CPGP COURSE

YOUR PARTNER IN GROWTH

REGULATORY AGENCY GOVERNANCE

- GLOBAL REGULATORY FRAMEWORK
- REGULATIONS AND GUIDANCES
- MUTUAL RECOGNITION AGREEMENTS
- REGULATORY INSPECTIONS
- ENFORCEMENT ACTIONS
- REGULATORY AGENCY REPORTING
- SITE MASTER FILE (SMF) AND DRUG MASTER FILE (DMF)

QUALITY SYSTEMS

- QUALITY MANAGEMENT SYSTEM (QMS)
- QUALITY UNIT (SITE) MANAGEMENT
- RISK MANAGEMENT
- TRAINING AND PERSONNEL QUALIFICATION
- CHANGE CONTROL AND MANAGEMENT
- INVESTIGATIONS AND CORRECTIVE AND PREVENTIVE ACTION (CAPA)
- AUDITS AND SELF-INSPECTIONS
- DOCUMENTS AND RECORDS MANAGEMENT
- PRODUCT QUALITY COMPLAINTS VS. ADVERSE EVENT REPORTS
- PRODUCT TREND REQUIREMENTS
- SUPPLIER AND CONTRACTOR QUALITY MANAGEMENT

LABORATORY SYSTEMS

- COMPENDIA (UNITED STATES, EUROPE, AND JAPAN)
- LABORATORY INVESTIGATIONS OF ABERRANT RESULTS
- INSTRUMENT CONTROL AND RECORD-KEEPING
- SPECIFICATIONS
- LABORATORY RECORD-KEEPING AND DATA REQUIREMENTS
- LABORATORY HANDLING CONTROLS
- STABILITY PROGRAMS
- RESERVE SAMPLES AND RETAINS

INFRASTRUCTURE: FACILITIES, UTILITIES, EQUIPMENT

- FACILITIES
- UTILITIES
- EQUIPMENT
- QUALIFICATION AND VALIDATION
- MAINTENANCE AND METROLOGY SYSTEMS
- CLEANING, SANITIZATION, AND STERILIZATION SYSTEMS
- AUTOMATED OR COMPUTERIZED SYSTEMS
- BUSINESS CONTINUITY AND DISASTER RECOVERY

MATERIALS AND SUPPLY CHAIN MANAGEMENT

- RECEIPT OF MATERIALS
- SAMPLING PROCESSES
- MATERIAL STORAGE, IDENTIFICATION, AND ROTATION
- SHIPPING AND DISTRIBUTION
- TRACEABILITY AND SOURCING
- SALVAGED/RETURNED GOODS AND DESTRUCTION

FILLING, PACKAGING, LABELING

- FILLING OPERATIONS AND CONTROLS
- ENVIRONMENTAL MONITORING
- IN-PROCESS AND FINISHED GOODS INSPECTIONS
- PARENTERAL PRODUCT INSPECTION
- PACKAGING OPERATIONS AND CONTROLS
- LABELING OPERATIONS AND CONTROLS
- FILLING AND PACKAGING RECORDS
- ARTWORK DEVELOPMENT AND CONTROLS

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

- QUALITY BY DESIGN CONCEPTS
- PHASE-APPROPRIATE GMP REQUIREMENTS
- RAW MATERIALS, PACKAGING, AND INFRASTRUCTURE FOR PRODUCT DEVELOPMENT
- NEW PRODUCT DEVELOPMENT STUDIES AND REPORTS
- SCALE-UP AND TRANSFER ACTIVITIES

STERILE AND NONSTERILE MANUFACTURING SYSTEMS

- MASTER BATCH AND COMPLETED BATCH RECORDS
- PRODUCTION OPERATIONS
- IN-PROCESS CONTROLS
- DISPENSING AND WEIGHING CONTROLS
- REQUIREMENTS FOR CRITICAL UNIT PROCESSES
- CONTAMINATION AND CROSS-CONTAMINATION
- REPROCESSED AND REWORKED MATERIALS

WHO SHOULD ATTEND?

YOU MUST HAVE THREE YEARS OF ON-THE-JOB EXPERIENCE IN ONE OR MORE OF THEAREAS OF THE CERTIFIED PHARMACEUTICAL GMP PROFESSIONAL BODY OF KNOWLEDGE

COURSE DURATION : 120 HRS (30 WEEK END)