



BIOSOLUTIONS BY **PAN**TM / MEDIA / REAGENTS / BUFFER

SEAMLESS TRANSITION FROM **RUO** TO **GMP**



BIOSOLUTIONS BY PAN™

/ MEDIA / REAGENTS / BUFFER

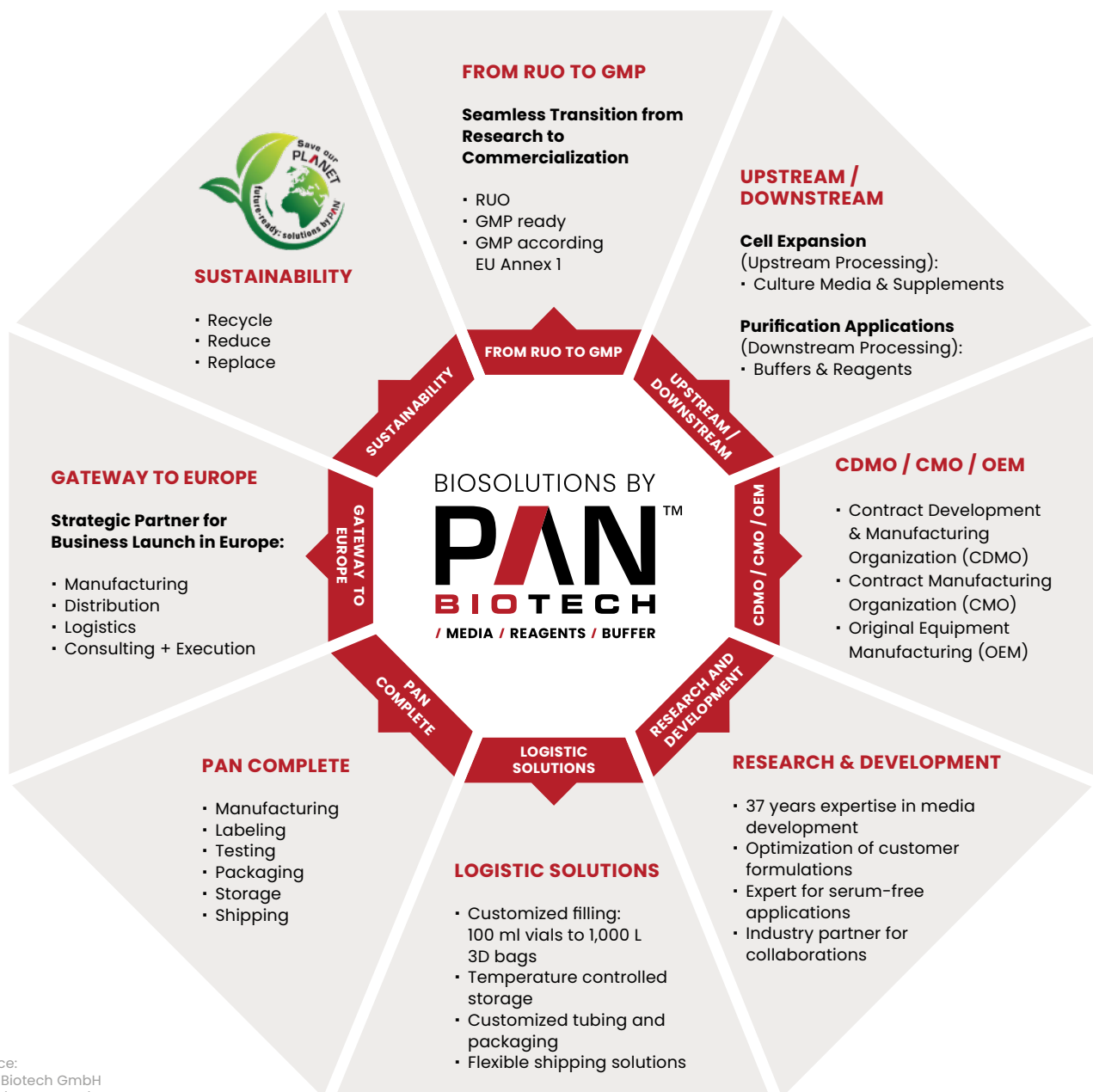
PAN-Biotech is a leading specialist in the production of sterile liquids for bioproduction, pharmaceutical applications and cell culture.

Our product portfolio includes **cell culture media, supplements and essential buffer solutions designed for research, industrial and clinical applications.** We provide **WFI quality water** and other critical reagents for cell expansion and purification in industrial processes.

Our core strength is flexibility, enabling us to offer customized solutions to partners in both, research and industry.

This includes state-of-the-art cell culture products in research and preclinical settings, all manufactured **according to ISO 13485 standards.**

For clinical applications, we facilitate a **seamless transition from RUO to GMP**, supporting **easy access to commercialization.**

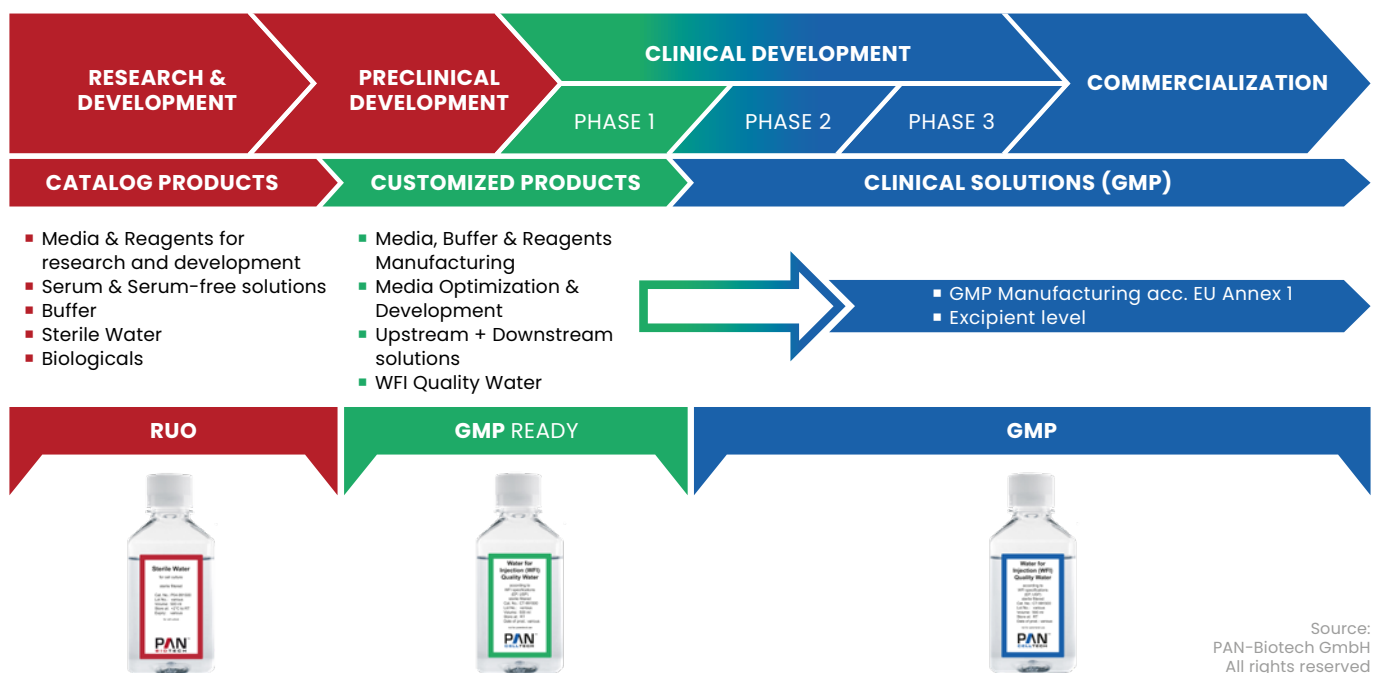


FROM RUO TO GMP

The development of a therapy application is complex: It starts as an idea in research and development, goes through preclinical and clinical studies until market approval and commercialization are achieved.

During this process the **shift from RUO to GMP** is a quality necessity but it is difficult to change key parameters like raw materials when a documented process is already established. Therefore, it is advisable to switch as early as possible to optimize costs and save valuable time. This transition process is crucial to ensure product

safety and efficacy, meets regulatory requirements, and ultimately, to secure market approval. We support you during the development from research to commercialization with our **media**, **reagents** and **buffer solutions**, which support a seamless transition with three perfectly tuned quality grades.



QUALITY FEATURES	QUALITY STANDARDS		
	RUO	GMP READY	GMP
Raw Materials	> Cell Culture Grade	EP / USP ^c	EP / USP ^c
Water	HPW	WFI quality water	WFI quality water
Production facility	Clean room class D to B	Clean room class D to B	GMP compliant clean room
Single-use equipment	N	Y	Y
Environmental monitoring	Scheduled	Scheduled	Extensive ^a
IPC (in-process-control)	Standard	Standard	Extensive ^a
Production record	Batch record	Batch record	Master Batch record
Final release as stated in CoA	Standard (e.g ph, Osmolality, Sterility)	Standard (e.g ph, Osmolality, Sterility)	Extensive ^a (e.g. Appearance, Mycoplasma, Endotoxin, Conductivity)
Analytical methods ^{b/c}	Qualified	Qualified	According to EP/USP
Suitability (in CoA)	RUO	RUO	For further manufacturing
Retain samples	Y	Y	Y
Change control ^b	N	N	Y
Quality agreement available ^b	N	N	Y

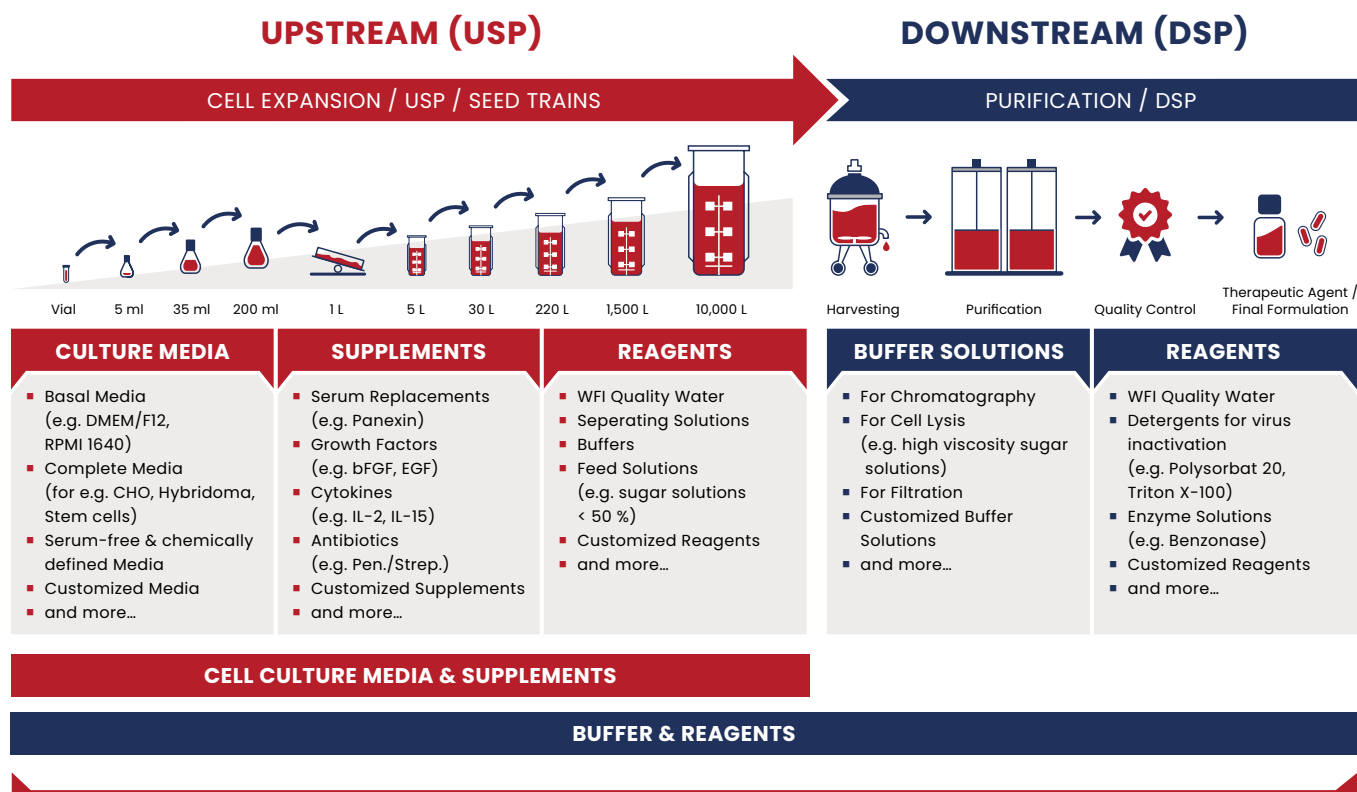
^a According to GMP · ^b Additional costs may apply · ^c Where applicable

UPSTREAM DOWNSTREAM

Production processes for vaccines, cell and gene therapies and biomolecules such as proteins involve two main stages: upstream (USP) and downstream (DSP) processing.

PAN-Biotech supports biotechnology with comprehensive solutions for both stages, offering customised products such as **culture media, reagents and buffer solutions**, available in various sizes from small vials to 3D bags. These products range in quality from

Research Use Only (RUO) to Good Manufacturing Practice (GMP) to meet your specific needs.



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Source:
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PAN-Biotech offers solutions for both upstream and downstream applications:

UPSTREAM APPLICATIONS:

- Cell expansion:** Our specialised media and supplements optimise cell growth and viability, supporting large-scale expansion for therapeutic applications.
- Bioreactor Optimisation:** We offer customised media formulations for use in bioreactors, ensuring optimal cell density and productivity.

DOWNSTREAM APPLICATIONS:

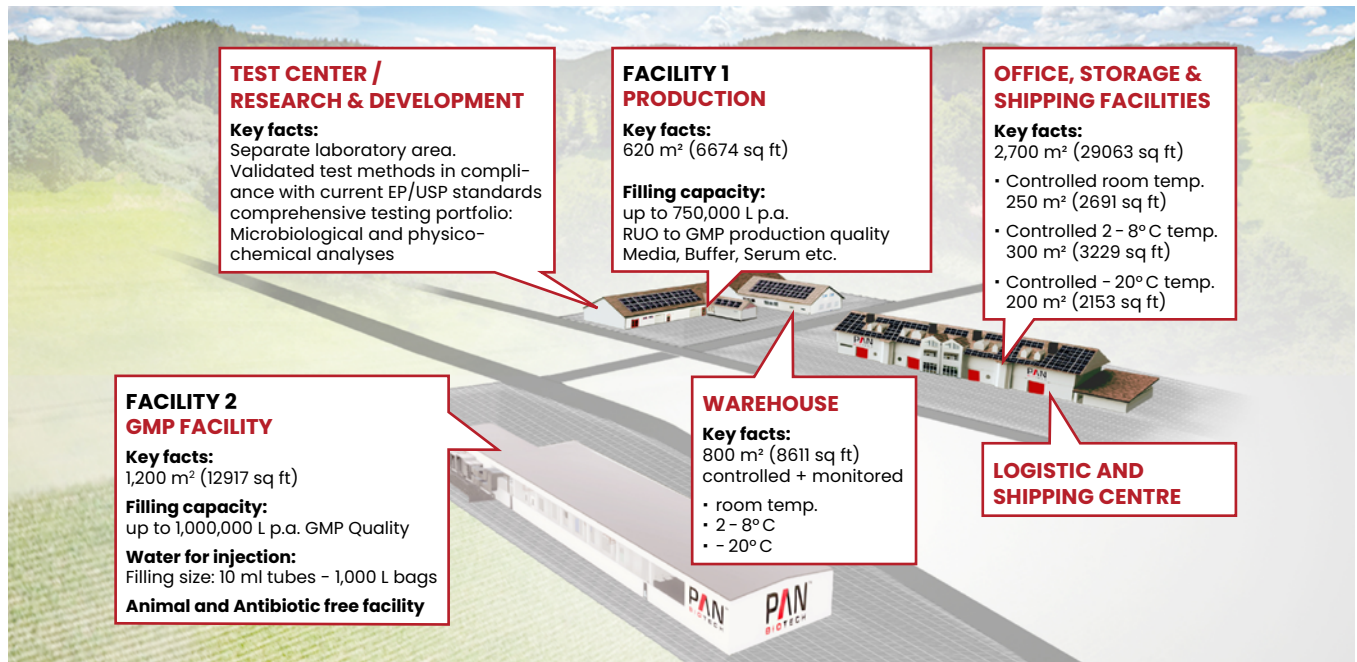
- Purification solutions:** PAN-Biotech offers a wide range of reagents and buffers for the purification of biomolecules, ensuring high purity and yield.
- Filtration and Separation:** Our high quality, customised buffers support efficient separation of target molecules, streamlining downstream processing workflows.

GMP MANUFACTURING AT PAN-BIOTECH

Our products play a crucial role in various life science applications, including Advanced Therapy Medicinal Products (ATMPs), Biopharmaceuticals, Cell and Gene Therapies, Vaccine Production, and more.

Whether you need media for cell therapy purposes, reagents or buffers for bioprocessing, we supply ready-to-use solutions for your GMP

applications. These products are manufactured in our new GMP (EU Annex 1) – compliant production facility under strict quality controls.



GMP FACILITY

Our new production facility, open since 2022, is built and qualified in accordance with to GMP acc. EU Annex 1 for sterile products.

Its state-of-the-art design enables fast, flexible and scalable production of your products in GMP quality, carried out by our qualified and highly trained personnel.



KEY FACTS:

- Exclusively production facility for antibiotics and animal derived components free products
- Class D to A cleanrooms
- 1,000,000 L filling capacity per year
- Lot sizes up to 1,000 L
- Sterile filling from 10 ml vials to 1,000 L Bags
- Single-use equipment
- Environmental monitoring according to GMP guidelines
- Established processes for customized productions GMP acc. EU Annex 1
- Audited by leading NASDAQ / DAX listed pharmaceutical and biotech companies

EMPOWERING YOUR BIOTECH JOURNEY



PAN-Biotech, is actively advancing its capabilities and product offerings in the following key areas:



CELL & GENE THERAPY

PAN-Biotech is at the forefront of the rapidly evolving field of cell and gene therapy, providing essential products and services to support groundbreaking research and clinical applications.

- **Cell Therapy**
- **Gene Therapy**
- **Custom Solutions**
- **Regulatory Compliance**
- **Proven Cell Culture Media**

Immune Cells / Stem Cells / Mesenchymal Stem Cells



mRNA TECHNOLOGY

PAN-Biotech is a leader in the emerging field of mRNA technology, providing solutions that support the development and production of mRNA-based therapies and vaccines.

- **mRNA Synthesis**
- **Process Development**
- **Cutting-Edge Development**
- **Proven Cell Culture Media**

HEK293 Cells



VACCINE PRODUCTION

PAN-Biotech plays a critical role in vaccine production, offering specialized products and expertise that enhance vaccine development and manufacturing processes.

- **Viral Culture Media**
- **Process Optimization**
- **Rapid Response**
- **Proven Cell Culture Media**

Vero Cells / MDCK Cells / BHK21 Cells / Sf9 Cells



ANTIBODY PRODUCTION

As a key player in the production of therapeutic proteins, PAN-Biotech offers a comprehensive range of products and services that support the development and manufacture of biologics.

- **Protein Expression**
- **Purification and Formulation**
- **Custom Manufacturing**
- **Collaborative Development**

CHO Cells / Insect Cells / Hybridoma Cells / HEK293 cells



Our focus on these areas ensures that PAN-Biotech remains at the cutting edge of biotech advancements, meeting the evolving needs of the industry and contributing to the development of next-generation therapies and treatments.

