

Unit 4: Inspections

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4.1 Inspection distinguished from audit

Units 3 and 4 are a deliberate pair, and the distinction between them opens this unit. An **audit** is performed by or for the organisation itself, or by a body it engages, and its force is contractual or systemic: findings oblige because the quality system says so. An **inspection** is performed by a **regulatory authority exercising legal power**: the inspector may enter, examine and copy records, take samples and require answers, by statute; the site may not decline, reschedule for convenience or limit the scope; and the outcomes are legal acts, licences granted, suspended or refused, certificates issued or withheld, enforcement under Unit 5. The technique on the floor looks similar, evidence, interviews, trails, because inspectors and auditors share a profession; the gravity differs entirely. Everything in this unit, the species of inspection, the inspectorate itself, its reports and certificates, and the root cause and CAPA machinery by which findings are answered, follows from that one distinction: this is the state reading the documents of Units 1 and 2.

4.2 Pre-approval inspections

The **pre-approval inspection (PAI)** is the inspection an authority performs before approving a marketing application, to verify that the facilities named in the dossier can actually do what the dossier says. In the FDA programme, which states the model most explicitly, a PAI pursues three objectives: **readiness for commercial manufacturing** (the facility, equipment, systems and people can make the product at commercial scale, with validation complete or credibly planned); **conformance to the application** (what will be done matches what was filed, in formulation, process, controls and site); and **data integrity** (the development, bioequivalence and stability data in the application are authentic, audited against raw records on the spot, the legacy of the generic drug scandals that created the programme). The European system reaches the same point by pre authorisation inspections ordered where the assessment raises questions, conducted by the supervisory authority of the member state where the site sits. A failed PAI does not merely embarrass: the application cannot be approved until the deficiencies are resolved, so the PAI converts the dossier's every claim into a hostage, which is why Unit 2's compilation discipline and Unit 3's self inspection are, in the long run, PAI preparation.

4.3 Inspection of pharmaceutical manufacturers

The routine **inspection of pharmaceutical manufacturers** is the surveillance engine of GMP: periodic, risk based in frequency, and systems in structure. The FDA's systems model, the template taught worldwide, inspects **six systems**: the **quality system** itself, then **facilities and equipment, materials, production, packaging and labelling**, and the **laboratory control system**, with the quality system always in scope and the others sampled by risk and rotation, so that over a cycle the whole factory is examined through the systems that govern it. The conduct follows the profession's rhythm from Unit 3 under legal colour: credentials presented, the site walked (the **walkthrough**, warehouse to production to laboratory to utilities, following the material and product flow), records requested and reviewed, personnel interviewed at their workplaces, and objectionable conditions recorded as they are found and discussed daily rather than sprung at the end. The inspector's working documents are the site's own: the site master file for orientation, batch records and validation files for evidence, and the self inspection reports of Unit 3, whose quality the

inspector is silently grading throughout: a site whose internal audits found nothing, in a factory with visible problems, has failed twice.

4.4 Inspection of drug distribution channels

GMP's writ runs past the factory gate, and this unit's second inspection territory is the **distribution channel**: wholesalers, distributors, depots, transport operations and the pharmacies and institutions at the chain's end. These inspections test good distribution practice (MRA101T Unit 4) at each holder: licensing and authorisation of the premises and its responsible person, storage conditions and their monitoring records, the integrity of the cold chain in transit, segregation of returned, recalled and suspect stock, the documentation of receipts and supplies that makes traceability real, and the handling of suspected falsified medicines. The regulatory logic is the distribution record of Unit 1 read backwards: the manufacturer can account for every batch only if every link in the channel kept the records this inspection verifies, so distribution inspections are what make recalls possible and falsification difficult across a whole market rather than inside one factory.

4.5 Quality systems for national GMP inspectorates

Who inspects the inspectors? The syllabus's answer is examinable and elegant: a national GMP inspectorate must itself operate a **quality system**. The requirements, set out in WHO guidance on quality systems requirements for national good manufacturing practice inspectorates and embodied in the practice of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), whose membership conditions audit the inspectorate itself, include: a legal basis and defined scope for inspections; documented procedures for planning, conducting, reporting and following up inspections; trained, qualified and conflict free inspectors, with continuing training; consistent classification of deficiencies and decisions, so two inspectors reach the same conclusion on the same facts; a system for handling appeals and complaints about inspections; and records sufficient for the inspectorate's own work to be audited, by peers in the PIC/S joint audit programme or in WHO's assessment of regulatory systems. Mutual recognition between countries, the acceptance of each other's GMP certificates that oils world trade in medicines, is extended only to inspectorates whose quality systems have themselves passed examination: the inspectorate quality system is the trust mechanism of the whole international structure.

4.6 The inspection report and the model certificate of GMP

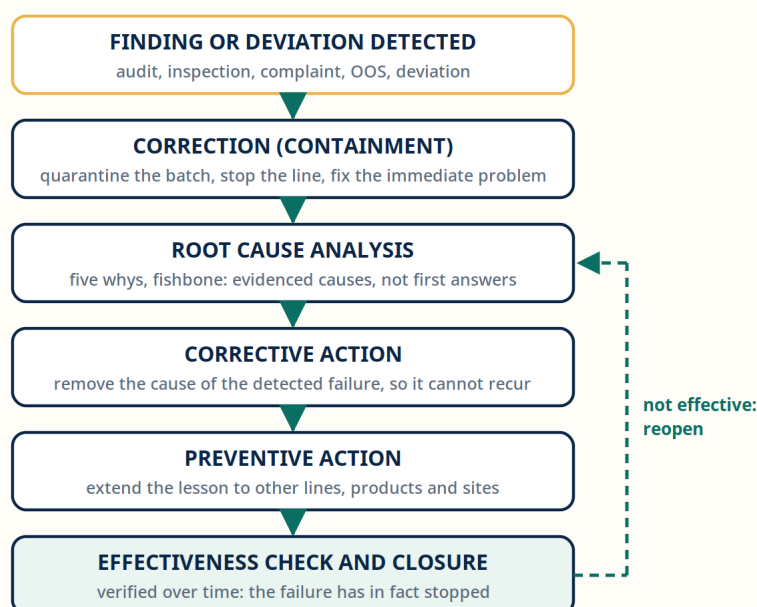
An inspection crystallises into documents, and two are named in the syllabus. The **inspection report** is the formal record: the site and scope inspected, the systems and areas covered, the evidence examined, the deficiencies found, classified (in the European usage, **critical, major and other**), the site's responses and commitments, and the inspector's conclusion on the site's GMP compliance status. It is written to be read by strangers, other authorities under information exchange, licensing boards, courts, which is why the report, like the audit report of Unit 3, is written in criterion, evidence and conclusion form. The **model certificate of good manufacturing practices** is the certificate form of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce: a standard certificate by which the competent authority of the exporting country attests that a manufacturing facility is in compliance with GMP and subject to its inspection regime, issued per site and product category and relied upon by importing authorities. Together, report and certificate are the exportable form of an inspection: the report carries the detail for those entitled to it, the certificate carries the conclusion for the world.

4.7 Root cause analysis

Every serious finding, deviation and complaint poses the same question: **why did this happen**, and **root cause analysis (RCA)** is the disciplined refusal to accept the first answer. Its logic is layered: the

immediate cause (the balance was misread), the **contributing causes** (the display was ambiguous, the shift was rushed), and the **root cause** (the system allowed an ambiguous critical display and an unchecked transcription to reach a batch record), and only action at the root layer prevents recurrence, which is the entire point. The classical tools are few and examinable: the **five whys**, iterative questioning down the causal chain; the **Ishikawa (fishbone) diagram**, which organises candidate causes under heads such as manpower, machinery, materials, methods, measurement and milieu; and, for complex failures, fault tree and failure mode analyses borrowed from risk management. RCA has professional failure modes of its own, which the draft names because examiners do: stopping at **human error** (a description, not a cause; the question is why the system made that error likely and undetectable), and choosing the cause that is cheapest to fix rather than the one the evidence supports. The output of a good RCA is a small set of evidenced causes, each owned, which is exactly the input the next section requires.

From Finding to CAPA



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Figure: The CAPA flow of sections 4.7 and 4.8: containment first, then root cause, then actions aimed at the cause, then proof that they worked.

4.8 Corrective and preventive action: CAPA

CAPA is the system that converts findings into fixed systems, and its terms are defined with legal precision in the quality literature (expressly in the device rule, 21 CFR 820.100, and in ICH Q10 for pharmaceuticals). A **correction** is the immediate fix of the detected problem (the batch is quarantined, the label stock is destroyed). A **corrective action** eliminates the cause of a detected nonconformity so it does not recur (the display is replaced, transcription is removed by direct capture, the SOP and training are revised). A **preventive action** eliminates the cause of a **potential** nonconformity so it does not occur, classically by extending the lesson sideways to other lines, products and sites where the same cause is latent. A working CAPA system triages its inputs (deviations, audit and inspection findings, complaints, OOS results, recalls), assigns each an owner and a risk scaled deadline, tracks root cause and actions to **verified effectiveness** (the check, after a defined period or number of batches, that the failure has in fact stopped), and escalates what ages. CAPA is where the units of this subject meet: it answers the audit of Unit 3, defends the inspection of this unit, and supplies the credibility on which the post approval commitments of Unit 5 are accepted. An inspector's shortest summary of a quality system is often simply this: show me your CAPA file, and I will tell you your culture.

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