

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.



## 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 \_\_\_\_\_

**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: \_\_\_\_\_

- |                                     |                          |                                     |                          |
|-------------------------------------|--------------------------|-------------------------------------|--------------------------|
| <input type="checkbox"/> 1-10L      | Number of reactors: ____ | <input type="checkbox"/> 11-25L     | Number of reactors: ____ |
| <input type="checkbox"/> 26-50L     | Number of reactors: ____ | <input type="checkbox"/> 51-100L    | Number of reactors: ____ |
| <input type="checkbox"/> 101-1000L  | Number of reactors: ____ | <input type="checkbox"/> 1001-2000L | Number of reactors: ____ |
| <input type="checkbox"/> 2001-4999L | Number of reactors: ____ | <input type="checkbox"/> 5000- x L  | Number of reactors: ____ |

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

**DS Bioreactor scale (adherent cells)** ☐ yes ☐ no

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

- |                                      |                          |                                      |                          |
|--------------------------------------|--------------------------|--------------------------------------|--------------------------|
| <input type="checkbox"/> 1-10 sqm    | Number of reactors: ____ | <input type="checkbox"/> 11-25 sqm   | Number of reactors: ____ |
| <input type="checkbox"/> 26-50 sqm   | Number of reactors: ____ | <input type="checkbox"/> 51-100 sqm  | Number of reactors: ____ |
| <input type="checkbox"/> 101-200 sqm | Number of reactors: ____ | <input type="checkbox"/> 201-499 sqm | Number of reactors: ____ |
| <input type="checkbox"/> 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)

**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**