

Course data sheet

Basic data

Code number		Semester	II. semester 2025	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	20			
Start:	18.09.2025	End: 19.09.2025	Location	Zoom platform	
Days	2	Course hours	16	Exam	yes
Price	95000 HUF	Application deadline	12.09.2025		
Comment					
Website (more information about the course)		https://semmelweis.hu/pharmacology/oktatas/posztgradualis-tanfolyamok/pharmacovigilance-in-practice-good-vigilance-practice-2025-september/			
Can participants register on the portal?		Yes.			

List of lectures

Index	Day	Appoint.	Duration (min.)	Title of the presentation	Performer	Position/academic degree
0.	18.09.2025 Thursday	08:45	15	Welcoming and introduction Learning outcome	Dr. Mátyás Pétervári	Semmelweis University
1.	18.09.2025 Thursday	09:00	60	GVP Modul I – II Pharmacovigilance systems, Pharmacovigilance System Master File Specialized topic: Management of PSMF, and PVAs	Dr. Barbara Reithauser-Nyíri	Gedeon Richter Plc.
2.	18.09.2025 Thursday	10:00	45	GVP Modul III Inspection	Dr. Adel Hatem	NNGYK (Hungarian NCA)
	18.09.2025 Thursday	10:45	15	BREAK		
3.	18.09.2025 Thursday	11:00	30	GVP Modul IV - audits	Dr. Barbara Reithauser-Nyíri	Gedeon Richter Plc.
4.	18.09.2025 Thursday	11:30	45	GVP Modul V - VII - Risk management systems; Periodic safety update report	Bíróné Dr Zsuzsanna Sándor (Modul V) Dr. Tamara Téglás (Modul VII)	NNGYK (Hungarian NCA)
	18.09.2025 Thursday	12:15	45	LUNCH BREAK		
5.	18.09.2025 Thursday	13:00	45	GVP Modul VI – Management of reports of suspected adverse reactions	Dr. Eszter Mátis, Nikolett László	Roche Hungary Ltd.
6.	18.09.2025 Thursday	13:45	60	GVP Modul IX – Signal management	Dr. Mátyás Pétervári	Semmelweis University
	18.09.2025 Thursday	14:45	15	BREAK		
7.	18.09.2025 Thursday	15:00	30	GVP Modul VIII and X	Dr. Júlia Pallós	PRAC member, NNGYK
8.	18.09.2025 Thursday	15:30	30	GVP Modul XV and XVI Safety communication and additional Risk Minimization Measures	Tamás Balázs	NNGYK (Hungarian NCA)
Index	Day	Appoint.	Duration (min.)	Title of the presentation	Performer	Position/academic degree
9.	19.09.2025 Friday	08:45	45	Challenges of drug safety considering innovative drug development.	Prof. Dr. Péter Ferdinandy	MTA doctor, Semmelweis University (SU) university professor/university associate professor
10.	19.09.2025 Friday	9:30	60	MDR – Medical device vigilance, introduction	Dr. Ágnes Horváth	CE Certiso Ltd.
	19.09.2025 Friday	10:30	15	BREAK		
11.	19.09.2025 Friday	10:45	45	Medical device risk management	Dr. Mátyás Pétervári	Semmelweis University
12.	19.09.2025 Friday	11:30	45	Safety referral procedures in the EU	Dr. Melinda Pálfi	NNGYK (Hungarian NCA)
	19.09.2025 Friday	12:15	45	LUNCH BREAK		
13.	19.09.2025 Friday	13:00	45	Recent EU pharmacovigilance regulation (EU 2025/1466) and its practical implications	Dr. Mátyás Pétervári	Semmelweis University
14.	19.09.2025 Friday	13:45	45	Engagement of HCP for pharmacovigilance	Dr. Balázs Máté Ádám	Semmelweis University
	19.09.2025 Friday	14:30	15	BREAK		
15.	19.09.2025 Friday	14:45	45	Benefit-risk assessment of medicines	Dr. Balázs Takátsy	Gedeon Richter Plc.

16.	19.09.2025 Friday	15:30	45	Latest scientific pharmacovigilance advancements	Dr. Balázs Máté Ádám	Semmelweis University
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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		