

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	Opening ceremony <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.	Massimo Dominici Università degli Studi di Modena e Reggio Emilia, Modena, Italy
	General introduction to analytical challenges for ATMPs <i>Chair: Francesco Epifano, "G. d'Annunzio" University of Chieti-Pescara</i>		
15.30-16.30		ATMPs: regulatory aspects	Michela Gabaldo Aptuit (Verona) Srl, an Evotec Company, Verona, Italy
16.30-17.30		Navigating the analytical lifecycle: strategic management for streamlined product development	Ilaria Visigalli GLP SR-Tiget, San Raffaele Scientific Institute, Milan, Italy
17.30-18.00	Workshop	Team challenge	Ilaria Visigalli GLP SR-Tiget, San Raffaele Scientific Institute, Milan, Italy
20.15	<i>Piadina Dinner</i>		

23rd September 2025

8.30-8.45	Registration		
	Analytical challenges in gene therapy <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	Werner Conze 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	Alessandro Armandi SCIEX, Milan, Italy
10.15-10.45	<i>Coffee break</i>		
	<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	Jasmina Puc 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	Sara Carillo National Institute for Bioprocessing Research and Training (NIBRT), Dublin, Ireland
12.30-13.30	<i>Lunch break</i>		

	<i>Chair: Giancarlo Aldini, University of Milan</i>		
13.30-14.30		LC-MS bioanalysis of oligonucleotide drugs: technology considerations and analytical challenges	Luca Ferrari 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	Sylwia Studzinska Nicolaus Copernicus University in Toruń, Toruń, Poland
15.15-15.45	<i>Coffee break</i>		
	<i>Chair: Federica Pellati, University of Modena and Reggio Emilia</i>		
15.45-17.25	PhD presentations	Advances in functional foods, nutraceuticals, and dietary supplements: from bioactive compound identification to comprehensive characterization and quality control	Ghaid W. A. Abualzulof University of Perugia, Perugia, Italy
		Advanced chemometric strategies in pharmaceutical analysis: MCR-ALS for the interpretation of complex chemical systems	Martina Chieffallo 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	Francesca Medri Alma Mater Studiorum University of Bologna, Rimini, Italy
		Development of immobilized enzyme reactors for use in the mRNA production process	Maša Nabergoj University of Nova Gorica, Nova Gorica, Slovenia
		LC-HRMS-based assay development for screening and characterization of selective inhibitors targeting pharmaceutically relevant enzyme isoforms	Salvatore Villani Università del Piemonte Orientale, Novara, Italy
	<i>Chair: Manuela Bartolini, Alma Mater Studiorum University of Bologna</i>		
17.25-17.45	Workshop	Team challenge results	Ilaria Visigalli Study Director at GLP - SR Tiget, Milan, Italy
20.15	<i>Social dinner</i>		

24th September 2025

8.30-8.45		<i>Registration</i>	
		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	Chiara Portugalli ACG Biologics, Milan, Italy
9.45-10.45		Flow cytometry validation to assess the number of circulating cells in preclinical studies	Silvia Lorenzi Aptuit (Verona) Srl, an Evotec Company, Verona, Italy
10.45-11.15	<i>Coffee break</i>		
	<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	Elena Piccoli Frontage Europe S.r.l., Nerviano, Italy

12.30-13.15		qPCR validation and application to biodistribution studies	Chiara Cazzin 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	Chiara Piubelli IRCCS Sacro Cuore Don Calabria Hospital, Verona, Italy
	<i>Chair: Marina Naldi, Alma Mater Studiorum University of Bologna</i>		
15.15-16.15	PhD presentations	Bridging Laboratory-Scale Insights and Industrial Demands in Viral Clearance of Therapeutic mAbs (case study: Pembrolizumab)	Dhruvkumar Hariharbhai Soni Università degli Studi di Milano, Milan, Italy
		Development of validated analytical platforms to be used for monoclonal antibodies characterization and quality control	Virginia Ghizzani Università degli Studi di Pavia, Pavia, Italy
		Improving the manufacturing of mRNA vaccines with thermoreversible aqueous biphasic systems and ionic liquids	Maria I. Sousa CICECO - University of Aveiro, Aveiro, Portugal
16.15-16.30	<i>Closing remarks</i>		