

PROGRAM

PHARMACOVIGILANCE IN PRACTICE – GOOD VIGILANCE PRACTICE

Hybrid international training course in English

7-8 OCTOBER, 2021

DAY 1 - 7 OCTOBER

08:45 Introduction
Challenges of drug safety considering innovative drug development
Péter Ferdinandy, Semmelweis University

09:30 GVP Modul I – II
Pharmacovigilance systems
Pharmacovigilance system master file
Attila Oláh, Gedeon Richter Plc.

10:30 GVP Modul III – IV
Inspection and audits
Barbara Reithauser-Nyíri, NIPN (OGYÉI)

11:30 Lunch Break

12:30 GVP Modul V
Risk management systems
Attila Oláh, Gedeon Richter Plc.

13:30 GVP Modul VI
Management of reports of suspected adverse reactions
Tímea Márton, Egis Pharmaceuticals Plc.

14:30 Break

14:45 GVP Modul VII
Periodic safety update report
Viktória Kis, Egis Pharmaceuticals Plc.

15:30 GVP Modul VIII and addendum
Post authorization safety studies
Orsolya Papp, NIPN (OGYÉI)

16:15 MDR – Medical Device Vigilance
Kornél Szerdi NIPN (OGYÉI)

DAY 2 - 8 OCTOBER

09:00 GVP Modul IX
Signal management
Orsolya Szokolóczi, Gedeon Richter Plc.

10:00 GVP Modul IX - addendum
Statistical signal detection
Mátyás Pétervári, Semmelweis University

11:00 Safety of food supplements and cosmetics
Fanni Solymos, Judit Hóvári, NIPN (OGYÉI)

12:00 Lunch Break

13:00 GVP Modul X
Additional monitoring
Júlia Pallós, NIPN (OGYÉI)

13:45 GVP Modul XV
Safety Communication
Júlia Pallós, NIPN (OGYÉI)

14:30 Break

14:45 GVP Modul XVI and addendum
Risk minimalization measures and educational materials
Júlia Pallós, NIPN (OGYÉI)

15:30 Artificial Intelligence and drug safety
Mátyás Pétervári, Semmelweis University

16:30 Exam Online, in the Moodle System

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