CG PHARMA & BIOTECH

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GMP-compliant manufacturer – Made in Germany

FACTS

Qualified partner of global (bio)pharma companies

Innovative products and solutions
- C-Made, customised formulations
- PharmProve®, bioprocessing chemicals and excipients
- Buffer solutions
- Cleaning in place solutions
- High quality water
- Vaccine - raw materials
- Plasma fractionation - raw materials

Quality and accreditations
- EU GMP certified acc. to Part 1 + 2
- Manufacturing authorisation according to the German Medicinal Products Act AMG §13
- IPEC-GMP for excipients certified by EXCiPACT standard

Cleanroom production and water
- 800 m² cleanroom (class C & D), clean corridor concept
- In-house production of Purified Water (AP) and Water for Injection (WfI)
- Scalable production set-up, from small scale to commercial production

Packaging for liquids and solids
- Various primary and secondary packaging options
- Custom 2D/3D single-use bags for liquids and powders
- Customer-specific multiway packaging

Warehouse and Logistics
- 3,200 pallet spaces for packaging materials, raw materials and finished products
- Temperature controlled
- Additional external storage capacities at warehousing service provider
- Customized logistics concepts

Your challenge - Our solution

(BIO)PHARMA AND CHEMISTRY

Your partner for high quality critical raw materials and excipients

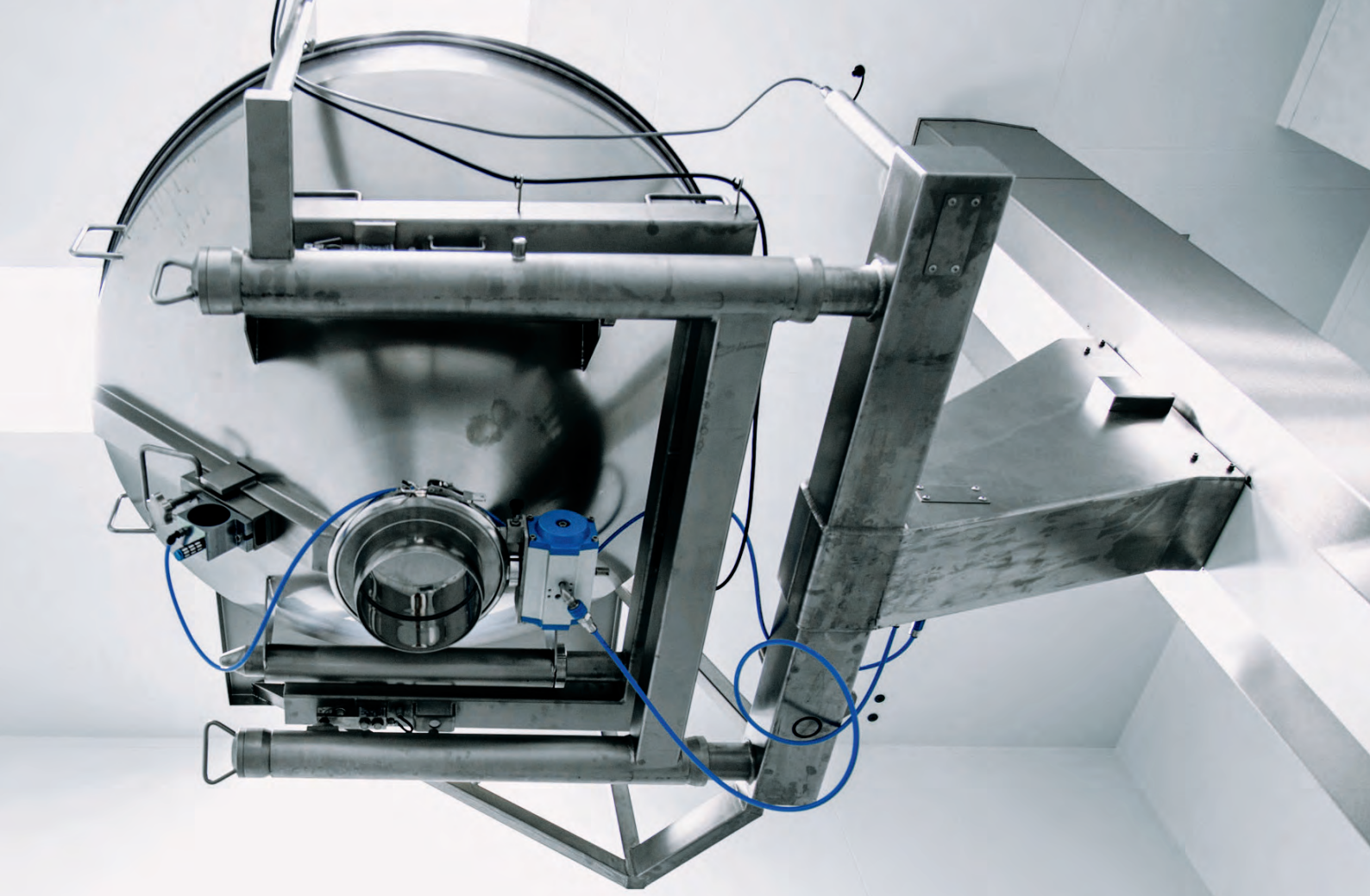
As a trusted partner to manufacturers of plasma-derived therapeutics and biologic drugs, CG Pharma & Biotech serves as an extended workbench for major (bio)pharma companies, supporting the industry's growing trend toward outsourcing buffers, process solutions as well as critical raw materials. Our mission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

"Our journey began with a vision for innovation and quality. Today, thanks to our dedicated team and strong partnerships, we are a trusted partner for the global (bio)pharma industry – delivering tailored solutions and setting new standards for the future."

Dr. Velte, Head of CG Pharma & Biotech

CG Pharma & Biotech is a business unit of CG 1962 and part of the CG GROUP, which consists of six member companies with locations across Germany. Driven by our commitment to continuous development, the foundation for the CG Pharma & Biotech division was laid in 2012 with the strategic decision to build a new facility featuring a dedicated temperature-controlled storage area and a GMP-compliant cleanroom production. This forward-looking investment marked the beginning of our journey to provide high-quality solutions for the (bio)pharmaceutical industry.

OUR HISTORY AND ACHIEVEMENTS	
2014 - 2017	Planing, construction, qualification and authority approval of the new production site
2017/2018	Production and release of first products and first customer audit
2022	Foundation and renaming of business unit CG Pharma & Biotech
2023	Lanuch of PharmProve® brand (raw materials for bioprocessing)
2025	Liquid handling capability extension for concentrated corrosive chemicals under protected environment
2025	Project SolidPro, start of planing and constructions for a new GMP solid manufacturing plant
2025	Implementation of IPEC-GMP quality standard via EXCiPACT certification



OUR MISSION

- GMP-Compliant Manufacturer – Made in Germany
- We provide an outstanding portfolio of high-quality, GMP-compliant raw materials and customized formulations, precisely tailored to meet the rigorous demands of biologics manufacturing, plasma processing, vaccine production, and many other applications.
- Our comprehensive offering includes advanced cleaning-in-place solutions, innovative process solutions, accurate buffer solutions, and a wide range of multi-compendial production chemicals and excipients—ensuring the highest quality for every stage of your production.

OUR PROMISE: YOUR CHALLENGE – OUR SOLUTION

CG Pharma & Biotech, part of the family-owned CG Group, delivers flexible, tailored solutions for your unique needs. We focus on long-term partnerships and invest in your success. We work closely with industry and regulatory bodies, including BPI, to support a secure and sustainable (bio)pharma sector in Europe.

Key Areas: efficient and secure supply chains through outsourcing

- Maximum productivity with external expertise
- Simplified processes and fewer interfaces
- Reduced risks across the value chain
- Sustainable cost savings
- Increased safety with ready-to-use chemicals and solutions

OUR QUALITY COMMITMENT

We are committed to continuous improvement and ongoing alignment with global GMP and quality standards to support the evolving needs of our clients and uphold the highest levels of patient safety. Our commitment to quality protects your processes and gives you peace of mind—so you can focus on your core business.

OUR KEY COMPETENCIES

- Custom manufacturing of sterile-filtered process solutions and excipients for upstream and downstream (bio)pharmaceutical applications.
- Ready-to-use sterile-filtered solutions in single-use bags, ideal for a variety of pharmaceutical processes.
- GMP cleaning solutions for critical CIP (Cleaning in Place) and SIP (Sterilization in Place) applications.
- Expertise in processing hazardous substances in cleanrooms, including corrosive and flammable materials.
- In-house production of Water for Injection (WfI) and Active Pharmaceutical Ingredients (API), ensuring complete control over quality and compliance.
- Pharmacopoeia-compliant raw materials for further use in production of DS and DP

Our scalable production capacity enables us to meet your needs flexibly, delivering “Made in Germany” quality at every step.

CUSTOMER IN FOCUS

Our concept:
tailored solutions to meet your specific needs

We understand the challenges of our partners and compliance with regulatory requirements. We accompany our partners on the path from the development stage cross lab scale to commercial production. Our services and products are tailored to the needs of our clients and can be selected and combined on a modular basis.

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

OUR CORE MARKETS

Our customers are leading companies in the (bio)pharmaceutical industry who rely on our expertise and high-quality products for a wide range of applications. We support critical processes and product development in areas such as:

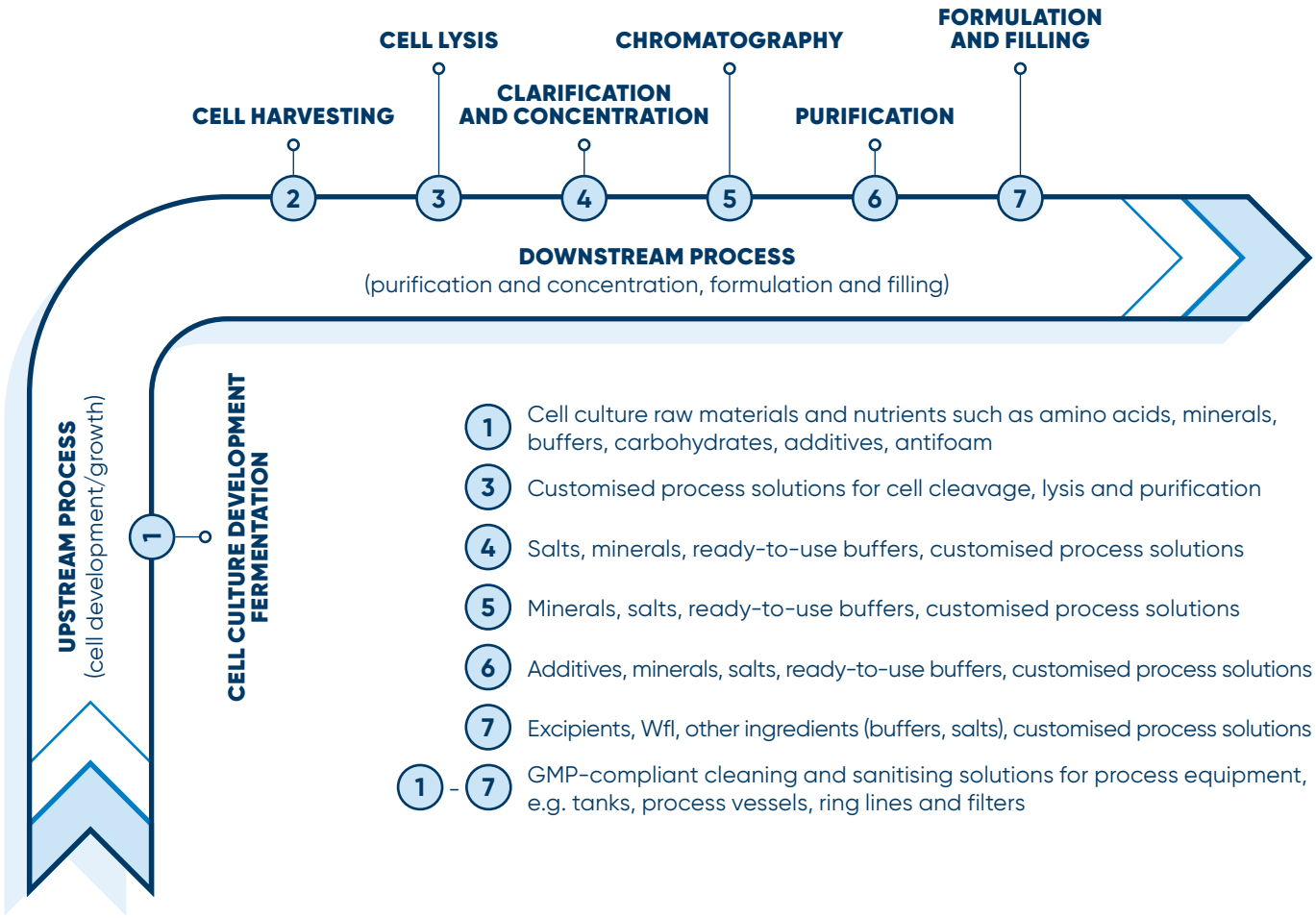
Biotechnology-based drug substances and drug products
- Vaccines (mRNA, recombinant DNA, cell culture-based and vector-based)
- ATMPs (Advanced Therapy Medicinal Products), including cell and gene therapies
- Cell culture media
- Monoclonal antibodies (mAbs)
- Biosimilars

Biological medicinal products
- Plasma-derived medicinal products (PDMP)
- Enzymes
- Heparins

Classic pharmaceuticals (chemical/synthetic drugs, APIs)
- Solid, liquid and semi-solid oral formulations
- Inhalation formulations
- Ophthalmic formulations
- Dialysis formulations

(BIO)PHARMACEUTICAL PRODUCTION PROCESS – COMPREHENSIVE SUPPORT

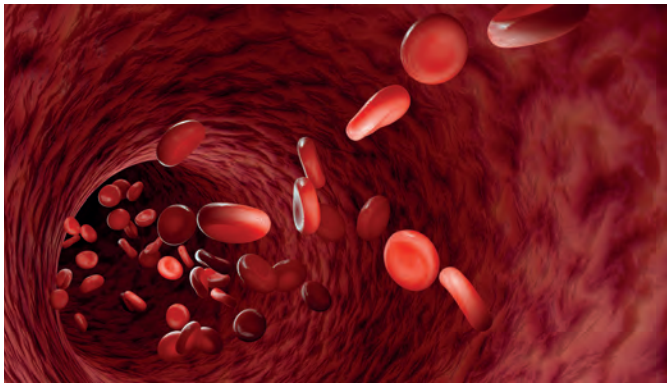
(Bio)pharmaceutical development and manufacturing requires precise processes and expert support. CG Pharma & Biotech offers products and solutions for major steps of of the drug substance and drug product production process, ensuring quality, safety and efficiency.



SUPPORTING YOUR PLASMA FRACTIONATION

As a leading developer, manufacturer and supplier of critical raw materials for plasma protein based manufacturers, we are providing reliable support from the start of development through to clinical phases and commercial production. Our commitment to the highest quality is reflected in our customised services and products, which are designed to seamlessly adapt to each client's individual requirements.

Our extensive range of high-quality raw materials, starting materials and excipients is designed to meet the unique needs of virus inactivation, precipitation elution and buffer solution preparation, all essential stages in the production of life-saving plasma-derived therapies. Thanks to our modular approach, you have the flexibility to select and combine the solutions that perfectly fit your needs.



CG Pharma & Biotech – essential raw materials and excipients for plasma derived medicinal products (PDMPs)

- Extensive experience in supporting the plasma industry
- EU-GMP certified manufacturing facility with Class C/D cleanrooms
- Tailored solutions for plasma fractionators – customized formulations and a comprehensive standard product catalogue

SERVICES

From standardised to customised

TAILORED SOLUTIONS

- Development and production of customised formulations
- In-house R&D department, from laboratory scale to commercial production
- Agile project management, consulting and planning

Fotodesign Andreas Braun

LAB CAPABILITIES

- In-house chemical/physical analytical laboratory
- Testing of starting materials according to pharmacopoeia (e.g. EP, BP, USP, JP, ChP)
- Finished product testing (e.g. appearance, pH, conductivity, density, refractive index, osmolality, assay)
- Microbiological testing (e.g. sterility, endotoxins, RNAse, bioburden)
- Stability testing

QUALITY

- Manufacturing authorisation according to the German Medicinal Products Act AMG §13
- Quality assurance agreements with customers and suppliers
- Batch release by authorised person
- Risk-based Management
  - Risk management system acc. to ICH Q9
  - Change control
  - CAPA / OOS System
- Continous improvement
  - Product quality review
  - Batch record review
  - Supplier qualification system
  - Audit and training system
- Qualification and validation acc. to Annex 15 EU GMP
  - Process, cleaning and method validation
  - Room and equipment qualification
  - Software validation
- EU GMP certified acc. to Part 1+2
- IPEC-GMP for Excipients certified by EXCiPACT standard

IN-HOUSE AP/WFI PRODUCTION

- Purified water (AP) according to EP, USP
- Water for injection (WfI) according to EP, USP
- 20,000 L storage tank (WfI)
- Production capacity: 500 L/h
- 10,000 L storage tank (AP)
- Production capacity: 4,000 L/h
- Continuous monitoring of water quality for compliance with the specification parameters

WAREHOUSE

- 3,200 pallet spaces for packaging materials, raw materials and finished products
- Temperature controlled
- Pest control
- Underground stainless steel storage tank with 30,000 L volume for pharmaceutical solutions
- Laminar flow sampling cabinet for contamination-free sampling of raw materials
- Additional external storage capacities at warehousing service provider

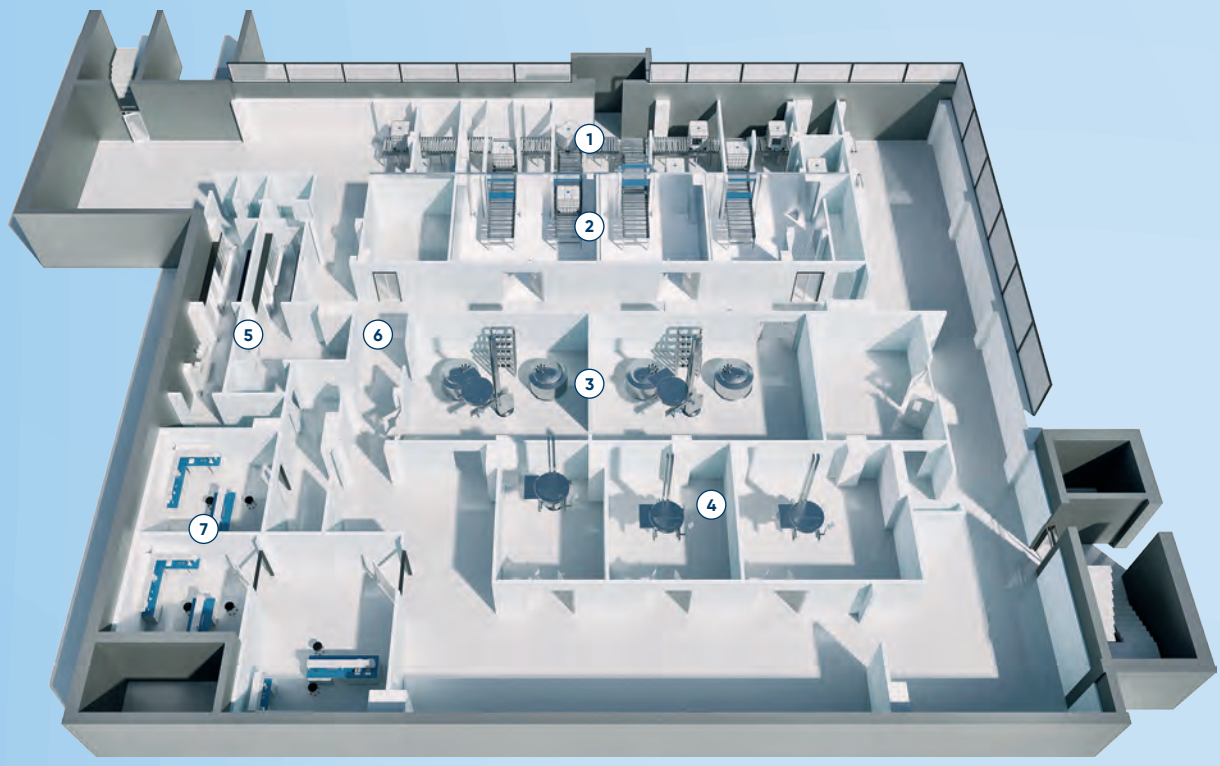
PACKAGING FOR LIQUIDS AND SOLIDS

- Filling in custom- esigned 2D and 3D single-use bags/manifolds from 1 L - 1,000 L
- Multiway transport/bioprocess containers for 3D single-use bags from 100 L - 1,000 L (CG Tainer)
- 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)

LOGISTICS AND TRANSPORT

- GDP-certified pharma logistics
- Temperature monitoring and GPS tracking
- Security against unauthorised access
- Isotainer bulk transport up to 20,000 L, general cargo (packaged goods)
- Customised logistics concepts
- International distribution network

CLEANROOM PRODUCTION



Facts and figures

- 800 m² cleanroom area, divided into liquid and solid areas
- Clean corridor concept
- Production facility free of animal components (AOF)
- Personnel airlocks
- Weighing of raw materials in cleanroom class C&D
- Compounding and filling in cleanroom class C&D
- 3 filling rooms for liquid media cleanroom class C&D
- 2 filling rooms for solid media cleanroom class C&D
- Automatic transport conveyor system with integrated weighing technology
- SIP/CIP system for sanitisation and cleaning with validated cleaning processes
- In-house quality control including microbiology
- Washroom to clean production equipment
- In-process use of nitrogen and ultra-pure steam

Production setup

- Multipurpose equipment with validated cleaning procedures
- Stainless steel vessel with integrated double agitator
- 2,000 L and 5,000 L stainless steel vessels with magnetically coupled agitator, heatable, temperature-regulated, inline pH control
- 2,000 L and 5,000 L plastic vessels (PVDF)
- Vessels on integrated scales for direct weighing of raw materials
- 200 L mobile vessel for pilot or small batches
- Weighing containers from 100 L - 1,000 L volume
- 1,000 L mobile single use mixer for small scale batch production

1 CONVEYOR SYSTEM

2 FILLING AREA

3 LIQUID AREA

4 SOLID AREA

5 PERSONNEL LOCK

6 CLEANROOM CORRIDOR

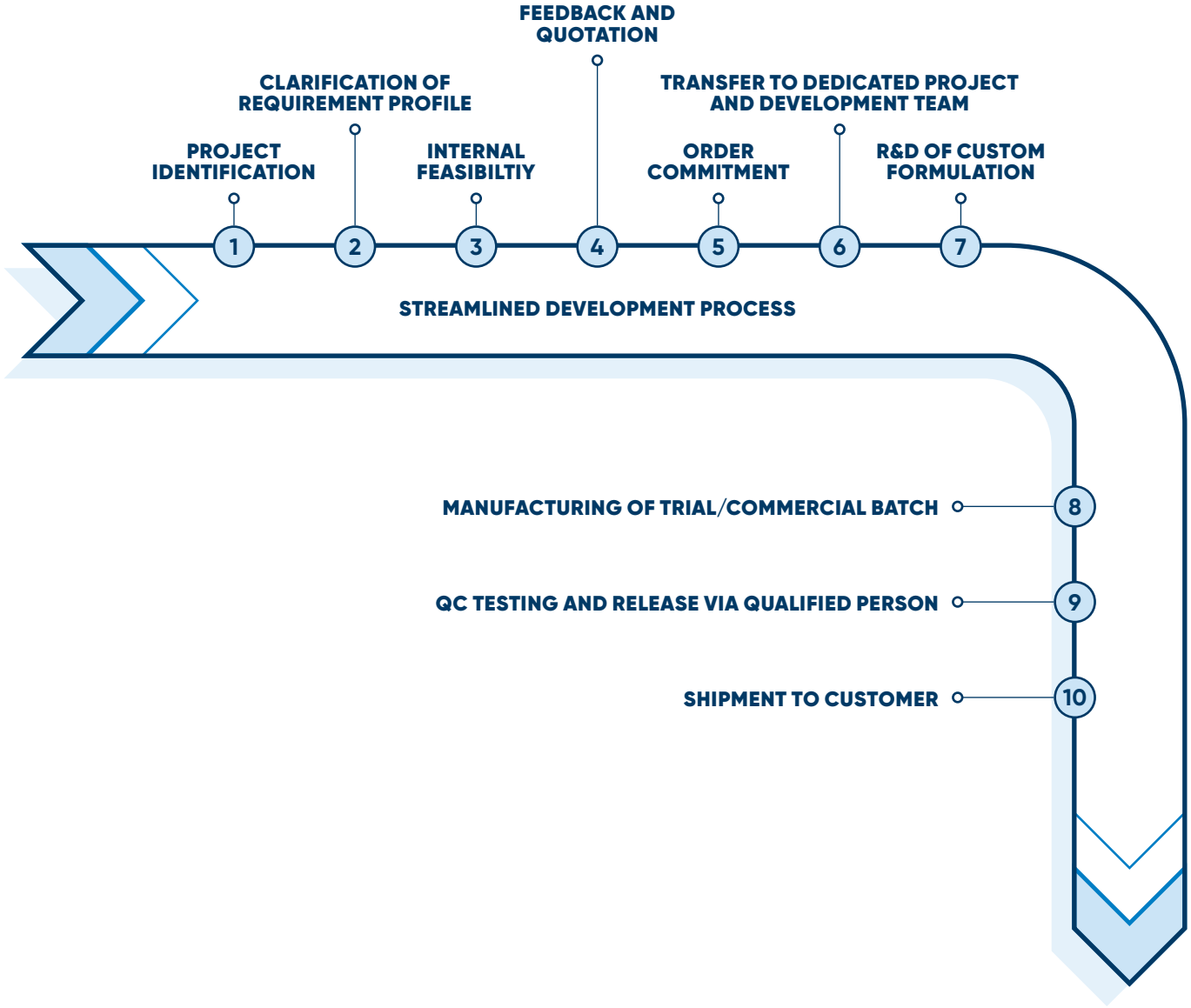
7 IPC LABORATORY

THE CG PHARMA & BIOTECH PARTNERSHIP APPROACH

From idea to implementation – creating your ideal solution together

Our working process is designed to make collaboration smooth and transparent from the very first contact. After an initial discussion with our Experts, we analyse your needs and clarify all requirements.

Our interdisciplinary team then reviews feasibility and provides you with a first price indication and timeline. Once you confirm with a Letter of Intent or Purchase Order, your project moves to our expert team, who manage all further steps—from detailed planning and risk assessment to formulation development, GMP documentation, and production. After final quality checks and release, you receive your goods along with all necessary documentation. This streamlined approach ensures efficiency, reliability, and the highest quality for your project.



OUR QUALITY COMMITMENT

Our operations adhere strictly to EU GMP guidelines (Parts 1 and 2) and align with ISO 9001:2015 requirements, underlined a strict quality management system. Our facility is fully GMP-qualified, with validated processes and comprehensive cleanroom monitoring supported by reflecting the requirements of the International Pharmaceutial Excipients Council (IPEC), which is demonstrated with our EXCiPACT (IPEC-GMP) certification. We operate under a German manufacturing license granted in accordance with Section 13 of the German Medicinal Products Act (AMG), meeting all obligations under the German regulatory framework for pharmaceutical production. Each batch undergoes a rigorous Batch Record Review, with final release by authorised personnel to meet all regulatory requirements.

FULLY CERTIFIED – OUR CERTIFICATIONS AT A GLANCE

PHARMA & BIOTECH		QUALITY & SUSTAINABILITY	
EU GMP certified acc. to part 1 + 2	GDP	ISO 9001	Responsible care
Manufacturing authorisation according to the German Medicinal Products Act AMG §13	IPEC-GMP for excipients certified by EXCiPACT standard	ISO 50001	EcoVadis
		ISO 14001	Kosher/Halal

CG CONNECTS –
YOUR EXPERTS AND OUR SPECIALISTS

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