

HERAX



PHARMA - PROCESS - IT - LEARNING



HERAX TRAINING ACADEMY 2017



TRAINING COURSES AT HERAX

HERAX offers high quality training for employees and IT professionals working within or for the pharmaceutical industry. We have more than 20 years of experience working in the international pharmaceutical industry with pharma business process improvements and IT system implementations.

HERAX currently offers the course, Pharma Introduction. Details about the course are available on the next page.

WHERE WILL THE TRAINING TAKE PLACE

HERAX offers both classroom training in Denmark and in-house training at your location. The classroom training is held in the scenic countryside setting in Holte, at Comwell, with easy access from the freeway and airport. On- or off-site, HERAX makes sure that the learning experience is optimal.

CLASSROOM TRAINING SCHEDULE

21-22 June 2017 (Comwell Holte, Denmark)

25-26 September 2017 (Comwell Holte, Denmark)

Courses are scheduled 9.00 – 16.30 first day, 8:30 – 16:30 the second day. The training course includes morning refreshments and lunch. Water, coffee and tea are available throughout the day. Parking is free of charge and internet access is provided.

DISCOUNTS

We offer an early bird discount of 5% if you sign up more than 21 days in advance. Volume discounts are available upon request.

INSTRUCTION LANGUAGE

English

SIGNING UP

Please use www.heraxacademy.com for signing up online, send an e-mail to training@herax.com or call +45 3049 0080. We will be happy to assist you with signing up and arranging travel and accommodations.

You will receive an invoice 14 days prior to course start.



PHARMA INTRODUCTION

DESCRIPTION

This course teaches the fundamentals of the core of pharmaceutical industry; how a product is discovered, developed, tested and marketed. The course includes all the development and administrative processes making up a pharmaceutical company. All roles involved in developing a new drug and the necessary regulatory framework are explained in detail.

In addition, we will go through all the IT systems that support the business processes used in Clinical Development, such as a Clinical Trial Management System, Electronic Data Capture, Safety Systems, Regulatory Management Systems, electronic Trial Master File, Statistical Computing Environment, and Clinical Data Warehouse.

The course also covers how the clinical data standards (CDISC) are applied to the business in order to improve the collection, analysis and reporting of clinical data.

Participation in a HERAX Training Academy course requires dedication and focus due to a high paced training method. We wish to impart the participants with a significant amount of knowledge so they can make a difference in the projects and daily work.

CONTENT

- Drug Development History
- Drug Development Overview
- Product Life Cycle
- Production and Logistics
- Discovery and Pre-Clinical
- Regulatory Overview
- Introduction to ICH (GxP)
- Quality Management
- Pharma IT Systems (e.g. EDC, CTMS)
- Clinical Development
- Investigational Medicinal Products
- Clinical Trial Phases
- Clinical Trial Planning and Design
- Clinical Trial Execution
- Data Management
- Trial Analysis and Reporting
- Drug Safety Regulations and Responsibilities
- Drug Safety Reporting
- Clinical Standards (CDISC)
- IT System Validation Overview

LEARNING OBJECTIVES

- Knowledge of the pharmaceutical development processes, the regulatory framework, and IT systems used
- Understand all aspects of the clinical development process, how the associated clinical systems support the processes and how the processes lead up to a new drug application
- Understand how to collect and analyze clinical data, and report on clinical trials

AUDIENCE

Pharmaceutical, healthcare, and IT professionals who require a broad perspective and deeper knowledge of the pharmaceutical industry, processes, standards, and IT systems.

DURATION

2 days course

PRICE

EUR 1.270 / DKK 9.450 + VAT pr person

IN-HOUSE COMPANY TRAINING

When delivering in-house training sessions, the Drug Development History module is updated, in collaboration with the client, to reflect the specific company history, therapeutic areas, and development specifics.

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