



THE IMPORTANCE OF GMP AUDITING SERVICES

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Good Manufacturing Practice (GMP) audits work to ensure products are made in accordance with appropriate quality standards and current industry best practices, and that they comply with applicable health authority regulatory requirements and guidance documents.

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.

Not only does compliance with GMP help manufacturers meet drug product requirements, but the framework also provides management with information on how effectively the quality of their processes and products are being controlled.



WHAT IS INVOLVED IN A GMP AUDIT?

The length of an on-site GMP audit depends on the complexity of the manufacturing process, company size and their history of compliance, but typically takes between two to three days for a simple audit or up to ten days for a complex site.

Example of audits include:

- > Pre-inspection audits of the site including a facility walk-through observation of pharmaceutical quality systems, sanitation, personnel, production controls, packaging and labelling
- > Pre-selection supplier/contract manufacturing organization (CMO) audits on behalf of the company
- > Routine review audits of existing CMOs
- > Gap assessment audits to confirm adherence to GMP standards
- > Supplier audits including API, excipient and packing component audits
- > Contract testing laboratory audits

Upon completion of the audit, manufacturers receive a report and a discussion of its findings, including recommendations on any improvements that may be required.

HOW CAN NSF INTERNATIONAL HELP?

Audits by third-party experienced auditors can help pharmaceutical firms to identify possible gaps in GMP compliance. This audit could be of the company's own facility, perhaps as part of an internal audit program, or of a supplier to the company.



NSF International can provide this support. Established in 1944, NSF is well-equipped to assist manufacturers with GMP inspection readiness thanks to a team of former regulatory agency inspectors and highly experienced auditing experts.

NSF GMP audits and subsequent remediation plans are trusted by pharmaceutical and biotech companies and regulatory agencies around the world.

If you are going to outsource your auditing, here are some things to consider from NSF's Executive Director Lynne Byers: "The EMA Quality of Medicines Question and Answers provides detailed guidance on steps to take when outsourcing audits. Specifically, they answer the question, 'Is an audit performed by a third party acceptable?' It is acceptable to outsource audits but there must be appropriate controls in place.

"It is important there is a contract and quality technical agreement in place (reference EudraLex Volume 4, Part 1, Chapter 7) and that the contract giver has assessed the contract acceptor's capability to perform the service.

"Both parties must also ensure that there are no conflicts of interest (e.g. a commercial relationship between the organization performing the audit and the organization being audited) or a personal conflict of interest of the auditor, for example, being employed by the auditee within the last three years or having a financial interest in the auditee."

ABOUT LYNNE BYERS



Lynne Byers has gained more than 35 years' of extensive pharmaceutical manufacturing management and QA experience working for three major international pharmaceutical manufacturers, culminating in the role of Global Head (VP) of External Supply Operations QA for Novartis in Switzerland. In addition, she worked as Head of Inspectorate and Licensing for the MHRA from 2004-2006. She joined NSF in 2017.

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