D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 13

Good Regulatory Practices



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

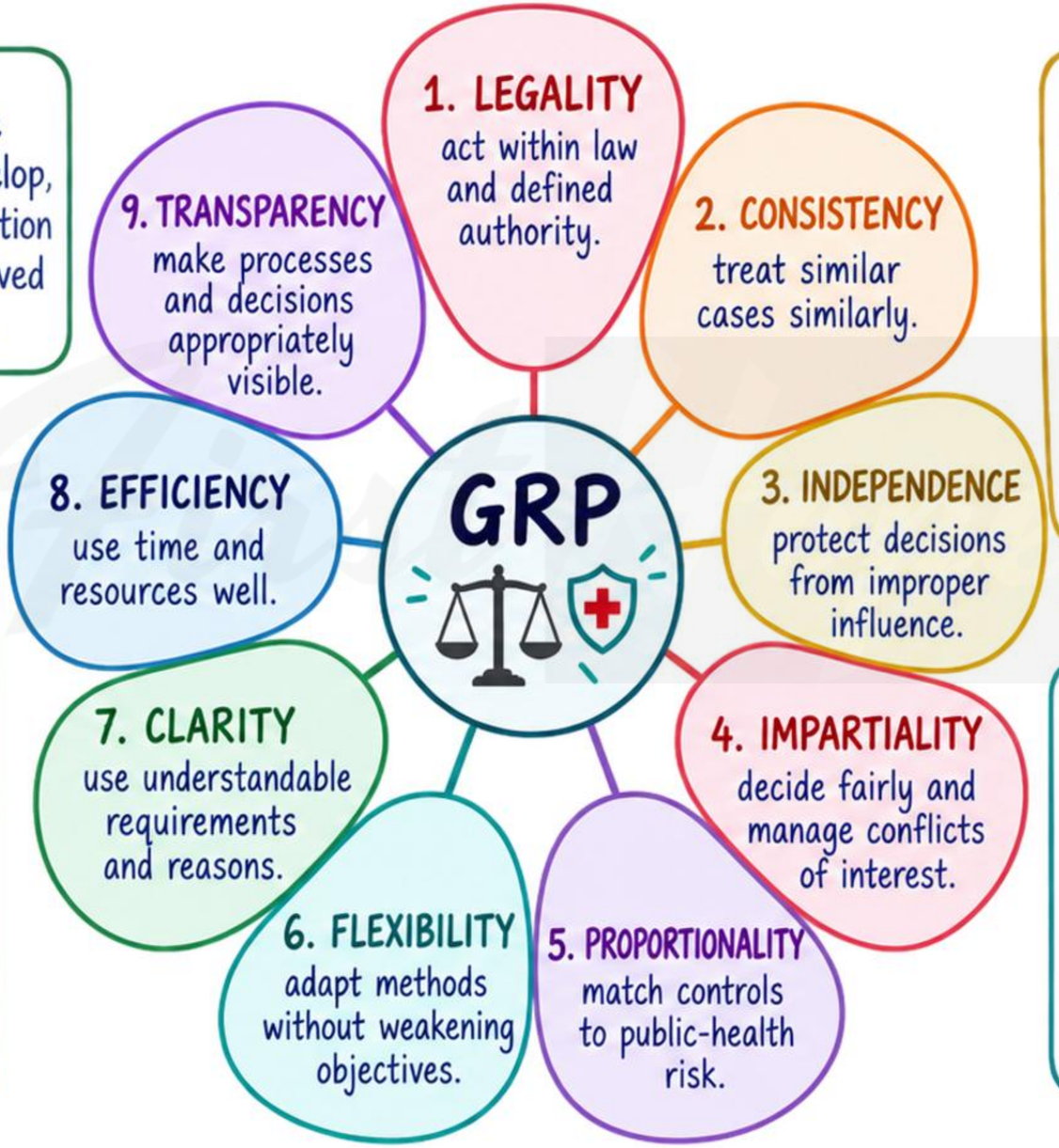
GOOD REGULATORY PRACTICES (GRP)

MEANING

Good Regulatory Practices (GRP) are principles and practices used to develop, implement, monitor and review regulation so that public-health goals are achieved lawfully, consistently and efficiently.

REGULATORY CYCLE





WHY GRP MATTERS

- Protects patients and the public.
- Supports products that are safe, effective or perform as intended, and are of assured quality.
- Makes decisions predictable, evidence-based and accountable.
- Uses regulatory effort in proportion to risk.

IMPORTANT DISTINCTION

GRP mainly guides regulatory authorities. GMP, GDP and GPP guide manufacturing, distribution and pharmacy practice.

This chapter applies GRP principles broadly to regulated establishments.

DOCUMENTATION IN REGULATORY PRACTICES

DRAFT → REVIEW & APPROVE → ISSUE & TRAIN → USE & RECORD → REVIEW / CHANGE CONTROL → RETAIN / ARCHIVE

WHY DOCUMENTATION IS ESSENTIAL

Documentation proves what was required, what was done, who did it and when. It supports traceability, inspection, investigation, recall and continual improvement.

CONTROLLED DOCUMENTS

Policies, SOPs, specifications, master records, forms and approved instructions. Each needs a title, unique number, version, effective date, approval and controlled distribution.

RECORDS

Completed evidence such as prescriptions, invoices, registers, batch records, test results, temperature logs, complaints, recalls, training and CAPA records.

GOOD DOCUMENTATION PRACTICES

- Clear, legible, accurate and recorded at the time of activity.
- Signed or attributable and dated.
- Corrections preserve the original entry and identify who changed it and when.
- Electronic records need authorised access, audit trail where applicable, backup and retrieval.
- Obsolete versions are removed from use but archived as required.

KEY RECORDS BY AREA

PHARMACY

prescriptions, purchase invoices, H1 / X records and storage logs.

MANUFACTURING

MFR, BMR / BPR, test results, deviations, OOS, CAPA and stability.

WHOLESALE

supplier, purchase, sale, batch, expiry, customer and transport records.

IMPORT-EXPORT

licences, permissions, invoices, certificates, customs and shipping records.

RETENTION IS RULE-SPECIFIC

Schedule H1 supply register: **3 years.**
Schedule X prescription copy: **2 years.**
Manufacturing records: at least **1 year** after expiry under current Schedule M.
Keep longer when another law, licence condition or institutional policy requires it.

H1 REGISTER — 3 YEARS

SCHEDULE X PRESCRIPTION COPY — 2 YEARS

MANUFACTURING RECORD — AT LEAST 1 YEAR AFTER EXPIRY

LICENSING AND RENEWALS

ACTIVITY ?

RETAIL

SALE LICENCES UNDER DRUGS RULES

- **Form 20** — drugs other than Schedules C, C(1) and X.
- **Form 21** — Schedules C and C(1), excluding X.
- **Form 20F** — Schedule X.

State Licensing Authority

WHOLESALE

SALE LICENCES UNDER DRUGS RULES

- **Form 20B** — drugs other than Schedules C, C(1) and X.
- **Form 21B** — Schedules C and C(1), excluding X.
- **Form 20G** — Schedule X.

State Licensing Authority

State Licensing Authority normally grants and inspects sale licences.

MANUFACTURE

MANUFACTURING LICENCES

- **Form 25** — drugs other than Schedules C, C(1) and X.
- **Form 25F** — Schedule X. drugs not in C or C(1).
- **Form 28** — Schedules C and C(1), excluding X.
- **Form 28B** — Schedules C and C(1), including X.
- **Form 28D** — large-volume parenterals, sera, vaccines and recombinant-DNA-derived drugs.

State Licensing Authority

IMPORT DRUG

IMPORT

DRUGS — Form 41 registration certificate plus Form **10** import licence, or Form **10A** for Schedule X, where applicable.

Central Licensing Authority

IMPORT DEVICE

IMPORT

MEDICAL DEVICES — application **Form MD-14** → import licence **Form MD-15** under Medical Devices Rules, **2017**.

Central Licensing Authority

VALIDITY THROUGH RETENTION FEE → Covered sale and manafacturing licences remain valid when the retention fee is paid before each succeeding **5-year** period. → **5 YEARS** → **Late payment: 2%** of licence fee for every month or part, allowed up to **6 months**. After that, the licence is deemed cancelled.

NOTE

Special products and purposes may require other forms, permissions or Central approvals.

FIRST IDENTIFY ACTIVITY → PRODUCT CATEGORY → APPLICABLE LAW / RULE → LICENSING AUTHORITY → CORRECT FORM

E-GOVERNANCE AND DIGITALIZATION IN REGULATORY AFFAIRS

SUGAM

online applications and services of CDSCO, including many drug and medical-device functions.

STATE PORTAL / XLN WHERE ADOPTED

sale, distribution or licensing services in States where adopted.



PvPI ADR REPORTING

reporting suspected adverse drug reactions to the pharmacovigilance system.

PHARMA SAHI DAAM

medicine-price information and complaint support linked with NPPA.

ICEGATE / eSANCHIT

electronic customs interface and upload of supporting trade documents.

GENERAL ONLINE WORKFLOW

REGISTER → SELECT SERVICE → COMPLETE FORM → UPLOAD DOCUMENTS → PAY FEE / E-SIGN → ANSWER QUERY → TRACK STATUS → RECEIVE DECISION → ARCHIVE

PURPOSE

E-governance moves regulatory applications, records, payments, communication and tracking into secure digital workflows.

BENEFITS

- Faster submission and status tracking.
- Standardised forms, time stamps and fewer transcription errors.
- Better traceability, analytics and communication.
- Reduced physical paperwork and repeated visits.

SAFE DIGITAL PRACTICE

- Use authorised accounts, strong access control and role separation.
- Protect patient, trade and regulatory confidentiality.
- Maintain accurate metedata, version control, audit trail where applicable, backup and disaster recovery.
- Verify acknowledgement, query and final order; preserve the complete electronic record.

DATA SECURITY

- Authorised access
- Audit trail
- Backup
- Confidentiality

KEY RULE

DIGITAL SUBMISSION ≠ AUTOMATIC APPROVAL.

The applicant remains responsible for truthful, complete and compliant information.

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