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Introductory GMP Training

This is a **self-taught** program, designed to be a new employee's first exposure to the GMP world, and consists of:

- Videotape discussing foundation GMPs (documentation, SOPs, contamination, etc.)
- Workbook for the student to follow along with the tape
- GMP Institute tape entitled: "The 10 Principles of GMP"
- Assessment quiz
- Glossary of GMP terms
- Two (2) articles of interest for future study

Program length: 1 ½ hours

*An assessment exercise will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

Foundation GMP Program for All Employees

The program is an overview of basic GMP concepts and emphasizes, to new employees, the importance of understanding and following government regulations. This program will give them a good background to promote regulatory compliance and at the same they will receive on-the-job training. Topics will include (but not be limited to):

- An introduction to the new drug development process
- A short history of FDA and US drug regulations
- The role of FDA and regulatory sanctions
- The purpose and structure of the GMPs
- The uniqueness of clinical supplies
- The roles of QA/QC
- The phases of clinical trials
- SOPs
- Contamination control (with a focus on air handling, PPE, pest control, and equipment cleaning)
- Good documentation practices, including correcting GMP documentation
- Change control
- Warehousing
- Component control
- Blinding concepts
- Stability (FDA / ICH)
- The fundamentals of equipment qualification
- Returned drug accountability
- Reserve samples
- Shipping validation

Program length: 6 hours

*All sessions will be given class exercises that will be conducted to demonstrate and practice “things learned”. An assessment exercise will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

GMP Refresher Training

Production

This program is presented to experienced employees in manufacturing and will focus on 4-5 of the principle subparts of the GMPs. Topics will include (but not be limited to):

- Maintenance and plant sanitation
- Component control
- Batch documentation
- Cleaning validation
- Equipment qualification
- Air handling
- Stability
- Flow of materials
- Current FDA inspectional initiative, using Warning Letters as examples

Program length: 2 hours

*All sessions will be given class exercises that will be conducted to demonstrate and practice “things learned”. An assessment exercise will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

Warehouse, Facilities, and Maintenance

This program is presented to the Warehouse, Facilities, and Maintenance staff. Topics will include (but not be limited to):

- Receiving and distribution
- Sanitation and maintenance
- Inspection of incoming material
- Prevention of component and product mix-up
- Temperature and humidity control
- Inventory control
- Essential documentation to ensure accurate distribution records

Program length: 2 hours

*All sessions will be given class exercises that will be conducted to demonstrate and practice “things learned”. An assessment exercise will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

GMP Refresher Training

Quality Assurance and Quality Control

This program is presented to experienced QA and QC employees and will focus on the essential roles of QA and QC. Topics will include (but not be limited to):

QA:

- Auditing
- SOP Approval
- Assuring GMP and SOP training
- Batch record review
- Product approval
- Protocol approval, before and after execution
- Developing and maintaining a CAPA initiative

QC

- Component sampling
- Status labeling and approval for processing
- On-line monitoring and sampling during manufacture
- Conducting OOS investigations
- Product testing for release and distribution

Warning Letters and 483s that have resulted from FDA biannual inspections will be discussed.

Program length: 3 hours

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GMP Refresher Training

Senior Management

FDA has consistently re-inforced the concept that Senior Management bears the responsibility for CGMP compliance. This program focuses on (but is not limited to) the following topics:

- FDA inspectional initiatives
- Systems-based FDA inspections
- Risk-based FDA inspections
- Recent Warning Letters and Consent Decrees
- Process Analytical Technology
- Part 11 Compliance

Program length: 2 ½ hours

*All sessions will be given class exercises that will be conducted to demonstrate and practice “things learned”. An assessment exercise will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

Good Documentation Practices for the Pharmaceutical Industry

Following good documentation practices, in compliance with FDA regulations, helps ensure control over your processes. Proper documentation tells what you did, when you did it and how you did it. These are important factors when reviewing GMP documents for audit reviews, out-of-specification and deviation investigations, and daily product release and document approval. Topics will include (but not be limited to):

- Why do we document?
- What makes a quality document?
- Correcting documents
- Using the correct writing instruments
- Personnel responsibilities
- Document review/verification
- Consistency of data entry
- Use of abbreviations
- Handling of raw data
- Recording data
- Signatures

Program length: 2 ½ hours

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Standard Operating Procedure (SOP) Training

Failure to follow a company's own procedures is one of the most common observations found during FDA inspections.

Employees will give many reasons why they find reading and following SOPs to be difficult and time consuming. Most of these reasons concern content, clarity, and training.

This program targets personnel that are, or will be, responsible for the development, review and approval, document control and training of your company's SOPs. Topics will include (but not be limited to):

- Purpose of having SOPs
- FDA expectations
- Determining need
- Developing and writing SOPs
- Authoring
- Reviewing and approving
- Document control
- Conducting SOP training
- Developing training assessments

Program length: 4 hours

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Train-the-Trainer

Experienced employees, who are Subject Matter Experts (SMEs), are always the best choice for training your staff on new job skills, procedures and processes. While these employees may be very knowledgeable, what is your assurance that they have the required skills to successfully transfer this knowledge? Do they understand the concepts of adult learning theories and how to apply them? Can they develop the necessary behavioral objectives for their training sessions which in turn prepare the trainees to be assessed on the transfer of knowledge from SME to trainee?

The FDA expects to see documentation, within your training program, that describes the criteria your company has set for determining who will be considered a qualified trainer for your in-house training programs.

This program targets Management and staff SMEs who will be responsible for training employees. The focus is on techniques that make training “come alive”. We also provide guidance on developing metrics to assess training effectiveness. Topics will include (but not be limited to):

- Government regulations and their relationship to training
- Proper training documentation
- Adult learning theory
- Developing behavioral objectives
- Communication skills
- Delivery skills, classroom versus structured on-the-job training
- Presentation skills
- Program design
- FDA expectations for a robust training program

Program length: 4 hours

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GMPs for the Laboratory

This program is presented to new and experienced QC laboratory analysts and will focus on the essential responsibilities of the QC laboratory. Topics will include (but not be limited to):

- CFR Parts 210 and 211, particularly those sections addressing laboratory controls
- CFR Part 11
- Following SOPs
- Change control
- Out of specification (OOS) and deviation investigations
- Method validation
- Stability testing
- Sample management
- Instrument calibration program
- Preventive maintenance program
- Good documentation practice for the laboratory
- Analyst training and certification
- Current FDA inspectional initiatives, using Warning Letters as examples

Program length: 4 hours

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GCP Training for Clinical Monitors and Regulatory Staff

This program is designed to refresh experienced employees currently working in Clinical Research Medical Services, Regulatory Affairs, and Quality Assurance. The presentation focuses on GCP principals using current industry issues to provide an interesting orientation to the regulations. Topics will include (but are not limited to):

- Errors in GCP documentation
- Source document review for adverse experiences
- Site initiation visit, strategies and tactics
- Interim monitoring visits, a training approach
- Scientific fraud, detection and response
- Multicenter program planning, issues and options
- Study medication accountability
- Drug sample retention requirements
- Site close-out visits
- Auditing techniques for monitors
- Shortening the queries process
- Premature termination: when, why, and how
- Documenting the monitoring visit
- Post-marketing safety tracking of AEs and SAEs

Program length: 4 hours

*Sessions will include class exercises that will be conducted to demonstrate and practice “things learned”. An assessment quiz will be given to determine successful knowledge transfer. Certificates will be presented to all attendees who complete the course.

Foundation GCP Training

This program is an overview of basic GCP concepts designed to provide new employees with sufficient understanding of the ICH GCP Guidelines to appreciate the need for compliance in their everyday work experience. Topics will include (but are not limited to):

- A history of the ICH Guidelines and their relationship to FDA Regulations
- The IND and NDA process
- Safety and efficacy
- Overview of the structure and purpose of GCPs
- The phases of clinical research
- Responsibilities of the sponsor (FDA 1571)
- Responsibilities of the investigator (FDA 1572)
- Institutional Review Boards and the Informed Consent process
- Source documentation
- GCP critical documents
- SOPs for the sponsor and investigator
- General concepts in biostatistics and data interpretation
- Post-approval regulatory requirements

Program length: 6 hours

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Clinical Supplies Fundamentals for the Virtual Company

This program will focus on the **best practices** for clinical supplies for the virtual company from both GCP and GMP perspectives. Topics will include (but are not limited to):

- GMP Essentials for clinical supplies
- Drug supply and the phases of clinical trials
- Patient and site complaint packaging and labeling (including child resistant/senior friendly packaging)
- Blinding concepts (single, double, double-dummy, package and 3rd party)
- Stability requirements for clinical supplies (including the requirements for comparator products that are blinded by over-encapsulation)
- Qualifying your clinical supplies contractor
- QA and QC for clinical supplies including pre-execution and post-execution batch record review and on-site monitoring
- Clinical site qualification for drug storage (specifically, what constitutes “safe, secure limited access”)
- Shipping procedures to ensure that identity, strength, quality and purity are not compromised (especially for products requiring refrigeration)
- Basic Import/export requirements, including proforma invoices
- Reserve (= retain) samples
- Drug accountability:
 - Shipment to site from sponsor or contractor
 - Receipt and dispensing logs at site
 - Return, reconciliation, and destruction
 - Potential re-use of returned supplies

Program length: 5 hours

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OSHA Training for the Pharmaceutical Industry

This program will focus on preparing your employees, and your facility, to meet OSHA requirements. Topics will include (but are not limited to):

- Fire Safety and the use of fire extinguishers
- Office safety
- Material Safety Data Sheets (MSDSs)
- HAZMAT/HAZCOM
- Respiratory fit testing
- Personal Protection Equipment (PPE)
- Containment facilities
- Contamination control
- Recordkeeping to meet OSHA requirements
- Conducting internal OSHA inspections
- Critical SOP requirements

Program length: 4 hours

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Preparing for an FDA Inspection

This program will focus on preparing employees for a successful FDA inspection.

Topics will include (but are not limited to):

- FDA systems-based and risk-based inspectional philosophy (reality vs practice)
- Developing an inspection checklist
- Conducting mock inspections
- Reviewing the guidance documents that FDA provides to its inspectors
- Critical review of recent Warning Letters and Consent Decrees
- What to expect when FDA comes
- How European inspections differ from US Inspections, and how to prepare for the QP inspection
- The critical SOPs of interest to FDA

Program length: 4 hours

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