MLC SERVICES · 03

GMP Audit Services

GMP audit services for pharmaceutical facilities, quality systems and supplier operations.

ML Consultancy conducts GMP audits for pharmaceutical manufacturers. Good Manufacturing Practice Audits (GMP audits) are conducted to ensure that products are made in accordance with quality standards and the best industry practices. It is to identify if the pharma company has full control over your processes, facility, and quality management system (QMS).

MLConsultants has a team of highly experienced GMP Auditors with comprehensive experience in conducting GMP audit services across the globe. Our GMP auditors are highly qualified and have undertaken numerous audits of API, Intermediates, Raw Material, Warehouse Facilities, Packaging Material Facilities, R&D/F&D Laboratories, and Finished dosage plants.

As regulations continue to tighten, authorities are demanding increased vigilance of the pharmaceutical supply chain and emphasizing the need for on-site audits. Manufacturers are required to conduct GMP audits of suppliers or have them conducted on their behalf by appropriately qualified and trained auditors. GMP audit identifies the risk factors that challenge the organizational critical area and further considers their significance.

MLConsultants provides a wide range of audit services to clients as per their specific needs. Having conducted numerous audits, MLConsultants now has a big GMP Audit Report Library with Long Validity of GMP Audit Reports.

BELOW ARE THE TYPES OF AUDIT OFFERED

INDEPENDENT SUPPLIER AUDIT: (GMP SYSTEM AND FACILITY AUDIT)

To evaluate the system and manufacturing facility in compliance to the regulatory expectation and quality standards. To ensure the capability of the facility to manufacture quality medicine. To determine the effectiveness of the Quality system implemented and adherence to the specified quality objectives.

Audit scope includes (Not limited to):

- Organizations
- Equipment control
- Personal
- Quality policy and Quality Management Systems
- Environment control
- Safety and security
- Material/Component Control
- Operational Control
- Finished Product control
- Good Documentation practice
- Good manufacturing practice
- Inspection history
- Computer system validation
- Data Integrity approach
- Business continuity plan

REMOTE AUDIT / VIRTUAL AUDIT

At MLConsultants, we have been conducting Remote GMP Audits/ Virtual Audits of suppliers for our clients. In the global pandemic situation, there have been many restrictions on travelling and this makes the on-site audit difficult. With the acceptance of Remote Audit by various regulatory agencies, many of our clients have suggested performing remote audit / Virtual audit. MLConsultants has well defined SOPs and systems to perform Remote Audits. So far, we have completed more than eighty Remote Audits on behalf of our clients.

GAP AUDIT

MLConsultants has been conducting GMP GAP audits for numerous Pharmaceutical Companies to assess their level of compliance with requirements of Desired Regulatory Agencies.

GMP GAP Audit is conducted to identify any GAP in the system and procedure to meet specific regulatory requirements and to mitigate the GAP with reasonable and logical solutions. A successful gap analysis identifies necessary changes in process, organization, and resources, and maps out a systematic approach with corrective and preventive actions for implementing solutions that effectively minimize risks to the organization.

REGULATORY COMPLIANCE AUDIT

A compliance audit is done for a comprehensive review of an organization's adherence to specific regulatory guidelines & specifications mentioned and to evaluate the strength and thoroughness of compliance preparedness. This audit also focuses on the QMS system and any loopholes to work on. Improves the Quality system and in turn compliance to regulatory.

VENDOR QUALIFICATION/ASSESSMENT AUDIT

To evaluate and qualify the vendors for procurement of the critical supplies like API, excipients, packaging material, contract manufacturer, materials & Goods etc. This vendor qualification audit ensures the vendor reliability and quality services/products to avoid any regularity concerns.

Audit scope includes (Not limited to):

- Vendor qualification/requalification system
- Vendor Quality management system
- Capabilities to deliver consistent quality
- Supply chain management
- Operation control
- Regulatory adherence
- Business continuity plan and Quality policy

PRE-INSPECTION AUDIT

This Audit is mainly conducted before any planned or announced regulatory inspection...

FAQ

Q. What is a GMP audit?

An audit that checks products are made to quality standards and good manufacturing practice, and that a pharmaceutical company has full control over its processes, facility and quality management system.

Q. What types of GMP audit does MLC offer?

Independent supplier audits (GMP system and facility), remote or virtual audits, and GAP audits.

Q. What does a supplier audit cover?

Areas including the quality management system, equipment and environment control, materials, operations, finished product control, documentation practice, computer system validation, data integrity and business continuity.

Q. Can GMP audits be done remotely?

Yes. MLC has defined SOPs and systems for remote audits, which regulators have accepted, and has completed more than eighty remote audits for clients.

Q. Which facilities do MLC's auditors cover?

API and intermediates, raw materials, warehouses, packaging material facilities, R&D/F&D laboratories and finished dosage plants.

Useful details to share when you enquire

- Facility type and products
- Proposed audit criteria and scope
- Existing quality records and previous observations

TALK TO MLC

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