



## CompuPharma Presents Essential Operator™ for Solid Dose Facilities

A modern solid dose 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

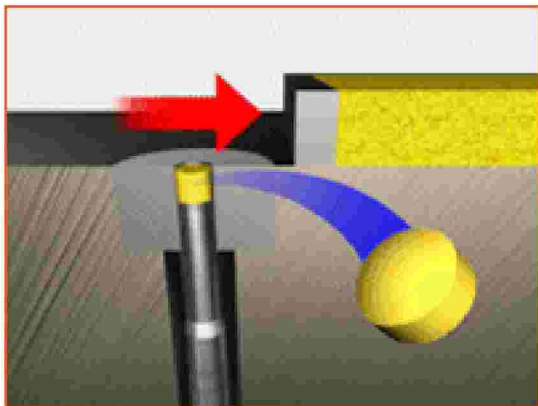
These challenges cannot be successfully met without the input of a competent, well-trained workforce.



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

- extract from FDA Warning Letter -

CompuPharma's Essential Operator™ for Solid Dose facilities e-Learning curriculum is specially designed for operators in the Solid Dose industry. It provides critical knowledge in key areas such as current Good Manufacturing Practice (CGMP), equipment, 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 solid dose processes and the equipment used 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 U.S. 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 Solid Dose Operators

This course covers everything an entry-level employee needs to know about basic CGMP in a solid dose 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 Manufacturer
- GMP Goals

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

Having grasped the basics of GMP, an operator now needs to move on to more advanced GMP concepts. **Advanced GMP for Solid 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 solid dose facilities and what information they should contain. It also describes the proper completion of records in solid 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 explained.



**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



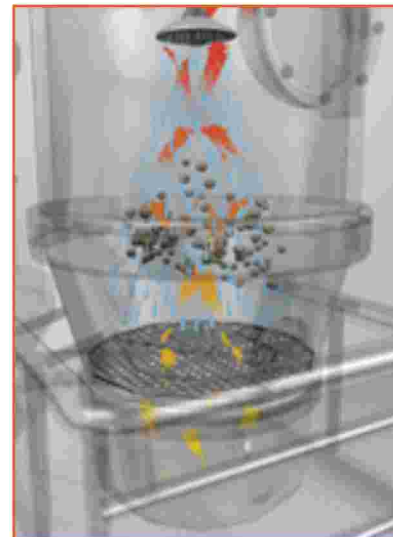
**Course Code:** SD-PUF  
**Course Title:** Process Understanding for Solid Dose Operators

Operators must be knowledgeable about the processes they work with on a daily basis. They should understand the *why* behind solid dose processes and not just the *how*. A thorough understanding of processing contributes to improving operational efficiencies and reducing waste and rework.

**Process Understanding for Solid Dose Operators** provides all of the information necessary to give a trainee a firm grasp of the basics of solid dose processes and ultimately make SOP and On-the-Job Training more efficient.

This course begins with an introduction to dosage forms and the most common dosage forms encountered in the pharmaceutical industry. It then goes on to describe in detail solid dose products and their manufacture.

The importance of water in solid dose manufacturing is underscored by an in-depth examination of the different grades of water required in a solid dose facility and the tests used to determine water purity. The most common water contaminants are discussed along with the different treatments used to purify water before it can be used in a pharmaceutical process.



#### Topics Covered:

- Dosage Form Introduction
- Solid Dosage
- Water Types & Testing
- Water Impurities & Treatment

**Course Code:** SD-PEF  
**Course Title:** Equipment Understanding for Solid Dose Operators

Operators with a thorough background knowledge of the equipment they encounter on a daily basis will contribute to greater efficiencies and less waste in the workplace.

**Equipment Understanding for Solid Dose Operators** provides the required foundation knowledge for trainees in this area – knowledge that will enhance and compliment SOP and On-the-Job Training.

This course examines the equipment used in the different stages of solid dose manufacturing including milling, blending, granulation, compression and coating. Important safety considerations are also highlighted.

The course also examines the key compliance issue of validation. A complete process validation is described using a v-blender as an example.

#### Topics Covered:

- Processing Equipment Introduction
- Milling
- Blending
- Filtration for Finished Dose
- Dryers
- Fluidized Beds
- Tablet Press
- Tablet Coater
- Kettles
- The Validation Stages

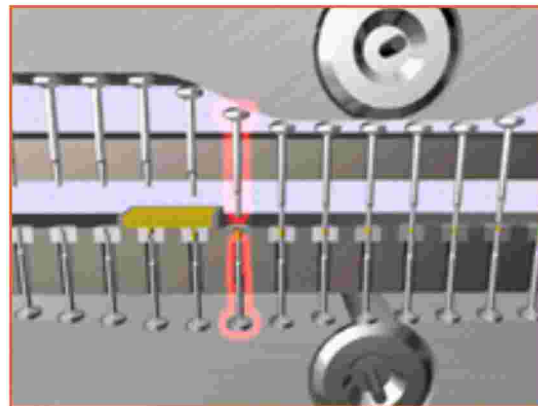


**Course Code:** BA-HAS  
**Course Title:** Health and Safety for Solid Dose Operators

Under the Occupational Safety and Health Administration (OSHA) Act, all employees must have Health and Safety Training. **Health and Safety for Solid Dose Operators** provides trainees with the basic knowledge required to work safely in a solid dose facility.

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