



Inorganic APIs

Metal–ligand complexes
Inorganic salts

cGMP process development
Analytical method development
Commercial manufacturing
Documentation and release certificates

A traditional competence of ChemCon

About ChemCon

ChemCon is a custom research and manufacturing partner with a clear focus on process development and cGMP-compliant small- to medium-scale production. Our custom-made products are used worldwide as material for all phases of clinical trials as well as commercial drug substances for applications in orphan diseases, oncology, paramedicine, and many more. A multidisciplinary team of PhD chemists covers comprehensive competences in cGMP-compliant chemistry:

- small-molecule organic chemistry
- inorganic chemistry including cytotoxic substances
- polymer chemistry
- purification/derivatization of natural products

Beside APIs, we produce excipients, diagnostics, reference standards, and specialty chemicals to your specification requirements.

+ *Tradition of inorganic APIs*

Founded by two inorganic chemists out of the department of bio-inorganic chemistry at the University of Freiburg, Germany, ChemCon has a long tradition of manufacturing inorganic APIs. The broad spectrum of products and their applications reaches from metal–ligand complexes used in cancer treatment to trace element salts for nutrient injections. Inorganic compounds handled at ChemCon include V, Cr, Mn, Fe, Cu, Zn, Mo, Ru, Pt, Au, Si, Ga, As, Se, or Te. Our inorganic expertise is complemented with state-of-the-art techniques, such as complex stability determination with potentiometric titration, multinuclear NMR spectroscopy, ICP–MS, or IC.

Our comprehensive services include:

- establishment of a synthesis process
- seamless upscale from g to multi kg
- transfer from R&D to cGMP
- analytical method development and validation
- material supply for clinical trials
- process validation and manufacturing of registration batches
- commercial routine supply (grams to hundreds of kilograms per year)
- injectable, ophthalmic, oral, or topic grade material

+ *Transfer from R&D to GMP*

ChemCon takes on projects at any stage of development. Our key competence is the customized transfer of individual projects into cGMP-compliant manufacturing processes. A modular development concept ensures transparency and cost efficiency throughout the entire course of the project: from R&D to commercial routine supply under one roof. ChemCon is looking back on two decades of experience and is manufacturing for multiple active DMFs.

+ *Quality control and quality assurance*

ChemCon's full in-house analytical services and quality control experts ensure highest quality and accurate cGMP documentation. Our quality assurance and regulatory affairs team assist you with comprehensive regulatory support – from the sourcing of the starting material all the way to the correct regulated shipment of your released product.

ChemCon has been inspected by the FDA and regional German authorities numerous times without deficiency.