

Summer School on Pharmaceutical Analysis 2025

New therapeutic approaches, new analytical challenges: nucleic acid-based therapeutics and cell therapy

Tentative Scientific Program

22nd September 2025			
13.00-14.00	Registration		
14.00-14.30	Opening ceremony		
	<i>Chair: Manuela Bartolini</i>		
14.30-15.30	Opening Lecture	ATMPs a challenge for the future	
15.30-16.30		ATMPs: regulatory aspects	
16.30-17.30		Critical attributes for gene and cell-based therapies	
17.30-17.50	PhD Presentation		
20.00	Piadina Dinner		

23rd September 2025			
	Nucleic acid-based therapeutics: analytical challenges		
	<i>Chair:</i>		
09.00-10.00		Characterisation of oligonucleotides by high performance liquid chromatography-mass spectrometry	
10.00-11.00		Impurity profile assessment	
11.00-11.30	<i>Coffee break</i>		
	<i>Chair:</i>		
11.30-12.30		Aggregates or higher order structure of the API in the product	
12.30-13.30		Analytical challenges for vector-based or promotor-driven oligonucleotides	
13.30-14.30	<i>Lunch break</i>		
	<i>Chair:</i>		
14.30-15.30		Analytical method for the quantitation of oligonucleotides in biological matrices	

15.30-16.30		Analytical methods for the assessment of pre-existing and drug-induced humoral anti-drug antibody (ADA) in preclinical studies	
16.30-17.00	<i>Coffee break</i>		
	<i>Chair:</i>		
17.00-18.00	PhD presentations	PhD presentation 2	
		PhD presentation 3	
		PhD presentation 4	
20.00	<i>Social dinner</i>		

24th September 2025

	Cell therapy: analytical challenges		
	<i>Chair:</i>		
9.00-9.40	PhD presentations	PhD presentation 5	
		PhD presentation 6	
	<i>Chair:</i>		
9.40-10.40		Cell therapies characterization and analysis	
10.40-11.10	<i>Coffee break</i>		
11.10-12.10		Flow cytometry validation to assess the number of circulating cells in preclinical studies	
12.10-13.10		qPCR validation and application to biodistribution studies	
13.10-14.10	<i>Lunch break</i>		
	<i>Chair:</i>		
14.10-15.10		Analytical methods for clinical monitoring/Analytical methods for dose concentration analysis of ATMP compounds	
15.10-15.45	Case studies	Case Studies on nucleic acid-based therapeutics and PNAs	
15.45-16.20		Case Studies on Cell Therapies	
16.20	<i>Closing remarks</i>		