



## CompuPharma Presents Essential Operator™ for Aseptic Facilities

A modern aseptic manufacturing facility faces a variety of regulatory and operational challenges including:

- Working in compliance with current industry GMP (Good Manufacturing Practice) regulations
- Reducing operating costs while maintaining product quality
- Increasing productivity and reducing levels of waste and rework

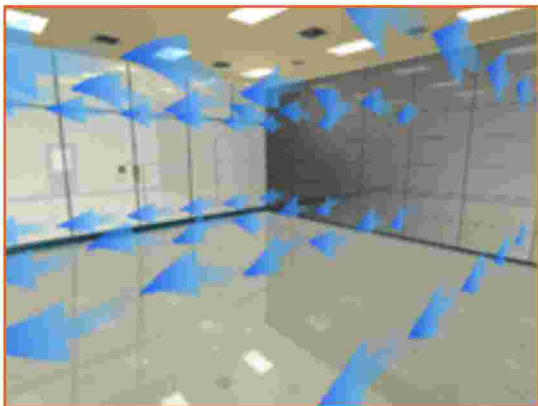
These challenges cannot be successfully met without the input of a competent, well-trained workforce.

"Persons engaged in manufacturing, processing or packing of drug and device products do not have adequate training to enable those persons to perform the assigned functions."

- extract from FDA Warning Letter to Aseptic Manufacturer -

To achieve and maintain product sterility, operators involved in aseptic manufacturing must be trained in the principles of aseptic technique. Most importantly, given the nature of aseptic manufacturing and the high risk of contamination, operators must receive this training before being allowed to enter an aseptic area.

CompuPharma's Essential Operator™ for Aseptic facilities e-Learning curriculum is specially designed for operators involved in aseptic manufacturing. It provides critical knowledge in key areas such basic microbiology, isolators, cleanroom CGMP, gowning, sterilization processes, and health and safety issues.



Accessed via the Internet or your company's intranet, each Essential Operator™ course is a multimedia learning experience that combines text, graphics, animation and audio to present critical knowledge in an engaging and interactive way.

Equipped with such knowledge, the transition from trainee to competent operator is made smoother and more efficient. **Standard Operating Procedures (SOPs)**, with their own particular industry jargon, become easier to understand. **On-the-Job Training** becomes more effective as trainees comprehend what they see and hear. A thorough grasp of the principles of aseptic manufacturing will contribute to improved operational efficiencies and a reduction in waste and rework.

"Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions."

- extract from Code of Federal Regulations 21 CFR Part 211 Current Good Manufacturing Practice For Finished Pharmaceuticals -

To help you build a competent, well-trained workforce that can confidently meet your company's compliance and operational challenges, CompuPharma recommends completion of the following Essential Operator™ courses:





**Course Code:** FD-GMP I  
**Course Title:** Essential GMP for Finished Dose Operators

This course covers everything an entry-level employee needs to know about CGMP in a pharmaceutical facility. It introduces the pharmaceutical industry and its products. It looks at the historical basis for GMP and how industry legislation has evolved up to the present day. The industry regulatory body FDA (Food and Drug Administration) and its functions are described in detail. The specifics of following CGMP are then covered with attention to dress codes, good health and hygiene habits, and contamination prevention in a controlled environment. Also covered are the implications of CGMP non-compliance for companies, employees and consumers.

**Topics Covered:**

- Introduction to the Pharmaceutical Industry
- Introduction to GMP for Finished Dose
- Regulatory Agencies
- Finished Dose Contamination Prevention
- Dress Codes for Finished Dose Manufacture
- GMP Goals

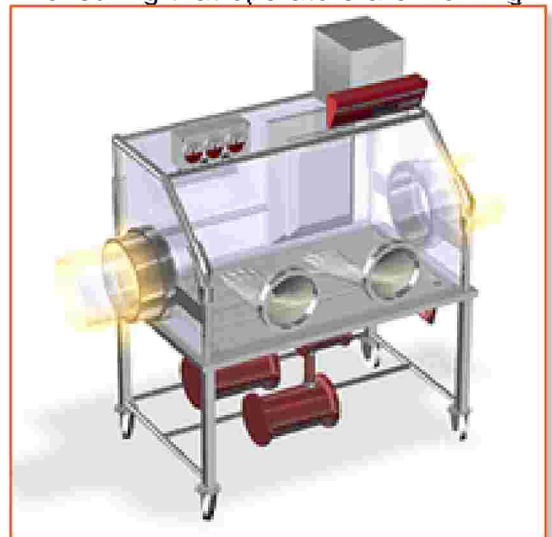
**Course Code:** FD-GMP II  
**Course Title:** Advanced GMP for Finished Dose Operators

Having grasped the basics of GMP, an operator now needs to move on to more advanced GMP concepts. **Advanced GMP for Finished Dose Operators** covers everything a trainee needs to know about more demanding CGMP topics such as SOPs, completing records, cleaning of equipment, QC status, use of computers, etc.

Standard Operating Procedures (SOPs) and records are critical in ensuring that operators are working in compliance with CGMP. This course begins by explaining why SOPs must be followed in finished dose facilities and what information they should contain. It also describes the proper completion of records in finished dose manufacturing including production records, equipment records, records of materials and laboratory sample records.

Proper labeling and cleaning of equipment are vital in avoiding mix-ups and product contamination. This course takes an in-depth look at both of these areas – the importance of accurate labeling is stressed, along with label distribution and reconciliation, while different equipment cleaning methods used in the pharmaceutical industry are also explored.

The course continues with CGMP in the warehouse and Quality Control (QC) status of materials and products. The CGMP design requirements for manufacturing facilities are also examined with emphasis on product flow, environmental controls, cleaning and sanitization. Finally, the basics of Information Technology and Good Computer Practice are presented.



**Topics Covered:**

- GMP - SOPs for Finished Dose
- GMP - Records for Finished Dose
- Personnel and Training
- Warehousing
- Cleaning of Equipment
- Sampling
- Buildings and Facilities
- Process Routine
- IT Use in Regulated Industries



**Course Code:** AP-PST I  
**Course Title:** Introduction to Aseptic Processing

Working in an aseptic environment requires specialized knowledge. The main threat of contamination to the product comes from operators themselves, therefore proper training is crucial.

A thorough understanding of aseptic processing is critical to reducing the risk of contamination and batch rejection or rework. Properly trained operators also contribute to improving overall operational efficiencies.

**Introduction to Aseptic Processing** provides all of the information necessary to give trainees a firm grasp of the basics of aseptic processing and ultimately make SOP and On-the-Job Training more efficient.

This course begins with an introduction to basic microbiology and the impact of microorganisms on pharmaceutical products. It then advances to cleanroom theory and design including the different areas of a cleanroom and potential sources of contamination.

The course goes on to discuss the use of HVAC (Heating Ventilation and Air Conditioning) systems and HEPA (High Efficiency Particulate Air) filters to control a cleanroom environment. It also introduces isolators and examines the components and functions of different types of isolators.

#### Topics Covered:

- Basic Microbiology
- Introduction to Cleanrooms
- HVAC
- Isolators



**Course Code:** AP-PST II  
**Course Title:** Essential Cleanroom GMP

The behavior of operators has a major impact on cleanroom performance. Operators must be aware of and strictly follow the rules associated with working in a cleanroom environment.

**Essential Cleanroom GMP** begins by describing in detail the specific GMP rules for operating in a cleanroom. These include rules on good hygiene, entering and exiting a cleanroom, and performing operations.

The critical area of gowning is covered with a description of cleanroom classification and the types of clothing required in each class of cleanroom.

Regular monitoring of environmental conditions is necessary to ensure a cleanroom is functioning correctly. The course details the various tests that must be carried out to assess if a cleanroom is functioning correctly.

Finally, the procedures required for the sanitization of the different areas of a cleanroom are detailed.

#### Topics Covered:

- Cleanroom Rules
- Gowning Introduction
- Cleanroom Tests
- Cleanroom Sanitization



**Course Code:** AP-PST III  
**Course Title:** Aseptic Processing - Sterilization

Aseptic processing involves the assembly of sterilized components and product in a specialized clean environment.

**Aseptic Processing - Sterilization** begins with an introduction to sterilization, explaining why products must be sterilized and listing the common types of sterilization processes.

The course then proceeds to describe in detail each of the sterilization processes: moist heat, dry heat, sterile filtration, radiation, and gas. The products suited to each type of process are described along with the equipment and procedures used and the critical sterilization parameters.

**Topics Covered:**

- Sterilization Introduction
- Moist Heat Sterilization
- Dry Heat Sterilization
- Sterile Filtration
- Radiation Sterilization
- Gas Sterilization



**Course Code:** BA-HAS  
**Course Title:** Health and Safety for Aseptic Process Finished Dose Operators

Under the Occupational Safety and Health Administration (OSHA) Act, all employees must have Health and Safety Training. This course begins with an examination of chemical and biological contamination and the most common types of accidents in the workplace. General safety rules are presented along with key areas of concern for both personal and general safety.

It explains safety rules and signs and provides a detailed treatment of chemical hazards and fire safety. Also covered are storage and handling of hazardous chemicals, waste disposal, and manual handling.

**Topics Covered:**

- Introduction to Safety
- General Safety Rules
- Chemical Hazards & Terminology
- Safety Symbols
- Storage and Handling
- Waste Disposal
- Fire Safety
- Hazardous Chemicals
- Manual Handling