Vaccine Safety and Pharmacovigilance

Tipologia	Data	Lingua	Location
Numero chiuso	From 07 April to 26 May 2022	Inglese	Online

INTRODUZIONE

This course will address safety and pharmacovigilance aspects unique to vaccines, which remain the most important preventive intervention for disease prevention in the most sensitive and vital age group of children, more so in the golden era of vaccination with newer vaccines, newer schedules and effectiveness, as also emergence of rare adverse events with increased usage.

The course is conceptualized to provide a comprehensive understanding on how vaccine safety is assured and monitored from pre-licensure to post-immunization and will serve as a medium of disseminating concise concepts and knowledge to all professionals working in the fields of clinical research, drug safety, pharmacovigilance, regulatory affairs and medical reviewers who deal with PV on a daily basis, to update their knowledge and practice PV in a global environment with the aim of minimizing risk to the patient – the ultimate goal!

The course is intended to add value to practice the science based on firm principles with unique real time examples and interactive workshops.

PROGRAMMA

Module 1 | An introduction to Pharmacovigilance
07 and 08 April 2022; 9 am – 12 pm CEST

- Welcome
- Introduction to Pharmacovigilance and Risk Management

- Principles of Pharmacovigilance
- How vaccines differ from drugs?
- Specificities of Vaccine Safety
- Discussion and Q&A

Module 2 | Vaccine Safety Regulations
14 and 15 April 2022; 9 am – 12 pm CEST

- Classification of adverse events
- Regulations
- Vaccine safety in developing countries
- Discussion and Q&A

Module 3 | Vaccine Safety in Clinical Trials
21 and 22 April 2022; 9 am – 12 pm CEST

- How vaccines cause adverse events
- Lessons learned and assessment of causal relationships
- Safety monitoring during clinical trials and safety elements of clinical trial elements
- Discussion and Q&A

Module 4 | Post Marketing Vaccine Surveillance
28 and 29 April 2022; 9 am – 12 pm CEST

- Post marketing surveillance
- Workshop on Post marketing surveillance and safety during clinical trials
- Discussion and Q&A

Module 5 | Pharmacovigilance Methods
05 and 06 May 2022; 9 am – 12 pm CEST

- Signal detection
- Risk management
- Pharmacoepidemiology
- Class exercises on PV methods
- Discussion and Q&A

Module 6 | The link between Quality and Safety
12 May 2022; 9 am – 1 pm CEST

- Quality in pharmacovigilance
- Inspections
- Role of QPPV
- Discussion and Q&A

Module 7 | Crisis Management
19 May 2022; 9 am – 1 pm CEST

- Crisis management
- Communication in pharmacovigilance
- Discussion and Q&A

Module 8 | Vaccine Vigilance Workshop
26 May 2022; 9 am – 1 pm CEST

- The workshop will describe how AE Detection differs between drugs and vaccines, commonly expected reactions, SAEs, methods for detecting SAEs, size of vaccine studies, VAERS, AEFI (WHO), Brighton collaboration group, how to investigate Vaccine reactions.
- Real time example: Assessing the safety of Covid19 vaccines
- Discussion and Q&A
- Closing remarks

A CHI È RIVOLTO

Professionals involved in clinical research, pharmacovigilance, medical reviewers, data managers, drug safety managers, regulatory affairs personnel, nurses, junior doctors planning to work in PV.

Participant Experience

Basic understanding of vaccinology and pharmaceutical clinical development

TECNICHE DIDATTICHE

Training will be based on interactive presentations with discussion and Q&A sessions. Two workshops with real time examples and case studies will be oraganised.

DOCENTE/I

Mihai Alexandru Bica
Director, Clinical Safety Physician, Department Global Clinical Safety and Pharmacovigilance at CSL Behring
Mihai Alexandru Bica is a Director, Clinical Safety Physician at CSL Behring in Marburg, Germany, Fellow of the Royal Society of Public Health in London, United Kingdom and Fellow of the Academy of Science in Siena, Italy. He obtained his medical degree at the University of Medicine Iasi, Romania in 2006 and specialised in infectious diseases epidemiology in 2012; He completed his MPH studying Health Management, Bioinformatics and Biostatistics and has an executive Master degree in Vaccinology and Pharmaceutical Clinical Development from the University of Medicine Siena, Italy where he graduated “cum laude” in 2016. He is currently overseeing the active monitoring and continued assessment of safety profiles of a wide range of therapeutics and conducts multiple clinical research activities in therapeutic areas such as Immunology, Infectious Diseases, Respiratory and Transplant. Previously he lead clinical and pharmaco-epidemiological research activities with prophylactic mRNA-based and recombinant vaccines focusing on rabies, influenza, meningitis, shigella and various oncological indications at GSK and CureVac AG. Prior to this he served as Head of the Epidemiology and Disease Control Department at the National Public Health Authority of Romania within the Ministry of Health where he coordinated several national programs for immunizations, infectious disease control and epidemic and pandemic preparedness. He has successfully interacted with international groups interested in clinical and epidemiological research as also public health issues regarding migrant health. These include the World Health Organization (WHO) or the European Centre for Disease Prevention and Control (ECDC). His publication includes several manuscripts on various topics in public health, infectious diseases, epidemiology and rare diseases

COSA SAPRAI FARE DOPO IL PERCORSO FORMATIVO

- Develop a comprehensive understanding on how vaccine safety is assured and monitored from pre-licensure to post-immunization

DURATA E INFORMAZIONI UTILI

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After the registration, you will receive all details about the connection.

The Masterclass will be confirmed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

Limited number: maximum 15 attendees.

The certificate of attendance of the whole training will be delivered to the participants who will attend the 80% of the training course at least.

QUOTE ISCRIZIONE

Super Early Bird: **€ 3.020,00*** (until 07 February 2022)

Early Bird: **€ 3.270,00*** (until 07 March 2022)

Ordinary: **€ 4.050,00***

Freelance – Academy – Public Administration**: **€ 2.310,00***

* *for Italian companies: +22% VAT*
**Early Bird discount not applicable to Freelance – Academy – Public Administration fee

The fee includes: tuition, organizational office assistance, teaching materials for each training and attendance certificate that will be sent after the complete masterclass via e-mail.

SEDE DEL PERCORSO FORMATIVO

Online training path on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before each module.