

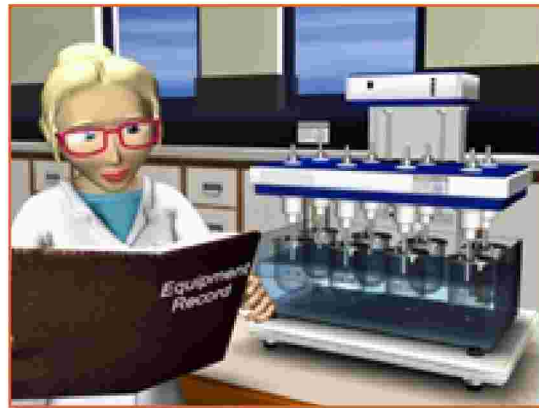


CompuPharma Presents Essential Analyst™ for Regulated Industries

A modern analytical laboratory faces a variety of regulatory and operational challenges including:

- Operating in compliance with GMP and other applicable industry regulations
- Optimizing use of available resources
- Consistently generating reliable and trustworthy data
- Minimizing errors, levels of retesting and waste

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



CompuPharma's Essential Analyst™ e-Learning curriculum is specially designed for analysts in regulated industries such as Finished Dose Pharmaceuticals, API/Bulk chemical manufacturing, Biotechnology and Medical Devices. It provides critical knowledge in key areas such as current Good Manufacturing Practice (CGMP), laboratory practices, techniques, and health and safety issues.



Accessed via the Internet or your company's intranet, each Essential Analyst™ 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 Analyst™ courses:

Course Code: AL-GMP
Course Title: Essential GMP for Laboratory Analysts

This course covers everything an entry-level analyst needs to know about CGMP in an analytical laboratory.

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 focus then shifts to the laboratory - a typical routine of a laboratory analyst is described, including responsibilities and duties. The different categories of tests - chemical, physical and microbiological - are presented and described. The importance of labeling and recording is also emphasized. The concept and operation of a Laboratory Information Management System (LIMS) is discussed.

The course continues with GMP rules of the laboratory. The proper procedure for receipt and storage of samples



is described. Use of Standard Operating Procedures (SOPs) and correct completion of records is dealt with in-depth. Solution preparation and equipment preparation are also described along with testing procedures and recording and sign-off of results.

Finally, there is an in-depth treatment of out of specification (OOS) and atypical results, which includes possible causes, the investigation process and preventive measures.

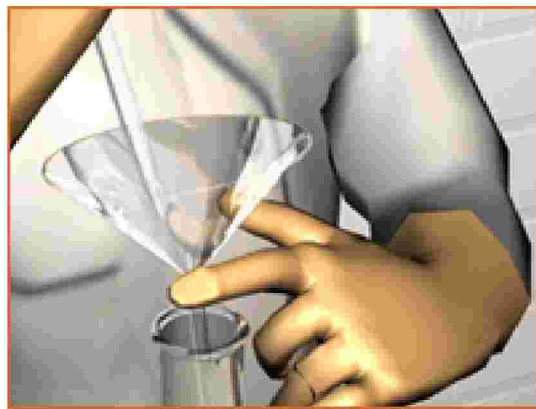
Topics Covered:

- Introduction to the Pharmaceutical Industry
- Testing Categories
- Laboratory GMP
- Routine of a Laboratory Analyst
- Laboratory Information Management Systems
- Out of Specification & Atypical Results

Course Code: AL-LPT
Course Title: Essential Analytical Techniques

This course presents a detailed look at those laboratory techniques which are essential knowledge for all competent analysts namely weighing, use of glassware, and solution preparation. Laboratory calculations and errors are discussed including statistical treatment of analytical results.

The course continues with an introduction to UV/VIS, AA and IR spectrophotometry. Finally, the principles of wet chemistry are discussed with a focus on pipettes, burettes and volumetric glassware.



Topics Covered:

- Weighing
- Solution Preparation
- Instrumentation
- Glassware
- Laboratory Calculations/Errors
- Wet Chemistry

Course Code: AL-LDT
Course Title: Dissolution Theory and Practice

There is a detailed treatment of dissolution including theory, stages of in vitro testing, preparation for testing and testing procedure.

Topics Covered:

- Understanding Dissolution
- Dissolution Equipment Set-Up
- In Vitro Dissolution
- Dissolution Testing



Course Code: AL-GVC
Course Title: IT Use and Analytical Validation

This course begins by explaining the basics of Information Technology and Good Computer Practice and describes how information technology is used in regulated industries.

The fundamentals of computerized systems validation are explained and how the validation process works.



This is followed by a detailed examination of 21 CFR Part 11 and its impact on regulated industries. There is particular emphasis on electronic records and signatures (ERES).

The course continues with an examination of analytical method validation. Analytical method validation is essential in demonstrating that a particular method is suitable for its intended use. It is a concept that all competent analysts must be able to grasp.

Areas covered include standards, LOD, LOQ, precision and accuracy. System suitability checks are explained and why they must be run prior to analysis. The steps involved in laboratory equipment qualification (DQ, IQ, OQ and PQ) are presented and explained.

Topics Covered:

- IT Use in Regulated Industries
- Introduction to 21 CFR Part 11
- System Suitability Parameters (HPLC)
- Computerized Systems Validation
- Method Validation Parameters
- Laboratory Equipment Qualification

Course Code: AL-HAS
Course Title: Health and Safety in the Laboratory

Health and Safety in the Laboratory explains how to work safely in the laboratory by following SOPs (Standard Operating Procedures), MSDSs (Material Safety Data Sheets), and using appropriate safety equipment. The terminology used in describing the hazardous properties of chemicals is explained as is the correct storage and handling procedures for hazardous chemicals. The course continues with an explanation of the different types of safety signs and the role they play in ensuring safety in the workplace.

Finally, the different categories of chemical laboratory waste are discussed and the procedures for their correct storage and disposal.

Topics Covered:

- Laboratory Safe Work Practices
- Hazardous Chemicals
- Chemical Laboratory Waste
- Chemical Hazards & Terminology
- Safety Symbols