Bringing Therapy Radioisotopes into Clinical Radiopharmacy – Some Regulatory Aspects

ESMIT

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Day 1 – Thursday, June 11, 2026			
		min	
09:00 - 09:15	Introduction of the Speakers	15	all
09:15 - 09:45	Introduction of participants and assessment of the Starting Knowledge*	30	all
	Session I -		
09:45 - 10:30	Pillars of GMP	45	AA
10:30 - 10:45	Q and A	15	all
10:45 - 11:15	Coffee Break	30	
11:15 - 12:00	Hospital radiopharmacy facility	45	NH
12:00 - 12:15	Q and A	15	all
	Session II -		
12:15 - 13:00	GMP of radiotherapeutics	45	DN
13:00 - 13:15	Q and A	15	all
13:15 - 14:00	Lunch Break	45	
	Session III -		
14:00- 14:30	Interactive session I: Implementation in a hospital radiopharmacy - layout and flows	30	all
14:30 - 15:00	Quality Control and method validation	30	DN
15:00- 15:15	Q and A	15	all
15:15 -15:30	Coffee Break	15	
	Session IV -		
15:30 - 16:00	Qualifications & Validation of facilities and equipment (SMF)	30	NH
16:00 - 16:30	GMP for clinical trials	30	AA
16:30 - 17:00	Interactive session II: Aseptic preparation and transfer	30	all
17:00 - 17:30	DISCUSSIONS and Wrap Up	30	all
17:30	End of Day 1		

Day 2 – Friday, June 12, 2026			
	Session V -		
09:00 - 09:45	Standard Operating Procedures	45	NH
09:45 - 10:00	Q and A	15	
10:00 - 10:45	Safety and Risk management	45	DN
10:45 - 11:00	Q and A	15	all
11:00 - 11:30	Interactive session III: building a SOP based on Pharmacopoeia monograph	30	all
11:30 - 12:00	Coffee Break	30	
	Session VI -		
12:00 - 12:45	Audits, Self inspections, OOS, CAPA	45	AA
12:45 - 13:00	Q and A	15	all
13:00 - 13:30	Interactive session IV: Handling OOS and recalls	30	all
13:30 - 13:45	DISCUSSIONS	15	all
	Session VII -		
13:45 - 14:05	Panel discussion (outstanding questions as emailed ahead of course from students)	20	all
14:05 - 14:25	Course evaluation and Debriefing	20	all
14:25	End of Day 2		