

Dear Sir or Madam,

On behalf of the **European Vaccines Hub (EVH)**, we are pleased to invite your company to participate in an information exchange aimed at mapping available capacity and expertise in Good Manufacturing Practice (GMP) production of vaccines, challenge agents for use in controlled human infection model studies and monoclonal antibodies for the European Union.

The EVH, under the mandate of **HERA** (Health Emergency Preparedness and Response Authority), is committed to strengthening manufacturing capacities within the European Union, with particular focus on pandemic preparedness and rapid response to health crises.

The objective of this initiative is to enhance our understanding of the European biomanufacturing landscape and to identify potential partners for future public health preparedness and emergency response contracts. Specifically, we aim to map:

1. Existing GMP-compliant facilities and production lines relevant to vaccine, challenge agent and monoclonal antibody manufacturing
2. Scale-up and scale-out capacities (from clinical to commercial scale)
3. Experience with regulatory submissions and adherence to international quality standards
4. Previous engagement in technology transfer or collaborations with public health institutions

**We would greatly appreciate your contribution by sharing information on your organization's capabilities, core expertise, and relevant experience. The data collected will primarily serve as a strategic reference for pandemic response planning. This is an opportunity to increase visibility within HERA's preparedness efforts.**

The data collected will be disseminated internally among EVH members and will serve as a potential starting point for product development projects and to inform the status of readiness in Europe within vaccine, challenge agent and monoclonal antibody manufacturing. Collected data may be made openly available on the EVH website, whereas proprietary information, as indicated by the data provider, will be handled to ensure its protection.

We look forward to your collaboration in this important effort to enhance pandemic preparedness capacity and strategic autonomy of the European Union.

If you have any questions or require any clarification, please do not hesitate to get in touch. To **return completed surveys** and any further correspondence, please contact us at [production@zepai.de](mailto:production@zepai.de).

Sincerely,

**ZEPAI**

Zentrum für Pandemie-Impfstoffe und -Therapeutika

Center for Pandemic Vaccines and Therapeutics

**Paul-Ehrlich-Institut**

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel

Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Str. 51-59

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[www.zepai.de](http://www.zepai.de)

Das Paul-Ehrlich-Institut ist eine Einrichtung im Geschäftsbereich des Bundesministeriums für Gesundheit.

The Paul-Ehrlich-Institut is an Agency of the German Federal Ministry of Health.



Paul-Ehrlich-Institut

## Building Readiness: EVH Manufacturing Capacity Survey

This survey helps EVH evaluate manufacturers and partners based on their capacity to support the rapid, scalable, and compliant production of vaccines, challenge agents or monoclonal antibodies, especially in the context of pandemic preparedness.

### PLEASE STATE GENERAL INFORMATION OF YOUR COMPANY

Name and position: \_\_\_\_\_

Contact email: \_\_\_\_\_

Date of survey: \_\_\_\_\_

Organisation: \_\_\_\_\_

Country: \_\_\_\_\_

Website: \_\_\_\_\_

### PLEASE STATE BIOLOGICAL MANUFACTURING EXPERIENCE

**Please complete a separate questionnaire for each 'product manufacturing experience' that you share with the EVH (e.g. mRNA/LNP or viral vector).**

#### Product manufacturing experiences in the past 10 years

Vaccines  yes  no

- mRNA/LNP  Viral vector  Recombinant protein
- Inactivated pathogen or purified inactivated virus
- Live attenuated virus
- Other: \_\_\_\_\_

Antibodies  yes  no

- Human monoclonal isotypes, chimeric or humanized
- Camelid or VHH  Bispecific
- Antibody-drug conjugate  Diagnostic use
- Other: \_\_\_\_\_

Oligonucleotides (sense, antisense)  yes  no

- DNA  mRNA
- Other: \_\_\_\_\_

Challenge agents (inoculum for CHIM)  yes  no

Organism, please specify \_\_\_\_\_

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strategic reference for pandemic response planning*

**Manufacturing platforms**

Egg       Yeasts       Bacteria       Mammalian       Insect  
 Fungi       Plant based system       Organoids       Full synthetic  
 Other: \_\_\_\_\_

**Services**

Upstream       Downstream       Cell line development       Cell banking  
 Non-sterile product manufacturing       Aseptic production manufacturing  
 Fill & finish  Other: \_\_\_\_\_

**Analytical / QC services**

Release testing of raw materials       Analytical methods validation  
 Analytical methods transfer       Analytical methods development  
 Release testing of product       Bioanalysis  
 Other: \_\_\_\_\_

**Quality Assurance services**

GMP documentation  
 Batch certification / release       QP in house  
 Other: \_\_\_\_\_

**Manufacturing services**

Scale-up       Scale-out  
 Formulation       Lyophilization  
 Pilot batches       Engineering batches       Registration batches  
 Other: \_\_\_\_\_

**Development services**

Preformulation studies       Formulation / Galenic design       Quality by Design  
 Process development       Process optimization       Process validation  
 Stability studies       Genetic analysis & Pharmacogenetics  
 Other: \_\_\_\_\_

### Regulatory services

CMC regulatory support  MAA submission support  
 CTD/eCTD compilation and submission  
 Other: \_\_\_\_\_

### GMP regulatory compliance approvals and experiences

National competent authorities  EMA (EU GMP)  WHO (GMP / HACCP)

### Containment (Biological safety level; BSL)

1  2  3  4

### DS Bioreactor scale (suspension) yes no

Details: \_\_\_\_\_

1-10L Number of reactors: \_\_\_\_\_  11-25L Number of reactors: \_\_\_\_\_  
 26-50L Number of reactors: \_\_\_\_\_  51-100L Number of reactors: \_\_\_\_\_  
 101-1000L Number of reactors: \_\_\_\_\_  1001-2000L Number of reactors: \_\_\_\_\_  
 2001-4999L Number of reactors: \_\_\_\_\_  5000- x L Number of reactors: \_\_\_\_\_

Other: \_\_\_\_\_

### DS Bioreactor scale (adherent cells) yes no

Details: \_\_\_\_\_

1-10 sqm Number of reactors: \_\_\_\_\_  11-25 sqm Number of reactors: \_\_\_\_\_  
 26-50 sqm Number of reactors: \_\_\_\_\_  51-100 sqm Number of reactors: \_\_\_\_\_  
 101-200 sqm Number of reactors: \_\_\_\_\_  201-499 sqm Number of reactors: \_\_\_\_\_  
 500- x sqm Number of reactors: \_\_\_\_\_

Other: \_\_\_\_\_

### Cell production process

Batch  Fed-batch  Perfusion/continuous

### Batch size

Small (FIH, Phase I-II)  Medium (Phase II-III)  Large (commercial)

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**Formulation services**  yes  no

LNP       Liposomes       Nanoparticle

Other: \_\_\_\_\_

Experience with Adjuvant

Oil-in-water emulsions       Saponin-based  
 Aluminum salts       TLR agonists/synthetic

Other: \_\_\_\_\_

**F&F**  yes  no

Available primary container formats

Vials       pre-filled syringes       cartridges

Other: \_\_\_\_\_

**Additional information**