

NEW: This training course will take place in a virtual format via a digital platform

Live virtual Instructor-led Training Course

ESSENTIALS OF PHARMACOVIGILANCE

Start date: 10th June 2020 - delivered across 1-2 weeks



Virtual Classroom

Overview

The purpose of this virtual workshop is to create an understanding of the key aspects of Pharmacovigilance (PV). It will provide an overview and introduction to the definitions such as sources of cases, MedDRA (Medical Dictionary for Regulatory Activities) coding, case processing, and a first glance at a PV database.

Course Objectives

- Get a grasp on essential definitions of PV
- Learn a good approach to MedDRA coding
- Understand the origin of cases and how to determine their validity
- Learn to distinguish between solicited and unsolicited cases
- Develop case assessment and processing skills
- Gain a first impression of a PV database

Course Modules:

Module 1: 10th June – 10:00-12:15 am (2.15hrs)

- Introduction of participants and trainers
- Overview of agenda
- Legal Basis
- Definitions
 - Adverse Events
 - Adverse Reactions
 - Event vs. Case
 - Seriousness
 - Valid and non-valid cases
 - Hands-on exercise: Valid or not?

Module 2: 22nd June – 10:00-12:00 am (2hrs)

- Expectedness
- Causality
- Unblinding
- Sources of cases
 - Spontaneous („unsolicited“) reports
 - Regulatory Authorities / EudraVigilance
 - Literature and Internet
 - Non-interventional Studies („solicited“)
 - Clinical Trials (“solicited“)
- Hands-on exercise: Classification of solicited and unsolicited cases

Module 3: 23rd June – 10:00-12:00 am (2hrs)

- Do you speak MedDRA?
 - Definition and Development of MedDRA
 - Scope/ Purpose of MedDRA
 - Structure of classification and clarification of MedDRA terms (SOC, PT, LLT, etc.)
 - Update and Support
- Browsing advices
- Hands-on exercise: MedDRA coding examples

Module 4: 1st July – 10:00-12:15 am (2.15hrs)

- Case processing
 - Receipt and confirmation
 - Duplicate Check, MedDRA Coding
 - Triage
 - Data Entry, Narrative Writing
 - Medical Assessment
 - QC
 - Submission
 - EudraVigilance
- Demonstration of an E2b compliant database

Interactive activities are core part of each module to help you to test and confirm you have met the learning objectives.

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Who should attend?

This workshop has been designed for anyone who wishes to achieve an understanding of the essentials of pharmacovigilance. Especially for newcomers in pharmacovigilance and/or those working in associated areas such as Clinical Operations, Medical Information, Regulatory, Affairs etc.

Course Leaders

Dr. med. Susanne Kienzle-Horn, Senior Consultant, SCRATCH Pharmacovigilance GmbH, Germany

studied medicine and informatics and started working in the pharmaceutical industry in 1990. In addition to her more than 25 years of PV experience resulting from practical work in this area, she has wide-ranging soft skills in areas like leadership, training and coaching. She is the founder of SCRATCH Pharmacovigilance GmbH, a service provider who supports, advises and trains pharmaceutical entities in Europe in all areas of pharmacovigilance.

Magnus Lühring, PV Training Specialist, SCRATCH Pharmacovigilance GmbH, Germany

started to work for SCRATCH Pharmacovigilance in 2005, directly after having completed his professional education as 'Medizinischer Dokumentar' (medical documentalist). His focus lies on ICSR processing in several PV databases, ICSR submissions to regulatory authorities, XEVMPD product maintenance, as well as lecturing and co-lecturing of PV seminars and MedDRA workshops. Since 2009, he is a "Certified MedDRA Coder" and, since 2014, he bears the title of "TÜV Certified PV Manager".

Continuing Education

This course is accredited by the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM).



SwAPP
Swiss Association of Pharmaceutical Professionals



ESSENTIALS OF PHARMACOVIGILANCE

4 Modules

REGISTRATION FORM

First Name*: _____

Last Name*: _____

Company*: _____

Job Title*: _____

Billing Address*: _____

Telephone*: _____

Email Address*: _____

Background: _____

Experience: _____

Are you a CTC employee? yes no

Are you a SwAPP member? yes no

Are you a SBA member? yes no

What do you expect to get from this course?

Do you wish to receive regular training updates? yes no

I agree to the [terms and conditions](#) yes

REGISTRATION INFORMATION

Dates: 10th June 2020: Module 1
22nd June 2020: Module 2
23rd June 2020: Module 3
1st July 2020: Module 4

Time:
Each module 2-2.15 hrs – 10:00 am – 12:00/12:15 pm

Delivery method:
Remotely via a digital platform. Delegates will receive login instructions within a week before the course starts.

Registration Fee: CHF 790.00 + 7.7% VAT
15 % reduction for SwAPP and SBA members
Special fees for CTC employees
Please contact training@ctcresourcing.com

Registration fees include: Course documentation. Upon completion of the online survey participants will be able to get their certificate of attendance.

Payment: After registration you will receive confirmation and an invoice with instructions on how to complete the bank transfer. Full prepayment is needed prior to the course start date.

Cancellation Policy:

- Cancellations received **more than 14 days before** course: **100% refund** less bank charges & cancellation fee of CHF 50.00
 - Cancellations received **7-14 days before** the course: **50% refund**
 - Cancellations received **7 days before** the course: **no refund**
- In case of no show, no refund will be made.

Please note that CTC reserves the right to cancel this course or to make minor alterations to the content and timing of the programme or to the identity of the speakers. In the unlikely event of cancellation, delegates will be offered a full refund. CTC will not, however, be held responsible for any related expense incurred by the participant.

Transfer Policy

Subject to agreement from CTC Clinical Trial Consulting AG (CTC) prior to the event, the registration may be transferred to another person from the same company or organization at no extra charge. Updated registration information will be required.

Photography and Video Policy

By attending this training, you give permission for pictures, images etc. of you, captured during the training through video, photo, and/or digital devices, to be used by CTC in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

Privacy Policy

At CTC, we're committed to protecting and respecting your privacy. To view our privacy policy, go to <https://www.ctcresourcing.com/about-us/privacy-policy/>

REGISTRATION:

✉ Email: training@ctcresourcing.com

✉ Internet: www.ctcresourcing.com

✉ Fax: +41 61 695 88 67

If you have NOT received an official confirmation 7 days after registering, please call CTC at +41 61 695 88 66 or send an email to training@ctcresourcing.com. THANK YOU!