Pharmaceutical: Current Good Manufacturing Practice

Successful current Good Manufacturing Practice (cGMP) in pharmaceuticals begins with a solid core of regulatory training from OverNite Software, Inc.

Current Good Manufacturing Practice is a regulatory prescription for generating drug products that are safe for humans and animals. In the United States, the Food and Drug Administration (FDA) requires pharmaceutical manufacturers and companies that conduct Phase III clinical trials to comply with cGMP regulations.

OSI's library makes compliance easy for companies in need of cGMP introductory and refresher training with fifteen Pharma cGMP courses.

Our courses are delivered via a state-of-the-art learning management system that allows you to customize curricula, adjust testing parameters, and even customize courses with site-specific content and photos.

For more information call 1.888.228.2473 or visit OverNiteCBT.com

ExxTend Learning™
the way the world learns.

PHARMA CURRENT GOOD MANUFACTURING PRACTICE

260 Introduction to Pharma Current Good Manufacturing Practice (cGMP) is an overview course that examines the basics of current good manufacturing practice (cGMP) in the pharmaceutical industry. This course also addresses U.S. Food and Drug Administration regulations that govern cGMP as well as other applicable industry and international standards. (30 min)

251 Pharma cGMP: Regulations explores the FDA regulation "Good Laboratory Practice for Nonclinical Studies" (21 CFR 58) as well as applicable EPA regulations (40 CFR 160 and 40 CFR 792) and OECD principles, the international counterpart to U.S. regulations. (45 min)

261 Pharma cGMP: Personnel examines the cGMP personnel responsibilities, qualifications, and requirements of personnel as well as key personnel involved in pharmaceutical manufacturing. (20 min)

262 Pharma cGMP: Validation defines validation and other terms used in the validation process. This course reviews the regulations and discusses the newest FDA guidelines, giving a more detailed review of what is recommended at each of the three stages of validation (process design, process qualification, and continued process verification). (25 min)

263 Pharma cGMP: Documentation discusses how to create and maintain cGMP-compliant records. This course emphasizes the importance of good documentation and discusses the four-tiered document system recommended for cGMP facilities, including a review of the documents and their contents (as required by the FDA in 21 CFR 211, Subpart J). (30 min)

264 Pharma cGMP: Standard Operating Procedures discusses the importance of having, 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 min)

265 Pharma cGMP: Buildings, Facilities, and Equipment examines current Good Manufacturing Practice for buildings, facilities and equipment involved in the manufacture of pharmaceutical products. (35 min)

266 Pharma cGMP: Controlling Materials examines the different types of materials utilized in pharmaceutical manufacturing and how they are controlled and regulated. (35 min)

267 Pharma cGMP: Sanitation and Hygiene explores current Good Manufacturing Practice for sanitation and hygiene in pharmaceutical manufacturing as it applies to personnel, facilities, equipment, materials and containers. (20 min)

268 Pharma cGMP: Sterile Pharmaceutical Production explores the manufacture of sterile pharmaceutical products, including general requirements, sterile production guidelines and sterile preparations. (40 min)

269 Pharma cGMP: Quality Unit discusses the quality system approach to cGMP, including major terms, concepts, best practices and FDA requirements. (30 min)

270 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 min)

271 Pharma cGMP: Inspections and Audits examines 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, as well as quality unit audits, frequency and triggers for external FDA audits and the FDA's six-system inspection model. (20 min)

272 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 min)

259 Electronic Records, Electronic Signatures explains which records fall under 21 CFR Part 11 (also known as Part 11), the characteristics that electronic records must have to be acceptable and how to control computer systems used to manage electronic records. The course also discusses the types of electronic signatures that are acceptable and the safeguards that must be used so that they will be non-refutable. (30 min)

280 Introduction to Food Current Good Manufacturing Practice (cGMP) discusses cGMP regulations, specifically 21 CFR 110, regulatory authorities, the Codex Alimentarius and other programs and standards of food safety. (25 min)

281 Food cGMP: Hazards to Food Safety reviews the major hazards to food safety that cGMP protect against. Topics include natural toxins, molds, microorganisms, pests, allergens, chemicals and physical contaminants. (50 min)

282 Food cGMP: Hygiene and Sanitary Operations examines the provisions of 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food with regard to personnel hygiene, sanitary operations and pest control in food manufacturing plants. (30 min)

283 Food cGMP: Building, 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 min)

284 Food cGMP: Production and Process Controls reviews the cGMP requirements for raw materials, manufacturing operations, warehousing and distribution (including proposals for modernization of the regulations). This course also reviews Quality Control in a food processing facility. (35 min)

285 Food cGMP: Recalls and Traceability examines recalls and traceability in the food manufacturing industry. Recall topics include types of recalls, action levels, roles of agencies, recall plans and plan evaluation. The course also discusses traceability, including its purpose, definition and methods. (35 min)

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