



## CompuPharma Presents Essential Operator™ for Medical Device Facilities

A modern medical device 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.

CompuPharma's Essential Operator™ for Medical Device facilities e-Learning curriculum is specially designed for operators in the medical device industry. It provides critical knowledge in basic GMP (dress codes, hygiene, etc.), advanced GMP (SOPs, records, etc.), 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 Analyst 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.

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:** MD-GMP I  
**Course Title:** Essential GMP for Medical Device Operators

This course covers everything an entry-level employee needs to know about basic CGMP in a medical device facility. It introduces the medical device industry and its products. It looks at the historical basis for GMP and how industry legislation has evolved up to the present day. The main 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 Medical Devices
- Regulatory Agencies for Medical Devices
- Dress Codes for Medical Devices
- Introduction to GMP for Medical Devices
- Hygiene for Medical Devices
- GMP Goals for Medical Devices

**Course Code:** MD-GMP II  
**Course Title:** Advanced GMP for Medical Device Operators

Having grasped the basics of GMP in MD-GMP I, an operator now needs to move on to more advanced GMP concepts. **Advanced GMP for Medical Device Operators** covers everything a trainee needs to know about more demanding CGMP topics such as SOPs, completing records, 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 medical device facilities and what information they should contain. It also describes the proper completion of records in medical device manufacturing including production records, equipment records, and records of materials.

Finally, the basics of Information Technology and Good Computer Practice are explained.

### Topics Covered:

- GMP - SOPs for Medical Devices
- Medical Devices - Personnel & Training
- GMP - Records for Medical Devices
- IT Use in Regulated Industries

**Course Code:** BA-HAS  
**Course Title:** Health and Safety for Medical Device Operators

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

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