

CG PHARMA & BIOTECH

Products and services –
from standard to customised



FACTS

Qualified partner of global pharma and biopharma companies

GMP compliant manufacturing of liquid and solid components for use as ingredient, starting material or excipient

GMP certified production facility with cleanrooms class C&D

Managing pharmacopoeia compliant raw materials (e.g. EP, BP, USP, JP, ChP)

In-house GDP logistics

“Made in Germany”

One vendor for multiple chemicals

Our key competencies:

- Manufacturing of customised, sterile-filtered (bio) pharmaceutical process solutions and excipients for upstream and downstream applications
- Standard catalogue products for several pharmaceutical applications
- Scalable from small scale to commercial production
- Ready-to-use sterile filtered solutions in single-use bags
- GMP cleaning solutions for CIP and SIP applications
- Processing of hazardous substances in the cleanrooms (corrosive and flammable)
- In-house production of Wfl and AP

Your challenge – Our solution

OUR UNIVERSE IS CHEMISTRY

CG 1962 | CG CHEMIKALIEN

Tradition and innovation: We know exactly where we come from. Our experience of more than 60 years is a strong foundation and is perfectly combined with our desire to continually break new ground, develop new products and exploit current technological opportunities.

Specialists and experts: We talk to our business partners on an equal footing. We connect specialists and experts on our side and theirs. We attach the utmost importance to the qualifications, education and training of our colleagues and employees. After all, expertise is the basis for real understanding.

Values pursued by CG: We see ourselves as a problem solver for our customers. In this task, we are committed to values that drive our thinking and actions. We are innovative, agile, qualified and sustainable.

OUR PROMISE: YOUR CHALLENGE – OUR SOLUTION!



OUR HISTORY

1962 It all started in 1962 –
foundation of Chemikalischen Gesellschaft (CG)

→ 1962 – 1979

- Expansion of the company premises by 15,000 square meters
- Acquisition of the chemical factory Dr. Reininghaus (Essen)
- Participation in Reher & Ramsden Nachflg. GmbH & Co. KG (Hamburg)
- Construction of a solvent tank farm and the two storey administration building
- Establishment of an own export department

→ 1980 – 1999

- Expansion of storage capacities
- Construction of the CG laboratory
- Acquisition of the SIL paint factory (Coppelnbrügge)

→ 2000 – 2009

- Acquisition of Wendt Chemie GmbH & Co. KG (Hamburg)
- Acquisition of shares in Wilhelm Jäkle GmbH & Co. KG (Nürnberg)
- Majority stake in Thommen Furler AG (Rüti near Büren, Switzerland)

→ 2010 – today

- Acquisition of CHEM-DIS GmbH (Eisenberg)
- Modernisation and increase of storage and production capacities
- Construction of the GMP certified CG Pharma & Biotech production facility, including GMP warehouse with 3,200 pallet places
- Construction of dedicated laboratory building
- Expanding business to APAC, LATAM, MEA and CIS
- Granting of manufacturing license according to §13 AMG

QUALIFIED CERTIFIED – OUR CERTIFICATIONS AT A GLANCE

QUALITY & SUSTAINABILITY	PHARMA & BIOTECH	HEALTH & NUTRITION
<ul style="list-style-type: none"> • ISO 9001 • ISO 50001 • ISO 14001 • SQAS/ESAD • Responsible care • EcoVadis • GDP 	<ul style="list-style-type: none"> • Manufacturing authorization according to German Drug Law • GMP 	<ul style="list-style-type: none"> • FSSC 22000 (HACCP) • Kosher • Halal

SALES REGIONS



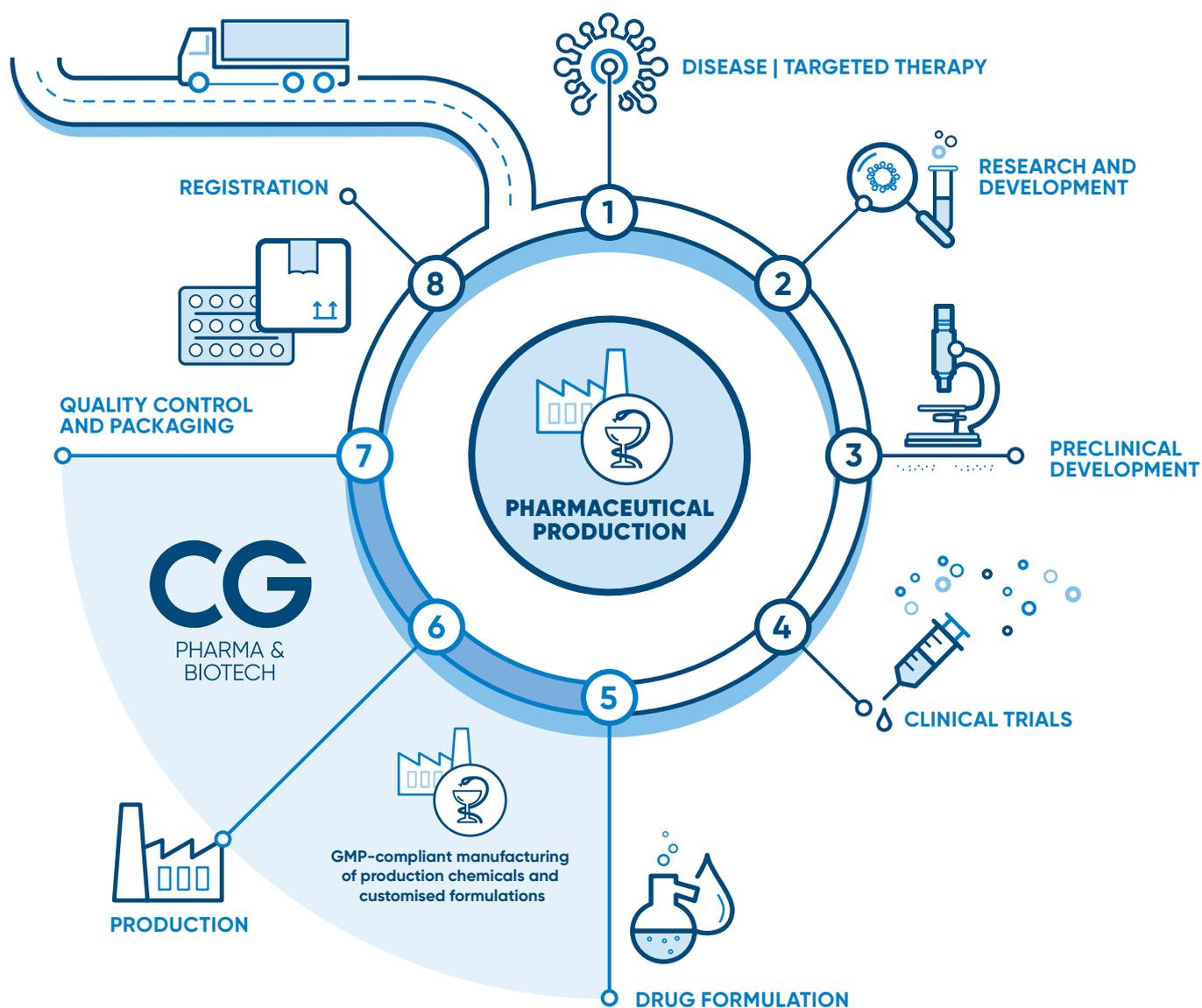
Germany Direct sales	Middle East, Africa Global key accounts and distributors
Switzerland Direct sales, key accounts	Asia Pacific Global key accounts and distributors
Europe Global key accounts	Latin America Distributors

CG PHARMA & BIOTECH

Quality, safety and efficacy

The management of critical raw materials is an increasingly complex yet critical component of the pharmaceutical/biopharmaceutical industrie's manufacturing processes.

As a manufacturer and supplier of critical raw materials, we understand the challenges of our partners and their regulatory requirements. We accompany our partners on the path from the development stage through the clinical phases 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.



OUR CONCEPT

C-MADE

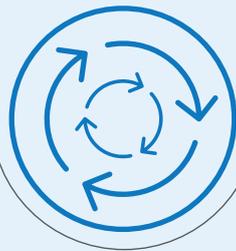
Manufacturing and development of **customised formulations** for the biopharma production process – upstream, downstream and final formulation steps

LIQUIDS

customised formulations

SOLIDS

customised formulations
simple and high complex mixtures



PharmProve®

Multi-compendial production chemicals for use as ingredient, starting material, excipient or API for manufacturing of (bio)pharmaceuticals

LIQUIDS

single components

SOLIDS

single components



APPLICATIONS AND PRODUCTS OF CUSTOMERS

Biotechnologic based drug substances and drug products

- vaccines (mRNA, recombinant DNA, cell culture based and vector based)
- ATMP's (advanced therapy medical products) cell and gene therapy
- cell culture media
- monoclonal antibodies (mAbs)
- biosimilars

Biological medicinal products

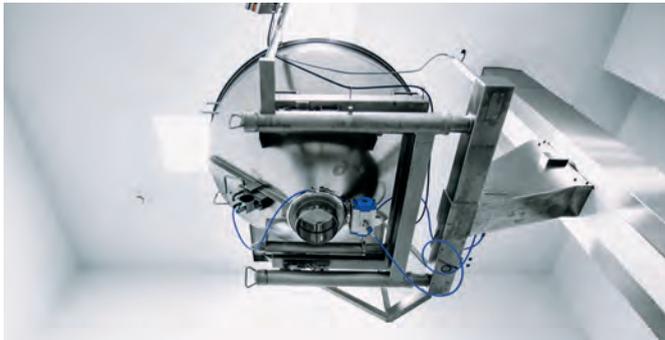
- plasma derived medical products (PDMP)
- Enzymes
- Heparines

Classic pharma (chemical/synthetic drugs, API)

- oral solid, liquid and semi-solid formulations
- inhalation formulations
- ophthalmic formulations
- dialysis formulations

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



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ANALYTICS

- 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 German Drug Law AMG §13
- Quality assurance agreements with customers and suppliers
- Batch release by authorised person
- Risk Base Management
 - Risk management system acc. to ICH Q9
 - Change control
 - CAPA / OOS System
- Continuous 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



AP/WFI IN-HOUSE 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 and humidity monitoring
- Pest control
- Underground stainless steel storage tank with 30,000 L volume for pharmaceutical solutions
- Laminar-flow sampling cabine for contamination-free sampling of raw materials



PACKAGING FOR LIQUIDS AND SOLIDS

- Filling in customised designed 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 container (IBC), isotainer up to 20,000 L
- Customer specific multiway packagings 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 monitored and GPS tracked
- Security against unauthorised access
- Isotainer bulk-transport up to 20,000 L, general cargo (packaged goods)
- Customised logistics concepts
- International distribution network

CLEANROOM PRODUCTION

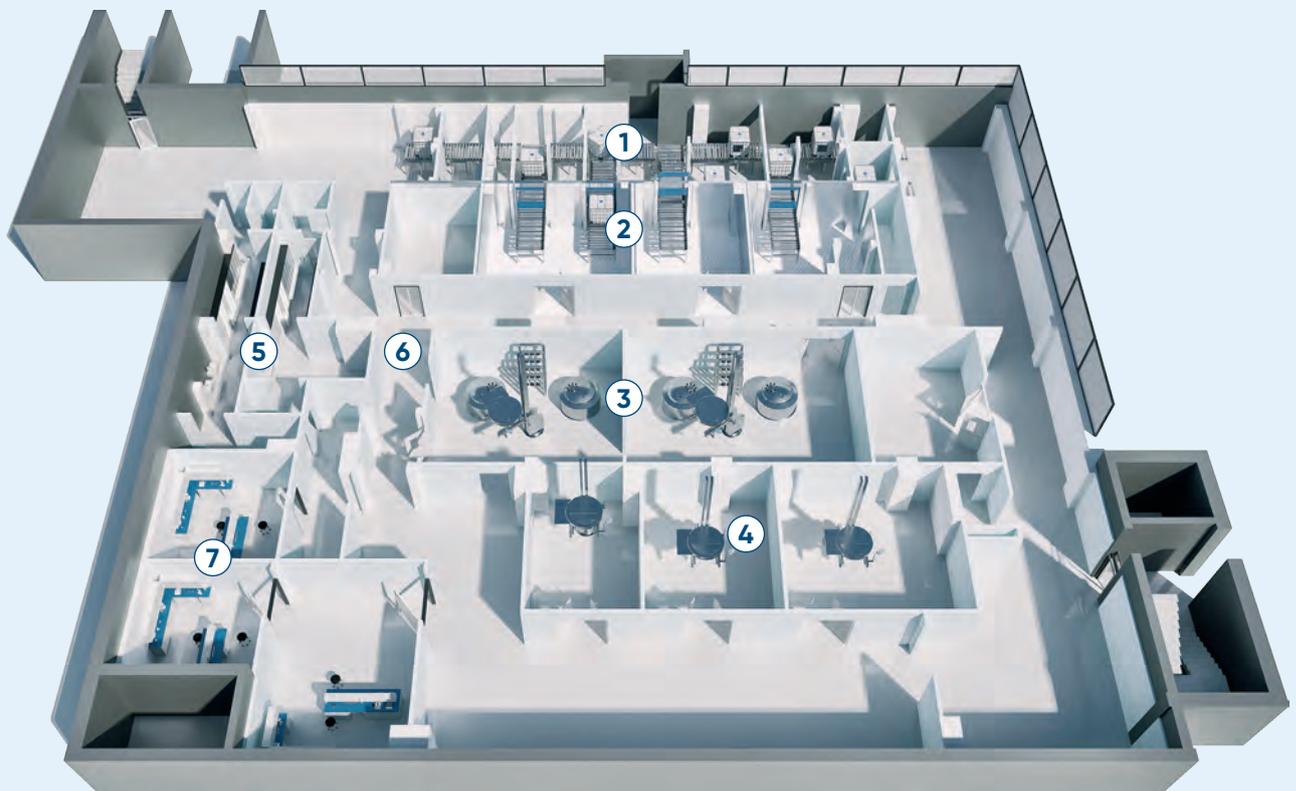
Facts and figures

- 800 m² cleanroom area, divided into areas liquid and solid
- Clean corridor concept
- Production facility free of animal components (AOF)
- Personnel locks
- 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 for cleaning production equipment
- In process use of nitrogen and ultra-pure steam

Production set up

- 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

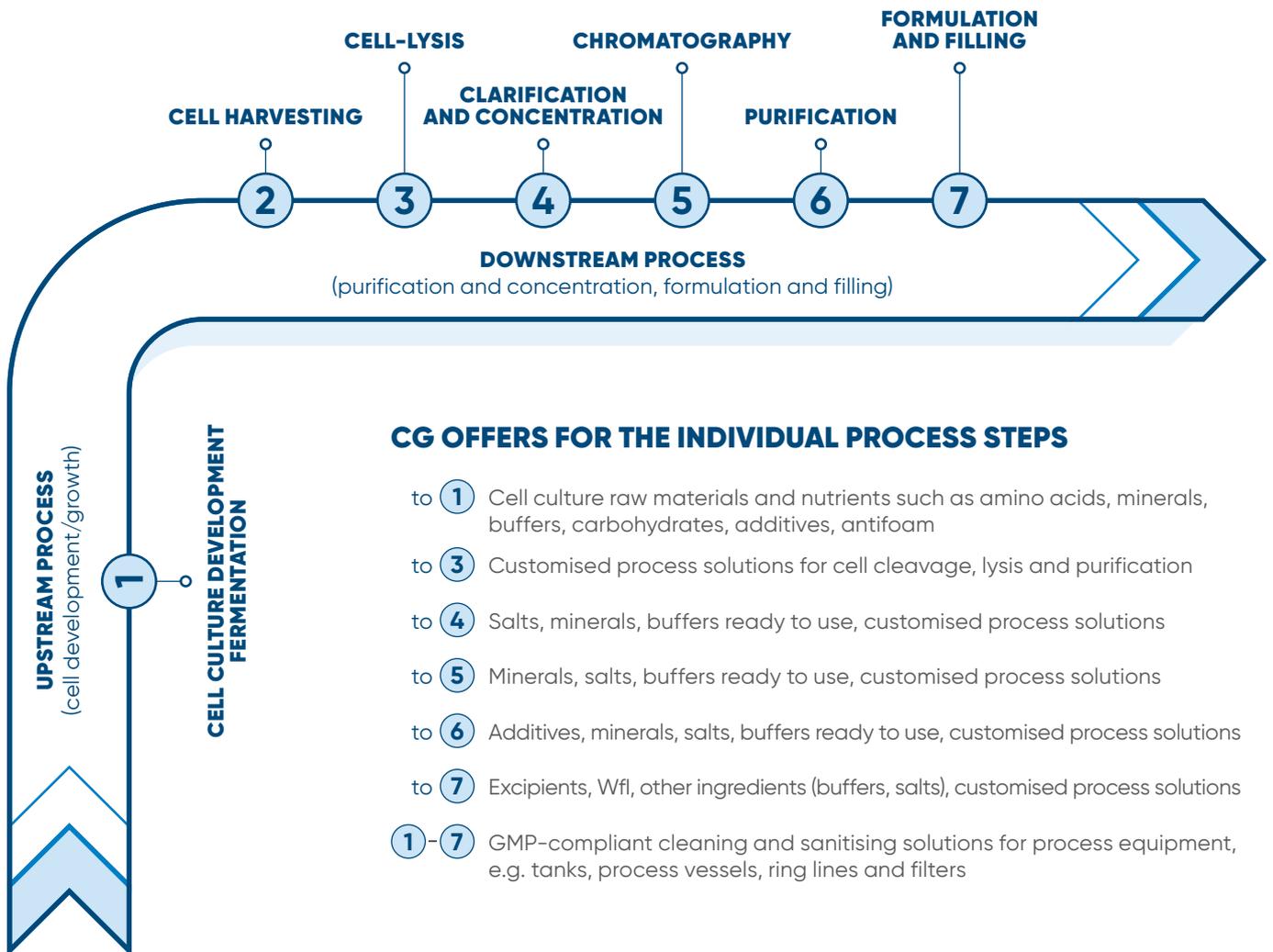
- | | |
|-------------------|----------------------|
| ① CONVEYOR SYSTEM | ④ SOLID AREA |
| ② FILLING AREA | ⑤ CHANGING AREA |
| ③ LIQUID AREA | ⑥ CLEANROOM CORRIDOR |
| | ⑦ IPC LABORATORY |





BIOPHARMACEUTICAL PRODUCTION PROCESS

CG Pharma & Biotech offerings for the individual process steps



UPSTREAM PROCESS (CELL DEVELOPMENT/GROWTH)

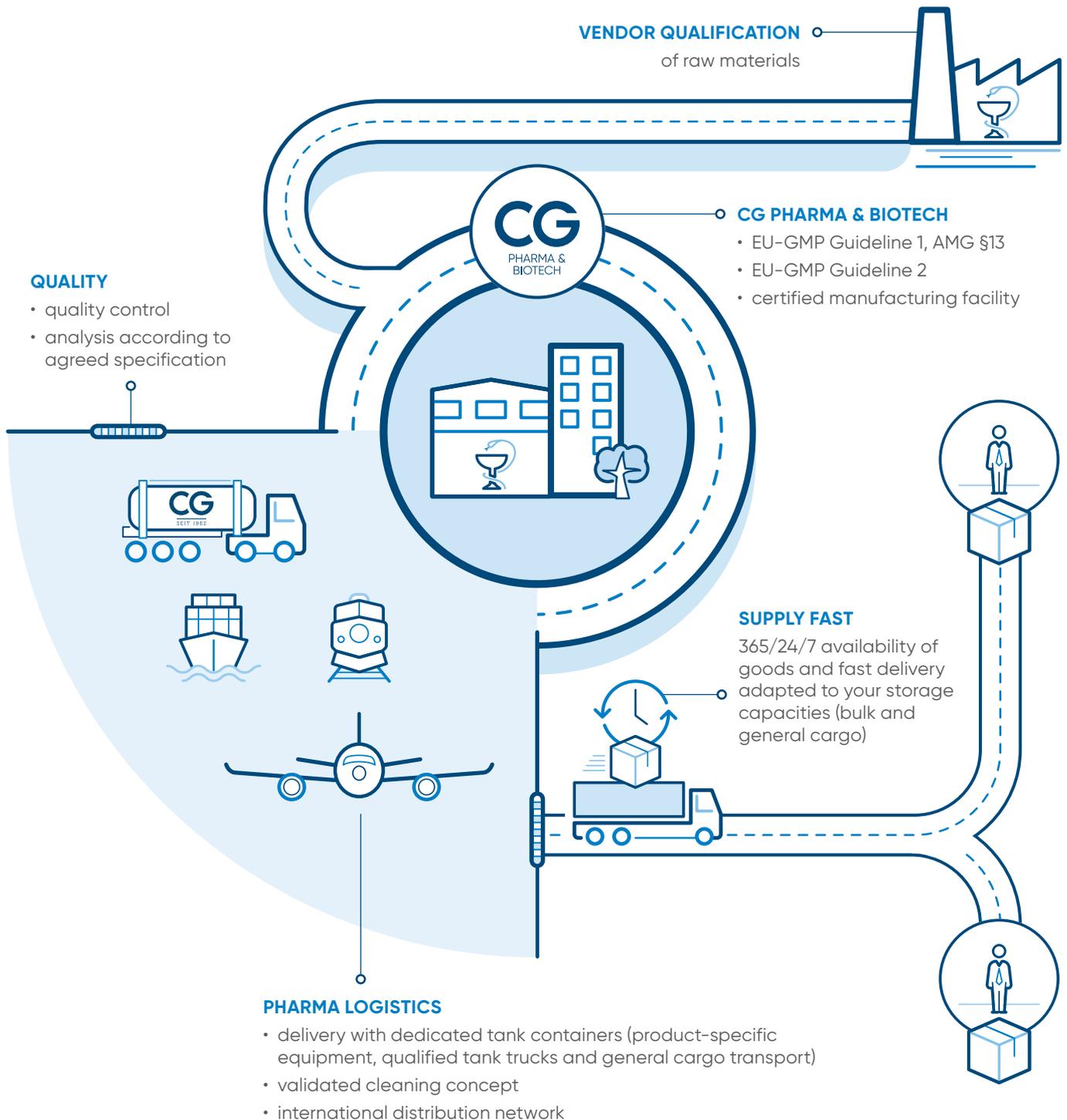
- ① **Cell culture development:** cell cultivation, fermentation in bioreactor (control of oxygen, temperature, pH and pressure) for optimal cell growth

DOWNSTREAM PROCESS (PURIFICATION AND CONCENTRATION, FORMULATION AND FILLING)

- ② **Cell harvesting:** microfiltration, centrifugation separation of cellular biomass from the fermentation broth
- ③ **Lysis:** dissolution of cells, mechanical removal of DNA/RNA components and filtration (TFF)
- ④ **Clarification and concentration:** subsequent ultrafiltration, diafiltration
- ⑤ **Chromatography:** purification and isolation; removal of impurities and unwanted components and molecules; types of chromatography: membrane chromatography, ion chromatography, affinity chromatography, hydrophobic interaction chromatography (HIC)
- ⑥ **Purification:** elimination of other possible contaminating molecules and homogenisation of the desired product and sterile filtration
- ⑦ **Formulation and filling:** active ingredient is formulated with other ingredients/excipients and filled into a form suitable for clinical administration

SYSTEMATIC SAFETY

Good reasons



CG CONNECTS – YOUR EXPERTS AND OUR SPECIALISTS

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