

BIOSOLUTIONS BY PAN™

/ MEDIA / REAGENTS / BUFFER

EU READY: SEAMLESS EXPANSION
TO SCALE YOUR BUSINESS IN EUROPE



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GATEWAY TO EUROPE

At **PAN-BIOTECH**, we understand the challenges of entering a new market.

That's why we **offer a full-service platform to help international companies start their business, launch their product, or idea in Europe – to scale up and expand further.**

From manufacturing and storage to distribution. We guide you at every step of this path including regulatory support to ensure a smooth and successful market entry.

As your European CMO and OEM partner, we provide agile and efficient production tailored to your needs.

MANUFACTURING



Our two facilities in Aidenbach, Germany offer:

Fast implementation with flexible packaging (primary, secondary, tertiary)

- Lot sizes up to 1,000 L
- Sterile aseptic filling from 50 ml vials to 1,000 L Bags
- Production from RUO to GMP with full QC testings, QA documentation
- **PAN Complete services:** Manufacturing, Labeling, Quality Control, Quality Assurance, Packaging, Storage and Shipping

DISTRIBUTION



We support your market presence across Europe with:

- Broad distribution network covering all EU countries
- Access into Academia, Biotech, Pharma, and Industry sectors
- Active network for: R&D, Cell and Gene Therapy, Antibodies, mRNA and Vaccine Production

STORAGE



- We offer secure, monitored storage from -20°C to room temperature
- Separate storage is available for sensitive products (e.g., animal-free or antibiotic-free)
- Use our site as your central EU logistics hub

SHIPPING



- We ship globally with temperature-controlled logistics and full documentation
- Our team is trained to meet GDP standards and can arrange certified forwarding partners to ensure regulatory compliance

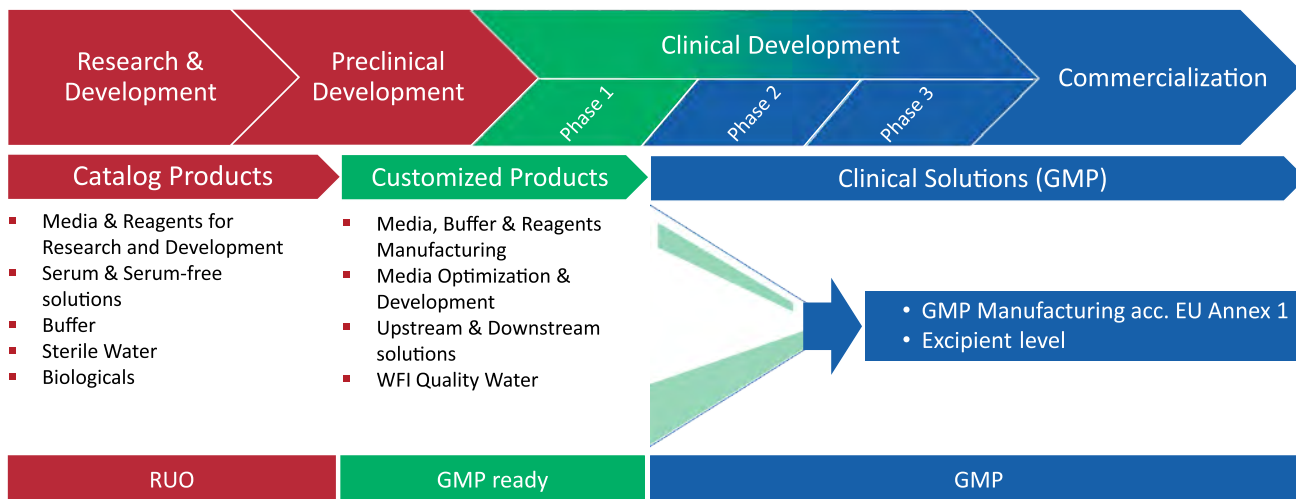
TESTING & STABILITY STUDIES



- We conduct extensive in-house quality testing and supplier traceability
- Available tests include Sterility, Endotoxins, Mycoplasma, pH, Osmolality, RNase/DNase and more
- Stability Studies up to 48 months are available in controlled conditions per an agreed plan

MAKING CRUCIAL STEPS IS ESSENTIAL, AND WE'RE HERE TO ASSIST:

- Growing brand awareness in Europe
- Increasing EU sales
- Establishing a legal entity
- Support Regulatory affairs



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TO THE FINISH LINE**

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EU-READY: SEAMLESS EXPANSION TO SCALE YOUR BUSINESS IN EUROPE

Whether you're a startup with ambitious goals or an established enterprise seeking new avenues, strategic expansion is key to long-term success.

For biotech and pharma companies, aiming to enter into the EU, partnering with a local manu-

facturer/partner offers a smart, capital-efficient path to market access.

By leveraging local expertise, infrastructure, and regulatory know-how, you can accelerate your EU entry and stay focused on what matters most.

Why Partner with PAN?

	FASTER TIME TO MARKET	Skip facility construction – start manufacturing immediately
	LOWER CAPITAL RISK	Limit investment in land, equipment and staffing
	LOCAL REGULATORY EXPERTISE	ISO 9001 and 13485 certified assure full compliance with GMP Annex 1-EU regulation /guidance
	EASIER REGULATORY APPROVALS	Lean on our manufacturing and testing experience with validated processes
	FLEXIBLE & SCALABLE MANUFACTURING	Adjust production volumes and logistics without reinvesting and choose from standard to customized solutions
	ESTABLISHED EU SUPPLY CHAIN	Reduce lead times and navigate tariffs with our long time suppliers ensuring a secured supply chain
	ACCESS TO TECHNICAL TALENT	Tap specialized expertise in development and production for high quality products
	REDUCED OPERATIONAL RISK	Minimize exposure to geopolitical and economic uncertainties

**STAY FOCUSED ON YOUR PROJECTS
WHILE PAN™ ENSURES A SMOOTH, COMPLIANT,
AND SCALABLE EU MARKET ENTRY.
BENEFIT FROM OUR 37+ YEARS OF EXPERIENCE.**

PROVEN CONCEPTS

CASE 1: PAN COMPLETE SERVICE

Due to the discontinuation of an existing supplier our partner required a new manufacturer for their product.

As a FDA registration of the product and full customization was required they were facing a difficult situation to secure their supply within a short time frame.



- **Successful FDA** product registration
- **Setting up secure supply chain** for complete customized packaging material
- **Raw material sourcing**
- **Production according** validated processes
- **Full QA / QC documentation**
- **Labeling / Packing**
- **Storage and On-demand shipping**

CASE 2: OEM (ORIGINAL EQUIPMENT MANUFACTURING)

A U.S.-based supplier of cell culture media was looking for an efficient, cost-effective solution to supply its products to customers across Europe. Shipping from the U.S. was time-consuming and expensive, and the company needed a reliable partner to localize its operations in Europe without compromising on quality or control.

PAN-Biotech was selected as the OEM partner, delivering a fully integrated solution including manufacturing, storage, and global distribution, with a strong operational presence across Europe.

Key elements of the partnership are as follows:

- **Complete tech transfer** of product specifications, packaging instructions, and shipping protocols
- **QC release** following the client's quality standards
- **Production under validated SOPs** ensuring consistency and compliance
- **Custom labeling and packaging** to align with the brand's global identity
- **Secure storage** in a dedicated warehouse
- **On-demand drop-shipping** to end users worldwide



CASE 3: CUSTOMIZED CMO / CDMO Service for Bottles and Bags – GMP Quality



A global operating company based in Japan was looking for an European Contract Manufacturing Organization (CMO/CDMO) that could produce and supply custom-formulated products under GMP (EU Annex 1) standards. Their primary goal: to launch a private-label product line for distribution to customers across Europe while ensuring

full regulatory compliance and seamless integration into existing GMP production environments.

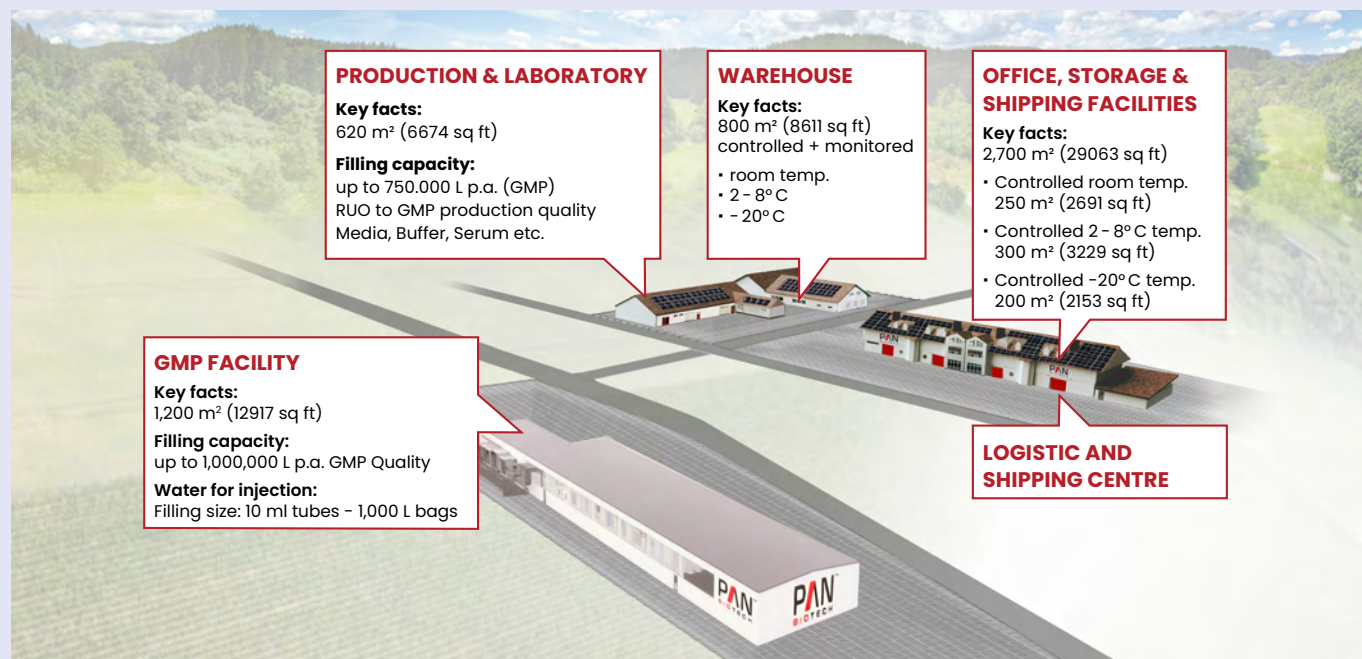
Since then **PAN-Biotech** is providing a tailored CMO/CDMO service model built on flexibility, compliance, and trust – **Key elements included:**

- **GMP-compliant production process development** for both new and existing products
- **Customized packaging formats** in single-use bags or bottles, designed to fit seamlessly into the partner's GMP workflows
- **Full QC testing and QA documentation** to meet European pharmaceutical standards
- **GDP-compliant logistics** with transportation to the partner's designated EU production site

GMP MANUFACTURING

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 1000 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

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