CG PHARMA & BIOTECH

C-MADE

Unlocking excellence in biopharma production, tailored GMP process solutions

FACTS
Qualified partner of global (bio)pharma companies
800 m² cleanroom (class C & D), vessel capacity up to 5,000 L
Dedicated development and project management team
In-house chemical/physical and microbiological lab
Release of each produced batch by a qualified person
Short time to market
Manufacturing upscaling capabilities
Customized packaging solutions (e.g. 2D/3D single use bags)
Quality and accreditations: EU GMP certified acc. to Part 1 + 2
"Made in Germany"

Our key competencies:

- Manufacturing of customer-specific sterile-filtered process solutions and excipients for upstream and downstream applications
- Ready-to-use sterile filtered solutions in single-use bags
- GMP-compliant cleaning solutions
- Processing of hazardous substances (corrosive, flammable) in the cleanrooms
- Scalable from laboratory scale to commercial production (single use mixing equipment)

Your challenge - Our solution

CUSTOMER IN FOCUS

Our concept:
tailored solutions to meet your specific needs

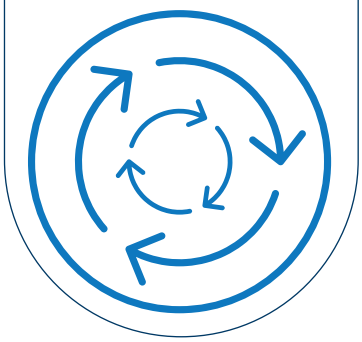
As a trusted partner of manufacturers for plasma-derived therapeutics and biologic drugs, CG Pharma & Biotech serves as an preferred partner for major (bio)pharma companies, supporting the industry's growing trend toward outsourcing buffers, process solutions as well as critical raw materials. Our mission is to enable Global biopharma companies to strengthen and localize their supply chains. With innovative solutions, we drive efficiency and sustainability across the industry. We are dedicated in supporting our customers reaching their strategic objectives while upholding the highest standards of quality.

C-MADE

Manufacturing and development of **customised formulations** for the (bio)pharma production process – upstream, downstream and final formulation steps

LIQUIDS
customised formulations

SOLIDS
customised formulations
simple and highly complex mixtures



PHARMPROVE®

Multi-compendial bioprocessing chemicals for use as raw material or excipient for manufacturing of (bio)pharmaceuticals

LIQUIDS
single components

SOLIDS
single components

STREAMLINE YOUR SUPPLY CHAIN BY OUTSOURCING ACTIVITIES

In biopharmaceutical manufacturing processes, various process solutions, buffer systems and cleaning solutions are required from cell culture (upstream) through purification (downstream) to the formulation and filling of the active ingredient. These are used under the strictest quality standards. A "make or buy" decision involves determining whether to create a product or service in-house or purchase it from an external source. In the context of customised GMP (Good Manufacturing Practice) biopharmaceutical process solutions, this decision carries several advantages.

INCREASED PRODUCTIVITY

REDUCED COMPLEXITY

RISK MITIGATION

COST REDUCTION

REDUCED OPEN HANDLING OF CHEMICALS THROUGH READY-TO-USE SOLUTIONS

C-MADE

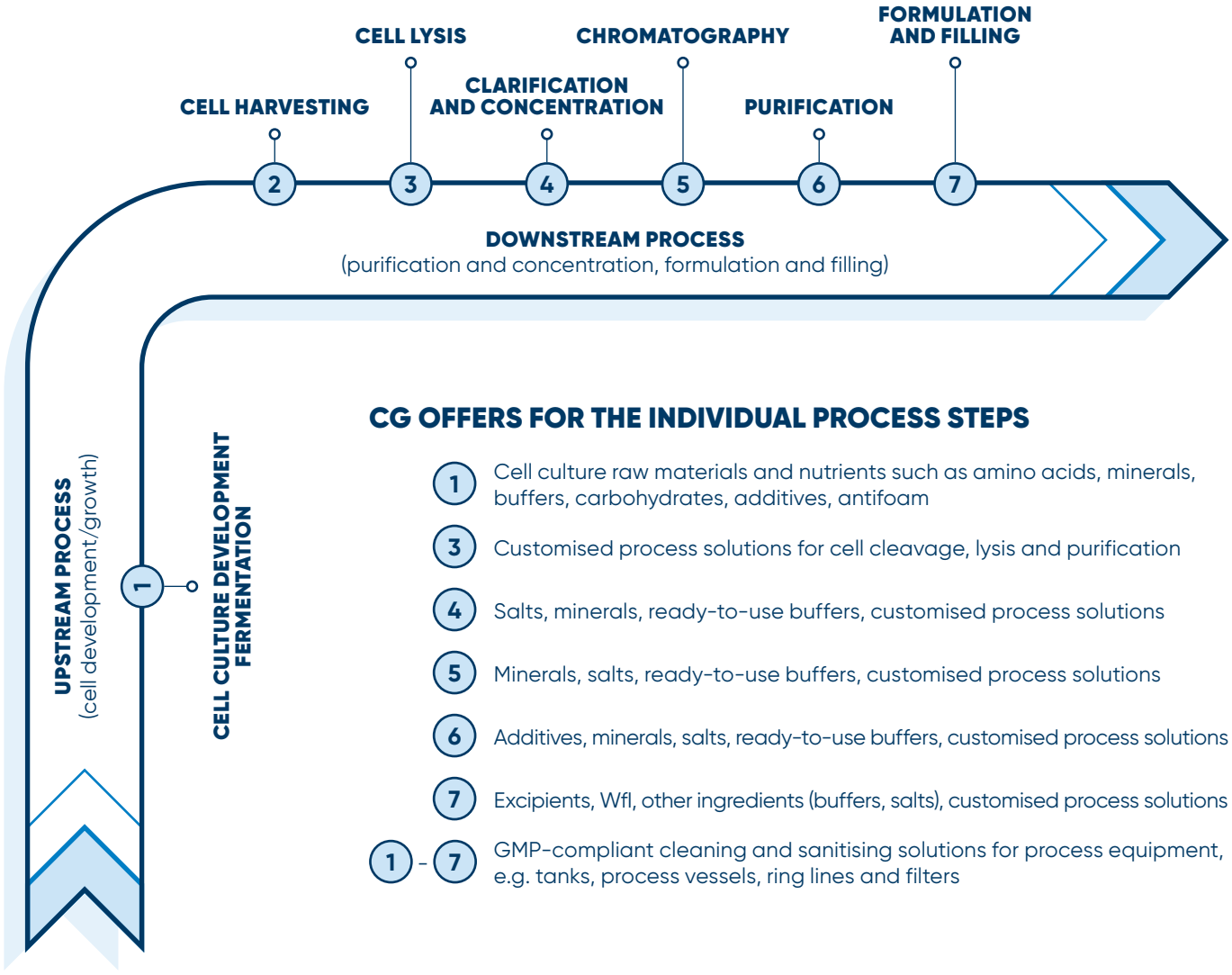
Sterile-filtered solutions to optimise biopharmaceutical production

In the complex landscape of biopharmaceutical production, precision and customisation are essential. We specialise in manufacturing customised formulations that are sensitively designed to secure your needs at every stage of the production process. From upstream to downstream processes and final formulation, our portfolio covers a wide range of essential products, including alcohols/solvents, strong acids/bases, buffers, high-quality water and salt solutions. Each formulation is tailored to your specifications, ensuring optimal compatibility and efficacy within your production process.

Our commitment is to offer tailored solutions that empower you to achieve the highest standards of quality and efficiency. We support you to improve your biopharma endeavours with formulations that are as unique as your innovations.

BIOPHARMACEUTICAL PRODUCTION PROCESS

CG Pharma & Biotech offerings for the individual process steps

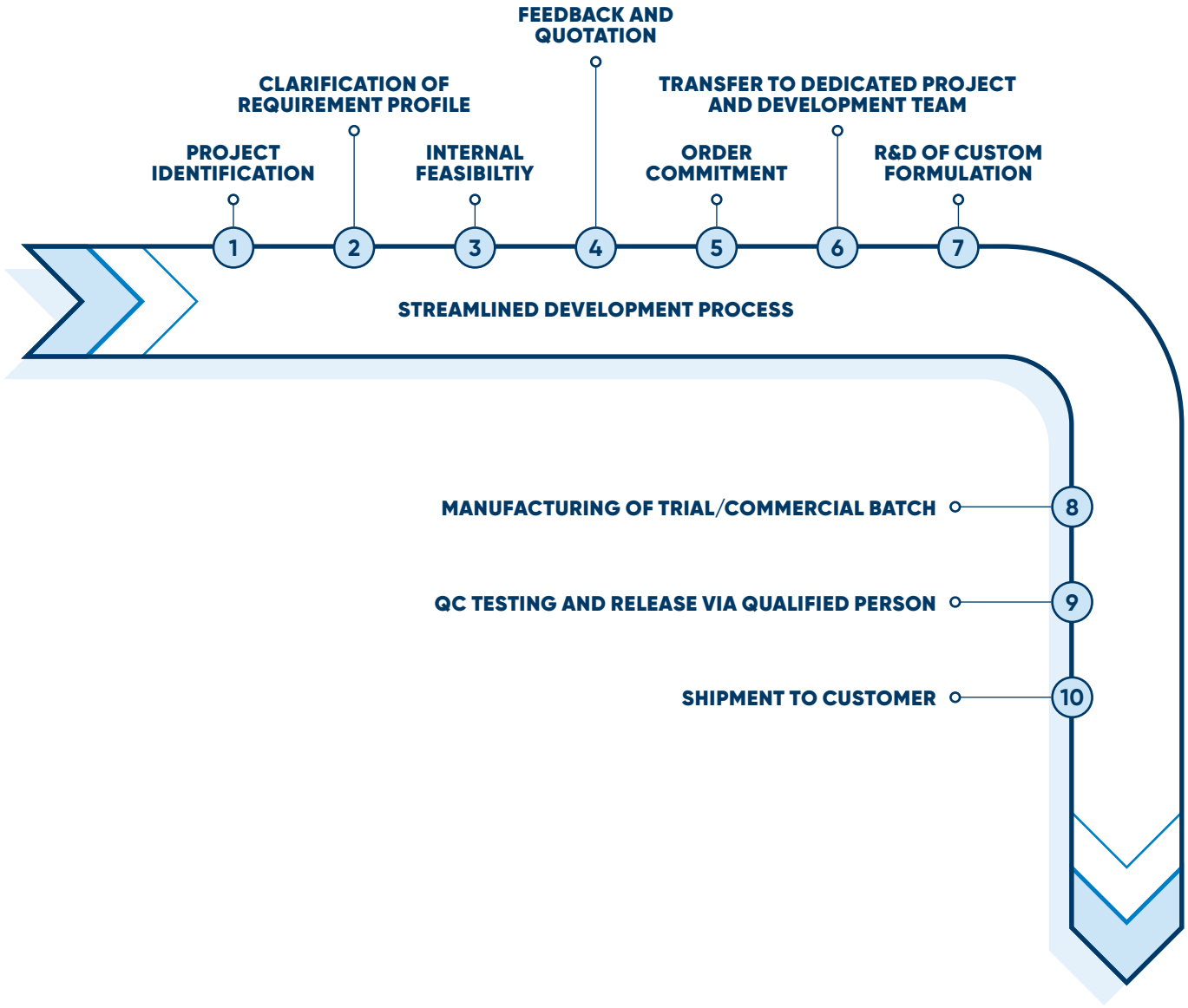


CG OFFERS FOR THE INDIVIDUAL PROCESS STEPS

- (1) Cell culture raw materials and nutrients such as amino acids, minerals, buffers, carbohydrates, additives, antifoam
- (3) Customised process solutions for cell cleavage, lysis and purification
- (4) Salts, minerals, ready-to-use buffers, customised process solutions
- (5) Minerals, salts, ready-to-use buffers, customised process solutions
- (6) Additives, minerals, salts, ready-to-use buffers, customised process solutions
- (7) Excipients, WfI, other ingredients (buffers, salts), customised process solutions
- (1) - (7) GMP-compliant cleaning and sanitising solutions for process equipment, e.g. tanks, process vessels, ring lines and filters

THE CG PHARMA & BIOTECH DEVELOPMENT PROCESS

Step by step to the perfect solution



PROFESSIONAL SERVICES

Ensuring quality, safety and regulatory compliance

MANUFACTURING CAPABILITIES

- 800 m² cleanroom area (C&D)
- Clean floor corridor concept
- Production and materials free of animal components (AOF)
- Batch sizes from 200 L – 5,000 L (preparation vessels stainless steel and PVDF)
- 1,000 L mobile single use mixer for small scale batch production
- Stirring, heating/cooling, inline pH control
- In-house production of purified water (AP) and water for injection (WfI)
- CIP system for validated cleaning procedures

LOGISTICS AND STORAGE

- 3,200 pallet spaces for packaging, raw materials and finished products
- Additional external storage capacities at warehousing service provider
- Temperature and humidity monitoring
- Pest-controlled storage areas
- Laminar flow sampling booth for contamination-free sampling of raw materials
- GDP-certified pharmaceutical logistics
- Temperature monitoring and GPS tracking
- Security against unauthorised access
- Tailor-made logistics concepts
- International distribution network

PACKAGING SOLUTIONS

- 2D and 3D single-use bags from 5 L – 1,000 L volume
- Customised bag design in consultation with our customer
- Pre-configured standard design available for fast-track development
  - Bag film material: multi-layer film
  - Bag sterilisation: gamma irradiation
  - Tubing material TPE
  - Connector main bag: MPC/MPX male
  - Connector sample bag: Luer Female + Clave Connector
- Sterile filtration 0.2 µm filter
- Storage and transport packaging for 2D and 3D single use-bags
- Highlight: in-house developed reusable plastic transport container CG Tainer for bags from 100 L – 1,000 L
- Various packaging options for liquids: 10 L – 25 L canisters, 220 L PE or steel drums, 1,000 L intermediate bulk containers (IBC), isotainers up to 20,000 L
- Customer-specific multiway packaging with validated cleaning concepts
- Various primary and secondary packaging options for solid raw materials ranging from 1 kg – 25 kg (e.g. plastic pail, cardboard box, PE cross-bottom bag with PE inliner)

QUALITY ASSURANCE/QUALITY CONTROL

- Production according to EU GMP guidelines
- Manufacturing authorisation according to German Medicinal Products Act AMG §13
- Certification according to ISO 9001
- Quality assurance agreements with customers and suppliers
- Change control management
- Supply chain information
- Process validation
- In-house chemical/physical laboratory
- In-process controls
- Testing of starting materials according to pharmacopoeias (e.g. EP, BP, USP, JP, ChP)
- Testing of finished products (e.g. appearance, pH, conductivity, density, refractive index, osmolality, assay)
- Microbiological testing (e.g. sterility, endotoxins, RNAse, bioburden)
- Stability testing

EXTRACT – EXAMPLES OF CUSTOMISED, GMP-COMPLIANT FORMULATIONS (LIQUID)

BUFFERS AND PROCESS SOLUTIONS

Development and production of custom-made buffer solutions, packaged and sterile-filtered in single use bags ranging from 1 – 1000 L volume. Available in a variety of sizes and configurations, including customizable bag designs, tubing, ports, and connectors, to ensure compatibility with different manufacturing systems.

ALCOHOLS/SOLVENTS	ORGANIC BUFFER SOLUTIONS	STRONG ACIDS
2-Propanol	EDTA buffer	Acetic acid
Ethyl alcohol absolute	Glucose	Citric acid
Ethyl alcohol + NaCl	HEPES buffer (with HCL, ethanol, NaCl, EDTA)	Hydrochloric acid
BALANCED SALT SOLUTIONS	Sucrose	Phosphoric acid
Ammonium sulphate	TEAA	**STRONG BASES**
Citrat buffer	TRIS	NaOH + NaCl
Sodium acetate	Urea buffer	Sodium hydroxide
Sodium chloride solution	**PHOSPHATE BUFFER SOLUTIONS**	**OTHERS**
HIGH QUALITY WATER	PBS buffer	Arginin
Purified water (AP)	Potassium dihydrogen phosphate	Glycine
Water for injection (WfI)	Sodium dihydrogen phosphate	Piperazine
	Sodium phosphate	Polysorbate

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