REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRIES

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INTRODUCTION: - A new molecule can cost millions of rupees or dollars to progress and any misstep can have a bigger impact on the company's position. Medicine plays an important role in human life, so it is necessary to formulate pharmaceutical regulations to ensure the quality, safety and efficacy of medicines. Regulatory affairs professionals are solely responsible for maintaining product compliance and maintaining all records. Most companies now have a department dedicated to regulatory affairs. Regulatory Affairs typically communicates with one of the FDA headquarters canters (e.g., Center for Drug Evaluation and Research) rather than local FDA regional offices. The gimps do not apply directly to regulatory affairs; however, they must understand and evaluate changes in drug manufacturing and testing activities to determine whether and when to notify the FDA. Today's pharmaceutical industry is well organized, systematic and compliant with international regulatory standards for the production of chemical and biological agents for human and veterinary use as well as medical devices, traditional herbal products and cosmetics. The development of materialistic drugs is highly controlled. Before each drug is approved for marketing, it must undergo careful inspection and clinical trials to ensure its safety, efficacy and quality. Regulators are an important interface between business, product and regulators, and their positive or negative perception will strengthen the regulator's discernment in the industry, for better or for worse. Therefore, the higher the scientific precision, the better the chance of the product reaching the market within the expected time frame.

OBJECTIVES OF REGULATORY AFFAIRS

- How and why the pharmaceutical industry and drug regulation in the United States
- Key regulations in the United States
- The EU framework and its regulations
- About stewardship of EU products Products of the European Union
- Pharmaceutical legislation in the EU
- Development of Indian pharmaceutical industry and pharmaceutical regulation at different times
- Types of marketing authorization procedures in the market in the EU market
- Important rules and laws in India
- Role of professional and regulatory affairs in the pharmaceutical industry

WHAT IS REGULATORY AFFAIRS

It is a unique combination of science and management to achieve important business goals within a drug development organization. From early non-clinical research to development, manufacturing and routine commercialization, touching everything about a medicine can make a big difference for patients and pharmaceutical companies.
PHARMACEUTICAL DRUG REGULATORY AFFAIRS

In the government's desire to protect public health, through the control of the safety and efficacy of products in the fields of pharmaceuticals, veterinary drugs, medical devices, pesticides, agricultural chemicals, cosmetics and auxiliary drugs. Companies that manufacture and sell these products must ensure that they provide quality products for the health and well-being of the public. Most companies now have a department dedicated to regulatory affairs. Regulatory Affairs typically communicates with one of the FDA headquarters centers (e.g., Center for Drug Evaluation and Research) rather than local FDA regional offices. The gimps do not apply directly to regulatory affairs; however, they must understand and evaluate changes in drug manufacturing and testing activities to determine whether and when to notify the FDA. The companies responsible for discovering, testing, manufacturing and marketing these products also want to ensure that the products they supply are safe and make a valuable contribution to public health and well-being. Regulatory Affairs (RA) must understand the regulatory requirements of all of the company's export markets.4

IMPORTANCE OF DRUG REGULATORY ISSUES

In this global competitive environment, reducing the time it takes for a product to reach the market is a key parameter and the success of a company depends on it. Therefore, it is economically important for a company to have proper control over its regulatory affairs activities. Submission of incorrect or insufficient data prevents timely positive assessment of marketing applications. Developing a new drug costs millions of dollars, and delaying its market launch by a single day creates significant financial considerations. Worse still, failure to report all required data or post mislabeled products can lead to product recalls. A law is a binding directive issued by an agency that explains how the law should be interpreted and followed. Failure to do so may land you in the “Warning Letters Sent” section of the FDA website, which is not good for the drug company.

A good regulatory affairs professional will take a “right the first time” approach and play a very important role in coordinating scientific efforts with regulatory requirements throughout the product life cycle, helping to reduce costs - by maximizing the efficiency use of company resources.

Regulatory Affairs is the first point of contact between the Ministry of Health/Government and the company.5

HISTORY OF REGULATORY AFFAIRS

Today, the RA investigates the production, quality assessment, and distribution of new pharmaceutical products that are increasingly global. As a result, manufacturing processes and supply chains for pharmaceuticals, including generic drugs, have become increasingly complex. Because the same medicine is often distributed in several regions of several countries, or used by patients all over the world. It is also more common for different manufacturing stages of the same product to take place in different countries, often far apart.

Also, at the same time, more and more common elements appeared in the cases filed by different jurisdictions. In the aftermath, disasters such as the vaccine, the sulfa elixir and the thalidomide disaster have revealed the urgency of regulatory affairs, with a marked increase in safety, efficacy and quality rules and regulations. medication. Therefore, Marketing Authorization (MA) and Good Manufacturing Practices (GMP) have also resulted in stricter rules. Table 1 summarizes the historical course of RA. Regulatory Authority is the link between business, product and regulation. They strictly regulate drug development through marketing authorization and commercialization. These regulatory standards are set by country-specific regulatory bodies, such as the FDA in the United States, EMA in Europe, TGA in Australia, and DCGI in India, among others. The history of RA is shown in Table 1.

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Development Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>1970</td>
<td>RA was began to develop in US as health care profession due to drug disasters.</td>
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<td>2.</td>
<td>1980</td>
<td>RA profession is emerging, recognized internationally and professional demand increased.</td>
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<td>3.</td>
<td>1991</td>
<td>Regulatory affairs Certification (RAC) was established</td>
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<td>4.</td>
<td>2000</td>
<td>RA profession was well established various rules and regulation, certification was started.</td>
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<tr>
<td>5.</td>
<td>2005</td>
<td>RA professional demand was emerged highly</td>
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<td>6.</td>
<td>2010</td>
<td>RA become indispensable, important and critical without which no pharmaceutical company can sustain manufacturing, purchase and sales, imports and exports, research and development</td>
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<td>7.</td>
<td>2011</td>
<td>DMF, CTD, ACTD become important for marketing authorization of pharmaceutical product and medical devices.</td>
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<tr>
<td>8.</td>
<td>2012 On Words</td>
<td>RA coupled with suspension or withdrawal or cancellation of license.</td>
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<tr>
<td>9.</td>
<td>Present</td>
<td>Regulatory department holds an important bridge between Pharmaceutical products, pharmaceutical companies and regulatory authorities or professionals in deciding the chances of drug discovery.</td>
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SCOPES OF INDUSTRY REGULATORY AFFAIRS PROFESSIONALS
ACTIVITIES OF PHARMA REGULATORY AFFAIRS IN INDUSTRIES
India is becoming a popular destination for clinical trials and R&D. The development of the pharmaceutical industry is expanding the scope of the pharmaceutical industry in India. There are many regulatory issues in Mumbai. The product life cycle phases are:-
1) Business Development
2) New Product Development
3) Manufacturing

Phase 1: Business Development
Plans development plans indicate that the company is defining international trade commitments, export pricing strategies, reasons for exporting, potential markets and customers for support, export financing options, legal requirements, foreign trade methods, transportation methods, overseas partnerships and investment capabilities. The general working principles lead to the development of an international business development plan as follows:
1. Products or services: Selecting the right product and identifying those with export potential requires careful thought on a profitable product to sell in the market.
2. Planning: The planning phase examines future business operations and forecasts what might happen.
3. Goal Setting: Goal setting to plan for global market entry and establish business goals can be challenging. Businesses should have short- and long-term goals for the business.

Phase 2: Development of new products
The main functions of coordination of the development of new products are:
- Formulation and development of the feasibility of the development of the formulation
- Product Design
- International Regulatory Affairs Requirements
- International Business Development Team
The various operational tools commonly used by the product development team when developing new generic drugs are:
- Verification and Formulary Details New Product Request Form (NPRF)

New Product Development Requests or Register with the Existing Products Company
This form is mainly consists of the following:

Master List
- Product Name
- Dosage Form
- Route of Administration
- Dosage
- Container Closure System
- Packaging Material
- Market details.
- Regulatory Guideline

New product development process mainly includes Next Steps:

1. Pre-Formulation Planning:
Once the product development is officially approved, the product development team must be ensured,
- Innovative product research
- Physicochemical parameters
- Container closure systems
- Stability studies
- Storage conditions
Based on the available data, a summary report must be prepared for the next step.

2. Final Formulation and Batch Testing:
- The Final Formulation Study Plan will contain rationale, data analysis of pre formulation studies, and planning for the first final formulation study
-Batch Temperature and Humidity
- This three-group stability study will last for six months
- After verifying the 3-6 month stability data for the stability group, the following steps will be followed for further development.

3. Records:
The "Records" section contains the following documents:
➢ Product Development Report
➢ Literature Investigation Report
➢ Innovator Sample Test Report
➢ Drug Excipient Compatibility Report
➢ Product Registration Laboratory Test Log

**Phase 3: Manufacturing**

Sterility process and manufacture of two classes of non-pharmaceutical products - sterile products. The manufacture of sterile products must meet specific requirements to minimize the risk of microbial contamination, particles and pyrogenic contamination. It all depends on the skills, training and attitude of the staff involved. Quality assurance is particularly important and such manufacturing must strictly follow established and validated preparation methods and procedures. Sole reliance on sterility or other aspects of quality should not be placed on end process or end product testing.¹⁰

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