (for business.).[29]

Before humans are inspected, an FDA application is filed. It covers chemistry, production, and quality assurance in significant detail. The following information must be included in the IND application: (1) Animal-based toxicology and pharmacology research. (2) Clinical investigators and protocols. (3) Data on the production process. After filing the IND, the sponsor must wait for 30 days. The Food and Drug Administration (FDA) has the power to verify the IND's safety. Section 312 of the 21 Code of Federal Regulations regulates the content and form of an IND application. If you want to do a clinical review, you must submit a "Investigator New Project" application. Fill out the "Drug Application" form in the order specified below.[30]

- FDA Form 1571
- Tables of contents

- Statement of intent and investigational strategy
- Sponsor's brochure
- Protocols are a set of rules that govern how • Data on chemistry, manufacturing, and control.
- Data on pharmacology and toxicology.
- Previous people/human experience.
- Additional information.

• New Drug Application (NDA)

A New Drug Application is required for marketing a new drug in the United States. An NDA includes information from the IND and clinical study data for showing safety and effectiveness. The FDA reviews NDAs within 60 days after filing.[31] The application has been divided into two sections: archival copy and review.

Archival copies of calculations and clinical trial case report forms act as a reference for FDA investigators seeking more information outside the review copy.

Review Copy: Each technical component is bound individually in each folder as a review copy. The technical sections should include the following: 2.1) Index. 2.2) FDA Form 356 H (copy). 2.3) A copy of the cover letter. 2.4) Authorization Letters 2. 5) A copy of the application statement is required.

The FDA will meet with the sponsor at least twice: after phase 2 clinical trials and before filing an NDA (pre-NDA). The analysis committee will look at this. Review the study results and determine whether to accept the plan or application.[32]

• Abbreviated New Drug Application (ANDA)

Products that share or closely resemble the active ingredients, dosage form, potency, mode of administration, usage, and labeling of a previously proven safe and effective medication are subject to ANDA. It is employed when a business want to market an exact copy of a product whose patent has expired. These medications, known as generics, has to conform to the bioequivalence and pharmaceutical standards. The Office of Drug Evaluation and Research within the Center for Drug Evaluation and Research receives an ANDA. The Generic Drugs category has been inspected and approved.[33,34]

• Supplemental New Drug Application (SNDA)

After granting the NDA or ANDA, any significant changes to the conditions must be recognized with a new NDA or ANDA. A subsequent NDA or ANDA with changes, such as packaging or ingredients, requires CDER approval. This category includes new-uses approvals for previously approved pharmaceuticals, which are more efficient than new-uses applications for previously approved treatments as they need less resources to review. For the first time, permission is necessary.[35]

• Common technical documents (CTD)

The common technical documents (CTD) are a set of application standards for the registration of medicines and designs that may be used in Europe, the United States (US), and Japan. It is a worldwide accepted approach for developing an application for a novel drug that will be presented to local regulatory agencies in the participating countries. CTD is a collaboration of three regulatory agencies: the European Medicines Agency (EMA), the Food and Drug Administration (FDA), and the Ministry of Health and Welfare in the United States (MHLW, Japan).

The International Council on Harmonization (ICH) updated the CTD with technical standards for pharmacological approval for human use. CTD is a worldwide accepted standard for arranging technical requirements to submit to regulatory agencies.[36]

• Objectives of CTD

- The main objective is to reduce the time required and resources utilized to assemble apps.
- It will facilitate the process of getting ready to submit electronically.
- To facilitate simultaneous submission in three regions.
- It will facilitate the sharing of regulatory data, ensuring quicker availability of new medicine.[37]

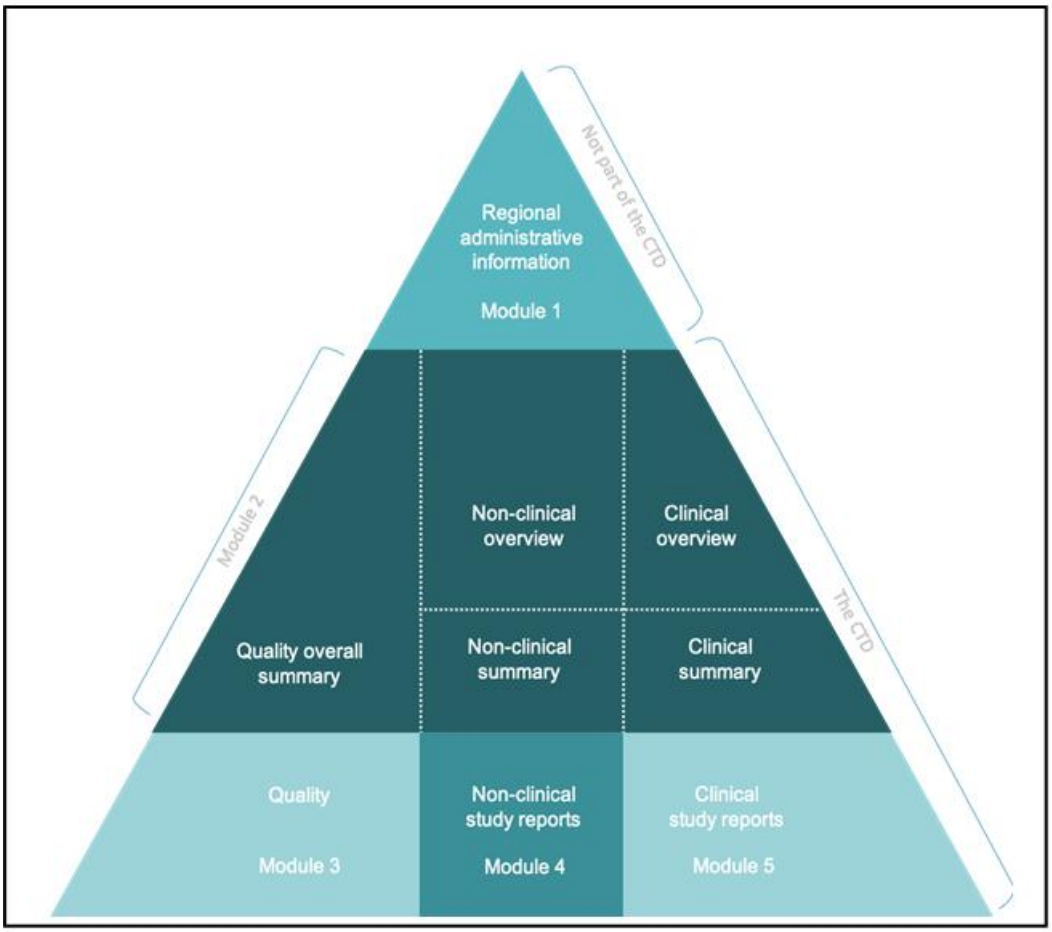

Figure: The CTD triangle. The Common Technical Document is organized into five modules. Module e 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

• Modules of CTD It can be organized into 5 Modules

- Module 1: administrative and prescribing information
- Module 2: common technical documents CTD summaries
- Module 3: Quality data
- Module 4: Nonclinical study reports
- Module 5: Clinical study reports

Format should be accessible and comprehensible, with a font size of 12 and Times New Roman typeface. Page layout should be A4 for EU and Japan, and 8.5 x 11 for the USA. When binding, ensure that the left hand margin is sufficient and that the information is not obscured or ambiguous.

1. The common technical document are details and surely acceptable by the regulatory authority.
2. The document can be easily review by the reviewer.
3. The submitted document should be dated and signed.
4. The document should be properly labelled as per the regulatory guidelines of the country.
5. Documents that can be required should be submitted as per the checklist to avoid rejection of the application or queries which in turn speed up the review process and approval.
6. The justification for certain tests should be properly mentioned and supportive documents should be attached.
7. Once dossier is prepared before sending it has to checked and verified for any mistakes.
8. In the report of the clinical study as per module 5 CRF, all the study reports should be attached with the documents.
9. If there are changes in any batch that should be mentioned and justify.

- **Advantages of CTD**
- Implementing a uniform submission format simplifies application review and prevents the need for additional key data or analytical tasks. Without this information might create unnecessary delays in approvals.
- Using a standard style for technical documentation helps save time and resources when preparing applications for human pharmaceutical registration. It also simplifies electronic submission preparation.[38]
- The implementation of CTD is expected to significantly reduce the amount of time and resources required by the industry to compile global registration applications.[39]

• Electronic common technical document (eCTD)

The eCTD is an electronic version of the CTD. From a regulatory point of view "The eCTD is defined as a interface for industry to agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission". The standard and modules have been agreed upon by major global bodies. Once a contribution is sent in eCTD format, future submissions for the application should also be in this format.

Technically, an eCTD is a set of common folders with PDFs and SAS files on a CD/DVD, which may also be uploaded using agency online portals. The eCTD backbone is an XML file that contains the submission's structure, linkages to files, and metadata such as check sums.

The eCTD submission is for the application, supplements, reports, master formulae, etc. the eCTD format is understandable and successfully applying in the submission is the biggest barrier. The application and promoter may be facing the problem when the document does not as per the required format because of the application should be rejected.[40]

• Benefits of eCTD

The eCTD should be simple to disseminate and review, resulting in better resource use, lower costs, and less stress for organizations. The eCTD should have a well-organized electronic table of contents that is searchable and self-validating. The FDA began using eCTD on January 1, 2008, and it later became the norm for electronic submissions at CDER. Beginning in 2007-08, the FDA mandated that all electronic submissions be in eCTD format. However, printed copies are still accepted. The number of ANDA filings to the FDA grew from 72 in 2006 to 1550 in 2009. To manage extensive submission data, including information on the sending and receiving organizations, manufacturers, IDs, and documents.[41]

• Common format for eCTD

- Narrative: Portable Document Format (PDF) [Calibri 12].
- Structure: Extensible Markup Language (XML).
- Graphic: Use PDF, whenever PDF is not supporting, use Joint Photographic Experts Group (JPEG), Portable network Graphics (PNG), Scalable Vector Graphics (SVG) and Graphic interchange Format (GIF).
- Font size 9 and 10 are suggested for tables.

- **The regulatory content information region.**

Region	Internet address	Electronic mail contact
European Union	http://www.emea.europa.eu	esubmission@emea.europa.eu
Food and drug administration USA	www.fda.gov/cder www.fda.gov/cber	esubprep@fda.hhs.gov esub@fda.hhs.gov
Ministry of Health, Labour and Welfare, Japan	http://weww.mhlw.go.jp http://www.pmda.go.jp	ectd@pmda.go.jp
Health Canada	http://www.hc-sc.gc.ca	ereview@hc-sc.gc.ca

• CONCLUSION

The pharmaceutical industry is one of the most heavily regulated industries on the planet. Regulatory Governing Bodies (Authorities) have been formed all around the globe to ensure that medicines for human use satisfy global standards of Quality, effectiveness, and safety. For example, FDA, TGA, CDSCO, EMEA, and others. The role of regulatory affairs is to design and implement regulatory strategies to ensure that the drug development team's combined efforts result in a product that is approved by regulatory bodies. Drug regulatory affairs is a dynamic subject that encompasses both scientific and legal elements of drug research, such as NDA, INDA, and ANDA. By following SOPs, ICH standards, and WHO – GMP guidelines, regulatory affairs experts assist the firm in avoiding problems like as poorly kept records, poor data presentation, and incorrect scientific thinking. Regulatory affairs plays a key role in all elements of drug regulations since the successful adoption of any new pharmaceutical product, new molecular entity, takes around 10 to 15 years and involves a significant amount of time and money.

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