

# Summer School on Pharmaceutical Analysis 2025

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

### Scientific Program

22nd September 2025			
13.00-14.00	Registration		
14.00-14.30	<b>Opening ceremony</b>		
	<i>Chair: Manuela Bartolini, Alma Mater Studiorum University of Bologna</i>		
14.30-15.30	Opening Lecture	Developing cell and gene therapies: a journey from concepts to patients.	<b>Massimo Dominici</b> Università degli Studi di Modena e Reggio Emilia, Modena, Italy
	<b>General introduction to analytical challenges for ATMPs</b> <i>Chair: Francesco Epifano, "G. d'Annunzio" University of Chieti-Pescara</i>		
15.30-16.30		ATMPs: regulatory aspects	<b>Michela Gabaldo</b> Aptuit (Verona) Srl, an Evotec Company, Verona, Italy
16.30-17.30		Navigating the analytical lifecycle: strategic management for streamlined product development	<b>Ilaria Visigalli</b> GLP SR-Tiget, San Raffaele Scientific Institute, Milan, Italy
17.30-18.00	<b>Workshop</b>	<b>Team challenge</b>	<b>Ilaria Visigalli</b> GLP SR-Tiget, San Raffaele Scientific Institute, Milan, Italy
20.15	Piadina Dinner		

23rd September 2025			
8.30-8.45	Registration		
	<b>Analytical challenges in gene therapy</b> <i>Chair: Eduardo Maria Sommella, University of Salerno</i>		
8.45-9.30		Chromatographic approaches for the analysis of Oligonucleotide Therapeutics and Vectors for AAV Gene Therapy	<b>Werner Conze</b> Tosoh Bioscience GmbH, Griesheim, Germany
9.30-10.15		Bringing it to the next level: highly sensitive characterization and quantification of oligonucleotide impurities and metabolites	<b>Alessandro Armandi</b> SCIEX, Milan, Italy
10.15-10.45	Coffee break		
	<i>Chair: Caterina Temporini, University of Pavia,</i>		
10.45-11.30		Analytical challenges in mRNA and pDNA production - Enhancing mRNA-based therapeutics safety and efficiency	<b>Jasmina Puc</b> Sartorius BIA Separations, Ajdovscina, Slovenia
11.30-12.30		Mass Spectrometry toolbox for the analysis of adeno-associated virus capsids used in gene therapy treatments	<b>Sara Carillo</b> National Institute for Bioprocessing Research and Training (NIBRT), Dublin, Ireland
12.30-13.30	Lunch break		

	Chair: Giancarlo Aldini, University of Milan		
13.30-14.30		LC-MS bioanalysis of oligonucleotide drugs: technology considerations and analytical challenges	<b>Luca Ferrari</b> F. Hoffmann-La Roche Ltd, Basel, Switzerland
14.30-15.15	Case study	Separation and determination of therapeutic oligonucleotide metabolites – Nusinersen case study for the treatment of spinal muscular atrophy	<b>Sylwia Studzinska</b> Nicolaus Copernicus University in Toruń, Toruń, Poland
15.15-15.45	Coffee break		
	Chair: Federica Pellati, University of Modena and Reggio Emilia		
15.45-17.25	PhD presentations	Advances in functional foods, nutraceuticals, and dietary supplements: from bioactive compound identification to comprehensive characterization and quality control	<b>Ghaid W. A. Abualzulof</b> University of Perugia, Perugia, Italy
		Advanced chemometric strategies in pharmaceutical analysis: MCR-ALS for the interpretation of complex chemical systems	<b>Martina Chieffallo</b> University of Calabria, Arcavacata di Rende, Italy
		Enhancement of the Alta Valmarecchia Area through the study of edible mushrooms and ancient grains for the development of a circular bioeconomy in food, nutraceutical, cosmetic, and pharmaceutical products	<b>Francesca Medri</b> Alma Mater Studiorum University of Bologna, Rimini, Italy
		Development of immobilized enzyme reactors for use in the mRNA production process	<b>Maša Nabergoj</b> University of Nova Gorica, Nova Gorica, Slovenia
		LC-HRMS-based assay development for screening and characterization of selective inhibitors targeting pharmaceutically relevant enzyme isoforms	<b>Salvatore Villani</b> Università del Piemonte Orientale, Novara, Italy
	Chair: Manuela Bartolini, Alma Mater Studiorum University of Bologna		
17.25-17.45	Workshop	Team challenge results	<b>Ilaria Visigalli</b> Study Director at GLP - SR Tiget, Milan, Italy
20.15	Social dinner		

## 24th September 2025

8.30-8.45		Registration	
	Analytical challenges in cell therapy <i>Chair: Erika Del Grosso, Università del Piemonte Orientale</i>		
8.45-9.45		Challenges in cell therapy characterization and analysis	<b>Chiara Portugalli</b> ACG Biologics, Milan, Italy
9.45-10.45		Flow cytometry validation to assess the number of circulating cells in preclinical studies	<b>Silvia Lorenzi</b> Aptuit (Verona) Srl, an Evotec Company, Verona, Italy
10.45-11.15	Coffee break		
	<i>Chair: Massimo Breda, Aptuit (Verona) an Evotec Company</i>		
11.15-12.15		Immunogenicity of ATMs: evaluation of the presence of anti-drug antibodies using ligand binding assays	<b>Elena Piccoli</b> Frontage Europe S.r.l., Nerviano, Italy

12.30-13.15		qPCR validation and application to biodistribution studies	<b>Chiara Cazzin</b> Aptuit (Verona) Srl, an Evotec Company, Italy
13.15-14.15	<i>Lunch break</i>		
	<i>Chair: Massimo Breda, Aptuit (Verona) an Evotec Company</i>		
14.15-15.15		The experience of mRNA and AdV vaccines: humoral and cellular biomarkers for the evaluation of the immune response to SARS-CoV-2 vaccination and breakthrough infections	<b>Chiara Piubelli</b> IRCCS Sacro Cuore Don Calabria Hospital, Verona, Italy
	<i>Chair: Marina Naldi, Alma Mater Studiorum University of Bologna</i>		
15.15-16.15	<b>PhD presentations</b>	Bridging Laboratory-Scale Insights and Industrial Demands in Viral Clearance of Therapeutic mAbs (case study: Pembrolizumab)	<b>Dhruvkumar Hariharbhai Soni</b> Università degli Studi di Milano, Milan, Italy
		Development of validated analytical platforms to be used for monoclonal antibodies characterization and quality control	<b>Virginia Ghizzani</b> Università degli Studi di Pavia, Pavia, Italy
		Improving the manufacturing of mRNA vaccines with thermoreversible aqueous biphasic systems and ionic liquids	<b>Maria I. Sousa</b> CICECO - University of Aveiro, Aveiro, Portugal
16.15-16.30	<i>Closing remarks</i>		