

## Our services

### PRIVATE LABEL

Quality Chemicals has built up over 70 years' experience in developing new grades of high-purity chemicals. We offer you our knowledge and manufacturing facilities to develop and manufacture products according to your requirements and your own brand.

This service's main goal is to provide you with cost savings on manufacturing a product which Quality Chemicals has been producing for years and deliver a global solution in the private label business.









### CUSTOM MADE



### TOLL MANUFACTURING

Quality Chemicals offer the service to process or manufacture a custom product using the raw material the customer provides.

### PRODUCT MODIFICATION

-  Granulometry
-  Milling
-  Solutions
-  Purity grades
-  Sieving
-  Mixing
-  Low-endotoxins products
-  Low perchlorates products











### PACKAGING SERVICES

-  Wide range of materials taking into account the chemical compatibility and characteristics of our solvents and reagents
-  UN approval: packaging approved
-  Food grade primary packaging according to regulation EU 10/2011 and amendment EU 1282/2001.
-  Our most popular packaging is an external cardboard box for easier waste management or reuse. Our boxes are stackable packaging
-  Vacuum packaging for sensitive products (i.e., hygroscopic products)
-  For plastic drums and paper bags we cover the pallet with a big "cardboard box to prevent dust getting into the drums and bags and Safe transport of the drums and bags.
-  Wide range of sizes: convenience and peace of mind for all our customers.

## Means of Quality at Quality

Our quality system involves specific implementation of quality concepts, standards, methodologies and tools, to achieve our quality-related goals

### THIS SYSTEM INCLUDES

-  Quality manual
-  Quality agreement
-  Audits: internal & external
-  Change control
-  Change notification
-  Training
-  Traceability
-  Control of record and stability
-  Continual improvement: CAPAS
-  Regulatory support

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## The first choice for high purity mineral salts

70 Years manufacturing salts

### CERTIFICATIONS



## We are quality

Quality Chemicals is a European manufacturer of high-purity salts. We are a chemical science company bringing raw materials to all kind of sectors: pharma, biopharmaceuticals, veterinary, animal and human nutrition, nutraceuticals, personal care and oral care, industrial, laboratory reagents, baby food.

We have been in the market for more than 70 years. We have two production plants, the ISO compliance plant close to Barcelona and our GMP plant close to Palencia. We have more than 40 APIs registered and every year we develop 7 new APIs on average.

## Our production plants

Our plants are multi-purpose, designed for:

- Ⓞ Chemical synthesis especially of inorganic products.
- Ⓞ Distilling of solvents
- Ⓞ Purification of salts
- Ⓞ Other activities; milling, sieving, drying, mixing

Our GMP plant has been operating since 2004 and complies with GMP guidelines ICH Q7-EU-GMP part II. It mainly produces excipients and APIs for the pharma, veterinary and biopharmaceuticals industries. In 2015 we earned Spanish Agency of Medicines and Medical Devices authorisation to produce APIs.

## Product

Our experience gained over the years has mainly focused on the production of inorganic salts, but also some organic salts. These salts can be manufactured under GMP conditions and also under ISO regulations.

### INORGANIC SALTS

- Ⓞ Chlorides
- Ⓞ Chlorates
- Ⓞ Fluorides
- Ⓞ Iodates
- Ⓞ Iodides
- Ⓞ Nitrates
- Ⓞ Molybdates
- Ⓞ Selenites
- Ⓞ Oxides

### ORGANIC SALTS

- Ⓞ Acetates
- Ⓞ Citrates
- Ⓞ Lactates
- Ⓞ Oxalates
- Ⓞ Tartrates
- Ⓞ Stearates
- Ⓞ Benzoates
- Ⓞ Formates
- Ⓞ EDTA

### SOLVENTS

We purify solvents in our plant in Esparreguera where we have four distillation units that allow us to offer specific parameters for our solvents product range. These solvents can be purified under GMP or ISO conditions.

### SOLUTIONS

We provide a wide range of solutions of our salts, ready-to-use. Please ask our sales team for any custom-made solution. These solutions can be prepared under GMP or ISO conditions.

### FREE-FLOWING SALTS

We offer two salts with no addition of anti-caking agent

- Ⓞ Potassium nitrate
- Ⓞ Potassium chloride

### PRODUCT GRADES

- Ⓞ **Pharma grade:** our mineral salts can be according to different pharmacopoeias: PhEur, USP, NF, BP, JP, DAB, CP
- Ⓞ **Food grade:** Our products involved in food grade comply with standards: FCC, EU 231/2012, EU 3/2011, CNFSS
- Ⓞ **Low chlorates and perchlorates** for baby food
- Ⓞ **Low endotoxins grade:** Products to be used as APIs or excipients in parenteral and injection solutions. Purified water is used in the manufacturing process with endotoxin content lower than 0.25 EU/ml and a limit of total aerobic count (TAMC) lower than 100 cfu/ml (according to CPMP/QWP/158/01 EMEA/CVMP/115/01).
- Ⓞ **Chemical grade:** involve grades required mainly for Quality Control Labs for laboratory reagents. Like ultra-pure grades: special grades, above ACS and ISO grades, etc. and Analytical grade, generally according to ACS.

## GMP PRODUCTS

The **GMP** are usually used by pharmaceutical, biopharmaceutical and veterinary companies as:

- Ⓞ Reagents
- Ⓞ Starting material
- Ⓞ Excipients, parenteral and non-parenteral
- Ⓞ API, parenteral and non-parenteral

They are produced under the European GMP Guide for the manufacturing of drug products part II, active substances (ICH Q7) and according to current IPEC.

### We also offer MULTICOMPEDIAL PRODUCTS:

the product can be supplied in compliance with the quality standards of individual pharmacopoeias, a combination of several of them or even without a monograph in any pharmacopoeia.

With the **GMP GRADE** we offer:

- Ⓞ Strict working conditions following ICH guideline Q7-part II, if API, or acc. to IPEC, if excipient.
- Ⓞ Customised solutions and tailored packaging to meet your needs
- Ⓞ Change control
- Ⓞ Full traceability
- Ⓞ Supplier audits
- Ⓞ Dedicated regulatory support
- Ⓞ Comprehensive dossiers in the international Ce-CTD format, acc. to ICH Module 3: Ⓞ CEP Ⓞ ASMF