REGULATORY AFFAIRS

Regulatory Affairs - What is it?

- Medicinal products, pharmaceuticals, veterinary medicines, medical devices, and food supplements – all these products are subject to regulations designed by governments to protect public health. The Regulatory Affairs department ensures that their companies comply with all of the regulations and laws concerning their business.
- The Regulatory Affairs department is an important part of the organizational structure of pharmaceutical companies. Internally it liaises at the interphase of drug development, manufacturing, marketing and clinical research. Externally it is the key interface between the company and the regulatory authorities.

Regulatory Affairs Defined

- Regulatory Affairs is a specialized profession within the pharmaceutical/biotechnology sector.
- Regulatory Affairs oversees company compliance with regulations and laws pertaining to the manufacture, marketing and development of regulated products.
- Regulatory Affairs acts as point of contact between the company, its products and regulatory authorities.
- Regulatory Affairs interacts with worldwide, federal, state, and local regulatory agencies (e.g., FDA (US), TGA (Australia), MHRA (UK), MCC (South Africa), etc) to assure...
  - licensing,
  - registration,
  - development,
  - manufacturing,
  - marketing and
  - labeling
  ……of pharmaceutical and medical products are conducted in compliance with all applicable rules.

Regulatory Framework

- Development, approval for marketing, manufacturing, and ongoing compliance of pharmaceutical/biotech products is among the most regulated activities of any industry.
- Regulations are complex systems of interrelated rules that govern a broad range of activities.
- These rules are continuously undergoing amendment and supplementation.
- Their main function is to assure that these products are safe (do no harm) and effective (do some good).
REGULATORY AFFAIRS

Why do we pay so much attention to regulation and process??

- It takes 8 to 15 years to develop a new drug/biologic product.
- Costs up to $800 million.
- Attention to early development, successfully execution of significant clinical studies helps to reduce number of development failures.
- Regulatory affairs provides insight/guidance into this development through agency wisdom collected in guidance, previous experience, market precedence, etc.

*Compliance with Regulator expectations therefore equates with development success. Patient Protection is of greatest importance*

Drug Discovery & Approval

1. Identify disease
2. Identify-Validate Pharmaceutical Target
3. Identify Lead Molecules
4. Optimize Lead Molecules
5. Preclinical Trials
6. Clinical Trials
7. Approval & Circulation
REGULATORY AFFAIRS

Cycle of Drug Approval – Birds Eye View
**REGULATORY AFFAIRS**

Some Major Regulatory Authority Bodies

<table>
<thead>
<tr>
<th>Flag</th>
<th>Country</th>
<th>Regulatory Authority</th>
<th>Expansion</th>
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<tbody>
<tr>
<td>![India Flag]</td>
<td>INDIA</td>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<tr>
<td>![USA Flag]</td>
<td>USA</td>
<td>USFDA</td>
<td>United States Food and Drugs Administration</td>
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<td>![Canada Flag]</td>
<td>CANADA</td>
<td>TPD</td>
<td>Therapeutic Products Directorate</td>
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<tr>
<td>![Europe Flag]</td>
<td>EUROPE</td>
<td>EMEA</td>
<td>European Agency for the Evaluation of Medicinal Products</td>
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<td>![UK Flag]</td>
<td>UK</td>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
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<tr>
<td>![Australia Flag]</td>
<td>AUSTRALIA</td>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>![South Africa Flag]</td>
<td>SOUTH AFRICA</td>
<td>MCC</td>
<td>Medicines Control Council</td>
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<td>![Brazil Flag]</td>
<td>BRAZIL</td>
<td>ANVISA</td>
<td>Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency Brazil)</td>
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<td>![Japan Flag]</td>
<td>JAPAN</td>
<td>PMDA</td>
<td>Pharmaceuticals and Medical Devices Agency</td>
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REGULATORY AFFAIRS

Common Technical Document (CTD)

Modular Structure of Common Technical Document

Module 1
Administrative and prescribing information (not harmonized)

Module 2
Quality overall summary
Nonclinical overview
Nonclinical summary

Module 3
Quality data

Module 4
Nonclinical study reports

Module 5
Clinical study reports

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