

CGMP GOOD MANUFACTURING PRACTICES COURSE

**YOUR PARTNER IN
GROWTH**



WHO SHOULD ATTEND?

THIS BROADLY BASED COURSE IS INTENDED FOR ALL SCIENTISTS AND TECHNOLOGISTS CONCERNED WITH THE DEVELOPMENT, PROCESSING OF PHARMACEUTICAL PRODUCTS, AND WITH RELATED DRUG REGULATORY AFFAIRS.

THE MATERIAL WILL BE PRESENTED IN SUCH A WAY AS TO BE OF VALUE TO A VARYING LEVEL OF EXPERTISE. THIS COURSE WILL ESPECIALLY BENEFIT THOSE IN:

COURSE TOPICS

QUALITY SYSTEMS

- A. QUALITY MANAGEMENT SYSTEM (QMS)
- B. RISK MANAGEMENT
- C. TRAINING AND PERSONNEL QUALIFICATION
- D. CHANGE CONTROL AND MANAGEMENT
- E. INVESTIGATIONS AND CORRECTIVE AND PREVENTIVE ACTION (CAPA)
- F. AUDITS AND SELF-INSPECTIONS
- G. DOCUMENTS AND RECORDS MANAGEMENT
- H. PRODUCT QUALITY COMPLAINTS VS. ADVERSE EVENT REPORTS

LABORATORY SYSTEMS

- A. COMPENDIA (UNITED STATES, EUROPE, AND JAPAN)
- B. LABORATORY INVESTIGATIONS OF ABERRANT RESULTS
- C. INSTRUMENT CONTROL AND RECORD-KEEPING
- D. SPECIFICATIONS
- E. LABORATORY RECORD-KEEPING AND DATA REQUIREMENTS
- F. LABORATORY HANDLING CONTROLS
- G. STABILITY PROGRAMS
- H. RESERVE SAMPLES AND RETAINS

**(10 SESSIONS /
WEEK DAYS)**



INFRASTRUCTURE: FACILITIES, UTILITIES, EQUIPMENT

- A. FACILITIES
- B. UTILITIES
- C. EQUIPMENT
- D. QUALIFICATION AND VALIDATION
- E. CLEANING, SANITIZATION, AND STERILIZATION SYSTEMS

MATERIALS AND SUPPLY CHAIN MANAGEMENT

- A. RECEIPT OF MATERIALS
- B. SAMPLING PROCESSES
- C. MATERIAL STORAGE, IDENTIFICATION, AND ROTATION
- D. DISPENSING AND WEIGHING CONTROLS
- E. SHIPPING AND DISTRIBUTION
- F. TRACEABILITY AND SOURCING
- G. SALVAGED/RETURNED GOODS AND DESTRUCTION

NONSTERILE MANUFACTURING SYSTEMS

- A. SOLID FACILITY AND SERVICES
- B. SOLID PROCESS AND EQUIPMENT
- C. SOLID IN PROCESS CONTROL
- D. REPROCESSED AND REWORKED MATERIALS

STERILE MANUFACTURING SYSTEMS

- A. STERILE FACILITY & SERVICES
- B. STERILE PROCESSES AND EQUIPMENT
- C. ENVIRONMENTAL MONITORING
- D. IN-PROCESS AND FINISHED GOODS INSPECTIONS
- E. PARENTERAL PRODUCT INSPECTION

FILLING, PACKAGING, LABELING

- A. FILLING OPERATIONS AND CONTROLS
- B. PACKAGING OPERATIONS AND CONTROLS
- C. PACKAGING MATERIAL
- D. LABELING OPERATIONS AND CONTROLS
- E. FILLING AND PACKAGING RECORDS
- F. ARTWORK DEVELOPMENT AND CONTROLS
- G. MASTER BATCH AND COMPLETED BATCH RECORDS