

PDA Shaping the Future of Vaccines Workshop 2025

Agenda

Monday, 22 September

CEST Daylight Time (UTC +2:00)

Welcome & Introduction

12:00 – 12:10

Falk Klar PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

Anna Czwarno Ms.Eng. Regulatory, Manufacturing & Supply Director, Vaccines Europe *Vaccines Europe*

Vaccine Development Strategies

Moderator: Anna Czwarno Ms.Eng., Regulatory, Manufacturing & Supply Director, Vaccines Europe, *Vaccines Europe*

Keynote Presentation: General Situation for Vaccine Development

12:10 – 12:30

- **Regulatory Presenter: Manuela Mura**, EMA Biological Health Threats and Vaccines Strategy, *European Medicines Agency (EMA)*

Accelerating Vaccine Development to Prepare and Respond to the Next Pandemic

12:30 – 12:45

- **Presenter: Adam Hacker**, Director and Head of Global Regulatory Affairs & Quality, *CEPI*

Industry Perspective

12:45 – 13:00

- **Presenter: Sibilia Quilici**, Executive Director Vaccines Europe, *Vaccines Europe*

12:05 – 13:00

Model-Driven Vaccine Development

13:00 – 13:15

- **Presenter: Rajat Desikan**, , *GSK*

Panel Discussion: Join a wide panel of regulatory, non-governmental, and industry representatives

13:15 – 14:00

- **Moderator: Cristiana Campa PhD**, External CMC Intelligence Lead, *GSK*
- **Panelist: Mats Welin MScPharm**, Scientific director, Biotechnology, *Medical Products Agency, Sweden*
- **Panelist: Adam Hacker**, Director and Head of Global Regulatory Affairs & Quality, *CEPI*
- **Panelist: Manuela Mura**, EMA Biological Health Threats and Vaccines Strategy, *European Medicines Agency (EMA)*
- **Panelist: Sibilia Quilici**, Executive Director Vaccines Europe, *Vaccines Europe*

14:00 – 14:30

Networking Coffee Break

Advancing European Competitiveness: Innovation in Vaccine Manufacturing

Moderator: Cristiana Campa PhD, External CMC Intelligence Lead, *GSK*

14:30 – 15:35	14:30 – 14:45	Overview of Regulatory Framework to Support Innovations for Vaccines: A Quality Perspective • Regulatory Presenter: Ragini Shivji PhD, , <i>European Medicines Agency</i>
	14:45 – 15:00	Innovations in Vaccine (Control) Strategies: What are the Learnings from Different Modalities? • Presenter: Pepijn Burgers PhD, Scientific Director Biologics AD , <i>JnJ Innovative Medicine</i>
	15:00 – 15:15	Innovation in Vaccine Manufacturing through AI, ML, and Modeling • Presenter: Mónica Perea-Vélez MSc, PhD, CMC Advocacy and Policy Director, <i>GSK</i>
	15:15 – 15:35	Interactive Part
15:35 – 16:05	Networking Coffee Break	
16:05 – 17:20	Advancing European Competitiveness: Innovation in Vaccine Manufacturing – Case Studies	
	16:05 – 16:20	Speedcell: Accelerating Protein-Based Platform Vaccines • Presenter: Jordi Ruano , Executive Director Operations Human Health, <i>HIPRA</i>
	16:20 – 16:35	Vaccines Multi Techno Platform Facility • Presenter: Alain Denis , Head of Modulus facilities and M&S Sanofi sites, <i>Sanofi</i>
	16:35 – 17:20	Group Discussion
17:20 – 17:35	Summary of the Workshop and Take-Home Messages Anna Czwarno Ms.Eng. , Regulatory, Manufacturing & Supply Director, Vaccines Europe, <i>Vaccines Europe</i>	
17:35 – 17:35	End of Workshop and Farewell	