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ENERGY LEARNING NETWORK
"Where Questions Become Knowledge"

Pharma Manufacturing (cGMP)

Library	Course Code	Course Name	Description and Length (in minutes)	
Pharma Manufacturing (cGMP)	251	Pharma cGMP: Regulations	Pharma cGMP: Regulations define current good manufacturing practices for the pharmaceutical manufacturing industry. This course contains an overview of 21 CFR Part 211 cGMP for Finished Pharmaceuticals, including the quality control requirements (personnel, facilities, labeling, and documentation) for manufacturing, packaging, and storing finished pharmaceuticals.	45 minutes
Pharma Manufacturing (cGMP)	260	Introduction to Pharma Current Good Manufacturing Practice (cGMP)	Introduction to Pharma Current Good Manufacturing Practice (cGMP) examines the basic cGMP regulations regulated by the Food and Drug Administration (FDA) and other applicable industry and international standards.	30 minutes
Pharma Manufacturing (cGMP)	261	Pharma cGMP: Personnel	Pharma cGMP: Personnel examines the cGMP roles, responsibilities, qualifications, and requirements of personnel involved in pharmaceutical manufacturing.	20 minutes
Pharma Manufacturing (cGMP)	262	Pharma cGMP: Validation	Pharma cGMP: Personnel examines the cGMP roles, responsibilities, qualifications, and requirements of personnel involved in pharmaceutical manufacturing.	25 minutes
Pharma Manufacturing (cGMP)	263	Pharma cGMP: Documentation	Pharma cGMP: Documentation discusses how to create and maintain cGMP-compliant records. This course emphasizes the importance of good documentation. It explains the four-tiered document system recommended for cGMP facilities, including a review of the documents and their contents.	30 minutes

Pharma Manufacturing (cGMP)	264	Pharma cGMP: Standard Operating Procedure	Pharma cGMP: Standard Operating Procedures discusses the importance of understanding and following standard operating procedures (SOPs). This course reviews the content of an SOP, discusses time-tested tips for effective writing of SOPs, gives an overview of the SOPs required by cGMP regulations, and explains the steps in an SOP management process.	20 minutes
Pharma Manufacturing (cGMP)	265	Pharma cGMP: Buildings, Facilities, and Equipment	Pharma cGMP: Buildings, Facilities, and Equipment examine current Good Manufacturing Practices for buildings, facilities, and equipment manufacturing pharmaceutical products, including design and construction considerations and equipment selection and maintenance.	35 minutes
Pharma Manufacturing (cGMP)	266	Pharma cGMP: Controlling Materials	Pharma cGMP: Controlling Materials examines the different requirements for control materials used in pharmaceutical manufacturing, including storage, containers, packaging and labeling, sampling, rejection and acceptance, and recalls.	35 minutes
Pharma Manufacturing (cGMP)	267	Pharma cGMP: Sanitation and Hygiene	Pharma cGMP: Sanitation and Hygiene explores current good manufacturing practices for sanitation and hygiene in pharmaceutical manufacturing as they apply to personnel, facilities, equipment, materials, and containers. Additional topics are sanitation in production operations and cross-contamination prevention.	20 minutes
Pharma Manufacturing (cGMP)	268	Pharma cGMP: Sterile Pharmaceutical Production	Pharma cGMP: Sterile Pharmaceutical Production examines requirements for sterile product manufacturing, including air classification, facilities and equipment, environmental monitoring, and production personnel. Types of sterilization methods are also discussed.	40 minutes
Pharma Manufacturing (cGMP)	269	Pharma cGMP: Quality Unit	Pharma cGMP: Quality Unit explains the quality system approach to cGMP that the FDA encourages. This course defines terms, explains concepts, and discusses best practices while also indicating the duties the FDA regulations require of the Quality Unit.	30 minutes

Pharma Manufacturing (cGMP)	270	Pharma cGMP: Complaints and Recalls	Pharma cGMP: Complaints and Recalls examines the complaint and recall process involving pharmaceutical products in distribution by looking at the investigation that takes place when a complaint is filed and the reasons for a recall.	20 minutes
Pharma Manufacturing (cGMP)	271	Pharma cGMP: Inspections and Audits	Pharma cGMP: Inspections and Audits examine self-inspections conducted by drug manufacturing facilities and external audits conducted by the FDA. Topics include the purpose, scope, and frequency of formal self-inspections, a quality unit, audits, frequency and trigger for external FDA audits, and FDA's six-system inspection.	20 minutes
Pharma Manufacturing (cGMP)	272	Pharma cGMP: Training	Pharma cGMP: Training addresses job competencies and the need for training in the pharmaceutical manufacturing industry. Topics include employee requirements, training triggers, technical training and evaluation, training reports, and specific training.	25 minutes
Food cGMP				
Food cGMP	280	280 Introduction to Food Current Good Manufacturing Practice (Food cGMP)	Introduction to Food Current Good Manufacturing Practice (Food cGMP) discusses cGMP regulations, specifically 21 CFR 117 and its provisions; regulatory authorities, the Food Codes, and other programs and standards of safe food manufacturing, including HACCP and HARPC (food plan).	25 minutes
Food cGMP	281	281 Food cGMP: Hazards to Food Safety	Food cGMP: Hazards to Food Safety reviews the major hazards to food safety that the Food cGMP protects against. Topics include natural toxins, molds, microorganisms, pests, allergens, chemicals, and physical contaminants. It also discusses the food safety plan and preventive controls to prevent contamination and allergen cross-contact.	55 minutes
Food cGMP	282	282 Food cGMP: Hygiene and Sanitary Operations	Food cGMP: Hygiene and Sanitary Operations examines the provisions of 21 CFR 117 Subpart B Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food about personnel hygiene, sanitary operations, and pest control in food manufacturing plants.	25 minutes

Food cGMP	283	283 Food cGMP: Building, Facilities, and Equipment	Food cGMP: Buildings, Facilities, and Equipment examines the regulatory requirements for the design, construction, and maintenance of a food manufacturing plant and its grounds. This course also examines equipment and utensils used in the plant as well as the plant's sanitary facilities and controls	30 minutes
Food cGMP	284	284 Food cGMP: Processes and Controls	Food cGMP: Processes and Controls review the cGMP requirements for raw materials, manufacturing operations, warehousing, and distribution. This course also describes processes and controls for raw materials inspection and segregation, including avoiding cross-contamination. It outlines good manufacturing operations, such as using sanitation standard operating procedures, preventive maintenance, and monitoring methods. It also describes a qualified individual's role in food manufacturing operations.	25 minutes
Food cGMP	285	285 Food cGMP: Recalls and Traceability	Food cGMP: Recalls and Traceability examines recalls and traceability in the food manufacturing industry. This course describes the role of the FDA regarding recalls, recall classifications, the elements of a recall plan, and plan evaluation. The course also discusses traceability, including its purpose, definition, methods, and applicable technology.	25 minutes
Good Laboratory Practice (GLP)				
Good Lab Practice (GLP)	253 GLP	253 GLP: Introduction to Good Laboratory Practice	Introduction to Good Laboratory Practice (GLP) is an overview course that explains good laboratory practices and their purpose. The course also examines GLP regulations in detail and the fundamentals of GLP.	20 minutes
Good Lab Practice (GLP)	252 GLP	252 GLP: Regulations	Regulations explores the FDA regulation 21 CFR 58 (Good Laboratory Practice for Nonclinical Studies) and two similarly applicable EPA regulations (40 CFR 160 and 40 CFR 792). This course outlines the quality issues addressed in a GLP program, including personnel and training, equipment operation, facility design, handling of test samples, nonclinical studies, and documentation and reporting.	60 minutes

Good Lab Practice (GLP)	254 GLP	254 GLP: Resources	Resources explore the required resources for a nonclinical laboratory study conducted according to good laboratory practice (GLP) regulations. Personnel, facilities, and equipment are discussed in detail.	20 minutes
Good Lab Practice (GLP)	255 GLP	255 GLP: Responsibilities	Responsibilities examine responsibilities mandated by 21 CFR 58 Good Laboratory Practice for Nonclinical Studies as they apply to test facility management, the study director, study personnel, the study sponsor, and the quality assurance unit.	20 minutes
Good Lab Practice (GLP)	256 GLP	256 GLP: Conducting the Study	Conducting the Study examines the conduct of nonclinical laboratory studies according to 21 CFR 58 Good Laboratory Practice for Nonclinical Studies, specifically the purpose and use of protocols and standard operating procedures.	25 minutes
Good Lab Practice (GLP)	257 GLP	257 GLP: Test Articles and Test Systems	Test Articles and Test Systems provide an overview of the characterization, special handling, and documentation requirements for test articles, control articles, and test systems to achieve good laboratory practices.	30 minutes
Good Lab Practice (GLP)	258	258 GLP: Records, Reports and Archives	GLP: Records, Reports, and Archives explains how to prepare for a data audit by creating compliant records. This course discusses how to compile these records into a final report for submission to the FDA and how these records must be archived.	25 minutes
Good Lab Practice (GLP)	259	259 Electronic Records, Electronic Signatures	Electronic Records, Electronic Signatures explains which records fall under 21 CFR 11, the characteristics of electronic records to be acceptable, and how to control computer systems used to manage electronic records. The course also discusses the acceptable types of electronic signatures and the safeguards that must be used so that they will be non-refutable.	30 minutes