API Manufacturing & Analytical Services

Excellence in the synthesis and analysis of pharmaceutical ingredients (APIs, GMP) and fine chemicals

ChemCon
Good Manufacturing Partner

WE ARE YOUR **GOOD**
MANUFACTURING PARTNER
FROM THE **BLACK FOREST.**

Content

small to medium scale: g to some hundreds kg/a

Early Stage **Clinical Phases** **Commercial**

About ChemCon

Your Good Manufacturing Partner

ChemCon GmbH, located at the foot of the Black Forest in Germany, is a contract development and manufacturing partner, specialized in transferring R&D projects into fully cGMP-compliant manufacturing processes.

Customers worldwide use our services to source APIs for clinical trials and/or commercial applications, excipients, reference standards, and all kinds of other high-quality specialty chemicals. With a history of more than 25 years, ChemCon has an outstanding inspection history by both the FDA and European health authorities.

Custom Development and Synthesis of APIs and Fine Chemicals under GMP

Our facilities are optimized for the production of small to medium quantities (i.e., grams to several hundred kilograms per year). With multidisciplinary expertise we can meet your individual demands for organic small-molecule APIs, inorganic salts and complexes including trace elements, polymers, and highly potent or controlled substances – all in full cGMP quality up to injection grade.

Pharmaceutical Chemical Analytical Services

ChemCon's analytical chemists support you with routine testing as well as tailor-made solutions following GMP and ICH guidelines as well as current monographs (USP, Ph. Eur., etc.). The extent of analyses and documentation is individually adjusted to your requirements.

Commercial Products

ChemCon is a provider of both exclusive and generic active pharmaceutical ingredients (APIs) and fine chemicals for a variety of applications. Our focus lies on the production of small to medium quantities of high quality specialty substances for your commercial purposes.

Regulatory Affairs and Quality Assurance

As a partner to pharmaceutical, biotechnology and chemical companies, quality is the center of ChemCon's activities. All our services are performed following or exceeding cGMP and ICH guidelines and regulations for the protection of health, safety, and environment.

WE **SOLVE** YOUR
CHEMICAL CHALLENGES

CDMO

ChemCon is your contract development and manufacturing partner for active pharmaceutical ingredients (APIs) and high-quality fine chemicals. Our broad chemical expertise ranges from small organic molecules over inorganic complexes and salts up to polymers in GMP quality. We specialize in transferring R&D projects from chemical synthesis development, via process scale-up and validation, into fully cGMP-compliant processes.

ChemCon's laboratories, cleanrooms, analytical services and quality assurance are ideal for the production of active pharmaceutical ingredients (APIs) in clinical trials or substances with a low annual demand. Some examples for applications are orphan diseases, critical and postoperative care, ophthalmology, or oncology and also intravenous excipients, diagnostics or dietary supplements.

Development

ChemCon takes on projects anywhere between an early research and development (R&D) stage, including synthesis development from scratch, and the transfer of your technical package for immediate process validation and manufacturing. Make use of the broad scientific know-how of our interdisciplinary team of chemists and chemical engineers to find the best chemical solutions for your project, whilst keeping full intellectual property.

Scale-up

The transfer of chemical processes to fully cGMP compliant manufacturing is a challenge that requires up-to-date regulatory and technical expertise, state-of-the-art infrastructure, and experience. ChemCon specializes in the seamless transition from synthesis scale-up to cGMP production. Beyond the course of your project in the lab, we can advise you in any related matter, may it be of regulatory significance or concerning the selection and validation of the correct analytical methods.

Manufacturing

When your drug has successfully passed clinical trials, you have reached one of your biggest goals. But what if your annual demand remains below a quantity that CMOs are commonly willing to supply?

ChemCon has found a way to bridge the gap between the profitable commercial production of small to medium quantities and highest, cGMP-compliant manufacturing standards excluding any cross-contamination risk.

Equipment

- NMR (400 MHz, quantitative, multinuclear, multidimensional)
- ICP-MS, ICP-OES
- HPLC (UV, DAD, RI, ELS, MS)
- GC and headspace GC (FID, NPD, TCD, MS)
- IC (suppressed conductivity)
- GPC (UV, RI, MALS)
- FT-IR (KBr, ATR, film)
- UV-vis photospectrometer
- Reaction calorimeter
- Rheometer
- Titration equipment (including KF)
- MP, bulk density, TOC determination equipment
- Ovens for LOD, ROI
- Polarimeter
- Equipment for microbiological control
- Stability chambers

Analytical Services

ChemCon provides you with state-of-the-art analytical services especially for drug substances. Our analytical chemists support you not only with routine testing but also with intelligent, tailor-made solutions to your challenges.

Our analytical suite is fully cGMP qualified and we combine state-of-the-art technology with extensive experience in developing and validating customized methods for each project.

Chemical Analysis

ChemCon's team supports you with routine analysis as well as individually adjusted methods for your project: characterization (spectroscopy, chromatography, mass spectrometry, NMR spectroscopy), determination of physical and chemical properties, structure elucidation as well as process control and monitoring.

Quality Control

ChemCon's quality control will be an intrinsic part of your project at any time. In order to ensure full regulatory compliance for your project and product specifications, close attention to every detail and strict adherence to applicable guidelines are essential – from the analysis of starting materials to the final API release.

Method development and validation

In close collaboration with you, we validate methods for your product according to current ICH Q2R guidelines or establish methods listed in international monographs. If methods and validation protocols are already available, we will transfer and establish your methods in our labs.

Qualification and release

ChemCon provides you with comprehensive analysis and documentation to certify your substances for use as a pharmaceutical ingredient. We also release starting materials or intermediates according to regulatory requirements, for example the use in GMP manufacturing.

Reference standards

ChemCon takes care of the comprehensive analysis and qualification of your required compound as a reference standard. We can qualify commercially available samples as well as compounds that have been synthesized in-house.

ROUTINE **SUPPLY** IN **SMALL** TO **MEDIUM** QUANTITIES

Commercial Products

Beside the contract development and manufacturing of chemicals on different quality levels on an exclusive basis, ChemCon is also service provider of high quality specialty substances for commercial purposes. Our focus lies on the production of small to medium quantities of generic active pharmaceutical ingredients (APIs) and fine chemicals for a variety of applications.

Active pharmaceutical ingredients (APIs)

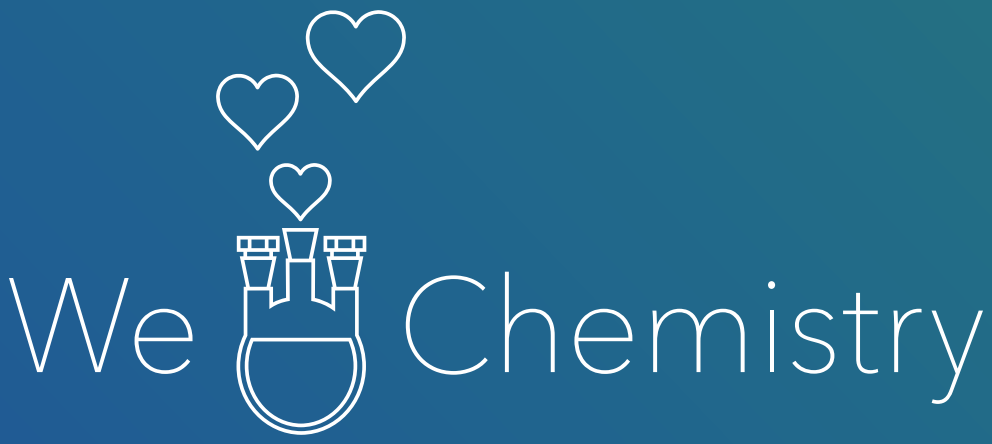
ChemCon's APIs are released to current monographs or to defined specifications, following validated internal methods. Quotes and release protocols can be customized to your needs for quantities and specifications for international markets. The list of GMP products manufactured by ChemCon includes organic and inorganic niche active ingredients as well as GMP-compliant inorganic metal complexes and salts or polymers.

Fine chemicals

ChemCon's ultrapure fine chemicals are used worldwide for various applications including in-vivo and in-vitro diagnostics, provocation substances, sensors, technical material for medical research, reference standards, starting materials, intermediates, or as building blocks.

Please check our current product list on our homepage **www.chemcon.com/en/products.**

As a contract laboratory, we also offer you the production of substances that are not yet part of our portfolio. This is of particular relevance for substances whose procurement in the desired quality and quantity is a challenge.



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