SUPPLIER QUALIFICATION GUIDE

BIOSOLUTIONS BY PAN™

/ MEDIA / REAGENTS / BUFFER

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GENERAL INFORMATION

INNOVATION - QUALITY - CUSTOMER FOCUS - INTEGRITY

At **PAN-Biotech**, innovation, quality, and customer focus are at the heart of everything we do. For over 30 years, we have been your trusted partner for **premium cell culture products – from sera, media, and serum-free systems to specialized reagents for cell and gene therapy, vaccine production, mRNA technology, and antibody production.**

We understand how critical it is to choose the right partners when building your supply chain. This **Supplier Qualification Guide** offers a focused yet comprehensive first look into who we are, how we operate, and what makes us a reliable choice for your supplier onboarding and qualification process.

We believe that **strong partnerships** begin with **transparency** and **shared standards.** This introduction is intended to open the door to deeper collaboration and provide the foundation for a qualified, trusted supplier relationship.

/ **COMPANY DETAILS**	PAN-Biotech GmbH Am Gewerbepark 6 94501 Aidenbach Germany Registration Number: DE130958995 Veterinarian number: Vet.-No.: DE09275000114
/ **CONTACT DETAILS**	Tel. +49 (0) 8543 601630 E-Mail: info@pan-biotech.de Opening hours: Mo. - Th. 8 am – 5 pm & Fr. 8 am – 3 pm
/ **COMPANY FORM**	Privately owned (GmbH)
/ **COMPANY HISTORY**	Founded in 1988 with over 37 years of experience in sales and production in the field of biotechnology.
/ **NUMBER OF EMPLOYEES**	85 (as of April 1st, 2025)
/ **ISO CERTIFICATION**	**PAN-Biotech is certified** according to **DIN EN ISO 9001** and **DIN EN ISO 13485** standards. You can obtain our valid ISO certificates on our website. www.pan-biotech.com
/ **GMP**	PAN-Biotech produces in facilities which comply with the current **EU-GMP-Annex 1 guidelines.**

PRODUCTS AND SERVICES

OUR PORTFOLIO INCLUDE:

/ **CELL CULTURE PRODUCTS RUO** (Research-Use-Only)	• Media • Reagents • Serumfree Systems • Sera
/ **EXPANDED PORTFOLIO (GMP)**	• WFI-quality water • TSB medium • PBS solutions • Sodium chloride solutions • Tris solutions • EDTA • Ammonium sulfate • Potassium acetate solutions • Basal media (e.g. M199, Alpha MEM, etc.) • Acetic acid • Serum replacement • Cryo-conservations media • RNase/DNase Neutralizer, Nuclease Decontamination solution And much more …

WHAT WE OFFER:

CUSTOM MANUFACTURING
Our production facilities are equipped to manufacture tailor-made formulations and products that precisely meet customer requirements while complying with all relevant regulatory standards.

PROCESS DEVELOPMENT
We collaborate closely with our customers to refine production processes, enhancing efficiency, reproducibility, and scalability.

REGULATORY EXPERTISE
PAN-Biotech provides expert support in meeting regulatory requirements, ensuring that products comply with international standards and enabling smooth market access worldwide.

OUR SERVICES

INCLUDE:

/ PROCESS DEVELOPEMENT	An **individual manufacturing instruction** is created for each product, detailing all relevant specifications, production steps, and packaging requirements – serving as the foundation for **safe, reproducible, and quality**-assured manufacturing. This can either be a manufacturing instruction developed by PAN-Biotech or an existing instruction provided by the customer. In the latter case, a structured **technology transfer** is carried out to ensure precise implementation of the customer's requirements in our production process.
/ DOCUMENTATION	**Included documents:** • Certificate of Analysis (CoA) • Safety Datasheet (SDS) • Product specification and composition sheet **Additional documents:*** • Extensive Production protocol (Master Batch Record) • Validation plan • Failure Modes and Effects Analysis (FMEA)
/ ADDITIONAL SEVICES*	• Manufacturing validations • Product-specific suitability test for test methods
/ STABILITY STUDY SERVICE*	• **ICH-compliant studies:** Assess effects of time, temperature, and light on physico-chemical and biological properties. • **Critical quality attributes:** Evaluation of pH, osmolality, conductivity, microbial stability and more, tailored to your product. • **State-of-the-art facilities:** Innovative laboratory and temperature-controlled storage solutions from -20 °C to +40 °C. • **Full study management:** From protocol development to data analysis and reporting. Our stability study services are designed to validate consistent quality of your culture media and buffer solutions, supporting the long-term success of your products by maintaining product integrity, performance, and safety under various storage conditions.

* Additional costs will apply.

SUPPLY-CHAIN INFORMATION

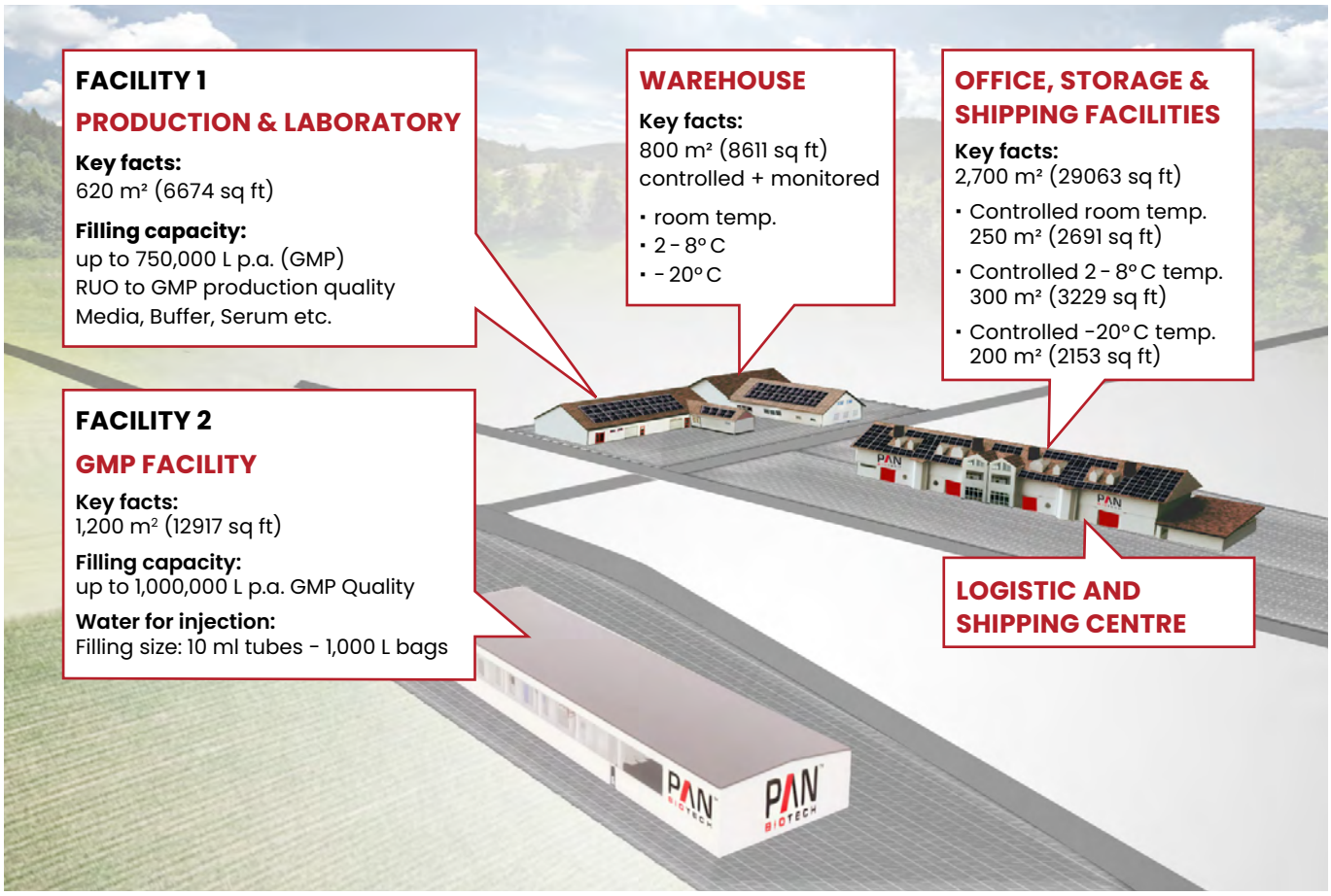
At **PAN-Biotech** we have been working successfully with our established suppliers for many years and have a stable and reliable supply chain in place. Through these long-term partnerships, we ensure **consistently high quality and on-time delivery.**

/ **RAW MATERIAL GOODS RECEIPT**	Every raw material goods receipt is routinely checked against the corresponding Certificate of Analysis (CoA). * Upon customer request, we also conduct identity verification using Raman spectroscopy to ensure the highest quality and safety standards. Additionally, further incoming goods inspections can be carried out for raw materials, if requested by the customer.
/ **CUSTOMER RAW MATERIAL PROCUREMENT**	If requested, we source specified raw materials to best meet our customer requirements. Alternatively, the required raw materials and/or consumables can be provided directly by the customer.
/ **SUPPLIER QUALIFICATION**	To continuously ensure our standards, we conduct regular supplier audits.

* Additional costs will apply.

MANUFACTURING INFORMATION

Our two production facilities offer solution for different requirements.
Our key advantage here: **Flexibility.**



FIND OUT MORE ABOUT OUR PRODUCTION CAPABILITIES:

/ PRODUCTION FACILITIES

PRODUCTION FACILITY 1:

- **RUO to GMP production quality**
- Filling capacity: up to 750,000 L p.a.
- Key feature: Possibility to process Antibiotics, Active ingredients & Animal-derived components

PRODUCTION FACILITY 2:

- **GMP (EU Annex 1) compliant production quality**
- Filling capacity: up to 1,000,000 L p.a.
- Key feature: WFI-quality water, Dedicated **animal component free** facility, single-use equipment

/ **WFI-QUALITY WATER SPECIFICATIONS**	The WFI-quality water in our GMP facility is prepared by reversed osmosis, deionization, ultrafiltration and sterile filtration from a Water for Injection (WFI) system that meets or exceeds current EP / USP specifications. Release criteria for WFI-quality water are also based on **EP / USP specifications** and guarantee an ease in **regulatory compliance.** **QC release criteria:** • Conductivity < 1.1 µS/cm • Total organic carbon (TOC) < 500 ppb • Endotoxin < 0.25 EU/ml • Sterile
/ **PRODUCTION PROCESS**	For the production of sterile products, filling takes place after sterile filtration through a 0.22 µm filter under aseptic conditions in class A (In B) cleanroom areas.
/ **MIN BATCH SIZE**	**Facility 1** • RUO (Research-Use-Only) min. of 10 L / Batch **Facility 2** • GMP grade (GMP EU Annex 1) min. of 25 L / Batch
/ **MAX BATCH SIZE**	Maximum Batch size is 1,000 L / Batch
/ **FILLING CAPABILITY**	**Individual Primary Packaging** • Vials (starting from 5 ml) • Bottles (50 ml – 1,000 ml) • Single-Use-Bag (500 ml – 1,000 L)
/ **INDIVIDUAL 2 D / 3 D BAG SETUP**	Customization of the tubing length and connectors for 2 D and 3 D bags. Individual setup for sampling – for example: Satellite Samples. (Available upon individual agreement)
/ **PRODUCTION DOCUMENTATION**	The documentation is paper-based on automatically electronically generated production records. Where applicable, all batches of raw materials used and all raw data are noted in the production records or added to the batch documentation.
/ **TRACEABILITY OF RAW MATERIALS USED IN PRODUCTION**	Traceability is ensured at all times through the ERP system, as each raw material batch is linked to the corresponding production batch.
/ **BATCH NUMBER ASSIGNMENT**	Batch numbers are assigned before production and are automatically printed on the batch documentation. The batch number consists of a three-digit running number and four digits indicating the month and year of production: XXXMMYY

QUALITY MANAGEMENT & QUALITY CONTROL

/ QUALITY MANAGEMENT SYSTEM	• Documented quality assurance system • Documented quality management manual with quality policy
/ DOCUMENTATION	• Documentation is paper based • Batch documentation is checked for completeness, traceability and comprehensibility. • Old revisions are cancelled and archived both electronically and on paper
/ INTERNAL AUDIT	• Annual internal and external audits • Where necessary, corrective and immediate actions are defined and monitored • Changes are assessed on a risk basis for their impact on product quality
/ OUR DEVICES	• Logbooks available for key equipment • Regular calibration of measuring instruments • Regular maintenance of equipment
/ QUALITY RISK MANAGEMENT	• Risk analysis is based on the principles of FMEA.
/ QUALITY CONTROL	• Documented test method validation process • Testing of each product batch prior to release • Collection via special release possible, including ,in test CoA • Regular microbiological monitoring of production and laboratory areas • Written specifications for control and quality of • Packaging/shipping materials
/ QUALITY TEST AND RESEARCH CENTER	• Documented work instructions for analytical procedures • Quality control analysis is largely carried out in our own laboratories • We only use accredited laboratories for external testing • Production of batch related certificates of analysis with a list of acceptance criteria and results

LABORATORY SERVICES

PAN-Biotech's Quality Control and Research Center offers precise analytical services for applications in pharmaceuticals, biotechnology and cell culture.

We perform **microbiological and physico-chemical testing according to Ph. Eur. and USP standards** – including **pH value, osmolality, density and conductivity**.

With validated methods, state-of-the-art equipment, and experienced personnel, we provide reliable support for ensuring the quality of your products and processes.

PRICING OVERVIEW

Explore our flexible pricing plans designed to meet your laboratory service needs. We offer transparent and competitive rates, ensuring the highest quality service for your research and diagnostic applications.

➜ **PLEASE SEE OUR COMPLETE PRICE LIST ON PAGE 10.**

YOUR RELIABLE PARTNER TO THE FINISH LINE

Scan here to connect with our experts

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LABORATORY SERVICES

PAN BIOTECH™

PRICING OVERVIEW:

PRODUCT	METHOD	CAT. NO.	PRICE
pH value	Ph. Eur. 2.2.3 / USP <791>	Test _ PH	69 €
Osmolality	Ph. Eur. 2.2.35 / USP <785>	Test _ Osmolality	119 €
Conductivity	Ph. Eur. 2.2.38 / USP <644>	Test _ Conductivity	69 €
Density	Oscillating U-tube method	Test _ Density	109 €
Endotoxin (in duplicates, per dilution)	Ph. Eur. 2.6.14, Method C /USP <85>	Test _ Endotoxin	169 €
Mycoplasma	According to Ph. Eur. 2.6.7	Test _ Mycoplasma	690 €
RNase (in duplicates, per dilution)	Fluorometric assay	Test _ RNase	319 €
DNase (in duplicates, per dilution)	Fluorometric assay	Test _ DNase	319 €
Sterility	According to Ph. Eur. 2.6.1 / USP <71>	Test _ Sterility	329 €
Raman Analysis	Raman spectroscopy	Test _ Raman	69 €
Cell growth performance (generation time; per cell line)	Cell culture	Test _ Cell growth	380 €
Cloning efficiency	Cell culture	Test _ Cloning	210 €
Plating efficiency	Cell culture	Test _ Plating	250 €
Total Protein	Colorimetric assay (Biuret reaction)	Test _ Protein	90 €
Glucose	Colorimetric assay (Trinder reaction)	Test _ Glucose	90 €
Hemoglobin	Colorimetric assay	Test _ Hemoglobin	60 €
Triglycerides	Colorimetric assay (Trinder reaction)	Test _ Triglycerides	90 €
Cholesterol	Colorimetric assay	Test _ Cholesterol	80 €
Albumin, Globulins	Serum capillary electrophoresis	Test _ Serum-CE	150 €
IgG	ELISA method	Test _ IGG	310 €
Tetracycline	ELISA method	Test _ Tetracycline	355 €
Stability study	Upon request	Test _ Stability study	Upon request