

Regulatory Aspects: Drugs, Biologics and Medical Devices

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Meaning of Regulatory Aspects

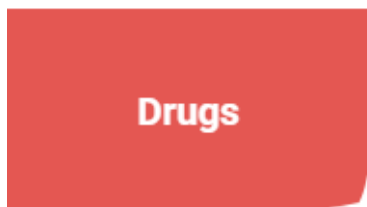
- **Regulatory aspects** are the laws, guidelines, and standards that must be followed before a medical product can be marketed and used.
- **They ensure products are:**
 - Safe
 - Effective
 - High quality
 - Properly manufactured
 - Correctly labeled
 - Monitored after approval

Why Regulation is Important

- Medical products directly affect human health.
- **Poorly tested or poor-quality products can cause:**
 - Serious side effects
 - Treatment failure
 - Disability
 - Death
- Regulation helps protect patients, healthcare providers, public health, and supports safe manufacturing practices.

What Are Medical Products?

- **Medical products generally fall into three groups:**



- Drugs
 - Biologics
 - Medical Devices
- Because they are different, their regulatory requirements also differ.

1. Drugs

Meaning

- **Drugs are chemical substances used for:**
 - Diagnosis
 - Prevention
 - Treatment or cure
 - Relief of symptoms

Examples:

- Paracetamol
- Antibiotics
- antihypertensives

Regulatory Focus for Drugs

- Identity – Is it the correct drug?
- Strength – Correct amount of active ingredient
- Purity – Free from harmful impurities
- Safety – Acceptable risks
- Efficacy – Does it work?
- Quality – Consistent manufacturing

2. Biologics

Meaning

- Biologics are products made from living systems and are usually more complex than chemical drugs.

Examples:

- Vaccines
- Blood products
- Monoclonal antibodies
- Recombinant proteins
- Gene and cell therapies

Special Regulatory Concerns

- Biologics are sensitive to manufacturing and storage conditions, so even small changes may affect the product.

Regulatory Focus for Biologics

- Source of biological materials
- Manufacturing controls
- Sterility and contamination risks
- Viral safety
- Immunogenicity
- Potency and biological activity
- Stability

3. Medical Devices

Meaning

- Medical devices are products used for medical purposes that usually act through physical or mechanical means rather than chemical action.

Examples:

- Syringes
- Catheters
- Stents
- Pacemakers
- Artificial joints
- Diagnostic and imaging devices

Device Categories

a) Simple devices:

- Thermometers
- Surgical gloves

b) Moderately complex devices:

- Infusion pumps

c) Highly complex devices:

- Pacemakers
- Heart valves

Regulatory Focus for Devices

Regulators assess:

- Design and material safety
- Performance and reliability
- Electrical or mechanical safety

- Sterility and biocompatibility
- Clinical performance
- Labeling and instructions for use

Key Differences in Regulation

Drugs

- **Focus on:**
 - Chemical quality
 - Safety
 - Clinical efficacy

Biologics

- **Focus on:**
 - Manufacturing consistency
 - Contamination control
 - Immunogenicity
 - Biological activity

Medical Devices

- **Focus on:**
 - Design and engineering safety
 - Performance
 - Clinical usability

Main Regulatory Authorities

- **Examples of major regulators:**
 - FDA – United States
 - EMA – Europe
 - MHRA – United Kingdom
 - CDSCO – India
 - PMDA – Japan

Role of Regulatory Authorities

- **They:**
 - Review applications
 - Approve or reject products

- Inspect manufacturing sites
- Monitor safety after approval
- Issue regulations and guidelines
- Take action on unsafe products

Main Stages of Regulation

Medical products usually go through these stages:

1. Discovery and Early Development

- Products are identified and studied.

2. Preclinical Testing

- Lab and animal studies for initial safety.

3. Clinical Testing

- Human studies to assess safety and effectiveness.

4. Marketing Approval

- Complete data submitted for regulatory review.

5. Post-Marketing Surveillance

- Product continues to be monitored after approval.

Important regulations involved in approval of a Medical Product

A. Good Laboratory Practice (GLP)

- **GLP** is a quality system for **non-clinical laboratory studies**.
- It ensures pre-clinical testing is done properly and data is reliable.

Main Purpose of GLP

- Proper planning of studies
- Correct documentation
- Accurate recording of results
- Integrity of laboratory data

B. Good Manufacturing Practice (GMP)

- **GMP** means products must be manufactured under **controlled conditions**.

GMP Ensures

- Consistent quality
- Clean environment



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