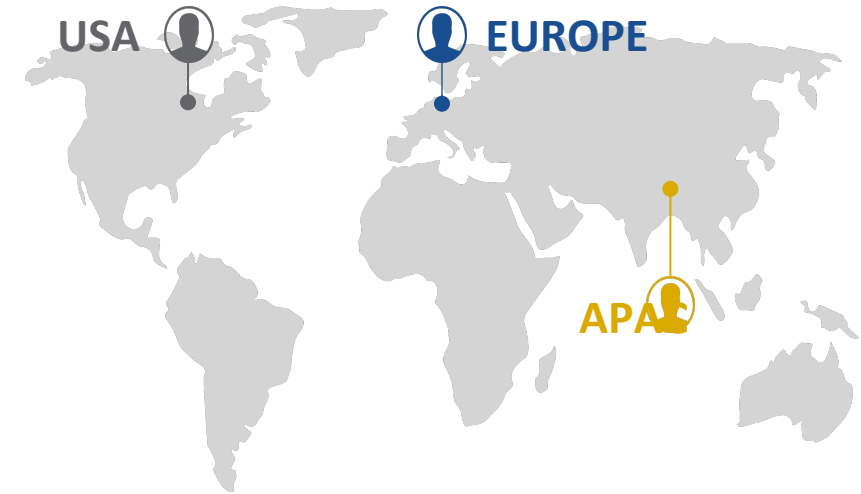
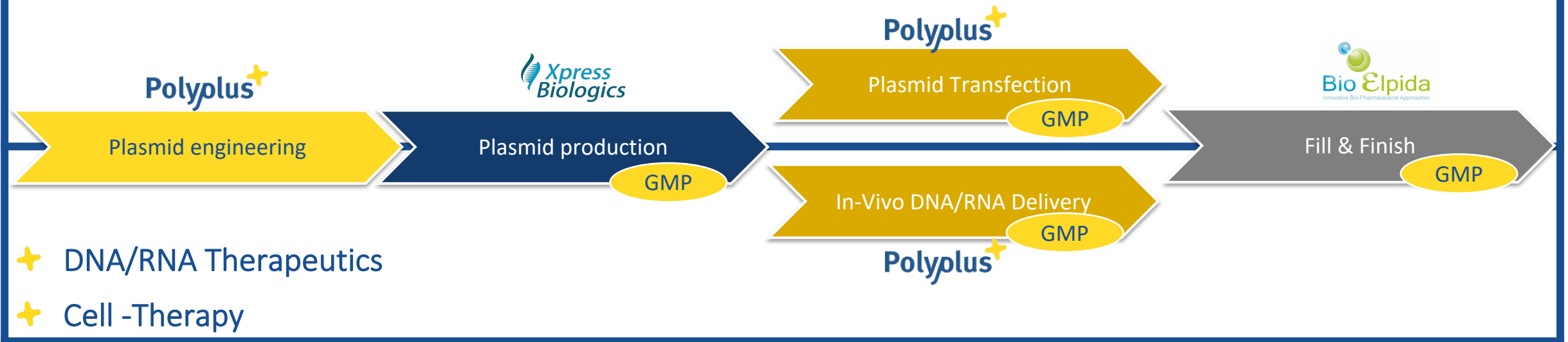

Bio Elpida CDMO activities
The 2nd of May 2023

Polyplus ATMP support

- + 22 years of expertise in Transfection solutions
- + Plasmid Engineering & GMP Manufacturing
- + GMP Fill & Finish
- + Support teams in Europe, Americas, Asia Pacific & China



+ Gene-Therapy Viral Vectors



Bio Elpida

Bio Elpida is a **CDMO offering** bespoke pre-clinical and clinical development services focused on **Innovative cell therapy projects**.

Our team of experts provides flexible and tailored approaches to achieve your



Biobanking

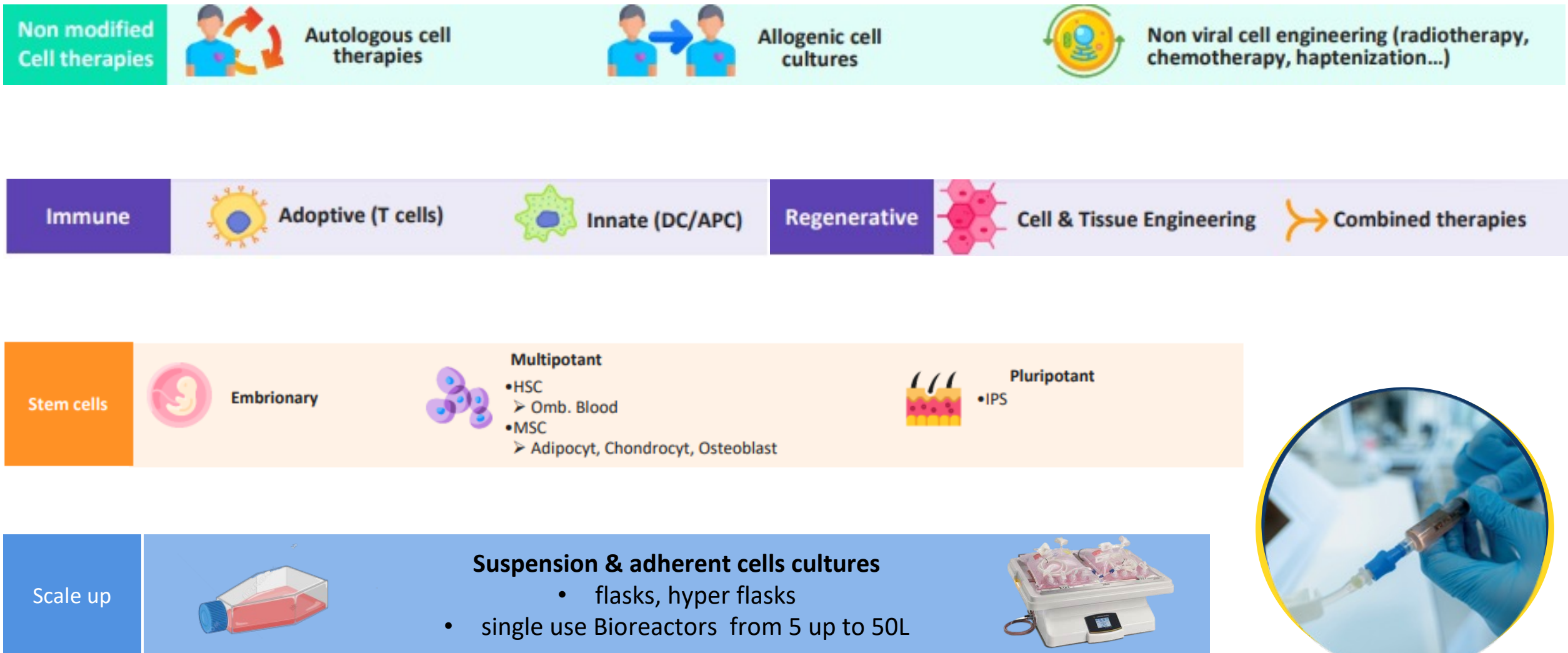


Development and
Manufacturing



Fill & finish

Bio Elpida's capabilities for cell therapies



Bio Elpida's capabilities for fill&finish

Formulation



Erlen/bags
➤ 20mL to 5L



Glass tank
➤ 5L to 25L



Paletank
➤ 70 to 200L



Repartition



Vials (1mL to 50 mL)
• Manual/open
➤ 2000 vials
• Semi Closed System,
Aseptic Technology
➤ 2000 vials



Cryotubes
• Manual/open
➤ 500 vials
• Semi Closed System,
Aseptic Technology
➤ 2000 vials



Bags (100mL to 2L)
• Closed
System
➤ 200 bags



Bottles (100mL to 2L)
• Manual/open
➤ 200 bottles
• Closed System
➤ 200 bottles

Sterilisation



Filtration



Autoclave



Irradiation (Ext.)

Bio Elpida facilities



R&D LAB



SUPPORT SERVICES



Direction Finance
Project Management
Business Development

GMP



A/B and A/C cleanrooms
QC lab / Warehouse
Quality Assurance

Our DNA, our goal

+ OUR DNA

For any project, our DNA is to develop a partnership based on trust, co-construction and transparency.



+ OUR GOAL

Becoming the partner of choice for all Biotechs involved in innovative cell therapy projects by offering flexible and tailor-made approaches in compliance with the regulatory framework.

Support service

Bio Elpida spans a **wide range of services** to support your pharmaceutical development from your **proof-of-concept** studies to your clinical trials completion

- ✦ Quality by Design approach Process
- ✦ Analytical developments **GMP sterile** manufacturing GMP Fill & Finish
- ✦ End-to-end quality control management
- ✦ Product **stability** programs



One example of CDMO/ Biotech partnership



Amplifying, Harvesting and Freezing huge gingival fibroblasts quantities in a dramatic **limited time** to manufacture an **innovative and cost-effective** medicine.

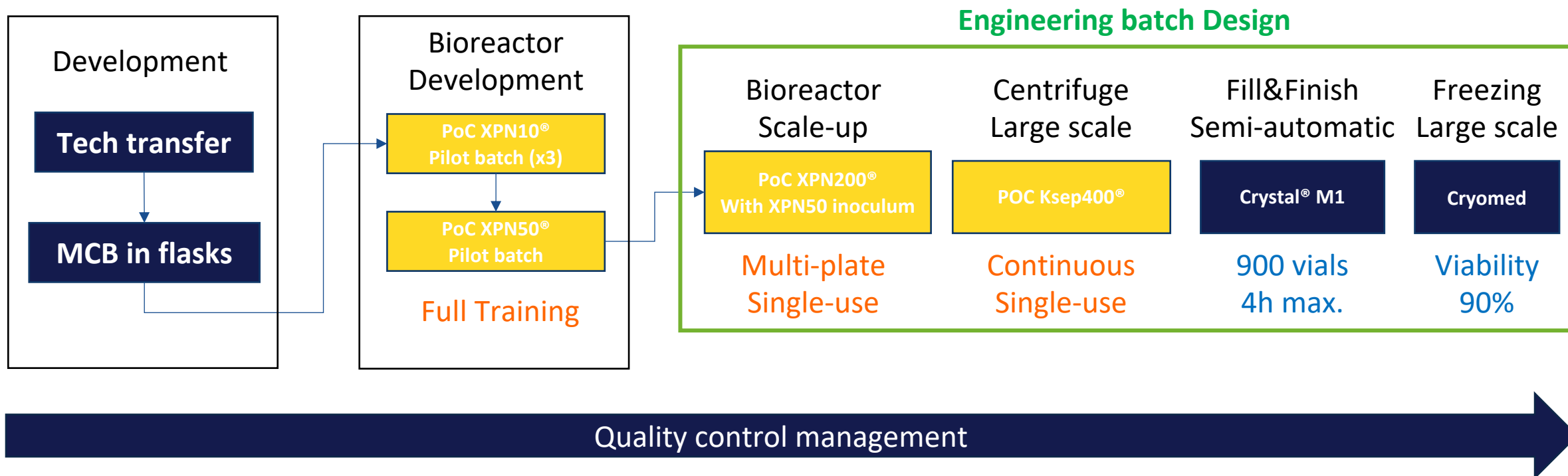
Attributes	Specification
Sterility	<i>Sterile</i>
Pharmaceutical form	<i>Injectable</i>
Concentration	<i>5.10⁶cells/ml</i>
Packaging	<i>Vial 2ml</i>
Filling volume	<i>1ml +/- 10%</i>
Potency	<i>IL-1ra dosage</i>



Design a bioprocess based on **tech transfer from flask** and a **scale-up of adherent cells** culture privileging **closed system** and **single-use** solutions to be **GMP-ready**.

Challenges to tackle
<i>Aseptic process</i>
<i>Particles</i>
<i>Low cell density, high volume to centrifuge</i>
<i>Fill and finish step</i>
<i>Pace</i>
<i>Analytical development</i>

One example of CDMO/ Biotech partnership



**MISSION:
POSSIBLE**

- ✓ Required live cells quantity on a minimum time
- ✓ High level of sterility assurance

European CT market trends and Bio Elpida Challenge

Growth of the sector over the last 10 years

Scope: Europe



- Market from **US\$1,700M** in 2010 to **US\$5,600M** in 2018, at a **CAGR of 17.3%** between 2010 and 2018. (1)

Scope: France



- 2.7 billion euros** in turnover generated by CDMOs in 2021.
- 36.9% growth** in turnover between 2010 and 2021. (2)

Note that this last percentage corresponds to the percentage increase in turnover over the period, and is therefore not comparable to the CAGR.

Growth forecast

Scope: Europe



The **average annual growth rate** of the market is estimated at **5.71%** between 2023 and 2028. (3)

Scope: France



The **sector's organic growth rate** is estimated at **4%** over the period 2022-2024. (2)

The advent of many innovative cell therapies is creating high expectations on CDMOs for outsourcing Biotech developments and manufacturing.

With its great agility to develop and manufacture in GMP conditions various ATMP for small to mid-scale productions Bio Elpida is ideally sized to tackle this challenge.

Sartorius Stedim Biotech to acquire Polyplus



Sartorius Stedim Biotech, a leading international partner of the biopharmaceutical industry, has signed an agreement to acquire Polyplus for approximately 2.4 billion euros from private investors, including ARCHIMED and WP GG Holdings IV B.V., an affiliate of Warburg Pincus.

Conclusion

Bio Elpida, Your best **CDMO partner** to safely speed-up your **developments and bioproductions**

Thanks for your attention !



Christophe Delmas
Bio Elpida
Head of Business Development

c.delmas@bio-elpida.com
Phone: + 33 6 17 33 48 19

www.bio-elpida.com