GMP Inspection Preparation Checklist

Background: This checklist provides program managers with an understanding of what to expect during a Good Manufacturing Practice (GMP) inspection of a pharmaceutical manufacturing facility and what may be required of you during this process. Typically, GMP inspections are coordinated by the product license holder's Quality Assurance (QA) department. As a program manager (PM), you may be requested to support the QA department with the inspection and act as a liaison between the QA department and the manufacturer.

GMP is a defined standard for pharmaceutical manufacturers to ensure that the production of pharmaceuticals is conducted in a controlled manner and that the product meets defined specifications.[1] GMP inspections are carried out by regulatory bodies to ensure compliance with country-specific GMP guidelines, Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidelines on GMP, and/or the World Health Organization (WHO) Guide to GMP.

- ☐ The QA team (reporting to the PM) will request the inspection agenda from the regulatory authority inspector to determine the scope of the inspection, as well as whether the inspection will be remote or on-site. The PM will share the inspection agenda and details with the manufacturer. Inspections are typically carried out every two to three years depending on the risk associated with the products manufactured at the relevant site.

  NOTE: *Inspectors may also make unannounced visits to conduct GMP inspections. There will be no notice of such visits in advance, but the inspector will share the objective of the inspection upon arrival.*

- ☐ The QA team will retrieve the regulatory authority's GMP guidelines and/or standards and share them with the PM, who will pass them along to the manufacturer.

- ☐ The manufacturer will review the shared GMP guidelines and the inspection agenda and conduct an internal assessment of facility records and sites and communicate any identified gaps or challenges with the PM.

- ☐ The manufacturer will prepare an inspection plan, including information on the standards, policies, systems, and facility areas where the inspection will be conducted and share it with involved staff to ensure that they are prepared to answer questions from the inspector. The manufacturer will brief the PM about the inspection plan and their readiness for the inspection.

- ☐ The PM will work with the QA team to support the inspectors with their travel plans (if requested) by recommending hotels, airports, etc. closest to the manufacturing site.

- ☐ The PM and QA team will ensure that applicable inspection fees are paid to the regulatory body prior to the inspection.

[1] https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines/production

- [ ] The QA team (working with the PM) will determine whether the manufacturer's site documentation is up to date, properly executed, and stored in a controlled location. The following list is an example of the standard site documentation that may be requested by the inspector:
  - Quality Manual
  - Site Master File (SMF)
  - Master documents and Specifications
  - Annual Product Quality Review Contracts/Master Service Agreements
  - Staff training records and qualifications
  - Signature logs, including records of all staff names and accompanying signatures
  - Equipment calibration and servicing records
  - Standard Operating Procedures (SOPs)
  - Previous inspection reports
  - Validation Master Plan, Protocols and Reports
  - Complaints procedures and Adverse Event (AE) files
- [ ] The QA team (working with the PM) will determine whether the manufacturing facility is ready for inspection. The following are examples of the areas of the facility that may be inspected:
  - Receiving area
  - Water systems
  - Warehouse
  - Sampling area
  - Dispensary areas
  - Production areas
  - Quality Control laboratories
  - HAVAC systems
- [ ] After the inspection, there will be an inspection closeout meeting. The manufacturer may be able to address and justify any identified non-conformities to be excluded from the inspection report.
- [ ] The manufacturer will request closeout details from the inspector, including when to expect the inspection report and what the timeline is for addressing the inspection non-conformities with a corrective and preventive action plan. The manufacturer will share this information with the QA team.
- [ ] The QA team (working with the PM) will work with the manufacturer to address and respond to any findings made by the Inspector in the report.
- [ ] If the GMP inspection is taking place as part of the product registration process, the PM can expect that registration timelines may be affected, as registration approval may not be issued until the manufacturing site is deemed to be GMP compliant. Some regulatory bodies include the GMP inspection in their registration timeline estimates, while others assess the need for an inspection during application review.
- [ ] If the GMP inspection is a routine inspection for a product that has already attained marketing authorization approval and if the manufacturing site is found to be non-GMP compliant, marketing authorization of the products manufactured at the site may be suspended pending resolution of GMP inspection findings.