Good Regulatory Practices (GRP)

Definition:

- Good Regulatory Practices (GRP) refer to a set of internationally recognized principles and systems that guide the development, enforcement, and monitoring of regulations in the pharmaceutical sector.
- The aim is to ensure:
    - Patient safety
    - Legal compliance
    - Product quality and efficacy
    - Transparency and accountability

Documentation in Regulatory Practices

Importance:

- Accurate documentation is essential for:
    - Legal compliance
    - Traceability
    - Audit readiness
    - Product recalls (if required)
    - Quality assurance

Key Documents Required:

Area	Types of Documentation
Community/Hospital Pharmacy	Prescription records, stock registers, narcotic drug records, invoice copies
Manufacturing	Batch Manufacturing Records (BMR), Batch Packaging Records (BPR), SOPs, GMP records
Wholesale	Purchase and sales invoices, stock and distribution records, cold chain maintenance logs
Import/Export	Bill of entry, shipping bill, invoice, Certificate of Analysis, import license

Note: Most of these records must be retained for at least **2 years** (or more in some cases, like Schedule X or narcotics).

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Licensing and Renewals

Types of Licenses Required:

Sector	License Type	Governing Authority
Community Pharmacy	Retail Drug License (Form 20, 21)	State Drug Control Authority
Hospital Pharmacy	Institutional or hospital pharmacy license (varies by state)	State Authority
Manufacturing	Drug Manufacturing License (Form 25, 28)	CDSCO + State Licensing Authority
Wholesale	Wholesale Drug License (Form 20B, 21B)	State Licensing Authority
Import	Form 10 (Import License), Registration Certificate (Form 41)	CDSCO
Export	No specific "export license," but requires COA, invoice, shipping documents, and manufacturer license	CDSCO + Customs

Renewal Procedures:

- Most licenses are now valid for **lifetime** with **periodic retention fees**.
- Renewal or retention must comply with timelines specified under the **Drugs and Cosmetics Rules**.
- Failure to renew or submit required fees leads to **license cancellation**.

E-Governance and Digitalization in Regulatory Affairs

- India has been rapidly adopting **digital tools** for improved regulatory transparency and efficiency.

Major Digital Initiatives:

Platform	Function
SUGAM Portal (CDSCO)	Online submission of applications for drug import, clinical trials, new drug approval
e-Gov Portal (State Drug Authorities)	Online drug license applications, renewals, and tracking
Pharma Sahi Daam (NPPA App)	Provides real-time drug pricing and price control information

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Pharmacovigilance Reporting (PvPI)	Online ADR reporting by healthcare professionals and consumers
Extended Licensing and Laboratory Node (XLN)	Tracks drug samples, test reports, and lab inspections (used in many states)

Benefits of E-Governance:

- Reduces human error and corruption
- Speeds up approvals and renewals
- Promotes transparency
- Provides centralized monitoring

GRP in Community Pharmacy

- Community pharmacies must follow Good Regulatory Practices (GRP) to ensure safe, ethical, and legal drug dispensing.

Regulatory Practices

- Hold a valid Retail Drug License:
  - **Form 20** (general drugs), **Form 21** (prescription drugs)
- Store drugs properly, especially temperature-sensitive items (e.g., vaccines, insulin).
- Do not dispense Schedule H, H1, or X drugs without a prescription.
- Avoid sale of expired, spurious, or unauthorized drugs.
- Ensure a registered pharmacist is present during working hours.

Documentation

- Maintain prescription records, especially for H1 and X drugs.
- Keep updated sales and purchase registers.
- Record labeling and dispensing details accurately.

Licensing

- Pharmacist must be registered with the State Pharmacy Council.
- Renew licenses periodically (usually every 5 years).
- Display license and registration visibly in the pharmacy.

E-Governance & Compliance

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- Use online systems for license application and renewal.
- Implement barcode/RFID for inventory management.
- Do not substitute drugs without prescriber or patient consent.
- Follow all prescription-only and confidentiality norms.

GRP in Hospital Pharmacy

- A hospital pharmacy must ensure compliance with Good Regulatory Practices (GRP) to support safe, efficient, and ethical medication management within healthcare institutions.

Regulatory Practices

- Must be headed by a qualified pharmacist.
- Maintain purchase and stock records for all drugs.
- Keep a narcotics register as per the NDPS Act.
- Follow internal audits and quality assurance protocols.
- Adhere to the hospital formulary; discourage irrational prescriptions.

Documentation

- Maintain inpatient and outpatient dispensing records.
- Keep inventory logs, expiry tracking, and temperature monitoring records.
- Maintain narcotics and psychotropic drug registers with strict compliance.

Licensing & Renewals

- Obtain an institutional license for in-house pharmacy operations.
- Renew licenses as per State Health Authority norms.

E-Governance & Compliance

- Integrate pharmacy operations with Hospital Information Systems (HIS).
- Utilize platforms like e-Aushadhi or Drug Management Information Systems (DMIS).
- Undergo inspections by drug inspectors and NABH accreditation bodies.

Good Practices

- Ensure separate storage for narcotics and high-risk medicines.
- Provide medication counseling to patients.
- Actively participate in pharmacovigilance and adverse drug reaction (ADR) reporting.

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