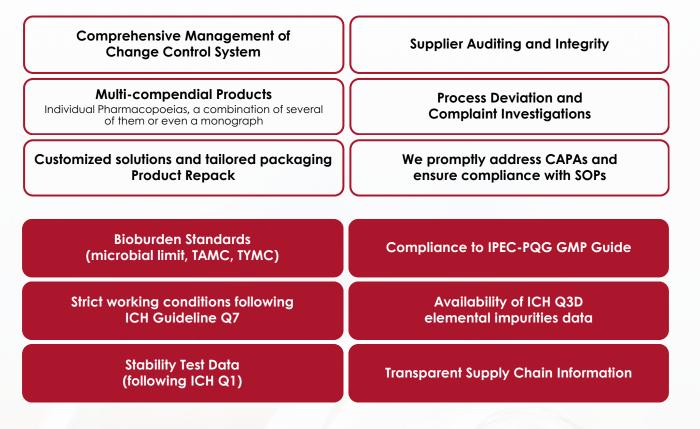
## **Quality Control & Quality Assurance**

We perform the quality controls in our two labs and release of the lots by our quality assurance team. Moreover, our analytical experts are ready to develop and validate the optimal analytical methods for each product, guaranteeing its quality and compliance before release.



Quality Chemicals: Ensuring Quality, Traceability & Compliance in every Product

## Parenteral Grade & Low Endotoxins

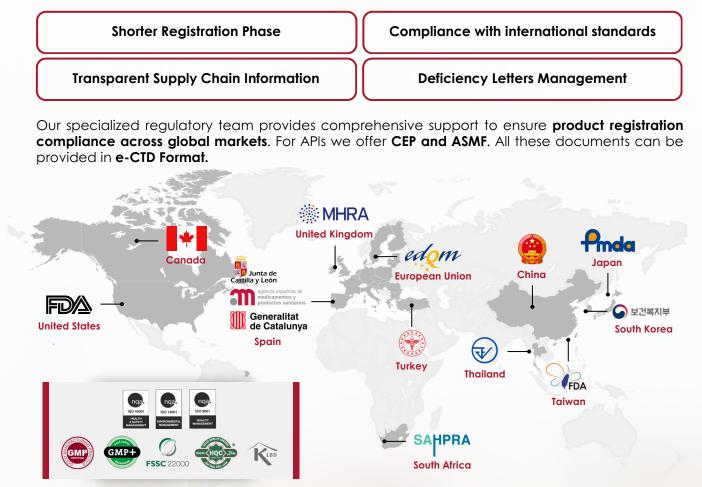
A special grade of water must be used when manufacturing APIs and excipients intended to be used in sterile, parenteral drug products.

The production of parenteral API ingredients requires absolute control over water purity and endotoxin levels. High-purity salts for parenteral use are manufactured at our GMP plant in Palencia under ICH Q7-compliant conditions.

Manufacturing wi	ith Purified Water	We have our own water production plant and we can reach WFI Water Quality	Different Presentations Available IBC, 10001, Isotank	
Endotoxin limit To <0.25EU/ml	otal microbial count <100CFU/mI	We can produce any of our salts in low-endotoxin grade on demand	Endotoxins Level <0.2 guaranteed	
Key Applications	Parenteral Nutrition (TPN)	Essential elements like Zn, Cu, Mn and Se	Microfiltered by 0.2 on request	
	Dialysis Solutions	Strict control of heavy metals in hemodialysis and peritoneal dialysis.		
	Bioprocesses & Cell culture	Trace elements supporting cell growth in biologics manufacturing.	We can manufacture any required	
	Vaccines & Gene Therapies	High-purity buffers and excipients for critical formulations.	concentration of Sodium Hydroxide and any other product on demand.	

## **Regulatory Expertise: Fast-Track Your Product to Market**

High-quality products, comprehensive documentation and superior customer support facilitate your efforts in qualification, risk assessment and registration process optimization.



## **GMP Solutions for Cleaning In Place**

Cleaning is a key operation in biopharmaceutical manufacturing for removal of product residues and microbial contamination. These processes, require GMP manufactured, low bioburden CIP solutions for cleaning of equipment, chromatography resins and filters.

CAS

## High Efficacy

Proven to effectively remove proteins, nucleic acids, and other organic residues.

#### **Broad Antimicrobial Action**

Inactivates most viruses, bacteria, yeasts, fungi, and endotoxins, making it a powerful cleaning agent.

#### Cost-Effectiveness

Economical in terms of procurement, usage, and waste management

Ease of Handling Simplifies detection, removal, and disposal processes.

#### PRODUCT

- 64-19-7 Acetic Acid Solutions
- 1336-21-6 Ammonia Solutions
- 1310-73-2 Sodium Hydroxide Solutions

## **Raw Material for Plasma Fractionation**

We provide raw materials for plasma fractionation to ensure the safe and efficient purification of plasma proteins like albumin, clotting factors and immunoglobulins. With strict quality standards, we support the production of high-purity, pathogen-free therapies for healthcare applications.

CAS	PRODUCT	CAS	PRODUCT
64-19-7	Acetic Acid Glacial	6131-90-4	Sodium Acetate 3-Hydrate
6381-92-6	EDTA Disodium Salt 2-Hydrate	7647-14-5	Sodium Chloride
56-40-6	Glycine (Aminoacetic Acid)	1310-73-2	Sodium Hydroxide Pellets
7647-01-0	Hydrochloric Acid Solution	6132-04-3	Tri-Sodium Citrate 2-Hydrate
7778-77-0	Potassium di-Hydrogen Phosphate	10049-21-5	Sodium di-Hydrogen Phosphate 1-Hydrate
7758-11-4	di-Potassium Hydrogen Phosphate Anhydrous	7558-79-4	di-Sodium Hydrogen Phosphate Anhydrous

## **Trace Elements: Purity for Your Formulations**

Trace Elements for Injection are indicated as part of intravenous solutions for parenteral nutrition. Our high-purity trace elements ensure consistency, safety, and compliance with stringent industry regulations.

CAS	PRODUCT	CAS	PRODUCT
10060-12-	5 Chromium (III) Chloride 6-Hydrate	13446-34-9	Manganese (II) Chloride 4-Hydrate
10125-13-	0 Copper (II) Chloride 2-Hydrate	7681-49-4	Sodium Fluoride
13478-10-	9 Iron (II) Chloride 4-Hydrate	10102-18-8	Sodium Selenite

## **Buffers for Cell Culture Media Production**

Buffer quality is key in biopharma, ensuring optimal pH and protein stability throughout production. Our GMP-grade buffers are low in endotoxins, DNases, RNases and proteases free, and support all major buffering systems for upstream and downstream processes.

CAS	PRODUCT	CAS	PRODUCT
64-19-7	Acetic Acid	7778-77-0	Potassium di-Hydrogen Phosphate
5949-29-1	Citric Acid 1-Hydrate	127-09-3	Sodium Acetate
7758-11-4	di-Potassium Hydrogen Phosphate Anhydrous	10049-21-5	Sodium di-Hydrogen Phosphate 1-Hydrate
7558-79-4	di-Sodium Hydrogen Phosphate Anhydrous	1310-73-2	Sodium Hydroxide 1N
7647-01-0	Hydrochloric Acid 1N	6132-04-3	Trisodium Citrate 2-Hydrate

# High-Quality Raw Materials for Pharma and Biopharma

We are a GMP-certified European manufacturer of high-purity mineral salts, specializing in API and excipient grades for the pharmaceutical and biopharmaceutical industries. With more than 30 years of experience, we have developed an in-depth understanding of international regulations, establishing us as a trusted partner for companies worldwide. Our expanding API portfolio includes over 45 internationally registered APIs in the last ten years, compliant with ICH guidelines, and we continuously invest in new product development.

## **Excellence in GMP Development & Manufacturing**

Quality Chemicals is a trusted partner for the pharmaceutical and biopharmaceutical industries, specialized in the contract development of **Raw and Starting Materials**, **Excipients and APIs according to GMP regulations**. Our core competence lies in the **production of tailor-made inorganic mineral salts**, as we can **adapt to the specifications and needs** of our customers. Headquartered in Barcelona, we have **two GMP production sites** and **two dedicated laboratories**.

Our experience in both complex R&D projects and structured and controlled GMP production makes us **the best choice to develop new APIs**. With our **in-house Quality Assurance department**, we guarantee to work in accordance with the most recent ICH Q7 guidelines.

We offer **GMP-certified micronization and milling**. Our advanced facilities ensure precise particle size reduction and uniform distribution for pharmaceutical applications. With our Malvern instrument, we can guarantee the particle size and distribution PSD.

### Our Key Advantages

Customization	Our products are crafted to your specification.
In-House Lab	Our in-house laboratory facilities provide quick and reliable analysis, ensuring the highest quality control standards.
Sustainability and Ethics	We prioritize responsible production every step of the way with practices such as decarbonization and solar panels.
Quality Systems	Our commitment to excellence is backed by our EU-GMP as well as ISO 9001 & 14001 & 45001 and FSSC 22000 certifications, reflecting our dedication to quality and safety.
Open to Audits	We welcome on-site audits and provide detailed Audit reports, demonstrating our commitment to transparency and accountability.
Stability	Our products undergo rigorous ICH Q1 guideline-compliant stability studies, guaranteeing consistency and reliability
Regulatory Support	Navigating regulatory matters can be complex. Our experts are here to guide you through the regulatory landscape, making the process smoother for you.
Kilo-lab	Our Kilo-Lab provides a controlled environment for small-scale manufacturing.



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Challenging the boundaries

Working together to improve quality of life



Where Purity Makes the Difference