CG PHARMA & BIOTECH

C-MADE

Unlocking excellence in biopharma production, tailored GMP process solutions

FACTS
Qualified partner of global pharma and biopharma companies
Support in product establishment through a project management team
In-house chemical/physical analytical laboratory
Release of each produced batch by a qualified person
Short time to market
Manufacturing expansion capabilities
"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
- Cleaning solutions for GMP CIP/SIP applications
- Processing of hazardous substances (corrosive, flammable) in the cleanrooms
- Scalable from laboratory scale to commercial production

Your challenge - Our solution

CG PHARMA & BIOTECH

We support your biomanufacturing journey

As a leading manufacturer and supplier of critical raw materials for (bio)pharmaceutical manufacturers, we understand the complex challenges that our partners face. We are your reliable partner, providing sustainable support from product indentification, through clinical phase development until commercial production. Our commitment to the highest quality standards is reflected in our customised services and products, which are designed to seamlessly adapt to each client's individual requirements. Thanks to our modular approach, you have the flexibility to select and combine the solutions that perfectly fit your needs.

C-MADE

Manufacturing and development of **customised formulations** for the biopharma production process – upstream, downstream and final formulation steps

LIQUIDS

customised formulations

SOLIDS

customised formulations
simple and highly complex mixtures

PharmProve®

Multi-compendial production chemicals for use as ingredients, starting materials, excipients or APIs 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

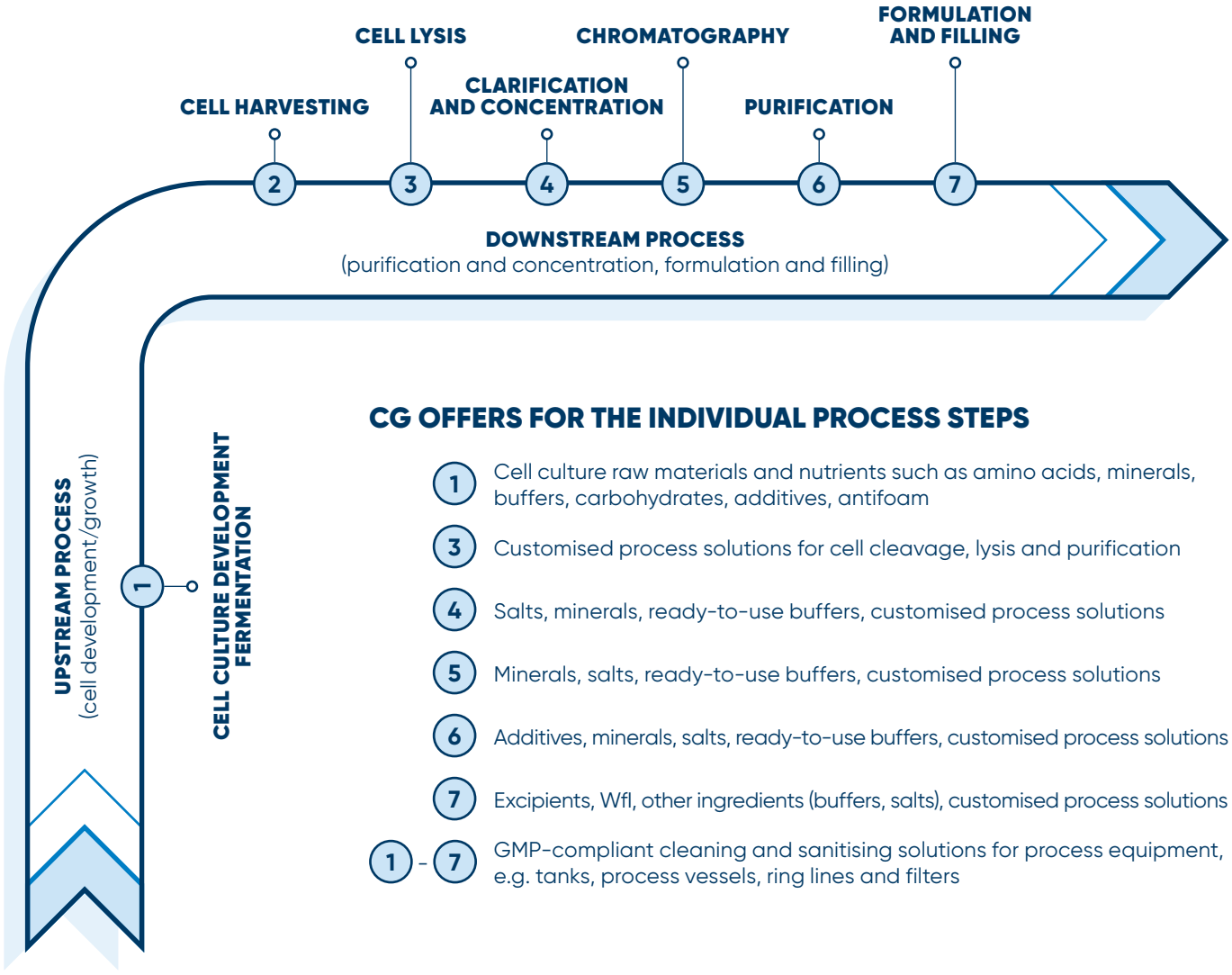
Sterile-filtered solutions to optimise biopharmaceutical production

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

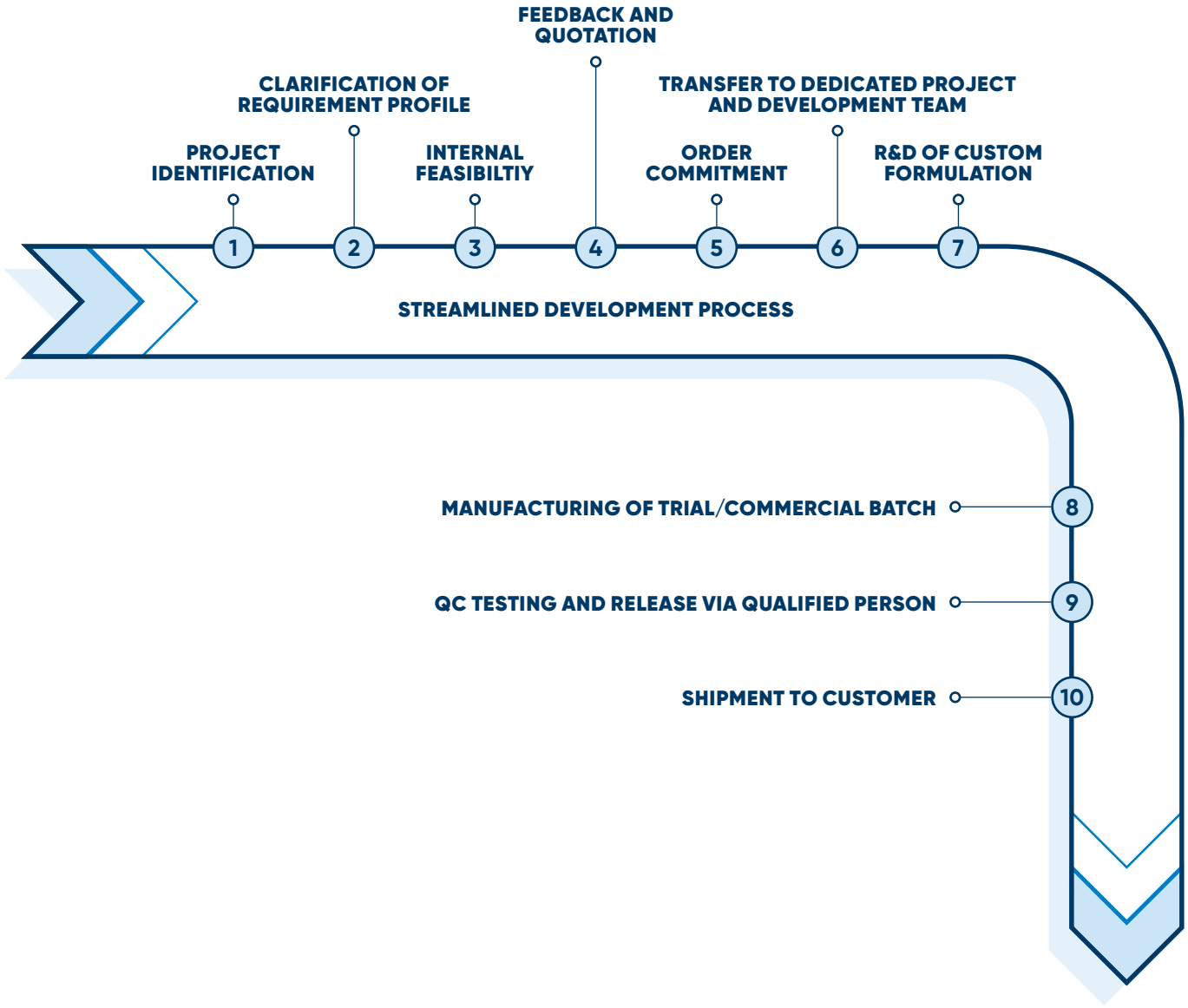


CG OFFERS FOR THE INDIVIDUAL PROCESS STEPS

- 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)
- 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
- 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

CUSTOMISED FORMULATIONS – EXTRACT OF FORMULATIONS

ALCOHOLS/SOLVENTS	
2-Propanol	Ethyl alcohol absolute
Acetone	

PHOSPHATE BUFFER SOLUTIONS	
PBS buffer	Sodium dihydrogen phosphate
Potassium dihydrogen phosphate	Sodium phosphate

BALANCED SALT SOLUTIONS	
Ammonium sulphate	Sodium acetate
Citrate buffer	Sodium chloride

SOLIDS	
Customised formulations	Simple and highly complex mixtures

HIGH QUALITY WATER	
Purified water (AP)	Water for injection (WfI)

STRONG ACIDS	
Acetic acid	Citric acid solution
Hydrochloric acid	Phosphoric acid

ORGANIC BUFFER SOLUTIONS	
EDTA buffer	Sucrose
Glucose	TEAA
HEPES buffer (with HCL, ethanol, NaCl, EDTA, various concentrations and pH values)	TRIS
	Urea buffer

STRONG BASES	
Sodium hydroxide pellets suitable for biopharmaceutical production EP, USP, JP	Sodium hydroxide solutions

CG CONNECTS –
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