GxP Auditing, Quality Services, and Training

GxP Solutions

Your Partner for Compliance

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About Us

Overview

GxP Solutions, a well-regarded consulting firm, specializes in offering customized solutions to the pharmaceutical sector, ensuring that quality decisions are grounded in both empirical data and evidence.

Audits, spanning from the initial stages of development to commercial product phases and post-marketing surveillance.

About Us

Established in 2023, GxP Solutions is **a minority-owned business**, qualifying as a diverse supplier. Our team of consultants comprises university graduates and seasoned auditors, each boasting over 17 years of experience in Quality Assurance, Quality Control, Validation, and Auditing in GxP disciplines.

Our Experience

GxP Solutions has collaborated with and is the preferred Quality Assurance (QA) provider for a diverse array of organizations, encompassing small, medium, and large pharmaceutical and biotechnology companies. Our expertise is specifically tailored to the following audit types.

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Audit Types

GCP

- Investigator Site Audits, First-In-Man Studies, Full Service CRO, Study Management Providers, Clinical Study Monitoring. Investigational Device Exemptions (IDE), Premarket Approval (PMA) application, and Premarket Notification Submission (510 (k))

GCLP

- Clinical Laboratories Supporting Testing of Clinical Trial Samples, Methods to be employed, control of methods, Quality Audit procedures. Computer Systems, Data Collection and Records, Sample Handling including repeat analysis, equipment use and maintenance, format, control, and review of SOPs. Specialist Laboratories, Academic Laboratories

GVP

- External Service Provider Vendor Audits, Local Affiliate/ Operating Company Audits, Process and System Audits, Business Partner Audits. PV Systems and their quality Systems. PV System Master File, PV Inspections, PV Audits, PV Risk Management systems, PV Collection, management and submission of reports of suspected adverse reactions to medicinal products, periodic safety update report, post authorization safety studies.

GDP

- API and IMP, Storage/ Distribution Centers, Test Laboratories, Document/ Records, Contract Management Organizations

GLP

- Pre-Clinical Trials, Animal Testing Facilities, Pre-Clinical Laboratory Supporting Testing of Non Clinical Samples (Animal Welfare). To ensure that Quality Systems is concerned with the organizational process and conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, archived, and reported.

GMP

- Drug Substance / API, Excipients / Chemicals, Sterile, Non-Sterile, Dietary Supplement and OTC Drug Products in Various Finished Dosage Forms Including Oral Liquids, Tablets/Capsules, Aerosol, Nasal Sprays, Creams, Emulsions, Ointments, Parenteral prodcuts, etc.

CSV

- Software suppliers, electronic records, electronic signatures, IT service providers, GXP related systems. To ensure that the risk assessments of the computerized systems defined the extent of CSV deliverables required to address specific gaps. The CSV deliverables and project needed to be reviewed/audited by the QA. Ensured global alignment of CSV projects with the company objectives.

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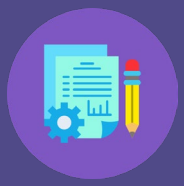
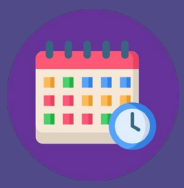
Our Audit Process



CONTRACT

NDA and MSAs prepared and sent for signing.



SCHEDULE

- Audit Dates Confirmed with Auditee.
- Auditor is assigned to audit based on Client Approval.
- Client & Auditor meeting is scheduled to discuss audit scope of work and share documents.

PREPERATION

GxP Solutions Auditor will prepare:

- Audit Plan
- Audit Conformation / Notification Letter
- Audit Agenda
- Pre-Audit Document / Data Request

All documents must be approved by Client before issuance to auditee.

AUDIT CONDUCT

Critical Findings will be escalated within 24 hrs. or immediately.

REPORT

GxP Solutions Peer Reviewed Draft report issued to Client for review & approval, within client timelines.

Audit report must be approved by Client before issuance to auditee.

FINALIZATION

Finalized report will be issued to client. Based on Client an Audit report or Observation Report may be issued. Also, an Audit Certificate may be generated.

CAPA FOLLOW-UP

GxP Solutions Auditor can receive, review, and approve audit response and follow-up on CAPAs until audit closure.

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Auditing Services

Through a deep understanding of our clients' requirements, GxP Solutions delivers cost-effective services that enhance quality and compliance.

With an eagle eye for detail, our team dives deep into the complex world of GxP regulations. We cover everything from GCP, GLP, to GMP and more. GxP Solutions can help you stay ahead of the curve, ensuring your products are safe and your practices sharp.

We are not just about quality auditing. We are about giving you peace of mind and a rock-solid foundation for your business to thrive.

Trust us to be your guide in the ever-evolving pharmaceutical

OUR PLEDGE

We promise to support you in your endeavor to provide safe and effective medicines for everyone, every day.

Our goal is to be your partner in compliance. By verifying steps in development, testing and manufacturing of medicines.

The GxP Solutions team is here to support you in making quality decisions regarding your products.

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GCP Audits

Our GCP Auditors shine a spotlight on the quality of your clinical trials. GxP Solutions auditing team, trust but verify every procedure, document, and computerized system to ensure everything meets regulatory requirements and the approved protocol. Furthermore, we look at how trials are planned, carried out, and reported to ensure of patient safety and data integrity.

GCP Audit Types

1. Site Audits

- Investigator site audits (e.g., Phase I, II & III)
- Non-Interventional Clinical Studies
- Investigator Site Files / Regulatory Binder

2. Vendor Audits

- Full Service CRO
- Site Management Organization (SMO)
- Safety Reporting
- Medical Writing
- Site Management
- Central / Clinical / Diagnostic Laboratory / IMP & Specimen Storage
- PK/PD/Bioanalytical Laboratory
- Interactive Response Technologies (IRTs)
  - Interactive Web Response Systems (IWRS)
  - Interactive Voice Response Systems (IVRS)
- Archiving / Documents Storage
- Translation Services

3. Document Audits

- Trial Master Files Audit
- Clinical Trial Report
- Common Technical Document
- Trial Master Files
- Protocol/Amendments
- Informed Consent
- Investigator's Brochure
- Case Report Forms
- Data Management Plan
- Data Protection/Privacy

GCP Audit Types

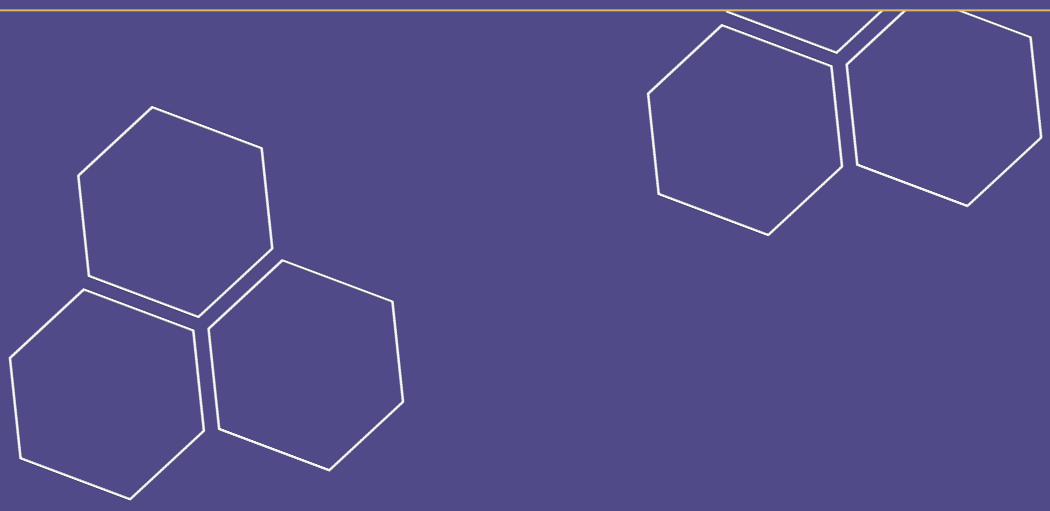
4. System and Process Audits

- Clinical Study Team Formation and Operational Planning
- Training
- Investigational Brochure Development
- Electronic submission audits
- Clinical operations and monitoring
- Data entry and data management
- Statistical Analysis Plan Development and Approval
- Study Blinding Unblinding
- Risk Management Planning and Development
- TMF Management
- Medical writing departments.
- QA In-Process Audits
  - Staff updated training records.
  - Appropriate protection of subject information
  - Consent process completion
  - Source document completion and review
  - CRF review to minimize correction of induced data entry errors.
  - Assurance of ongoing equipment calibration and maintenance
  - Proper handling of investigative products, Documentation addressing accountability, Dispensing,
  - Awareness of any protocol or study changes based on shared data with investigators.
  - Facilities and Equipment,
  - Documentation of laboratory inspections
  - Records of temperature logs and temperature excursions

GCP Audit Types

5. Inspection Readiness and Mock Inspection

- Investigator site audits (e.g., Phase I, II & III)
- Non-Interventional Clinical Studies
- Investigation of fraud and misconduct
- For Cause / Serious Breach Audits
- CAPA Management
- Risk Assessments
- Gap Analysis
- QMS Projects



Purpose of GCP Auditing

GCP auditing plays a crucial role in maintaining compliance with GCP guidelines. It involves systematic and independent examination of all processes related to the conduct of clinical trials to ensure they are in line with GCP requirements.

The primary purpose of GCP auditing is to identify areas of non-compliance and recommend corrective actions to improve the overall quality of clinical research.

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GCLP / GLP Audits

Our GCLP / GLP Audits will allow your lab's work glow with confidence! GxP Solutions forensic auditing zooms in on laboratory processes reviewing for data integrity and compliance to the protocol, assess study director oversight and controls in place to assure the study is correctly performed using best laboratory practices.

Our auditors will review all study documents, QA phase inspections, results, facilities, equipment, bioanalytical methods and more. To verify that the experiments and tests were done correctly.

With GxP Solutions, you're not just good; you're gold-standard great in the world of laboratory practices!

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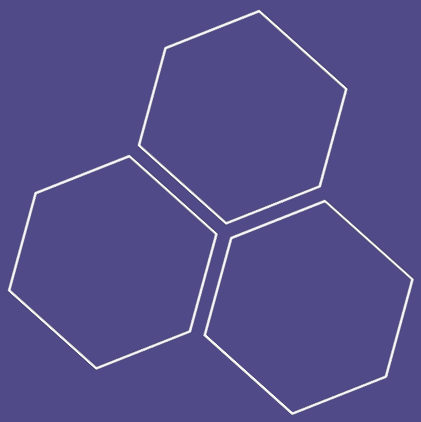
GCLP Audit Types

1. Clinical GCLP Auditing

- Bioanalysis Testing
- Flow Cytometry Testing
- qPCR Testing
- Vendor Audits
- Equipment / System Validation
- QMS System
- Archives
- Gap Analysis
- QMS Projects
- Inspection Readiness and Mock Inspection



GLP Audit Types

1. Non-Clinical (GLP) Auditing

- Laboratories
- Internal GLP Study
- Internal GLP Facility
- External GLP Study
- External GLP Facility
  - Developmental & Reproductive Toxicology Study
- Neurobehavior Study (Animal Model)
- Toxicology Study (Animal Model)
  - Vivarium / Animal Husbandry
- Bioanalysis Testing
  - Method Validation
  - Sample Analysis
  - Pharmacokinetics / Pharmacodynamics (PK/PD) Studies
  - Anti-Drug Antibody (ADA) Testing
  - Flow Cytometry Testing
  - qPCR Testing
  - Biomarker Testing
  - Immunology Testing
  - Immunohistochemistry Testing
  - Pathology / Histopathology Testing
- QMS System
- Archives
- Gap Analysis
- QMS Projects
- Inspection Readiness and Mock Inspection

Purpose of GCLP / GLP Auditing

Laboratories are a fundamental source of scientific evidence critical for clinical research and decision making in clinical diagnostics and patient care. Because of this, it is essential that laboratories meet quality and management standards so that the results they produce are unbiased, accurate and complete.

GVP Audits

Our GVP Auditors partner with our clients to watches over the safety of medicines after they are in use. Assessing Pharmacovigilance activities and practices from development through commercial operations. Confirming compliance with local and global Pharmacovigilance regulations and the Pharmaceutical Pharmacovigilance Agreement during each audit. Assuring regulatory compliance and patient safety is our priority.

Let's team up to make sure the medicines are not only effective but also safe for everyone!

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GVP Audit Types

1. Business License Partner
2. PV LOC/Affiliate Audits
3. Service Provider/Vendor Audits
    - Case processing
    - Literature search
    - Call center/Medical Information
    - Translation
    - Archiving
    - Clinical safety activities at CROs
    - Regulatory Intelligence Service
    - Market Research/PAP/PSP
    - Aggregate Reporting
    - Specialty Pharmacies
4. Animal Health PV
5. Clinical Drug Safety PV
6. PV Inspections (Include Agencies)
7. Medical Device Safety
8. PV Audits in Japan

GVP Audit Types

9. Gap Analysis
10. QMS Projects
11. Internal PV System and Process Audits
    - SOP Management
    - Training
    - Pharmacovigilance System Master File (PSMF)
    - Expanded Access Program
    - Adverse Event Reporting
    - Internal Aggregate Reporting
    - Signal Detection
    - PV Agreements
    - Investigator Initiated Studies (IIS)
    - Company core data sheet (CCDS) Development
    - Reference Safety Information Systems (package insert, SmPC, etc.)
    - REMS / Risk Management Plan (RMP)
    - DSUR/PBRER

Purpose of GVP Auditing

Monitoring the safety of medicines to ensure:

1. Protecting patients:
    - GVP audits ensure that pharmaceutical companies adhere to regulatory requirements, continually assess drug safety, and take appropriate measures to protect patients from harm.
2. Improving the safety and efficacy of pharmaceutical products:
    - GVP audits identify potential issues and improve the overall safety and efficacy of pharmaceutical products.

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GMP Audits

The GMPs help create systems that ensure proper design, monitoring, and control of manufacturing processes and facilities. When applied as designed, GMPs help prevent instances of contamination, mix-ups, deviations, failures, and errors.

Our GMP auditors will cover all aspects of production from the starting materials, Quality Management System (QMS), quality controls, premises, and equipment to the training and personal hygiene of staff.

Each GxP Solutions GMP audit will assess the manufacturing of our clients' products, by examining the people, processes, procedures, and premises used for manufacturing.

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GMP Audit Types

1. Third-Party Internal Audit
2. Gap Analysis
3. QMS Projects
4. Mock Inspection & Readiness
5. Finished Goods Manufacturing (Drugs, Devices & Biologics)
    - Contract Manufacturing Organization (CMO)
    - Contract Manufacturing Partner (CMP)
    - Contract Development Manufacturing Organization
    - Good Tissue Practices (GTP)Supplier /Vendor Auditing

5. Raw Material Suppliers
    - APIs – Active Pharmaceutical Ingredient
    - Excipients – Chemicals to stabilize and support the API within the drug.
    - Testing Materials - Biological Indicators, Endotoxin Spikes, Chemical / Sterilization Indicators

6. Contract Labs
    - Third-Party Laboratory Testing (accredited and non-accredited)
    - Contract Research Organizations (CROs)

6. IT Service Suppliers
    - IT Service Center / Data Repository
    - Software (GAMP5 Cat 3, 4, 5)

6. Facilities Services
    - Critical Systems/Maintenance (e.g., HVAC/HEPA, Pest Control)
    - Accredited Calibration
    - Non-Accredited Calibration

GMP Audit Types

7. Primary, Secondary and Tertiary Packaging Components
    - Primary Packaging Materials / Components (e.g., product contact surfaces - bottles, tips, caps, vials, stoppers, etc.)
    - Secondary Packaging Materials - Critical Print (e.g., labels, leaflets, package inserts, literature, brochures, etc... that contain instructions related to product)
    - Tertiary Packaging Components – Outer packaging (individual folding cartons, package inserts, shippers, etc.
    - Manufacturing Components - Sterile Filters
    - Clinical Primary / secondary packaging
    - Finished Drug Product Re-packager or Re-labeler.
    - Secondary Drug Product Co-Packager/Re-Labeler

8. Service Suppliers
    - Sterilizers for Components
    - Sterile Cleanroom Supplies
    - Packaging/Printed Materials
    - Labeling Artwork Services
    - Archive/Data and Document Management (DDM)
    - Biorepository
    - Patient Assistance Program
    - Sterilization Services (EtO, Gamma, E-Beam, X-Ray)
    - Destruction of Drugs
    - Finished Product Sample Management
    - Consultants
    - Translators
    - Warehouse and Depot services

Purpose of GMP Auditing

GMP audits protect the end user, by ensuring products are safe for use, meet customer expectations, and are produced consistently.

GMP auditing confirms that a manufacturers products are made and controlled in accordance with health authority approved manufacturing processes, quality standards, current industry best practices, and that manufacturers comply with applicable health authority regulatory requirements and guidance documents.

Good Manufacturing Practice

GDP AUDITS

With GxP Solutions performing your GDP Audits, be assured that our auditors verify quality and integrity of pharmaceutical products throughout their distribution process.

It involves verifying the receiving process, maintaining proper storage, transportation, warehouse mapping, computerized system validation, disaster recovery, security, and handling practices to prevent contamination, damage, or loss of efficacy of medicines.

Our team is here to make sure your hard work pays off, keeping everything cool, clean, and cared for.

GDP Audit Types

Good Distribution Practices (GDP) are performed for pre-clinical, clinical, and commercial goods.

1. Warehousing Operations
2. Depot/Distribution Centre
3. Clinical Packaging/Distribution
4. Systems/Internal Processes
5. Re-packaging/ Re-labelling
6. Kitting Operation
7. Just-in-Time Labeling operations
8. Computer System Validation (CSV)

Purpose of GDP Auditing

GDP auditing is crucial for maintaining the quality and safety of pharmaceutical products. It ensures that medicines reach patients in their intended form without any compromise on their effectiveness. Key reasons why GDP auditing is essential are:

- Compliance with regulatory requirements
- Safeguarding patient health
- Protection of company reputation

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CSV Auditing

Harness the power of our CSV Auditors to make your computerized systems GxP compliant. Our auditors will assure CSV audits are performed in the laboratories and in manufacturing operations to assure data integrity, security and regulatory compliance.

GxP Solution auditors will focus on research & development, laboratory lab notebook manual, batch record manufacturing process, analytical testing, stability process, and raw material storage & packaging.

CSV Audit Types

Good Distribution Practices (GDP) are performed for pre-clinical, clinical, and commercial goods.

1. FDA 21 CFR Part 11 / EU Annex 11 Compliance
2. Medical Devices
3. IT Change Control
4. Gap Analysis
5. QMS Projects
6. Inspection Readiness and Mock Inspection
7. Colocation/Data centers
8. Computer System Validation

Purpose of CSV Auditing

Just because the equipment or software boasts compliance, does not guarantee that the purchased items meet the regulatory requirements, nor would they meet your company's requirements for Computer System Validation (CSV).

Furthermore, the validation of computers helps to handle any unanticipated challenges and complications during processes, avoid loss of data, continuous improvement and updates increase the efficiency of the systems so that the quality is built in the entire system at all the steps.

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QA Services

Through a deep understanding of our clients' requirements, GxP Solutions delivers cost-effective services that enhance quality and compliance.

With an eagle eye for detail, our team dives deep into the complex world of GxP regulations. We cover everything from GCP, GLP, to GMP and more. GxP Solutions can help you stay ahead of the curve, ensuring your products are safe and your practices sharp.

We are not just about quality consulting. We are about giving you peace of mind and a rock-solid foundation for your business to thrive.

Trust us to be your guide in the ever-evolving pharmaceutical landscape.

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Risk Management & Audit Program Services

Using this GxP Solutions methodology, your organization can optimize your GxP audit program to reduce costs, focus on high-risk suppliers / Vendors during audit scheduling, identify high risk internal system and process audits, or focus on high value topics when conducting an audit.

- Risk Based Audit Scheduling
- Auditor Efficiency and Effectiveness

GAP Analysis

GxP Solutions can provide Gap analysis services for all GxP controlled documents (e.g., procedures, work instructions and forms) to assure these controlled documents reflect current regulatory requirements and currently in use process steps. Gap analysis should be performed for regulatory guidelines such as data integrity and risk management. As well as controlled documents relating to the following GxP disciplines (e.g., GCP, GLP, GCLP, GVP, GMP, GDP and CSV) to eliminate noncompliance.

GxP Solutions can perform the following activities:

- Harmonizing procedures across facilities
- Identifying regulatory gaps in current procedures
- Correct SOP content or write new procedures based on audit findings.
- Developed a CAPA plan to correct identified gaps.
- Implement and monitor action plan until completion.

Inspection Readiness & Support

GxP solutions can help your organization conduct mock inspections and third-party internal audits and more to keep your sites prepared.

- Conduct Mock Inspections.
- Conduct Third-Party Internal audits (e.g., system and process audits).
- Conducting Pre-approval inspections
- Regulatory inception training on how to run a back room and front room efficiently.
- Identifying roles, responsibilities and equipment needed to host an inspection.
- Develop storyboards to explain hard to understand issues, deviations, and CAPAs that evolved with time, changes in budget and loss of knowledge with staff turnover.
- Train staff on the do's and don'ts when hosting an health authority inspection.

QMS Development / SOP Writing and Review

GxP Solutions experience in GxP Quality Systems allows us to provide our clients with support writing procedures/SOPs and developing a GxP quality system in the areas of GCP, GVP, GMP, GDP and offering ad hoc advice. For example, QMS development procedures may include the following, as well as GxP discipline specific policies and procedures.

- Quality Manual & Roles and Responsibilities
- Document Management and Archiving
- Change Control
- Investigation, Deviation and Corrective Action and Preventative Action
- Vendor / Supplier Management
- Internal Audit
- Training Program & Training Records
- Management Review
- Validation Master Plan
- Equipment Operation
- Equipment Qualification
- Preventative Maintenance and Calibration
- Risk Management
- Equipment Operation and Maintenance

Remediation & Regulatory Compliance Support

GxP Solutions can as your inhouse project manager and advisor for addressing regulatory compliance and remediation activity. Our advisory service will cater around your needs to correct regulatory findings. GxP Services include the following and more.

- Develop a strategy to address regulatory findings.
- Guide you in responding to Health Authorities
- Provide SME review and support for procedural updates.
- Re-train staff
- CAPA Management
- Review Data & Conduct investigations
- Project Management of CAPA investigations
- Third Party oversight and release of product
- Conduct phase inspections post remediation activity
- Ad hock requests

Third-Party QA / QC Support and Ad Hoc Consultancy

GxP Solutions can as your inhouse consult for various tacks the require third party peer review, or guidance. Our advisory service will cater around your needs and support your QA group to meet business obligations. GxP Services include the following and more.

- Managing Contract Manufacturing Operations and Oversight
  - CAPA and Complaint Management
  - Batch Record Review and Release
  - Reviewing and approving Annual Product Quality Reviews (APQR)
  - Product Release
- Review and approve manufacturing and technical documents (e.g., Validations & Qualifications)
- Provide SME review and support for procedural updates.
- Conducting GxP audits

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Training Services

GxP Solutions provides two (2) different training courses within GxP disciplines (e.g., GCP, GCLP, GVP, GLP, GMP, GDP and CSV) that provide essential information.

The training courses can be tailored to your business needs and can highlight specific areas that require special attention. GxP Solutions delivers cost-effective services that will enhance quality and compliance within your organization.

NOTE: All courses are live group or webinar training events only.

Good Clinical Practice (GCP) Training

This GCP training courses provides an essential information about ICH E6 (R2). This training is developed as an interpretation of the ICH E6 Good Clinical Practice consolidated guidelines. It is an introduction to GCP and can serve as a refresher course. It is suitable for everyone involved in clinical research.

- Course 1 - Good Clinical Practice (e.g., ICH E6 (R2) Regulations
  - Introduction
  - Ethics Committees
  - Investigators
  - Informed Consent
  - Sponsors
  - Monitors
  - Clinical Trial Protocol
  - Recording and Reporting
  - Essential Documents

- Course 2 - Good Clinical Practice (GCP) Auditing Course
  - Module 1: Investigational Product Development, the FDA, and Good Clinical Practice Guidelines
  - Module 2: Auditing as a Profession and Compliance Tool
  - Module 3: The Types of Clinical Research Audits and Preparation
  - Module 4: Quality Systems for Auditing
  - Module 5: Risk-Based Auditing and Developing Risk-Based Auditing Plans
  - Module 6: The Auditing Process: Clinical Investigator
  - Module 7: The Auditing Process: Institutional Review Board/Ethics Committee
  - Module 8: The Auditing Process: Sponsor/CRO
  - Module 9: Gathering and Disseminating Information: Verbal and Written Communication
  - Module 10: Regulatory Classification and Communication: Recent Inspection Findings

Good Laboratory Practice (GLP) Training

This GLP training courses provides an essential information about nonclinical study regulations. This training is developed as an interpretation of the FDA 21 CFR Part 58 regulations. The course is divided into two (2) options with the following scope:

- Course 1 - Good Clinical Laboratory Practice (GLP) regulations covering the following topics.
  - Introduction
  - Module 1: History of GLPs
  - Module 2: Subpart A: General Provisions
  - Module 3: Subpart B: Organization and Personnel
  - Module 4: Subpart C: Facilities
  - Module 5: Subpart D: Equipment and Computer Systems
  - Module 6: Subpart E (Part 1): Test Facility Operations - SOPs and Reagents/Solutions
  - Module 7: Subpart E (Part 2): Test Facility Operations - Animal Care
  - Module 8: Subpart F: Test and Control Articles
  - Module 9: Subpart G (Part 1): Protocols for Nonclinical Studies
  - Module 10: Subpart G (Part 2): Conduct of a Nonclinical Study
  - Module 11: Subpart J: Records and Reports

- Course 2 - Good Clinical Laboratory Practice (GLP) Auditing Course. Topics may include:
  - Standard operating procedures (SOPs)
  - Study conduct
  - Review of Study-specific documentation and data
  - Test and control article characterization and handling (e.g., Storage container labeling)
  - Test and control article mixtures with carriers
  - Reagents
  - Test facility management
  - Study director responsibilities
  - Study personnel
  - Quality assurance unit
  - Final study report (including contributing scientist reports)
  - Archival of study records
  - Facility/equipment
  - Animal care
  - Electronic data capture systems

Good Clinical Laboratory Practice (GCLP) Training

This GCLP training courses focus on a single GCLP reference for global clinical research laboratories with regard to laboratories that support clinical trials.

The course is divided into two (2) types. Topics discussed will include the following.

- Organization and Personnel
- Equipment
- Testing Facility Operations
- Test and Control
- Test Method Validation and Verification
- Records and Reports
- Physical Facilities
- Specimen Transport and Management
- Personal Safety
- Laboratory Information Systems
- Quality Management

- Course 1 - Good Clinical Laboratory Practice (GLP) regulations is a crucial supplement to the broader GCP rules that govern clinical trials. The principles should be followed by all labs involved in analyzing samples from clinical trials to ensure that the work is reliable, and ethical and can accurately be used to support the findings of the trial.

- Course 2 - Good Clinical Laboratory Practice (GCLP) Auditing Course will cover how to verify compliance with both GCP and GLP regulations and site procedures are followed.

Good Pharmacovigilance Practice (GVP) Training

This GVP training courses focus on the activities relating to the detection and prevention of adverse effects and problems associated with medicines. The course is a complete training solution or may serve as a refresher course for those working in Pharmacovigilance.

Course Details:

- Course 1 - Good Pharmacovigilance Practices (GVP) course covers key topics in Pharmacovigilance including:
    - The Pharmacovigilance System and Its Quality Systems
    - Pharmacovigilance System Master File (PSMF)
    - Pharmacovigilance Inspections
    - Risk Management Systems
    - Management And Reporting of Adverse Reactions.
    - Periodic Safety Update Report (PSUR)
    - Post Authorization Safety Studies
- Course 2 - Pharmacovigilance and Drug Safety Auditing Course will include the following topics. With a focus on how to verify compliance with GVP regulations.
    - Pharmacovigilance (PV) Roles and Responsibilities
    - PV Quality management Systems
    - Training
    - Product Quality Complaints (PQC)
    - Product Recall Management
    - Medical Information Enquiries
    - Vendor Management
    - Regulatory Affairs
    - Case Processing
    - Aggregate Reporting (e.g., PSUR/PBRERs)
    - Risk Management
    - Archiving
    - Computer System Validation for PV Systems

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Good Manufacturing Practice (GMP) Training

This GMP training courses focus on activities relating to manufacturing, testing, and quality assurance to ensure that drug product is safe for human consumption. While the course is aimed at drug manufacturing, topics in this course overlap other GMP operations including aseptic and non-aseptic Drugs, Medical Device, Biologics, Active Pharmaceutical Ingredients (API), Excipients, etc. The course is a complete training solution or may serve as a refresher course for those working in cGMP.

- The course is divided into two (2) types. Topics discussed will include the following.
    - Introduction
    - Module 1: Pharmaceutical Quality System
    - Module 2: Production and Process Controls
    - Module 3: Laboratory Controls & Microbiology Testing
    - Module 4: Facilities & Equipment
    - Module 5: Materials System
    - Module 6: Packaging & Labeling

- Course 1 - Good Manufacturing Practices (GMP) course covers key topics as referenced in 21 CFR Part 210 and 211.

- Course 2 - Good Manufacturing Practices (GMP) Auditing Course will cover key topics to confirm compliance with 21 CFR Part 210 and 211 and site procedures.

Good Distribution Practice (GMP) Training

This GDP training courses focus on activities relating to both clinical and commercial products. To ensure that products reach the end-user in pristine condition and protects the supply chain from counterfeit or contaminated products. The course is a complete training solution or may serve as a refresher course for those working in GCP/GDP and cGMP/GDP environments.

- The course is divided into two (2) types. Topics discussed will include the following.
    - Introduction
    - Module 1: Quality System
    - Module 2: Personnel
    - Module 3: Premises and Equipment
    - Module 4: Documentation
    - Module 5: Operations
    - Module 6: Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls
    - Module 7: Outsourced Activities
    - Module 8: Self-Inspections
    - Module 9: Transportation

- Course 1 - Good Distribution Practices (GDP) course covers key topics as referenced on FDA 21 CFR Part 211, EMA Good Distribution Practice for Medicinal Products and WHO good distribution practices for pharmaceutical products.

- Course 2 - Good Distribution Practices (GMP) Auditing Course will cover key topics to confirm compliance with FDA 21 CFR Part 211, EMA Good Distribution Practice for Medicinal Products and WHO Good Distribution Practices for Pharmaceutical Products.

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Computer System Validation (CSV) Training

This CSV training courses focus on validation activities relating to both clinical and commercial products. To ensure that software meets end-user and regulatory requirements for FDA 21 CFR Part 11 and EMA Annex 11 requirements. The course is a complete training solution or may serve as a refresher course for those working in CSV environments.

- The course is divided into two (2) types. Topics discussed will include the following.

- Course 1 - Computer System Validation (CSV) course focuses on developing and implementing regulated computer systems with an appropriate level of documented evidence to satisfy FDA expectations.
  - Introduction
  - Module 1: The regulatory expectations for computer validation
  - Module 2: Relevant FDA warning letters
  - Module 3: The tasks and deliverables expected for computer validation.
  - Module 4: Why validation processes vary so much.
  - Module 5: Strategies for practical, yet defensible computer validation
  - Module 6: SOPs required for system operation and maintenance.
  - Module 7: 21 CFR part 11 and it's implications for common regulations.
  - Module 8: An active discussion of part 11 examples and audience questions
  - Module 9: The implications of GAMP 5 on computer validation

- Course 2 - Computer System Validation (CSV) Auditing course focuses on how to evaluate a computerized system for appropriate level of documented evidence to satisfy regulatory expectations.

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Contact Details

Contact us to see how we could help you and to discuss your individual requirements.

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