

Course data sheet

Basic data

Code number		Semester	II. semester 2023	Nature	Optional
Main title	Pharmacovigilance in practice – Good Vigilance Practice				
Condition	Qualified program				
Organizer	Semmelweis University, Department of Pharmacology and Pharmacotherapy			Contact person	Dr. Anikó Görbe 2104416
Partner	Sanovigado Ltd.				
Target group	1. internal medicine 2. internal medicine angiology 3. vascular surgery 4. pharmacology 5. gastroenterology 6. family medicine 7. neurosurgery 8. cardiology 9. hand surgery 10. clinic.lab.exam. (hygiene.) 11. clinical biochemist 12. clinical pharmacology 13. clinical oncology 14. thoracic surgery 15. molecular biological diagnostician 16. molecular genetic diagnostics 17. nephrology 18. neurology 19. neuroradiology 20. orthopedics 21. orthopedics and traumatology 22. medical laboratory diagnostics 23. radiology 24. rehabilitation medicine 25. rheumatology 26. surgery 27. sports medicine 28. heart surgery 29. traumatology			University	Vocational and Continuing Education Center of Semmelweis University
Accr.point	32				
Start:	05.10.2023	End: 06.10.2023	Location	Zoom platform	
Days	2	Course hours	16	Exam	yes
Price	35000 HUF	Application deadline	30.09.2023		
Comment					
Website (more information about the course)	https://semmelweis.hu/pharmacology/oktatas/posztgradualis-tanfolyamok/a-farmakovigilancia-gyakorlatban-good-vigilance-practice/				
Can participants register on the portal?	Yes.				

List of lectures

Index	Day	Appoint.	Duration (min.)	Title of the presentation	Performer	Position/academic degree
1.	05.10.2023 Thursday	09:00	45	Challenges of drug safety considering innovative drug development.	Prof. Dr. Péter Ferdinandy /Dr. Anikó Görbe	MTA doctor, Semmelweis University (SU) university professor/university associate professor
2.	05.10.2023 Thursday	09:45	60	GVP Modul I – II Pharmacovigilance systems, Pharmacovigilance system master file Specialized topic: Management of PSMF, and PVAs	Dr. Gábor Erdei	Senior Pharmacovigilance Compliance Manager, Richter Gedeon Plc.
3.	05.10.2023 Thursday	10:45	15	BREAK		
4.	05.10.2023 Thursday	11:00	60	GVP Modul III – IV Inspection and audits.	Dr. Gábor Koncsik	Pharmavigilance Manager, Servier Hungaria Ltd.
5.	05.10.2023 Thursday	12:00	60	LUNCH BREAK		
6.	05.10.2023 Thursday	13:00	60	GVP Modul V - VII - Risk managements systems; Periodic safety update report.	Dr. Viktória Kis	Head of Department, Egis Gyógyszergyár Zrt.
7.	05.10.2023 Thursday	14:00	60	GVP Modul VI – Management of reports of suspected adverse reactions. Additional topic: Management of ICSRs from social media, and combined (medical information, product quality complaint) sources	Dr. Kristóf Kovács	Case management team leader, Egis Gyógyszergyár Zrt.
8.	05.10.2023 Thursday	15:00	15	BREAK		
9.	05.10.2023 Thursday	15:15	60	GVP Modul VIII and X	Dr. Júlia Pallós	PRAC member, NNGYK

Index	Day	Appoint.	Duration (min.)	Title of the presentation	Performer	Position/academic degree
10.	06.10.2023 Friday	09:00	60	GVP Modul IX – Signal management	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy
11.	06.10.2023 Friday	10:00	60	GVP Modul XV and XVI	Dr. Júlia Pallós	PRAC member, NNGYK
	06.10.2023 Friday	11:00	15	BREAK		
12.	06.10.2023 Friday	11:15	60	MDR – Medical device vigilance	Dr. Ágnes Horváth	CE Certiso Ltd.
	06.10.2023 Friday	12:15	60	LUNCH BREAK		
13.	06.10.2023 Friday	13:15	60	Implementation of websites, software and mobile applications for pharmacovigilance purposes	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy
14.	06.10.2023 Friday	14:15	60	Artificial intelligence and drug safety.	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy

Vocational college(s)

Numb.	Vocational college(s)	Point	Comment
1.	Internal medicine, endocrinology, diabetes and metabolic diseases		
2.	Angiology and vascular surgery		
3.	Clinical Pharmacology		
4.	Gastroenterological and hepatological		
5.	Home medicine		
6.	Neurosurgery		
7.	Cardiology		
8.	Traumatology and hand surgery		
9.	Medical laboratory		
10.	Oncology and radiation therapy		
11.	Surgery		
12.	Nephrology and dialysis		
13.	Neurological		
14.	Radiological		
15.	Orthopedic		
16.	Rehabilitation, physical medicine and medical aids		
17.	Rheumatology		
18.	Sports health		
19.	Heart surgery		