

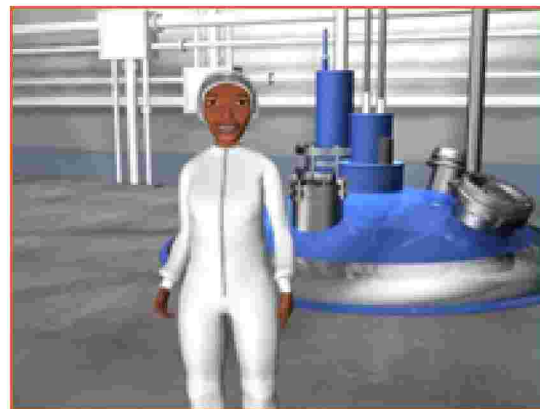


CompuPharma Presents Essential Operator™ for API/Bulk Facilities

A modern API/Bulk 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

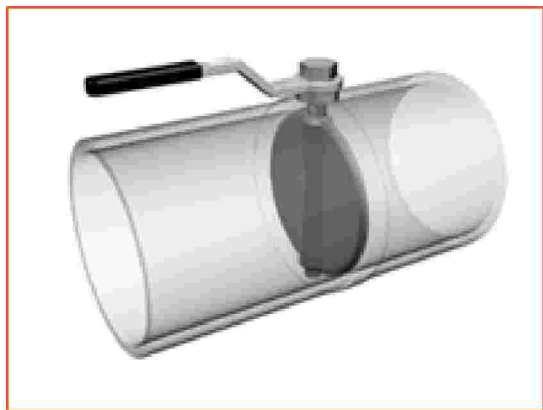
These challenges cannot be successfully met without the input of a competent, well-trained workforce.



"Examples of your firm's failure to follow CGMPs in API production include...lack of adequate training for...manufacturing employees."

- extract from FDA Warning Letter -

CompuPharma's Essential Operator™ for API/Bulk facilities e-Learning curriculum is specially designed for operators in the API/Bulk 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 API/Bulk processes and the equipment used will contribute to improved operational efficiencies and a reduction in waste and rework.

"There should be an adequate number of personnel qualified by appropriate education, training, and/or experience to perform and supervise the manufacture of intermediates and APIs."

- extract from ICH Q7A -

- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7A -

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: BA-GMP I
Course Title: Essential GMP for API/Bulk Operators

This course covers everything an entry-level employee needs to know about CGMP in an API/Bulk facility. It introduces the pharmaceutical industry and its products. It looks at the historical basis for CGMP 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 APIs
- Regulatory Agencies
- API Contamination Prevention
- Dress Codes for APIs
- GMP Goals for APIs

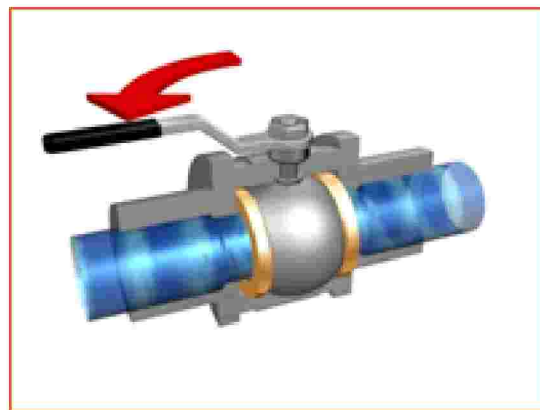
Course Code: BA-GMP II
Course Title: Advanced GMP for API/Bulk Operators

Having grasped the basics of GMP, an operator now needs to move on to more advanced GMP concepts. **Advanced GMP for API/Bulk 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 explains why SOPs must be followed in API/Bulk facilities and what information they should contain. It also describes the proper completion of records in API manufacturing including batch production records (BPR), master production records, equipment records, records of materials and laboratory sample records. The importance of accurate labeling in an API/Bulk facility is also addressed, along with label distribution and reconciliation. Finally, the basics of Information Technology and Good Computer Practice are explained.

Topics Covered:

- GMP - SOPs for APIs
- GMP - Records for APIs
- Labeling in API Facilities
- IT Use in Regulated Industries





Course Code: BA-PUA
Course Title: Process Understanding for API/Bulk Operators

Operators must be knowledgeable about the processes they work with on a daily basis. They should understand the *why* behind API processes and not just the *how*.

Process Understanding for API/Bulk Operators provides all of the information necessary to give a trainee a firm grasp of the basics of API/Bulk processes and ultimately make SOP and On-the-Job Training more efficient.

This course begins with the fundamentals of controlling and monitoring chemical reactions. The key API processes are examined in detail including crystallisation, distillation and reflux, drying and filtration. Also explained are the symbols used to represent key process equipment, pipe-work and gauges and the interpretation of basic Process Flow Diagrams (PFDs). The importance of water in API processes is underscored by an in-depth examination of the different grades of water required in an API 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 chemical process.

Topics Covered:

- Chemical Reactions – Introduction
- Chemical Reactions – Properties
- Distillation & Reflux
- Crystallization
- Drying
- Filtration
- Water Types & Testing
- Water Impurities & Treatment
- Process Flow Diagrams (PFDs)

Course Code: BA-PEA
Course Title: Equipment Understanding for API/Bulk Operators

Operators in the API/Bulk industry require a firm understanding of chemical reactor design. **Equipment Understanding for API/Bulk 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 common types of reactors and auxiliary equipment and describes the typical operation of a reactor from charging and sampling to phase separation. Important safety considerations are also highlighted. In addition, it looks in detail at other key equipment used in the API/Bulk industry including centrifuges, valves and pumps. As with Process Understanding for API/Bulk Operators (BA-PUA), 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.



Topics Covered:

- Chemical Reactor Design
- Working with Reactors
- Centrifuges
- Reciprocating Pumps
- Rotary & Centrifugal Pumps
- Valves

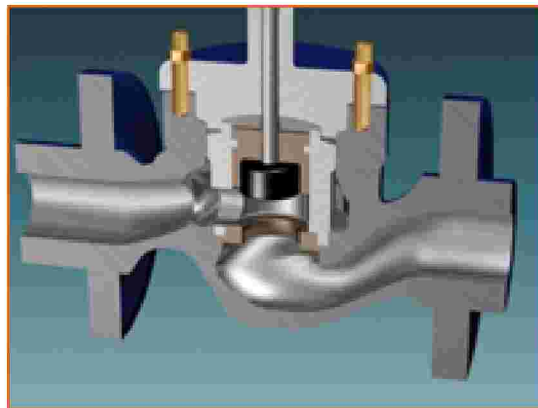


Course Code: BA-HAS
Course Title: Health and Safety for API/Bulk Operators

Under the Occupational Safety and Health Administration (OSHA) Act, all employees must have Health and Safety Training. **Health and Safety for API/Bulk Operators** provides trainees with the basic knowledge required to work safely in an API/Bulk 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