

Pharmaceutical GMP



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Intertek's global reach is our major strength linking suppliers in one part of the world with buyers in another. We independently audit factories and inspect goods in the countries of origin across the whole supply chain on behalf of clients and consumers located in the products' final market. In fact we can test the same product to a range of international standards if required.

Intertek has 576 offices offering inspection, auditing and certification services and 338 laboratories worldwide providing a wide range of standard and custom testing programmes.

Our resources are strategically placed, providing appropriate services in each country. These needs

are continuously reassessed, and we are constantly evaluating manufacturing and market trends to best serve our customers.

Intertek is in the ideal position to help our customers and clients meet the Quality, Safety and Ethical standards irrespective of their, or their customer's location in

the world. Our mix of testing, inspection, auditing and consultancy services is unparalleled in the consumer goods arena making Intertek the supplier of choice for many of the world's leading brands.

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The Pharmaceutical Industry is one of the most highly regulated industries in the world. Pharmaceutical manufacture is complex and practices vary from manufacturer to manufacturer and yet, such practices shall remain within the principles and guidelines of Good Manufacturing Practice. Good Manufacturing Practice is the Quality Assurance that ensures products are consistently produced and controlled to the quality standards appropriate for their intended use and conform to the regulatory requirements stipulated by health authorities.

Intertek, a global company, comprises a team of interdisciplinary experts in science and technology, specialising from fundamental science to cutting-edge technology.

Intertek is a recognised leader in third-party conformity assessment on industrial processes, good manufacturing practice, and total quality management.

With an in-depth knowledge and industrial experience in the Clean Concept and the code of GMP, together with an extensive international network of experts in the pharmaceutical industry, Intertek is able to identify and define your needs in

conformance to GMP guidelines, be they compliance or validation requirements.

Intertek is your partner in quality assurance from design phase to performance qualification. Intertek will work closely with you, either early in the project timeline or interpose at any point at your request, to provide the most cost effective measures in attaining pharmaceutical GMP certification and a competitive edge in the market.

Intertek is known for its unbiased integrity, its technical expertise and professionalism, and its 100% customer satisfaction service.

Conformity Assessment - An Integral or a Selected Approach

Conformity Assessment Programs tailor-made to suit your company needs, either an integral system, or a specific target program.

Standards:

European GMP - Good Manufacturing Practice EEC part I & part II

GMP: Good Manufacturing Practice U.S. FDA, U.K. MCA, WHO

GLP: Good Laboratory Practice

ISO 22716: Cosmetic - GMP - Guidelines on Good Manufacturing Practices

CE Mark

European Standards for Medical Devices: ISO 13485, ISO 14971 - Quality management systems - requirements for regulatory purposes.

ISO 9001

ISO 15378: Primary packaging materials for medicinal products.

IPEC - Good Manufacturing Practices Guide for Pharmaceutical Excipients

[Audit and Action Plans to Evaluate and Safeguard Compliance](#)

Depending on its quality system and industry requirements, each type of business adopts its unique quality standards and practices. Whilst the purpose of all audits are the same, the elements and steps involved in the audit process may differ depending on the type of audit required and its applied regulation standards. Intertek, with over twenty years of experience in quality management and compliance services spanning over a wide spectrum of industries, can design audit and action plans to accommodate your needs, be they EC standards, FDA regulations, or WHO concerns.

In the audit process, Intertek "photographs" the company's existing quality system, and superimposes it on the reference system. This allows an exact

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assessment on the company's conformity performance.

Intertek then recommends a plan of action which allows the company to achieve the quality assurance required. An action plan may include corrective actions on:

- documentation & record control
- manufacturing process and equipment
- training
- validation and qualification

Working with the company, Intertek takes an active role to ensure corrective actions are instituted and implemented. As a result, specific non-conformity items will be corrected, the cause of non-conformity will be rooted out, and any unforeseen non-conformity items will be identified and rectified, leading to full compliance.

Pharmaceutical and
Biotechnology Industries

Research and Development
Laboratories

Medical Devices

Electronic and Optical Components

In the sectors of: Hospital, Fine Chemicals, Cosmetics, Perfumes, Sanitary Products, Central Kitchen, Catering Service, Restaurants, Plastics and Packaging Industries.

Education & Training

Keeping up with new standards

To maintain the lead in business and ensure product quality and safety, company personnel must continually enhance their skills and improve their performance by keeping up with updated quality references and their applications.

This requires personnel training, which Intertek provides. Intertek offers an extensive range of training courses and they include: on-site training, e-learning, inter-company training, competence and knowledge evaluation and training development programs.

Inter-company training allows personnel to absorb current information more easily, to compare his/her experience with others from different sectors of the business and to take stock of current regulations and practices.

Intertek e-learning offers GMP training via the internet, allowing personnel to learn 24 hours a day, without constraints, while developing autonomy and confidence. Intertek's e-learning offers more flexibility in training schedules, better cost control, and the competitive industry advantage you seek.

For on-site training, the emphasis is geared towards personalised programs tailored to the company's specific training objectives, and working with the confines of the company.

Intertek offers personalised instructions and can design training development programs and co-ordinate courses that satisfy your needs and optimise output and efficiency.

Available in: In-House, Training, All Dosage Forms, Pharmaceuticals, Biotechnology, Medical Devices, Cosmetics, Q.C. Laboratory, Buck Line Chemicals, GMP Management, Total Quality Management, Warehousing, Packaging.

Validation Equipment and Processes

A company that makes medications today must be able to prove that it does so with absolute reliability, under optimal secure conditions, and with extreme uniformity to allow for exact reproduction. Therefore, all manufacturing equipment and processes must be qualified and validated to insure performance.

With its extensive knowledge in various pharmaceutical manufacturing processes, automated computer control systems, laboratory & information systems, and qualification, validation & audit programs, Intertek is qualified to assist clients assess and define their compliance and validation requirements, from individual operating systems to entire facility, and provides the necessary resources to achieve these objectives. Intertek qualification and validation services include:

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- Design and Review of Validation Master Plan facility and processes
 - facility and processes
 - material and product flows
 - process and system specifications. GMP policy
 - planning and follow up

Writing and Review of Validation Policies, Guidelines and SOP from Design Qualification to Performance Qualification steps

- System Installation Qualification, Operation Qualification, and Performance Qualification on
 - HVAC and Cleanrooms
 - Laminar Flow Hoods
 - Safety Cabinets
 - Sterilisation Systems
 - Water System
 - Sanitation
 - Pure Gases Line
 - Freeze Dryers
 - Aseptic Filling Lines
 - Production Equipment (dry, liquid, pasty form)

Equipment Testing and Inspection

Qualifying equipment and installation - Maintenance programs

Pioneer in testing and inspection for more than 25 years, Intertek performs on-site testings and inspections on equipment employing the most updated standards and regulations.

Specialised Intertek technicians conduct testings and inspections on equipment with calibrated instruments at industrial sites worldwide, and undergo constant training to remain up-to-date with new safety regulations, quality reference systems, and other appropriate new technologies.

Expertise and flexibility are the two essential attributes of the inspection and testing department, allowing Intertek to do on site testings and inspections when it suits the company, depending on its technical demands and reference systems.

Test report in accordance with international standards and regulations will include:

- Standards and monographs
- Testing and inspection protocol
- Specifications
- Raw data
- Calibration certificates
- Verification of compliance

Available for: Clean Room, Laminar flow work stations, Safety Cabinet, Insulators, Sterilization and Sanitation Equipment, Regulated Temperature Rooms, Freeze Dryers, Cold Tanks, Pure Water Systems, Pure Gas Lines, Washing and Particulate Removing.

Product Development & Testing

Your partner in R & D and quality assurance

Equipped with advanced and calibrated testing equipment, Intertek meets the stringent requirements demanded by the pharmaceutical industry on product development and testing. With controlled humidity and temperature facilities, Intertek conducts stability studies and testing programs that save you time and money.

- Solid Dosage Forms
 - uncoated tablets
 - coated tablets
 - buccal tablets
 - sublingual tablets
 - hard/soft gelatin capsules
- Disintegration
- Dissolution
- Drug Release
- Liquids/Parenterals
- Tablet Hardness
- Traditional Chinese Medicine
- Friability
- Microbiological
- Pharmaceutical Actives
- Chemical
- Classical Room-Temperature Storage Stability Studies
- Viscosity
- Accelerated Stability Studies
- pH

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