



OVERVIEW OF DRUG REGULATORY AFFAIRS: ROLE, FUNCTION, REGULATORY AUTHORITIES

S. Aravindhraj*

Kasthooribha Gandhi Pharmacy College, Namakkal.

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Corresponding Author: S. Aravindhraj

Address: Kasthooribha Gandhi Pharmacy College, Namakkal.

Email Id: aravindivi0305@gamil.com

ABSTRACT

Drug Regulatory Affairs (DRA) plays a crucial role in ensuring the safety, efficacy, and quality of pharmaceutical products. It involves navigating complex regulatory requirements set by health authorities such as the FDA, EMA, and WHO to achieve market authorization for drugs. The regulatory landscape is dynamic, with evolving guidelines and standards that govern the clinical trials, manufacturing, marketing, and post-marketing surveillance of drugs. This field is essential in safeguarding public health by ensuring that drugs meet stringent safety and efficacy standards before reaching consumers. DRA professionals bridge the gap between pharmaceutical companies and regulatory bodies, ensuring compliance with national and international regulations while promoting innovation in drug development. As globalization continues to shape the pharmaceutical industry, the importance of harmonizing regulatory standards across regions has become more pronounced, aiming for faster drug approvals and better access to treatments worldwide. The regulatory affairs is an government bodies which is act an regulatory authorities. They work under the government agencies. Drug Regulatory Affairs (DRA) can work an organization of ICH, CDSCO, GLP, GCP, CGMP. Their major work is to control safety, efficacy, quality of the drug and also to control the side effects, errors of the drug. The regulatory authorities is responsible for the approval of new drug. Regulatory affairs professionals is also known as regulatory compliance professionals. In this article we focus regulatory affairs role and regulatory authority. They can provide the drug manufacturing ethics to the production department in pharmaceutical industry. It is a position mostly found within regulated industries, such as pharmaceuticals,

medical devices, cosmetics, agrochemicals (plant protection products and fertilizers), energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods). They have an crucial function in industries like pharmaceuticals, biotechnology, and medical devices.

KEYWORDS: To know about Regulatory affairs role, Functions, pre - approval and post - approval, regulatory authorities.

INTRODUCTION

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.(1)

The regulatory authorities is responsible for the approval of new drug application and maintain the documents of new drug for as long periods, and also to maintaining the drug safety, efficacy, and quality.

Regulatory affairs (RA), is a profession that deals with an organization's adherence to regulatory compliance. It is a position mostly found within regulated industries, such as pharmaceuticals, medical devices, cosmetics, agrochemicals (plant protection products and fertilizers), energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods). Regulatory affairs professionals, also known as regulatory compliance professionals.(2)

Functions of Regulatory Affairs: (3)

Regulatory affairs is a crucial function in industries like pharmaceuticals, biotechnology, and medical devices, focusing on ensuring that products meet the necessary legal and regulatory requirements for approval and marketing. Key functions of regulatory affairs include:



- **Compliance with Regulations:** Ensuring that products comply with all relevant local and international regulations, including FDA (U.S.), EMA (Europe), and other regulatory bodies.
- **Product Registration:** Preparing and submitting regulatory documentation for product approval and market access.
- **Labeling and Packaging:** Ensuring that product labels meet regulatory requirements and reflect accurate information.
- **Market Surveillance:** Monitoring products post-launch to ensure ongoing compliance and handling any safety or quality concerns.
- **Regulatory Strategy:** Developing strategies to gain market approval in various regions and advising companies on regulatory requirements for new products.

List of functions (4)

1. Regulatory Strategy Development

- Develop strategies to navigate regulatory pathways efficiently for drug approval.
- Anticipate and address potential regulatory challenges during product development.

2. Preparation and Submission of Dossiers

- Prepare comprehensive dossiers such as the Common Technical Document (CTD) or electronic CTD (eCTD) for submission to regulatory agencies.
- Manage submissions for Investigational New Drug (IND) applications, New Drug Applications (NDA), and Marketing Authorization Applications (MAA).

3. Regulatory Compliance and Maintenance

- Ensure continuous compliance with changing regulations throughout the product lifecycle.
- Handle post-approval variations, renewals, and updates to dossiers.

4. Support for Clinical Trials

- Prepare Clinical Trial Applications (CTAs) and ensure compliance with Good Clinical Practice (GCP).
- Liaise with regulatory authorities to gain approvals for trials and manage amendments.

5. Labeling and Advertising Compliance

- Review product labeling, packaging, and promotional materials for compliance with regional regulations.
- Ensure all claims made in advertising are accurate and supported by evidence.

6. Coordination with Regulatory Authorities

- Act as a primary contact point between the organization and regulatory bodies like the FDA (U.S.), EMA (Europe), and CDSCO (India).
- Respond to queries and deficiency letters and negotiate expedited approval processes when applicable.

7. Pharmacovigilance and Risk Management

- Monitor and report adverse drug reactions (ADRs).
- Develop and maintain Risk Management Plans (RMPs) to ensure drug safety post-market.

8. Harmonization of Global Regulatory Requirements

- Align submissions with international guidelines (e.g., ICH, WHO).
- Customize dossiers to meet region-specific requirements.

9. Product Lifecycle Management

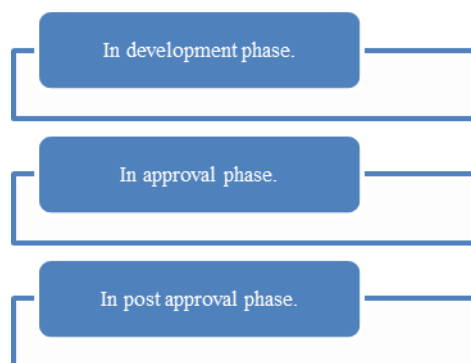
- Oversee regulatory aspects of product development, launch, and eventual withdrawal from the market.
- Handle applications for line extensions and manage patent expirations.

10. Training and Documentation

- Train internal teams on regulatory updates.
- Maintain records of submissions and regulatory correspondence for audits.

Role of Regulatory Affairs in Pharmaceutical Industry: (5)

The drug Regulatory affairs department role is to work and organization and to approve the new drug, to regulate the drug safety, efficacy, and quality. Drug Regulatory Affairs (DRA) can work an organization of ICH, CDSCO, GLP, GCP, CGMP. They work under the government agencies. Their major role is regulate the safety, efficacy, quality of pharmaceutical drug in the pharmaceutical industry. The various role in pharmaceutical Regulatory affairs are mentioned below



In Development Phase. (6)

Drug Regulatory Affairs (DRA) plays a pivotal role in the development phase of pharmaceuticals, ensuring compliance with legal, scientific, and quality standards while facilitating efficient market approval processes.

Overall view of drug regulatory affairs roll in development phase

Regulatory Strategy Development:

- DRA professionals design a regulatory strategy tailored to the product type, target market, and development timeline. This includes identifying applicable regulations, standards, and guidelines for drug development in target regions (e.g., FDA in the USA, EMA in the EU, CDSCO in India).
- They plan preclinical and clinical studies to meet regulatory expectations, reducing the risk of rejection during submission.

Preclinical and Clinical Development Oversight:

- During preclinical studies, DRA ensures adherence to Good Laboratory Practices (GLP) for toxicology and pharmacology studies.
- For clinical trials, DRA helps secure approvals from regulatory agencies (e.g., Investigational New Drug [IND] applications) and ethical committees. They ensure compliance with Good Clinical Practice (GCP) guidelines and monitor trial design to align with regulatory requirements.

Documentation and Submission Management:

- Preparation and submission of high-quality regulatory dossiers (e.g., IND, Clinical Trial Applications [CTA], or Common Technical Document [CTD]).
- DRA ensures the documentation includes all critical sections, such as Quality (CMC), Non-Clinical, and Clinical Modules.

Regulatory Liaison

- Acts as the primary contact point between the pharmaceutical company and regulatory authorities.
- Engages in meetings, consultations, and negotiations with agencies to address questions or resolve issues related to submissions.
- Compliance with Standards:
- Ensures the drug development process adheres to international guidelines like ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and WHO standards.
- Monitors evolving regulatory requirements and ensures that ongoing development activities remain compliant.

Risk Management

- Identifies regulatory risks early in the development phase and proposes mitigation strategies to ensure smooth progression through regulatory checkpoints.

Post-Approval Planning

- Prepares for post-marketing regulatory obligations, including pharmacovigilance requirements and lifecycle management of the drug.

In Approval Phase

Drug Regulatory Affairs (DRA) professionals play a pivotal role during the approval phase of pharmaceutical products. Their primary responsibility is to ensure that a drug complies with the regulatory requirements of the target market and meets safety, efficacy, and quality standards. Below is a detailed breakdown of their role in this phase

Responsibility of drug regulatory affairs (7)**1. Compilation and Submission of Regulatory Dossiers**

- DRA teams prepare comprehensive regulatory dossiers like the Common Technical Document (CTD) or eCTD, depending on the market (e.g., the FDA, EMA, or local health authorities).
- These dossiers include modules covering:
 - Module 1: Administrative and product information.
 - Module 2: Summaries of quality, safety, and efficacy.
 - Module 3: Quality (pharmaceutical documentation).

- Module 4: Non-clinical study reports.
 - Module 5: Clinical study reports.
 - Accurate and timely submission of these documents ensures smooth communication with regulatory agencies.
2. Liaison with Regulatory Authorities
- DRA professionals act as a bridge between the company and regulatory agencies.
 - They handle inquiries, respond to deficiencies, and address agency feedback during the review process.
 - Effective communication ensures transparency and facilitates faster approvals.
3. Compliance with Guidelines
- Regulatory teams ensure the product aligns with current guidelines such as the International Council for Harmonisation (ICH), FDA regulations, or EMA standards.
 - They monitor changes in regulations and update submission strategies accordingly.
4. Risk Assessment and Mitigation
- Identify potential regulatory hurdles and propose strategies to mitigate risks.
 - Address concerns related to manufacturing, labeling, clinical trial data, and product specifications proactively.
5. Labeling and Packaging Approval
- Review and ensure the drug's label meets legal and scientific standards.
 - DRA ensures labeling includes all required safety and usage information to avoid regulatory rejection.
6. Post-Approval Commitments
- Regulatory professionals outline post-approval commitments such as pharmacovigilance plans or additional clinical studies requested by agencies.
7. Timely Market Access
- By streamlining submission processes and addressing deficiencies promptly, the DRA team ensures faster approval timelines.
 - This enables quicker patient access to the drug and supports the company's commercial objectives.

Approval of Investigational New Drug Application

The investigational New Drug Application is type of applications which consist the drug has goes to non clinical trials. Application can be used for pre- Clinical studies. The pre – clinical

trial team can send the IND to the regulatory bodies. The regulatory bodies can inspect the drug properties like molecules, dose regimen, GMP, GLP, etc,

After approval of Investigational new drug application, the team will go ahead for procedure of non clinical trials. In before starting procedure for non clinical trials, they should get permission from animals ethic committee.

Approval of New Drug Application

The new drug application is apply for marketing the drug after successful clinical trials. Application should forward to Regulatory bodies and the give approval for marketing. Before approval, the regulatory bodies can inspect the drug safety, efficacy, quality. Once the inspection is clear, the will be marketing for public use.

Drug Regulatory Inspector [DRA Inspector]

The drug regulatory affairs agencies can send one person as an inspector to the applied industry. The inspector should have knowledge about the general inspection and some test about drug.

The inspector should provide a detailed inspection report to the regulatory bodies. The report should be in document. The document should contain.

Inspector details.

- Name
- Age
- Experience
- Regulatory agencies name
- Contact details.

Drug details.

- Drug name
- Dose regimen
- Batch number
- Industry name
- Trade name
- Mfg and exp date
- Drug composition

- Drug formulation procedure
- Clinical and non clinical trials report
- Other reports.

Post Approval Phase (8)

a) Regulatory Compliance and Lifecycle Management

- Ensure continued compliance with evolving regulations.
- Manage variations (minor and major changes) to approved products.

b) Post-Marketing Surveillance (PMS) and Pharmacovigilance

- Oversee pharmacovigilance activities and adverse event reporting.
- Submit Periodic Safety Update Reports (PSURs) or Periodic Benefit-Risk Evaluation Reports (PBRERs).

c) Renewals and Re-Registrations

- Handle periodic re-registration and renewal of marketing authorizations.
- Submit updated information (stability data, clinical updates).

d) Labeling Updates

- Ensure labeling, packaging, and prescribing information are updated with new safety, efficacy, or quality data.

e) Change Management

- Manage regulatory submissions for changes in manufacturing, raw materials, or packaging.

f) Market-Specific Regulatory Support

- Address post-approval requirements unique to specific markets or regions.

g) Recall and Withdrawal Management

- Coordinate product recalls or withdrawals with regulatory agencies.

h) Regulatory Intelligence

- Monitor new regulatory trends, guidances, and policies.
- Provide strategic input for long-term product planning.

i) Support for New Indications or Line Extensions

- Prepare submissions for new indications, dosage forms, or combination therapies.

j) Collaboration with Internal Teams

- Work closely with internal teams (manufacturing, marketing, R&D) to address regulatory needs.

Pre - Approval and Post - Approval Regulatory Affairs: (9) (10)**Pre - Approval**

- Pre-Approval Regulatory Affairs involves activities that occur before a drug, device, or product receives marketing authorization. It includes:
- Clinical Trial Applications (CTA): Preparation and submission of protocols to regulatory agencies.
- IND/NDA/BLA Submissions (FDA): Investigational New Drug (IND), New Drug Application (NDA), or Biologics License Application (BLA) preparation.
- Regulatory Strategy Development: Aligning research and development goals with agency requirements.
- Scientific Advice Meetings: Interactions with agencies like FDA, EMA, etc., for guidance during development.
- Regulatory Intelligence: Monitoring changes in regulations and guidelines and assessing their impact on product development.

Post – Approval

- Post-Approval Regulatory Affairs refers to activities that ensure ongoing compliance and support product lifecycle management after marketing authorization:
- Labeling Updates: Ensuring product information stays current with safety and efficacy data.
- Variation Filings: Submitting changes like manufacturing process updates, site changes, or formulation adjustments.
- Pharmacovigilance: Monitoring adverse events and reporting to authorities.
- Periodic Safety Updates (PSURs/PBRERs): Submission of safety and risk-benefit reports to agencies.
- Market Expansion: Securing approvals in additional regions or countries.
- Regulatory Compliance: Ensuring ongoing adherence to regulatory requirements, including GMP, GCP, and GLP.
- Lifecycle Management: Managing changes to approved products, such as formulation changes or new indications, through appropriate regulatory submissions.

Regulatory Agencies (5)

- Central Drug Standards and Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures

for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country.

- Drugs Controller General of India (DCGI), With respect to licensing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests. It along with CDSCO.
- Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the Control and supervision of food safety, tobacco products, dietary supplements, prescription and over the counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) – Promotes global standards for drug regulation.
- Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products
- Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK.
- World Health Organization (WHO) – Oversees international public health.
- European Medicines Agency (EMA) – Regulates medicines and healthcare products.
- Health Canada: Regulates drugs, medical devices, and health products in Canada.
- Ministry of Health of the Russian Federation and Federal Service for Surveillance in Healthcare. Regulates medicines and healthcare products.
- South African Health Products Regulatory Authority (SAHPRA): Regulates medicines, medical devices, and clinical trials.
- Health Sciences Authority (HSA): Ensures the safety and efficacy of health products, including medicines and medical devices.
- Federal Commission for Protection against Sanitary Risks (COFEPRIS): Regulates medicines, health products, and food safety

- Saudi Food and Drug Authority (SFDA): Regulates drugs, medical devices, and food products.
- National Health Surveillance Agency (ANVISA): Regulates drugs, medical devices, and healthcare services in Brazil.
- National Medical Products Administration (NMPA): Regulates drugs, medical devices, and cosmetics in China.
- Pharmaceuticals and Medical Devices Agency (PMDA): Ensures the quality and safety of medicines and medical devices.

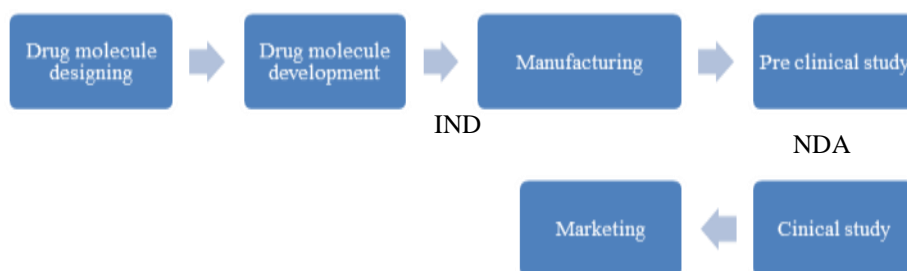
Regulatory Authorities In India

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- State Drug Control Authorities: Regulate the manufacture, sale, and distribution of drugs within respective states. Functions are Issue licenses for drug manufacturing and distribution. Monitor compliance with drug quality standards. Inspect pharmacies, wholesalers, and manufacturers. Works in coordination with CDSCO.
- National Pharmaceutical Pricing Authority (NPPA): Regulates drug prices to ensure accessibility and affordability of medicines. Functions are Fixes and revises the ceiling price of essential medicines under the Drug Price Control Order (DPCO). Monitors prices of decontrolled drugs. Established under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.
- Indian Pharmacopoeia Commission (IPC): Sets standards for drugs in India. Key. Publishes the Indian Pharmacopoeia (IP), which provides quality standards for medicines. Ensures drugs meet safety and efficacy requirements.
- Department of Pharmaceuticals (DoP): Formulates policies for the pharmaceutical sector. Functions are Promotes the growth of the pharmaceutical industry. Oversees initiatives

like Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) to provide affordable medicines.

- Food Safety and Standards Authority of India (FSSAI): Regulates nutraceuticals, dietary supplements, and food-related products. Operates under the Food Safety and Standards Act, 2006.
- Bureau of Indian Standards (BIS): Ensures quality standards for medical devices and equipment. Sets mandatory certifications for certain medical devices.

Process to Formulate the Pharmaceutical Drug



DISCUSSION

To discuss this article is to study about the Regulatory affairs role, functions, regulatory agencies, pre approval and post approval regulatory. The regulatory affairs can act as major role to regulate or maintain or govern the safety, efficacy, quality of the drug.

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