FACT SHEET

GOOD MANUFACTURING PRACTICES (GMP) FOR PHARMACEUTICALS

Navigate the complex regulatory landscape where pharmaceutical products face stringent quality and compliance requirements across global markets, with health authorities enforcing comprehensive GMP regulations to ensure product safety, efficacy, and quality throughout the manufacturing process.

Succeeding in this challenging environment requires expert knowledge of FDA's 21 CFR Parts 210/211, EU GMP guidelines, Health Canada regulations, and ICH standards to ensure regulatory approval, secure patient safety, and strengthen your pharmaceutical reputation through demonstrated quality excellence and consistent GMP compliance.

Intertek's Good Manufacturing Practice (GMP) audits for Pharmaceuticals ensures that products are manufactured and controlled to meet rigorous quality standards while complying with regulatory requirements set by health authorities worldwide. Compliance with GMP helps manufacturers and distributors meet national and international regulatory requirements, ensuring patient safety and product integrity.

Intertek's audit solutions streamline the compliance process, reduce audit costs, and minimize the time burden on both manufacturers and suppliers. Trust Intertek's specialized GMP audit services to verify compliance and strengthen your quality systems.

PARTNER WITH INTERTEK FOR GMP EXCELLENCE EVERY STEP OF THE WAY

From supply chain to finished product and patient delivery, we're your trusted solution for quality and compliance — designed to stand out and deliver results.

INTERTEK'S GMP AUDITING AND CERTIFICATION SERVICES FOR PHARMACEUTICALS

Our comprehensive pharmaceutical auditing services include:

Pharmaceuticals - OTC drugs (NSF-ANSI 455-4)

- Auditing scheme specifically designed for over the counter (OTC) pharmaceutical products.
- Industry-recognized standard focused on US market requirements for OTC drugs.
- Covers compliance with FDA regulations including 21 CFR 210/211 with emphasis on OTC-specific requirements.
- Accepted by major retailers seeking verified quality assurance for OTC pharmaceutical products.
- Helps manufacturers demonstrate compliance to retail partners and streamline supplier qualification.

Pharmaceutical GMP audits (US FDA 21 CFR Parts 210/211)

- Comprehensive audits to US FDA regulatory requirements for over the counter (OTC) pharmaceutical products, prescription drug products and active pharmaceutical ingredients.
- Applies to pharmaceutical manufacturing operations, contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs), packaging facilities, laboratory controls, pharmaceutical warehousing facilities and third-party logistics providers (3PLs).
- Helps manufacturers prepare for FDA inspections and maintain compliance.
- Internal Audit Partnership Services - Independent, objective assessment of your quality systems by Intertek experts, providing the unbiased evaluation regulators expect while allowing your team to focus on core operations.

Pharmaceutical EU GMP Compliance Audits (EudraLex Volume 4)

- Assessment to European Union GMP guidelines (EudraLex Volume 4).
- Evaluation of quality systems, production processes, and documentation practices.
- Preparation for regulatory inspections by European health authorities.
- Support for maintaining Certificates of GMP Compliance.

Pharmaceutical GMP Compliance Audits for Health Canada (GUI-0001)

- Audit of pharmaceutical operations for compliance with Health Canada GMP regulations.
- Comprehensive assessment against Division 2 of the Food and Drug Regulations.
- Applies to manufacturing, packaging, labeling, distribution, and quality control.
- Ensures compliance with Canadian regulatory expectations for domestic and imported products.

ICH Q7/Q9/Q10 Quality Systems and GMP Audits

- Evaluation of pharmaceutical quality systems against International Council of Harmonization Guidelines.
- Verification of GMP compliance for active pharmaceutical ingredients (ICH Q7).
- Assessment of the quality risk management processes (ICH Q9).
- Assessment of pharmaceutical quality systems (ICH Q10).

GOOD MANUFACTURING PRACTICES (GMP)
FOR PHARMACEUTICALS

Custom Audits for Pharmaceutical Manufacturers and Suppliers

- A flexible audit solution tailored to assess quality and compliance across pharmaceutical operations and supply chain.
- Customizable audit scope for pharmaceutical manufacturing facilities, supply chain partners covering contract manufacturers (CMOs & CDMOs), subcontractors, testing laboratories, and suppliers of registered starting materials, intermediates, excipients, third party logistics, warehousing partners and laboratories for release testing of finished product/starting materials, service providers (logistics partners, transporters, IT services, etc.).
- Support for global or national internal audit programs.
- Assessment of data integrity practices and adherence to 21 CFR Part 11 and Annex 11 for electronic records and computerized systems.
- Audit Material Development through collaborative development between Intertek and client, client-defined requirements or integration of multiple standards and regulations.
- Standards & Regulations Coverage:
  - FDA Regulations (21 CFR Parts 210/211, 11, 600-680 for biologics)
  - EU GMP Guidelines (EudraLex Volume 4)
  - Health Canada Regulations (GUI-0001)
  - ICH Guidelines (Q7, Q8, Q9, Q10)
  - The Pharmaceutical Inspection Co-operation Scheme - PIC/S GMP Standards
  - Active Pharmaceutical Ingredients Committee (APIC) Guidelines
  - IPEC Guidelines for Pharmaceutical Excipients
  - ISO 15378 (Pharmaceutical Packaging Materials)
  - Quality Management Systems (ISO 9001, ISO 13485)
- Audit Approach:
  - Comprehensive assessment against selected requirements.
  - Tailored checklist development.
  - Focus on client-specific quality and compliance priorities.
  - Evaluation of outsourced processes and supply chain controls.

Intertek's pharmaceutical audits supplement your internal resources with specialized expertise to drive continuous improvement across your organization. Our independent auditors bring extensive industry experience and objective evaluation to every process they assess, supported by advanced quality management methodologies that enhance both efficiency and effectiveness.

Additional Pharmaceutical Solutions:

We support pharmaceutical manufacturers in achieving and maintaining compliance with global standards across the product lifecycle:

Good Manufacturing Practice (GMP)
Comprehensive auditing and advisory services ensuring quality in production processes and facilities.

Good Distribution Practice (GDP)
Verification of proper storage, transportation, and distribution controls to maintain product integrity.

Good Laboratory Practice (GLP)
Assessment of laboratory operations for non-clinical safety studies and quality control testing.

Good Clinical Practice (GCP)
Evaluation of clinical trial processes to ensure standards compliance and data reliability.

Good Pharmacovigilance Practice (GVP)
Review of systems for monitoring and reporting adverse events and drug safety.

Mock Regulatory Inspections
Preparation for official health authority inspections through gap analysis and remediation planning.

Quality Management System (QMS) Development
Implementation and improvement of QMS for consistent compliance with pharmaceutical standards.

Training & Consultation
Tailored training programs and expert consultation on GMP best practices.

Data Integrity Assessments
Comprehensive evaluation of systems and processes to ensure reliable, accurate data throughout the product lifecycle.

Validation Services
Support for process validation, cleaning validation, computer system validation, and analytical method validation.

Pharmaceutical Supply Chain Auditing
Comprehensive evaluation of suppliers, contract manufacturers, distributors, and other partners to ensure end-to-end compliance and quality management.

GMP & CMC Pharmaceutical Laboratory Services
Comprehensive testing services supporting Chemistry, Manufacturing, and Controls (CMC) activities in compliance with GMP requirements.

Biopharmaceutical Development Support Services
Specialized solutions for biologics development, manufacturing scale-up, and regulatory submission preparation.

Pharmaceutical Testing and Analysis
Expert laboratory services verifying product safety, efficacy, and quality throughout your development cycle, from raw material testing to final product release.

FOR MORE INFORMATION

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