

WORKSHOP “ESSENTIALS OF PHARMACOVIGILANCE”

Date to be announced

1-Day Course

Overview

The purpose of this 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 Topics

- Definitions and legal background
- Sources of cases
- MedDRA – hands on
- Case processing
- Demonstration of an E2B(R3) compliant database

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”.

Learning Methodology

Interactive sessions with a mix of lectures, hands on training and knowledge transfer, case studies to illustrate theory, exercises to gain first experience and test the knowledge, group work, & Q&A sessions.

“Essentials of Pharmacovigilance”

1-Day Course

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 require help in finding hotel accommodation?
☐ yes ☐ no

Do you wish to receive regular training updates? ☐ yes ☐ no

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

REGISTRATION INFORMATION

Date: *to be announced*

Time: **09:00 – 17:00 hrs**

Venue:

CTC AG, Münchensteinerstr. 41, CH-4052 Basel

Directions:

Tram 15, tram stop «Grosspeterstrasse»

Registration Fee: CHF 950.00 + 7.7% VAT

15 % reduction for CTC employees, SwAPP and SBA members

Special fees for CTC employees

Special rates available for PhD Students, please contact training@ctcresourcing.com

Registration fees include: Course documentation, refreshments, lunch and a course participation certificate.

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.

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!

☐ These dates do not suite me - Please provide me with new training dates once available:

First Name*: _____

Last Name*: _____

Email Address*: _____