



**HERA** HEALTH EMERGENCY  
PREPAREDNESS AND  
RESPONSE AUTHORITY  
#HealthUnion

# **HERA Industry days**

## **H**ealth **E**mergency Preparedness and **R**esponse **A**uthority

2 & 3 June 2025, Brussels

## Side session

# Scalable manufacturing for crisis preparedness

# Scalable manufacturing for crisis preparedness



Csaba GALI  
HERA 03



Josep FERRES COROMINAS  
Quality Compliance &  
Contract Manufacturing  
Executive Director, HIPRA



Gemma LAHUERTA  
Director of injectable  
product development and  
CDMO lead, Reig Joffre



Joachim BUG  
Head of ZEPAI



Karen VAN HOEY  
Vice President, New Product  
and LCM Lead, Global  
Technology & Engineering



Dominique MAUGEAIS  
Independent Consultant



# **Scalable manufacturing for crisis preparedness**



# **Our panelists**

# Dr Joachim BUG

- Acting Director
- Centre for Pandemic Vaccines and Therapeutics (ZEPAI)



- **Studied pharmacy at the universities of Marburg and Würzburg, Germany.**
- **Wrote his doctoral thesis on pharmaceutical technology.**
- **After many years in international management positions in the pharmaceutical industry, joined ZEPAI in October 2021, taking charge of vaccine production, which also includes the management of pandemic preparedness contracts.**
- **In early 2024, he was appointed Acting Director of ZEPAI at the Paul-Ehrlich-Institut (PEI).**

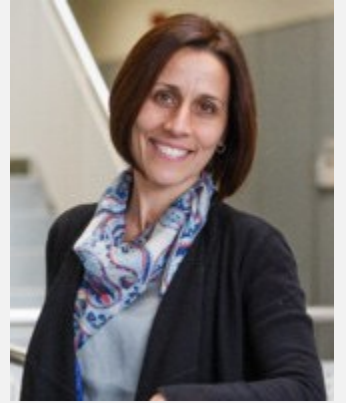
# Josep FERRÉS i COROMINAS

- Quality compliance and Contract Manufacturing Executive Director, Qualified Person, EUFab Project Director
  - HIPRA
- 
- **Bachelors in Chemistry. MBA, PhD**
  - **30+ years at HIPRA specializing in veterinary vaccine manufacturing**
  - **Led expansion into human vaccine production during the COVID-19 pandemic**
  - **Broad expertise across R&D, Regulatory Affairs, Production, QC, and QA**
  - **20+ years optimizing facilities, processes, and procedures**
  - **Dedicated to strengthening the Pharmaceutical Quality System, especially in aseptic processing**
  - **Currently leading cross-functional teams for EUFAB project execution**



# Gemma LAHUERTA

- CDMO Head
- Laboratorio Reig Jofre



- **Degree in Chemistry from the University of Barcelona.**
- **She completed a Management Development Program at IESE Business School**
- **20+ years at Reig Jofre, overseeing the development of injectables from clinical stages to scale-up and effective commercialization, along with third-party development initiatives.**
- **Previous experience working with Ferrer Internacional and INDO**
- **Over 25 years of expertise in pharmaceutical product development, with a primary focus on injectable medicines, including small molecules, biological and vaccines**
- **Co-Leader of the EU FAB project**

# Dominique MAUGEAIS

- Consultant – Vaccine Manufacturing Expert
  - 6 years in vaccine manufacturing and industrial strategy consulting
  - 28 years in vaccine manufacturing operations, supply chain and strategy



• Experience	Period	Company
• <b>Vaccine Manufacturing Expert in Gavi deal team in charge of COVAX C19 portfolio</b>	2020-23	Gavi   COVAX
• <b>Vaccine strategic advisor – Gates grant program director</b>	2022-25	MARBIO
• <b>VP Industrial Operations and Site Head – Marcy l’Etoile</b>	2015-18	SANOFI PASTEUR
• <b>Global Head of Manufacturing Operations – Novartis Vaccines manufacturing network</b>	2012-15	NOVARTIS Vaccines GSK
• <b>VP Industrial Operations and Site Head – Val de Reuil [A/H1N1 manufacturing site]</b>	2008-11	SANOFI PASTEUR
• <b>VP Global Supply Chain and Industrial Strategy</b>	2005-08	SANOFI PASTEUR

# Karen VAN HOEY

- Vice-President, New Products and Lifecycle Management
- Pfizer Global Supply



- **Holds a Master in Bioscience Engineering at Ghent University, Belgium**
- **Joined Pfizer in 2006 in as a manufacturing engineer. She held several positions at the Pfizer Global Supply Manufacturing site at Puurs - Belgium, before joining the Global Technology, Engineering and Launch division of the Pfizer manufacturing unit.**
- **Plays a pivotal role in shaping the future of innovative therapies, driving cross-functional alignment from early development through commercialization.**
- **Acted as a driving force in advancing mRNA-based platforms, contributing to the successful development and launch of breakthrough vaccines and therapeutics.**



# **Panel discussion scene-setter**

## Panel discussion scene-setter

Crisis manufacturing to respond to health emergencies poses unique challenges for pharmaceutical companies, particularly for vaccine manufacturers.

- Number of potential threats posed
- Unique, customised response needed for each emergency
- Quantities required to respond to an emergency
- Speed of the response
- Shelf-life/storage conditions of vaccines

## Panel discussion scene-setter

Examples of EU and global initiatives to support scaling up manufacturing :

- EUFab vaccine manufacturing capacity reservation network
- European Vaccines Hub
- WHO Health Technology Access Program
- CEPI 100 day mission

## Panel discussion scene-setter

The aim of this session is to understand how manufacturers:

- Understand and navigate within these challenges
- Ensure their supply and manufacturing chains are robust and resilient
- See the future of manufacturing and how this impacts crisis response
- Use new technologies to improve crisis response

# Let's engage!

Please use Slido to post your questions during the discussion and they can be put to the panel  
#heraindustrydays2025



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# Thank you