CG
PHARMA &
BIOTECH

CG PHARMA & BIOTECH

Products and services – from standard to customised

HIGHLIGHTS
Audited partner of global pharma and biopharma companies
GMP compliant production of liquid and solid components for use as ingredient, starting material or excipient
EU-GMP certified production facility: manufacturing authorisation §13 German Drug Law; cleanroom production according to ISO 7/8
Pharmacopoeia compliant raw materials (e.g. EP,BP,USP, JP, ChP)
In-house GDP logistics
„Made in Germany"
Part of CG 1962 | CG Chemikalien

Our competences:

- Manufacturing of customised, sterile-filtered bio-pharmaceutical process solutions and excipients for upstream and downstream applications
- Standard catalogue products for further manu-facturting use
- Scalable solutions from small scale to commercial production
- Ready-to-use hydrated buffer- and process-solutions, filled in sterile single-use bags
- GMP-compliant cleaning solutions for CIP and SIP applications
- Processing of hazardous substances in the clean-room (corrosive, flammable)
- In-house production of WfI 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 (Coppenbrügge)

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, Swizerland)

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, manufacturing license §13 AMG, GMP warehouse 3,200 pallet places
- Construction of a 5-storey laboratory building
- Expanding business to APAC, LATAM, MEA and CIS

QUALIFIED CERTIFIED – OUR CERTIFICATIONS AT A GLANCE

QUALITY & SUSTAINABILITY

- ISO 9001
- ISO 50001
- ISO 14001
- SQAS/ESAD
- Responsible care
- EcoVadis

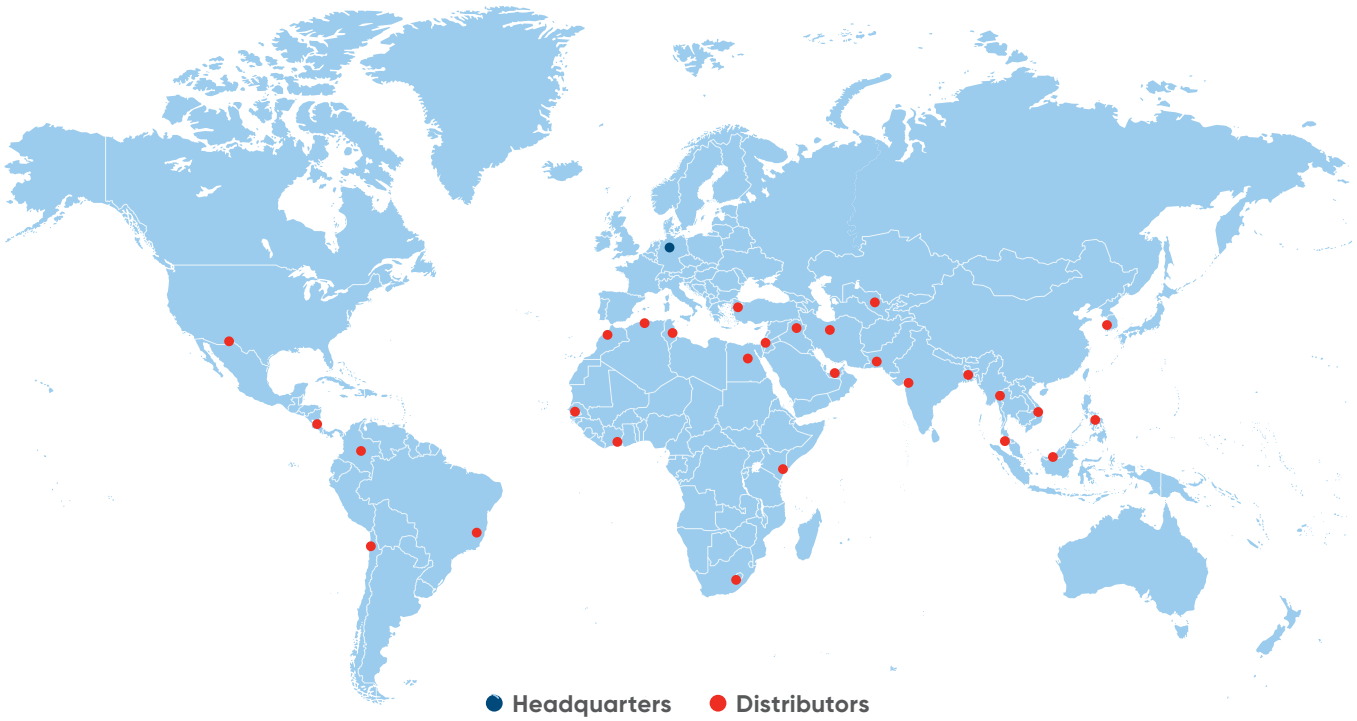
PHARMA & BIOTECH

- German Drug Law: AMG §13
- GMP
- GDP

HEALTH & NUTRITION

- FSSC 22000 (HACCP)
- Kosher
- Halal

SALES REGIONS



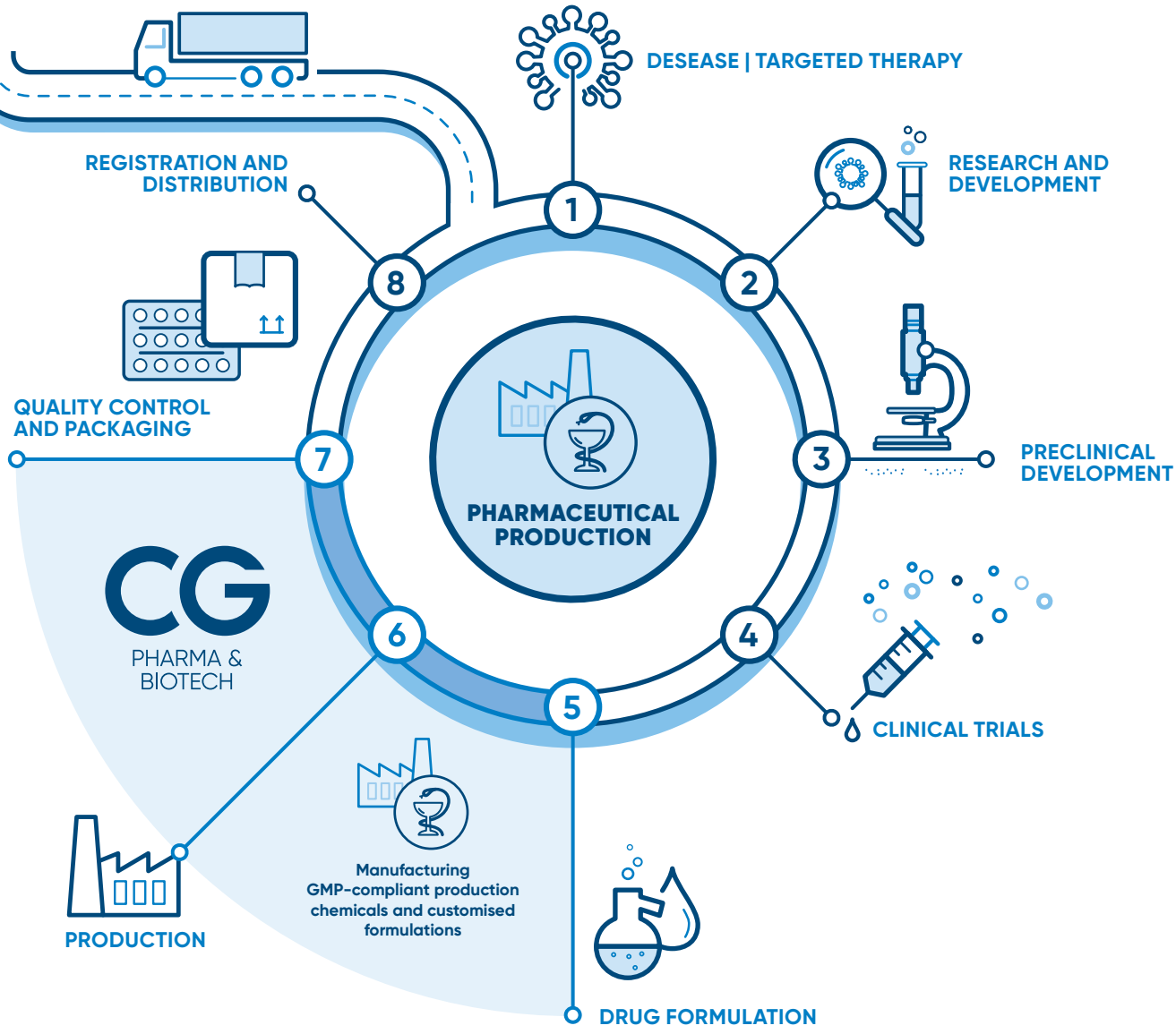
Germany | Direct sales	**Middle East, Africa** | Global key accounts and distributors
Switzerland | Direct sales, key accounts	**Asia Pacific** | Global key accounts and distributors
Europe | Global key accounts	**Latin America** | Distributors

CG PHARMA & BIOTECH

Systematic safety

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

As a developer, manufacturer and supplier of critical raw materials, CG Pharma & Biotech understands the challenges of our partners and compliance with 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

Manufactoring 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 manufactoring of pharma and biopharmaceuticals

LIQUIDS
single components

SOLIDS
single components

CUSTOMERS – APPLICATIONS AND PRODUCTS

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

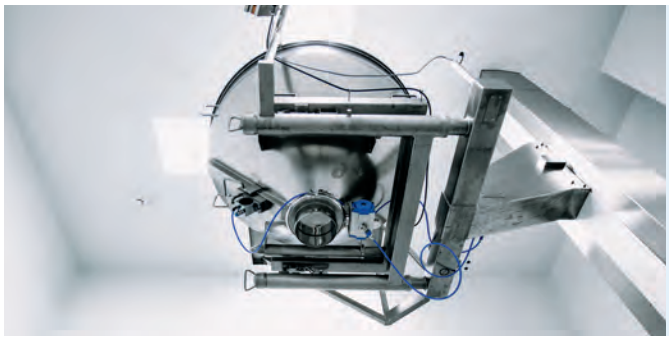
- plasma derived medical products (PDMP)
- Enzymes
- Heparines

Classic pharma (chemical/synthetic drugs, API)

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

SERVICES

From standard to special



TAILORED SOLUTIONS

- Development and production of customised formulations
- In-house development department, from laboratory scale to commercial production
- Agile project management, consulting and planning
- Short "time to market"

ANALYTICS

- In-house chemical/physical analytical laboratory
- Cleanroom laboratory for in-process controls
- 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, TAMC/TYMC, bioburden)
- Stability study program (in-house/external)

QUALITY

- Risk management system according to ICH Q9
- Robust ISO 9001 quality management system
- EU-GMP-certified
- Manufacturing authorisation according to German Drug Law AMG §13
- Accepted supplier qualification system
- Change control management
- Quality assurance agreements with customers
- Validated procedures and processes
- Batch record
- Batch release by qualified person (QP)

WFI | AP IN-HOUSE PRODUCTION

- Purified water (AP) filled in bulk for further processing
- Water for injection (WFI) according to EP, USP
- 20,000 L storage tank
- Production capacity: 500 L/h
- Purified water (AP) according to EP, USP
- 10,000 L storage tank
- Production capacity: 4,000 L/h
- Continuous monitoring of water quality for compliance with the specification parameters: conductivity, pH, TOC, endotoxins, sterility, TAMC/TYMC

WAREHOUSE

- 3,200 pallet spaces for packaging materials, raw materials and finished products
- Temperature and humidity monitored and controlled 15 °C - 25 °C
- Pest control monitored
- 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 (extractable and leachable data available for bag film material)
- Multiway transport/bioprocess containers for 3D-single-use bags from 100 L - 1,000 L (CG Tainer)
- Various FDA compliant 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
- Special 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

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

CLEANROOM PRODUCTION

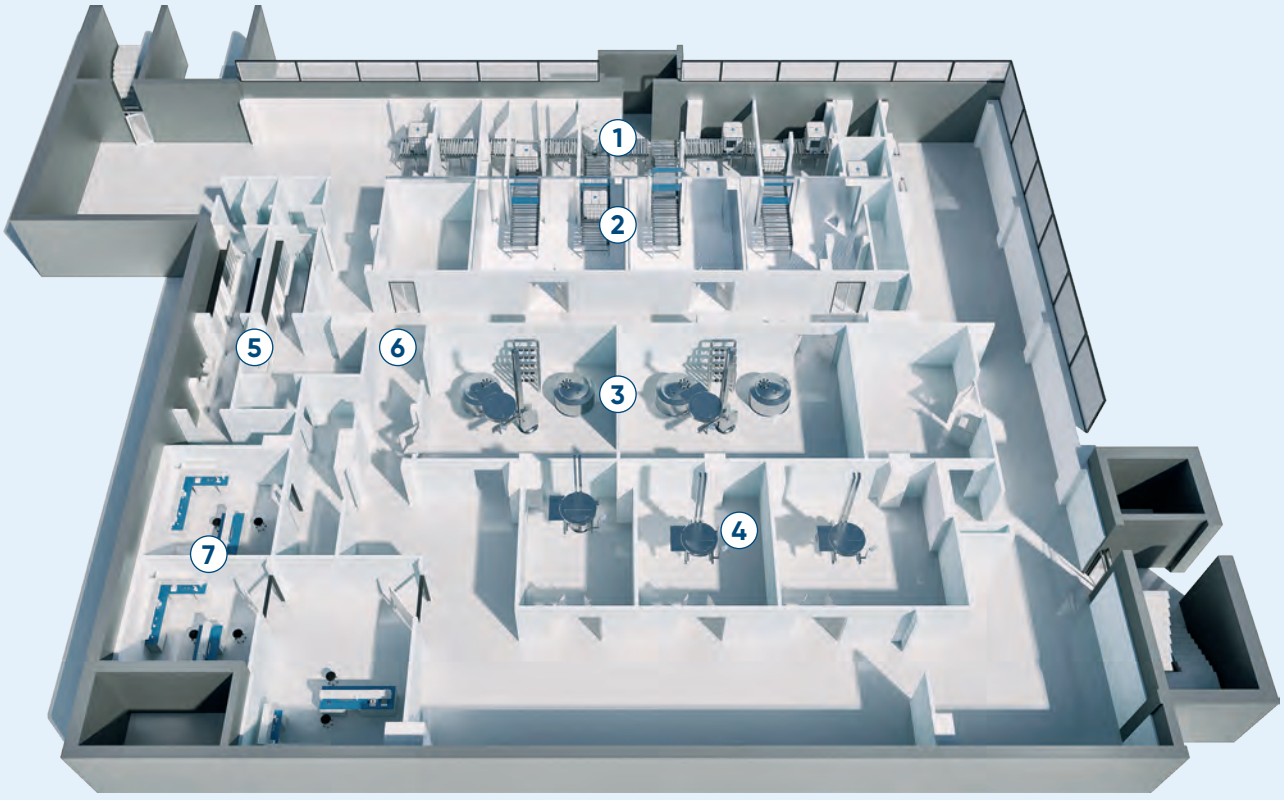
Facts and figures

- 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 ISO 8
- Compounding and filling in cleanroom class ISO 7
- 3 filling rooms for liquid media cleanroom class ISO 7
- 2 filling rooms for solid media cleanroom class ISO 8
- Fully automatic transport conveyor system with integrated weighing technology for feeding in raw materials, packagings and discharging finished products
- In-house nitrogen and ultra-pure steam generation
- CIP/SIP system for sanitisation and cleaning with validated cleaning processes
- In-house quality control including microbiology
- Washroom for cleaning production equipment

Production set up

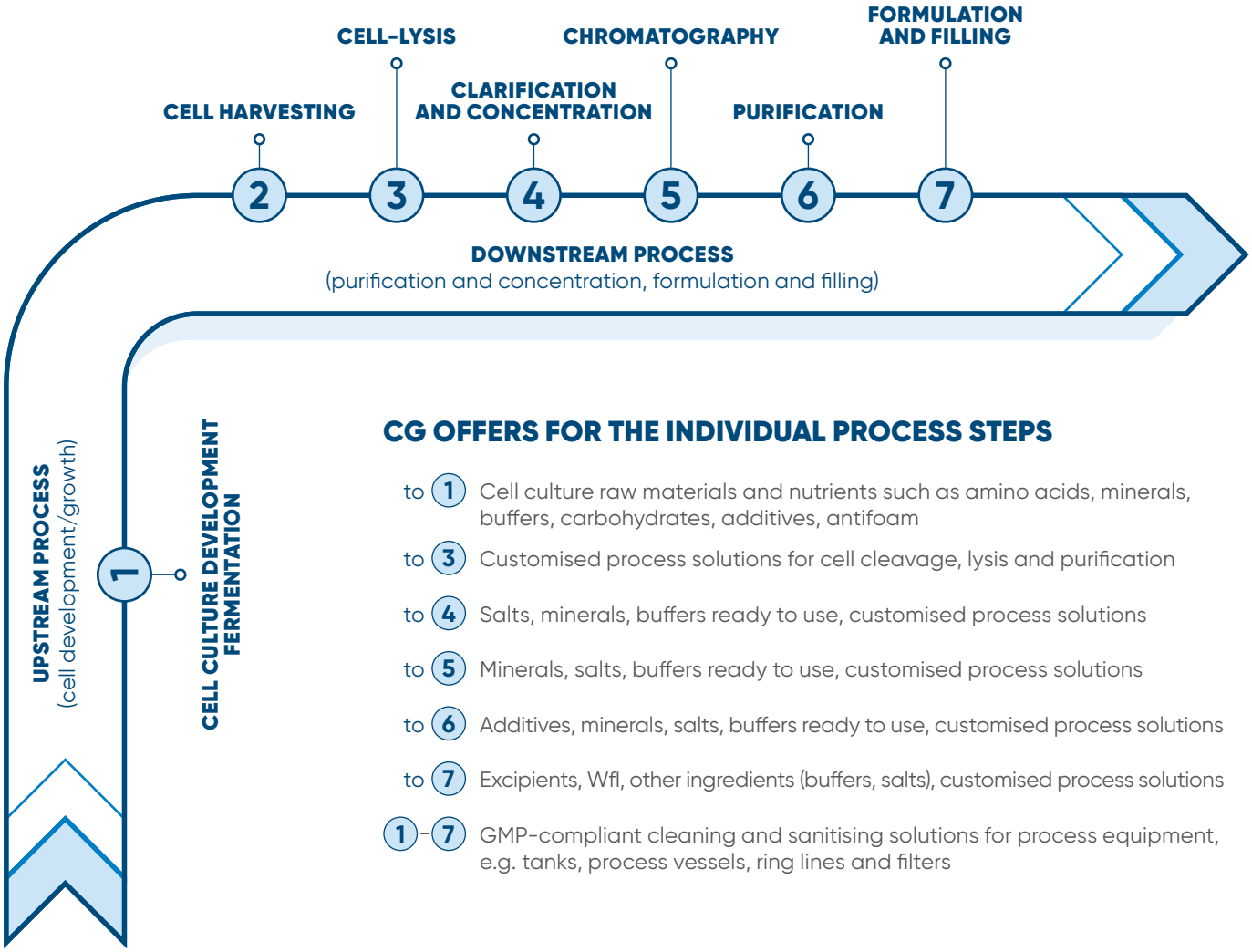
- Multipurpose equipment with validated cleaning procedures for product changeover
- 20,000 L stainless steel vessel with integrated double agitator
- 2,000 L and 5,000 L stainless steel vessels with magnetically coupled agitator, heat able, coolable, online pH-measurement
- 2,000 L and 5,000 L plastic 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**
2 **FILLING AREA**
3 **FLUID AREA**
4 **SOLID AREA**
5 **CHANGING AREA**
6 **CLEANROOM CORRIDOR**
7 **IPK LABORATORY**



BIOPHARMACEUTICAL PRODUCTION PROCESS

CG Pharma & Biotech offerings for the individual process steps



CG OFFERS FOR THE INDIVIDUAL PROCESS STEPS

- to 1 Cell culture raw materials and nutrients such as amino acids, minerals, buffers, carbohydrates, additives, antifoam
- to 3 Customised process solutions for cell cleavage, lysis and purification
- to 4 Salts, minerals, buffers ready to use, customised process solutions
- to 5 Minerals, salts, buffers ready to use, customised process solutions
- to 6 Additives, minerals, salts, buffers ready to use, customised process solutions
- to 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

UPSTREAM PROCESS (CELL DEVELOPMENT/GROWTH)

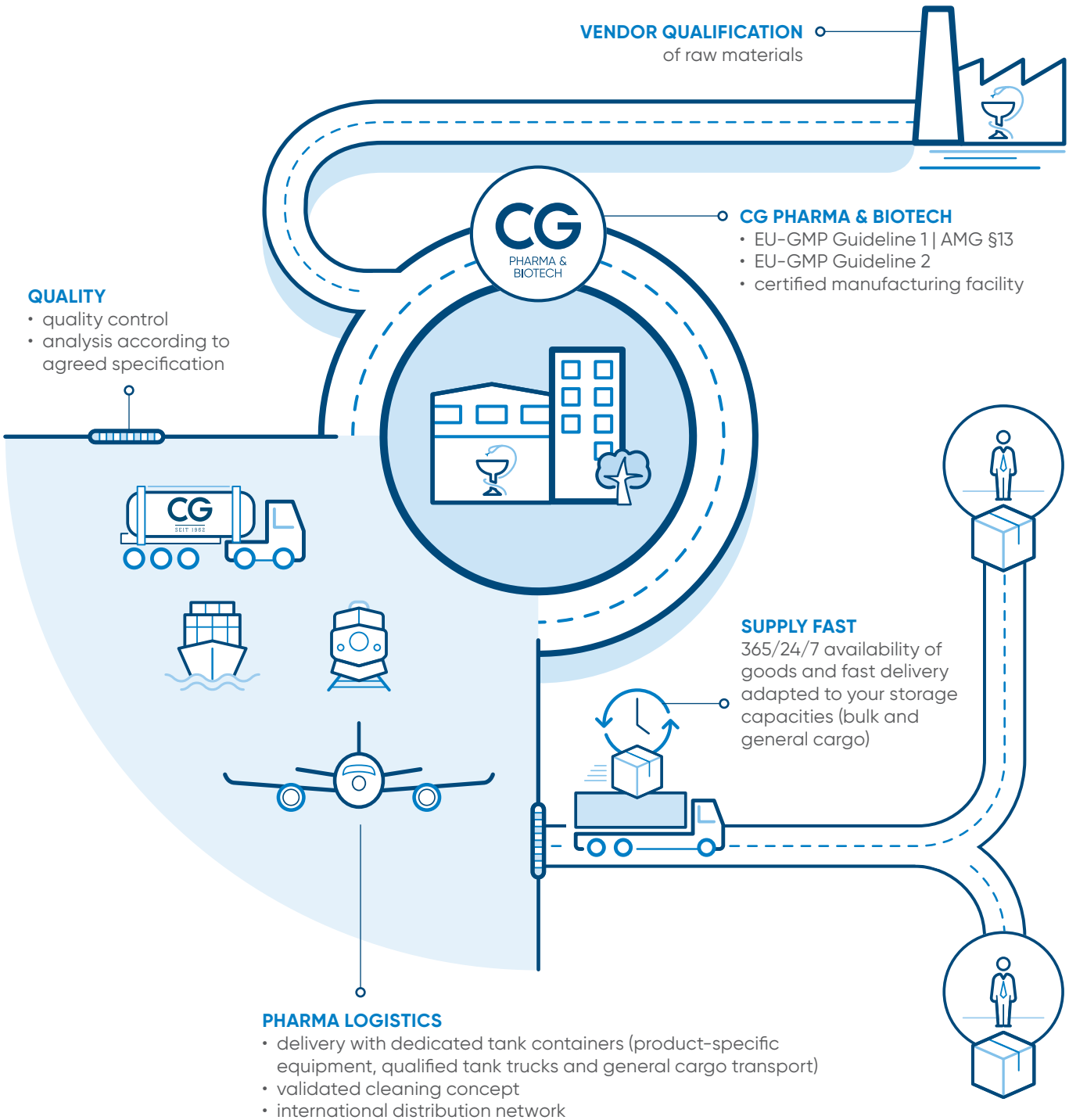
1. **Cell culture development:** cell cultivation, fermentation in bioreactor (control of oxygen, temperature, pH and pressure) for optimal cell growth

DOWNSTREAM PROCESS (PURIFICATION ANDCONCENTRATION, 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



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