

Course data sheet

Basic data

Code number		Semester	II. semester 2024	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.			University	Vocational and Continuing Education Center of Semmelweis University
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				
Accr.point	20				
Start:	19.09.2024	End: 20.09.2024	Location	Zoom platform	
Days	2	Course hours	16	Exam	yes
Price	95000 HUF		Application deadline	13.09.2024	
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
0.	19.09.2024 Thursday	08:45	15	Welcoming and introduction Learning outcome	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy
1.	19.09.2024 Thursday	09:00	60	GVP Modul I – II Pharmacovigilance systems, Pharmacovigilance system master file Specialized topic: Management of PSMF, and PVAs	Dr. Gábor Erdei	Senior PV Compliance Manager, deputy QPPV; Global Regulatory Science Directorate / Global Patient Safety Department / Global Pharmacovigilance Compliance Unit, Richter Gedeon Plc.
2.	19.09.2024 Thursday	10:00	45	GVP Modul III Inspection	Hatem Adel Ph.D.	GMP/GDP/GVP Inspector, Hungarian NCA
	19.09.2024 Thursday	10:45	15	BREAK		
3.	19.09.2024 Thursday	11:00	30	GVP Modul IV - audits	Barbara Reithauser-Nyíri	Aurobindo APL Swift Services (Malta) Ltd.
4.	19.09.2024 Thursday	11:30	45	GVP Modul V - VII - Risk management systems; Periodic safety update report	Dr. Viktória Kis	Head of Department, Egis Gyógyszergyár Zrt.
	19.09.2024 Thursday	12:15	45	LUNCH BREAK		
5.	19.09.2024 Thursday	13:00	45	GVP Modul VI – Management of reports of suspected adverse reactions	Dr. Kristóf Kovács	Case management team leader, Egis Gyógyszergyár Zrt.
6.	19.09.2024 Thursday	13:45	60	GVP Modul IX – Signal management	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy
	19.09.2024 Thursday	14:45	15	BREAK		
7.	19.09.2024 Thursday	15:00	30	GVP Modul VIII and X	Dr. Júlia Pallós	PRAC member, NNGYK
8.	19.09.2024 Thursday	15:30	30	GVP Modul XV and XVI	Dr. Júlia Pallós	PRAC member, NNGYK
Index	Day	Appoint.	Duration (min.)	Title of the presentation	Performer	Position/academic degree
9.	20.09.2024 Friday	08:45	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
10.	20.09.2024 Friday	9:30	60	MDR – Medical device vigilance, introduction	Dr. Ágnes Horváth	CE Certiso Ltd.
	20.09.2024 Friday	10:30	15	BREAK		
11.	20.09.2024 Friday	10:45	45	Future data sources for pharmacovigilance use	Maurizio Sessa	
12.	20.09.2024 Friday	11:30	45	Artificial intelligence and drug safety	Jan Petracek	Institute of Pharmacovigilance
	20.09.2024 Friday	12:15	45	LUNCH BREAK		
13.	20.09.2024 Friday	13:00	45	Ecopharmacovigilance	Joan Dsouza	ISOP
14.	20.09.2024 Friday	13:45	45	Engagement of HCP for pharmacovigilance	Dr. Máté Ádám Balázs	Semmelweis University
	20.09.2024 Friday	14:30	15	BREAK		
15.	20.09.2024 Friday	14:45	45	Pharmacovigilance map of CEE and Balkan region	Dr. Mátyás Pétervári	Semmelweis University, Department of Pharmacology and Pharmacotherapy

16.	20.09.2024 Friday	15:30	45	Latest scientific pharmacovigilance advancements	Dr. Szandra Marton	Semmelweis University, Department of Pharmacology and Pharmacotherapy
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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		