

Unit 1: Current Good Manufacturing Practices

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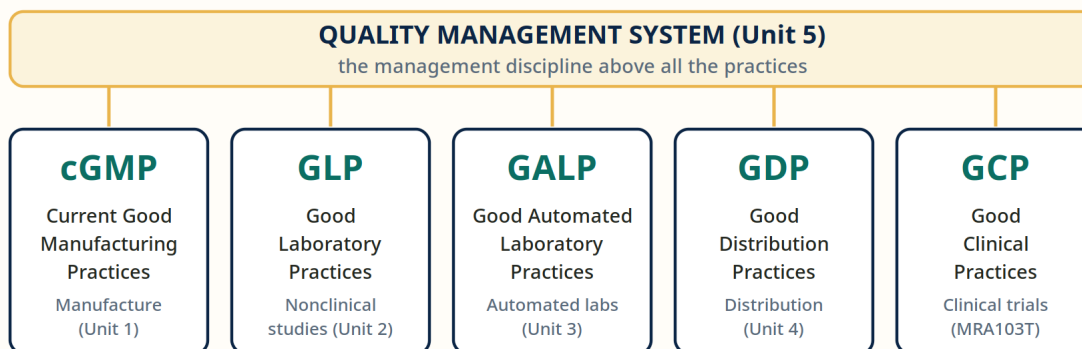
Good Regulatory Practices, subject code MRA101T, is the opening core subject of M.Pharm Regulatory Affairs, Semester 1. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks. Regulatory Affairs is the one specialisation whose Semester 1 does not include Modern Pharmaceutical Analytical Techniques; instead, its first subject is this tour of the "good practices", the codified ways of working that make pharmaceutical work trustworthy enough for a regulator to accept. The subject studies four practices and the system that binds them. Unit 1 covers current Good Manufacturing Practices (cGMP), the rules under which medicines and medical devices are made, through the three great frameworks: the United States regulations in 21 CFR Parts 210 and 211, the European principles in Directive 91/356/EEC, and the WHO guidelines, with the GAMP 5 guide for computerized systems and the GHTF documents for medical devices alongside. Unit 2 covers Good Laboratory Practices (GLP), the rules under which nonclinical safety studies are run, through the US FDA regulations in 21 CFR Part 58, their documentation and audit machinery. Unit 3 covers Good Automated Laboratory Practices (GALP) and 21 CFR Part 11, the rules that keep electronic records and computerized systems honest. Unit 4 covers Good Distribution Practices (GDP), the rules that protect a finished medicine on its journey from factory to patient. Unit 5 gathers the whole into Quality Management Systems: quality concepts, total quality management, quality by design, Six Sigma, out of specification handling, change control, validation and qualification, the ICH process, ISO 13485 and CDSCO guidance. A student who masters this subject can read any later regulatory topic, dossier, audit or inspection, in its proper frame.

1.1 The good practices family: what this subject is about

Modern pharmaceutical regulation does not only judge products; it judges the way work is done. Over the second half of the twentieth century, each stage of a medicine's life acquired its own written code of good practice, and the codes together are nicknamed the **GxP family**, where x stands for the stage: **GMP** for manufacturing, **GLP** for nonclinical laboratory studies, **GCP** for clinical trials, **GALP** for automated laboratory systems, **GDP** for distribution, and their younger relatives such as GVP for pharmacovigilance. This subject teaches four of them in depth and the quality management system that sits above them all.

A good practice code has a recognisable anatomy wherever it appears. It states principles rather than recipes; it requires trained and named responsible people; it demands that procedures be written before they are performed (in standard operating procedures), that work be recorded as it happens, and that deviations be investigated rather than hidden; and it provides for independent checking, by a quality unit inside the organisation and by inspectors outside it. The practices differ in what they protect. GMP protects the patient from a badly made batch. GLP protects the regulator from safety data that cannot be trusted. GALP protects electronic records from silent corruption. GDP protects the medicine, after release, from heat, theft, mix-ups and falsification. Unit 5's quality management system is the management discipline that makes all of them run in one organisation rather than as four separate rulebooks.

The Good Practices Family (GxP)



Each practice protects something different: the batch, the study data, the electronic record, the journey, and finally the patient.

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Figure: The GxP family mapped to the stages of a medicine's life that each practice governs, with the quality management system above them all.

1.2 cGMP: meaning, and why the word "current" is there

Current Good Manufacturing Practice (cGMP) is the body of regulation that requires manufacturers to control their operations so that every batch of a drug product has the identity, strength, quality and purity it claims. The FDA's classic summary is that cGMP provides systems assuring the proper design, monitoring and control of manufacturing processes and facilities: appropriate raw materials, robust operating procedures, reliable testing laboratories, and detection and investigation of quality defects.

The small letter **c**, for **current**, is the most examinable letter in the subject. It was added deliberately when the United States revised its GMP regulations in 1978, to record that GMP is not a frozen 1963 checklist: companies are expected to use current technology and current systems, so a practice that was acceptable a generation ago (handwritten records where validated electronic systems now exist, for example) can become a deficiency without any change in the regulation's text. History explains the shape of the rules. The sulfanilamide elixir disaster of 1937, in which a toxic solvent killed more than a hundred people, produced the US Federal Food, Drug, and Cosmetic Act of 1938; the first GMP regulations followed in 1963; the thalidomide disaster drove the 1962 efficacy amendments in the United States and, in time, licensing systems everywhere; and the 1978 revision produced the modern cGMP text of Parts 210 and 211 that Unit 1 now studies. Every GMP clause since has the same logic: a failure happened, was understood, and was converted into a standing control so it need not happen again.

1.3 The United States framework: 21 CFR Part 210 and Part 211

In the United States, drug cGMP lives in Title 21 of the Code of Federal Regulations in two companion parts. **Part 210** states the current good manufacturing practice in manufacturing, processing, packing, or holding of drugs in general terms: it sets the status of the regulations (they have the force of law, and a drug made outside them is adulterated), defines key terms, and states how the rules apply when components or products are handled by more than one firm. **Part 211** states the cGMP for **finished pharmaceuticals**, the operative detail, organised in subparts that a student should be able to recite as a map of a factory's obligations:

Part 211 subpart	What it controls
A, General provisions	Scope and definitions

Part 211 subpart	What it controls
B, Organization and personnel	The quality control unit, responsibilities, personnel qualifications, training and hygiene
C, Buildings and facilities	Design, construction, lighting, ventilation, plumbing, sanitation, maintenance
D, Equipment	Design, size, location, cleaning, maintenance, calibration, computerised systems control
E, Control of components and drug product containers and closures	Receipt, identification, sampling, testing, approval or rejection, storage and retesting
F, Production and process controls	Written procedures, deviations, in-process controls, yield calculation, equipment identification, time limits
G, Packaging and labeling control	Material examination, label issuance and reconciliation, packaging operations, tamper evident packaging, expiration dating
H, Holding and distribution	Warehousing, distribution procedures, oldest stock used first
I, Laboratory controls	Testing and approval or rejection, specifications, sampling plans, stability testing, reserve samples, laboratory animals and records
J, Records and reports	The master production and control records, batch production and control records, distribution records, complaint files
K, Returned and salvaged drug products	Handling, testing and disposition of returns

Three features of the American text repay attention. First, the **quality control unit** of Subpart B is given explicit authority and responsibility to approve or reject everything that bears on quality, and that authority may not be overridden by production interests: the seed of every later quality system idea is here. Second, the regulations are written as **floors, not ceilings**, minimum requirements in deliberately general language, which is why the FDA supplements them with guidance documents and why inspection findings cite the regulation while arguing from current practice. Third, the system is enforced by **inspection**: FDA investigators inspect facilities, record objectionable conditions on Form FDA 483, and the agency can escalate to warning letters, import alerts, seizure, injunction and consent decrees, the enforcement ladder that MRA102T meets again from the documentation side.

The Three cGMP Frameworks of Unit 1

WORLD HEALTH ORG.

WHO GMP main principles
for pharmaceutical products
(WHO Technical Report Series)

Certification Scheme:
the Certificate of a
Pharmaceutical Product (CPP)
for world trade

WHO prequalification for
UN agency procurement

Foundation beneath India's
Schedule M

One idea in three legal settings: quality is built in, recorded, and independently checked

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Figure: The United States Parts 210 and 211, the European GMP principles and the WHO guidelines: three statements of one idea, written for three different legal settings.

From hazard to standing control: how GMP rules are born
A failure with harm (contamination, mix-up, wrong strength)
-> Investigation finds the system gap, not only the error
-> A control is written into regulation or guidance
-> Inspectors verify the control in every later facility
-> The failure mode becomes examinable, auditable, rare

1.4 The European framework: Directive 91/356/EEC and the GMP principles

The syllabus names the European statement of GMP as the **principles and guidelines of good manufacturing practice laid down by Commission Directive 91/356/EEC** of 13 June 1991, for medicinal products for human use, and directs attention to **Articles 6 to 14**, the operative articles in which the principles themselves are stated. Read in order, the articles build the same factory as Part 211, from the top down: a **quality management** requirement that the manufacturer operate a system of quality assurance incorporating GMP; **personnel** requirements (sufficient qualified staff, an organisational chart, training, hygiene); **premises and equipment** fit for their intended use and maintained to minimise contamination and error; **documentation** that is clear, controlled and retained; **production** conducted to clear instructions with in-process controls and validation; **quality control** independent of production, with sampling and testing to specifications; rules for work contracted out (**contract manufacture and analysis**) so responsibility cannot be outsourced away; a system for **complaints and product recall**; and **self inspection**, the manufacturer's duty to audit itself against the principles and correct what it finds. The directive has since been recast (Directive 2003/94/EC, and today the principles live for daily use in **EudraLex Volume 4**, the EU GMP Guide, whose Part I chapters mirror these article subjects), but the syllabus's choice of the 1991 text is deliberate: it is the cleanest short statement of the principles, and examiners ask for it by its article structure. A student should know both addresses: 91/356/EEC Articles 6 to 14 for the examination, EudraLex Volume 4 for the workplace.

1.5 The WHO framework: cGMP guidelines for the world

The **World Health Organization** writes GMP for the countries that have no large inspectorate of their own and for the products that move between all countries. The WHO GMP main principles for pharmaceutical products, published in the WHO Technical Report Series and revised over the years, state the same requirements in the same order (quality management, sanitation and hygiene, qualification and validation, complaints, recalls, contract production, self inspection, personnel, premises, equipment, materials, documentation, production and quality control), and they are supplemented by specific guidelines, for example for sterile products, biological products and water systems. WHO GMP matters commercially out of proportion to its length, for two reasons. First, the **WHO Certification Scheme** on the quality of pharmaceutical products moving in international commerce, under which a member state issues a Certificate of Pharmaceutical Product (CPP) for an exported medicine, rests on the exporting country's GMP being WHO aligned, so WHO GMP is the passport system of the world drug trade. Second, **WHO prequalification** of medicines, vaccines and diagnostics for UN agency procurement requires WHO GMP compliance at the manufacturing site. For India, whose industry exports to every regulatory tier, WHO GMP and the national Schedule M (Unit 5) are the twin foundations beneath the stricter US and EU systems.

1.6 GAMP 5: good practice for computerized systems in manufacturing

A modern plant runs on software: programmable logic controllers, manufacturing execution systems, laboratory information systems, electronic batch records. The syllabus therefore pairs the GMP texts with **GAMP 5**, the ISPE (International Society for Pharmaceutical Engineering) guide, "A Risk-Based Approach to Compliant GxP Computerized Systems". GAMP 5 is a guide, not a regulation, but regulators accept its

method, and it supplies the working vocabulary of the whole subject's automation side: the **life cycle** of a computerized system from concept through operation to retirement; **software categories** (Category 1 infrastructure software, Category 3 non-configured products, Category 4 configured products, Category 5 custom applications) that scale the validation effort to the risk; specification and verification matched in a V shape (Unit 5 returns to this); and the principle that effort should follow **patient safety, product quality and data integrity** risk rather than paper volume. GAMP 5 is the bridge between this unit and Unit 3: GALP and Part 11 govern laboratory automation in the same spirit.

1.7 Medical devices and IVDs: the GHTF guidance documents

Medicines are not the only regulated products in this subject. For **medical devices** and **in vitro diagnostic medical devices (IVDs)**, the harmonisation work was done by the **Global Harmonization Task Force (GHTF)**, founded in 1992 by regulators and industry of the founding economies, and succeeded in 2011 by the **International Medical Device Regulators Forum (IMDRF)**, which maintains and extends the GHTF document library. The GHTF wrote in **five study groups**, and their division of labour is the examinable map: **SG1**, regulatory systems, definitions, essential principles of safety and performance, and the summary technical documentation (STED); **SG2**, post-market surveillance and vigilance reporting; **SG3**, quality systems for device manufacturers (the direct ancestor of the device QMS requirements taught in Unit 5 through ISO 13485); **SG4**, auditing of device quality systems; **SG5**, clinical safety and performance. Device GMP thus differs from drug GMP in accent rather than in kind: design control and risk management move to the centre, because a device's quality is largely fixed at the design desk, and the quality system standard is ISO 13485 rather than a CFR part. MRA203T takes devices up in full; this unit's duty is to place the GHTF documents correctly, as the device world's GMP library.

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