GMP for Radiopharmaceuticals

	duration	speaker

Facilitators:	Dana Niculae (DN)
	Philip Elsinga (PE)
	Antero Abrunhosa (AA)

Day 1			
		min	
9:30 - 09:45	Introduction of the Speakers	15	all
09:45 - 10:15	Introduction of participants and assessment of the Starting Knowledge*	30	all
	Session I -		
10:15 - 10:45	Basics of GMP part 1	30	PE
10:45 - 10:55	Q and A	10	all
10:55 - 11:10	Coffee Break	15	
11:10 - 11:55	Basics of GMP part 2	45	DN
11:55 - 12:05	Q and A	10	all
	Session II -		
12:05 - 12:30	Site Master Plan and Facility monitoring	25	DN
12:30 - 12:40	Q and A	10	all
12:40 - 13:40	Lunch Break	60	
	Session III -		
13:40- 14:10	Interactive session I: Basics of GMP	30	all
14:10 -14:30	DISCUSSIONS	20	all
14:30 - 15:10	Qualifications & Validation, User Specific Requirements	40	PE
15:10 - 15:20	Q and A	10	all
15:20 -15:30	Coffee Break	10	
	Session IV -		
15:30 - 16:00	Validation of a new tracer	30	PE
16:00 - 16:30	MA Dossier	30	AA
16:30 - 16:50	HANDS ON SESSION I: WRITING A URS	20	all
16:50 - 17:10	Interactive session II: MA vs Clinical Trials	20	all
17:10 - 17:30	DISCUSSIONS and Wrap Up	20	all
17:30	End of Day 1		

Day 2			
	Session V -		
09:00 - 09:40	Standard Operating Procedures	40	AA
09:40 - 10:00	Out of Specifications	20	PE
10:00 - 10:10	Q and A	10	all
10:10- 10:30	Interactive session III: WRITING a SOP, SMF chapters	20	all
10:30 - 10:50	DISCUSSIONS	20	all
10:50 - 11:05	Coffee Break	15	
	Session VI -		
11:05 - 11:45	Quality risk management	40	AA
11:45 - 11:55	Q and A	10	all
11:55 - 12:15	HANDS ON SESSION II: Validations and Qualifications	20	all
12:15 - 12:35	HANDS ON SESSION III: Facility planning, monitoring, risk assesment, OOS	20	all
12:35 - 12:55	DISCUSSIONS	10	all
	Session VII -		
12:55 - 13:10	Panel discussion (outstanding questions as emailed ahead of course from students)	15	all
13:10 - 13:30	Course evaluation and Debriefing	20	all
13:30	End of Day 2		