IHI Call Days | Call 9

Strengthening the biomanufacturing ecosystem for biotherapies

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Link to the IHI brokerage platform:

- Proposal sharing tool: https://ihicalldays2024.converve.io/index.php?page=profiles&action=show&params%5Bid%5D=700&params%5Bshow%5D=tech

- Participant profiles: Caroline Desvergne, Françoise Charbit https://ihicalldays2024.converve.io/index.php?page=profiles&action=show&params%5Bid%5D=39&params%5Bshow%5D=comp

https://ihicalldays2024.converve.io/index.php?page=meet_request_meetings&action=detail&params%5Bq%5D=charbit&params%5B_filtered%5D=1&params%5Bshow%5D=pers&params%5Bsort_by%5D=comp_name&params%5Bevent_id%5D=1&params%5Bid%5D=90&params[pers_id]=85

Challenges and objectives

- **Public unmet need and problems to be solved:**
  - Still scarce and costly access to biotherapies for European patients
  - European sovereignty needs to be strengthened in terms of biomanufacturing capacities
  - Biotherapies often involve lengthy, complex, and costly development processes
  - ► **Existing processes need to shift towards efficient and sustainable biomanufacturing**

- **In relation with the specific objective n° 2 of the IHI SRIA**:
  - **Potential output: "**Innovations in manufacturing, exploring new decentralised, automated or semi-automated technologies or processes such as 3D-(bio)printing and mRNA platforms".
  - **Expected impact: "**Patients and industry benefit from innovative manufacturing processes such as 3D printing, on-demand small-scale GMP synthesis, on-site portable production systems etc".

- **In relation with the EC communication and strategy** "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU" (March 2024) welcomed by **EFPIA and Europabio**
- **Taking advantage of previous initiatives (e.g. iConsensus IMI2 project)**

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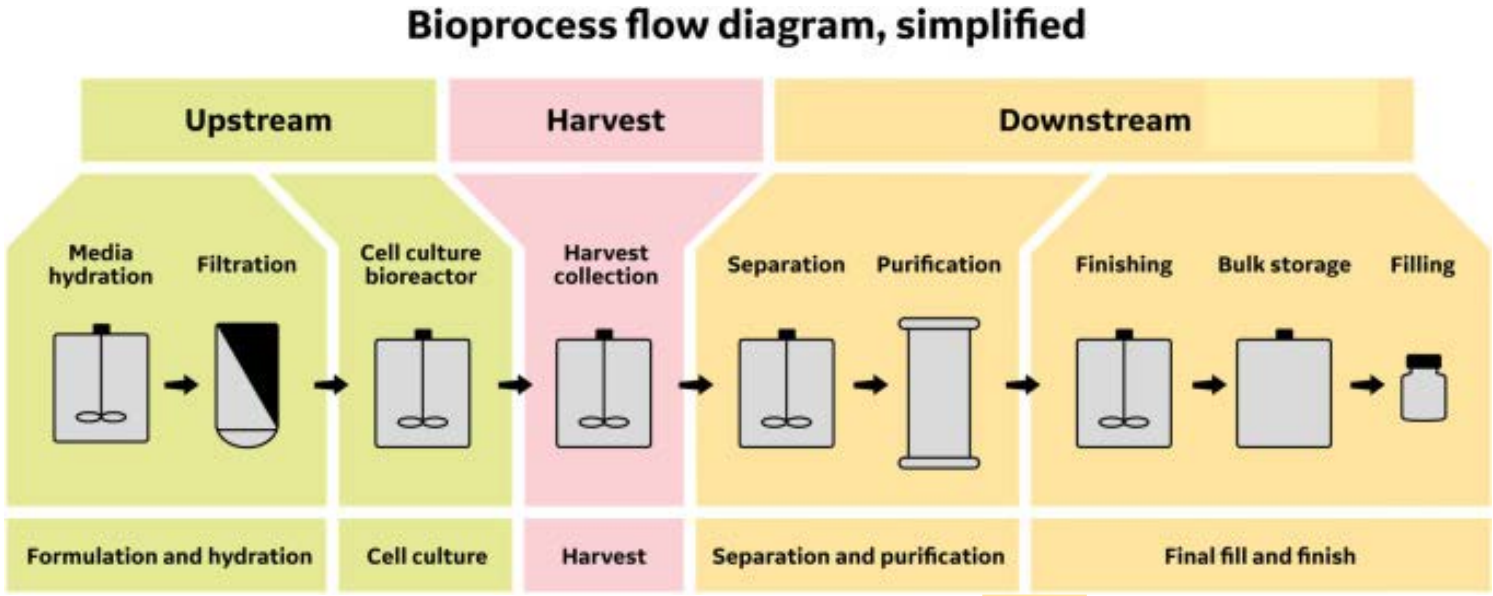
Our proposal: reinforce process analytical technologies (PATs) for a more competitive and sustainable biomanufacturing sector

Enhance cooperation and sharing between technology developers and industrials to support translational research and concrete implementation for **more cost-effective and sustainable biotherapies (ATMPs, vaccines, antibodies, therapeutic proteins…)**



Need for in/on line PATs for bioreactor closed loop control

Need for in/on/at line PATs for the detection of impurities and quantification of bioproducts

Process monitoring

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K.P. Clappet al. Biopharmaceutical Processing, Elsevier Ed, 2018, 97

PATs for bioprocess monitoring at CEA-Leti

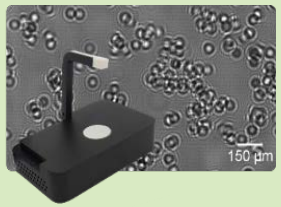
Sensors for USP and DSP monitoring

- On-line physicochemical sensors
- At-line cell imaging
- Integration of characterization tools
- AI, data treatment and analysis
- Automation / closed-loop control

USP (upstream process)

CMOS imagers and holographic microscopy

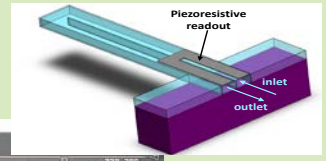
Miniaturised multiparametric electrochemical sensing platforms

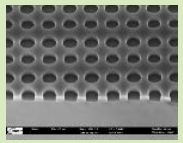


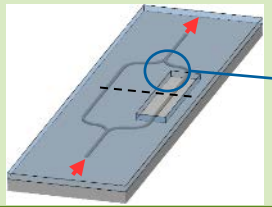
DSP (downstream process)

Micromechanical biosensors

Optical/photonic biosensors

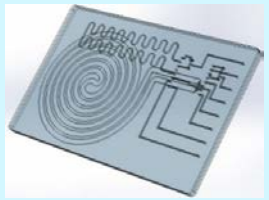


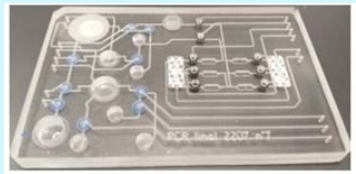




Microfluidics for automated solutions

- Cell and fluids manipulation, sample preparation
- Cell transfection (EC or US)
- Full automation including actuators, imaging and sensing
- Adapted to small batch processing (cell therapies), micro-factories





Eco-innovating / regulatory-compliant solutions

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A wide public-private collaboration is essential

To achieve concrete and impactful results

- Provide a panel of new biomanufacturing tools that are **performing, cost-effective, versatile, regulatory-compliant, sustainable** to fulfill various needs
- Implement the solutions in **realistic industrial use-cases**
- **Assess the novel performances** (time, cost, sustainability) in comparison with existing processes
- **Build a strong network** involving all actors of the domain (academic research, pharmaceutical & biotech companies, CDMOs, equipment manufacturers, suppliers of technological solutions & consumables, etc..)

Envisioned contribution of the industry

- **Pharmas and biotech**: use-case owners for existing processes optimization / novel tools implementation / performance validation
- **Digital tools / equipment manufacturers**: technology developers in collaboration with academia, RTOs
- **Regulatory / environmental impact experts**: support for regulatory-compliance, standardization and sustainability of tools/processes

Outcomes and Impact

Expected outcomes

- **Advance and validate novel technologies in real use-cases** to address the current bottlenecks of the field
- **Set an ecosystem** of excellence technological centers to develop, improve key technologies, tools, methods, processes (sensors, digital tools, automation, etc..)
- **Make available these technologies** to all actors including the research community, academia, clinics, small to medium-sized enterprises (SMEs), healthcare professionals, biotech, medical technology and pharmaceutical companies, and patients to ensure the translation from research to concrete solutions
- **Promote information sharing** among the biomanufacturing community for a better accessibility and wide adoption of the solutions

Impact

- **Benefits for patients** who receive more effective and safe biotherapies
- **Benefits for industrials, technology developers** thanks to a better and more cost-effective development of biotherapies due to improved scientific and technological processes
- **Benefits for the European sovereignty/competitiveness** by more attractiveness for biotherapies development due to the availability of sustained, interconnected networks of technological and scientific centers of excellence

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Expertise and resources

- **We have:**
  - **CEA-Leti**, Innovative Technologies for Health (IKOP possibilities): our last report here
    - Partner of the CALIPSO consortium (Sanofi, Capgemini, Ypso-Facto, GPC Bio, CEA, and CentraleSupélec): “Online Process Sensors and Innovative Bioproduction Solutions”
    - Partner of the SELPHI consortium (Servier, Sanofi, Iprasense, MTInov): “develop and industrialize a new generation of sensors based on holographic imaging for the monitoring of cellular states in real time, without cell marking”
  - **France BioLead (Laurent Lafferrere, CEO)**: Representing the French Biopharmaceutical Manufacturing Industry, France BioLead brings together all the players of the French biomanufacturing community (academic research, training providers, pharmaceutical & biotech companies, CDMOs, CROs, equipment manufacturers, suppliers of technological solutions & consumables, professional unions & associations, health clusters) and is supported by the French State.

- **Additional needed expertise :**
  - Pharmas, industrials with processes to be improved thanks to novel and versatile technologies
  - Equipement manufacturers / Technology developers (SME, RTOs, academia..)
  - …

+ in-kind contributions

If you are interested by this topic to share views and expand the idea contact us: *caroline.desvergne@cea.fr*, *francoise.charbit@cea.fr*