



## API Manufacturing Services

Comprehensive service for your chemical development and cGMP manufacturing demands in small to medium quantities:

- Custom synthesis development
- Process upscale
- Transfer to cGMP
- Commercial API manufacturing
- Quality control
- Quality assurance and regulatory support





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## ChemCon

*Your Good Manufacturing Partner for small to medium quantities*

ChemCon is your contract development and manufacturing partner for small-molecule active pharmaceutical ingredients (APIs) and high-quality fine chemicals. We specialize in transferring research and development projects from chemical synthesis development, via process scale-up and validation, into fully cGMP-compliant processes.

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 small-molecule organic APIs, inorganic compounds, polymers, and highly potent or controlled substances – all in full cGMP quality. This is of particular relevance with respect to more and more stringent regulatory demands for drug components that did not require cGMP documentation until recently.

Comprehensive in-house cGMP- and ICH-compliant analytical services, stability studies, documentation, quality assurance, and regulatory support complete our services. ChemCon was FDA inspected successfully in 2000 and has been inspected numerous times since by US and European authorities without any critical observation.

In addition to our pharmaceutical services, we also manufacture high-quality fine chemicals for specialized technical applications.

DEVELOPED...  
UPSCALED...  
MANUFACTURED!



## Step one: DEVELOPED...

### **Your material for preclinical studies or formulation development**

- literature research and technology transfer
- route scouting and process optimization
- synthesis of key starting materials
- efficient scale-up from milligrams to kilograms
- development and establishment of analytical methods

### **We attend your project with broad scientific know-how in:**

- small-molecule organic chemistry
- inorganic chemistry
- polymer chemistry
- purification and derivatization of natural compounds
- analytical chemistry



## Synthesis development

*Passionate chemists await your challenges*

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. To ensure an efficient development progress, all our scientists are coached in project management skills. 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.

A very special customer service is provided by our in-house technical team: To optimize your process efficiently, our experienced technicians design or modify production equipment to the specific requirements of your project. This can save time, money, and improve safety.





## Step two: UPSCALED...

### **Your first cGMP material for clinical studies**

- vendor qualification for cGMP starting materials
- process scale-up to your requirements
- seamless process transfer from R&D to cGMP
- preparation of all necessary cGMP documents
- validation of analytical methods
- release packages
- regulatory support

## Chemistry transferred from R&D to cGMP

*Organic, inorganic, polymeric*

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. Our facilities are optimized for small- to medium-size cGMP batches (grams to multiple kilograms), perfectly meeting your requirements for clinical trials and stability studies. 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.

We do not shy away from a challenge: ChemCon has a track record of manufacturing cytotoxic and highly potent APIs and is equipped and experienced to handle controlled substances.





## Step three: MANUFACTURED!

### **Your commercial API**

- routine production from grams to several hundred kilograms per year
- injectable, ophthalmic, oral, or topic grade
- process validation
- analytical services and quality control
- comprehensive cGMP documentation
- release by quality assurance
- regulatory support



## Commercial manufacturing

### *Routine supply in small to medium quantities*

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 (grams to multiple hundred kilograms per year) and highest, cGMP-compliant manufacturing standards excluding any cross-contamination risk. Almost two decades ago, we established our award-winning and innovative production strategy of mobile, dedicated equipment. Again, our in-house technical team can give your dedicated equipment the finishing tailor-made touch required for an optimum production process – always accounting for current regulatory restrictions.



#### Manufacturing facilities

- three qualified cleanrooms
- reactors up to 400 L
- pressure reactors up to 100 bar
- temperature range from  $-90^{\circ}\text{C}$  to  $+200^{\circ}\text{C}$
- freeze dryers
- distillation equipment
- milling equipment
- centrifuges and pressure filters
- chromatographic separation equipment



## ANALYTICAL SERVICES

### ChemCon's analytical experts offer:

- routine characterizations
- in-process and quality control
- identity, quantitative, and limit tests
- impurity profiles
- analysis according to current monographs (e.g., Ph. Eur., USP)
- tailor-made tests for your specific requirements
- method development and validation
- microbiological tests
- synthesis, purification, characterization, and qualification of reference standards
- comprehensive cGMP documents and release certificates

## Quality control

### *ChemCon's in-house analytical services*

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 is essential – from the analysis of starting materials to the final API release. 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.

#### A selection of our analytical equipment

- NMR (quantitative, multinuclear, multidimensional)
- FT-IR, UV-vis
- HPLC, GC, GPC, IC
- ICP-MS, LC-MS, GC-MS
- titration equipment
- polarized-light and classical microscopes
- polarimeter, rheometer
- MP, bulk density, and TOC determination equipment
- ovens for LOD and ROI
- precision balances
- equipment for microbiological control and release
- stability and photostability chambers
- facilities for controlled sample storage







## QUALITY

### Inspection and audit history:

- FDA inspected successfully since 2000
- cGMP qualified by European authorities since 2006
- ISO 9001 certified for many years
- > 100 customer audits

### Regulatory support:

- registration documents
- CEPs for APIs with a pharmacopoeial monograph
- ASMFs and DMFs
- CMC section support

## Quality assurance and regulatory affairs

*Trust is good – control is essential*

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 (in particular ICH Q7, relevant for APIs) and regulations for the protection of health, safety, and environment. Internal audits ensure that each and every member of ChemCon's team is committing to current regulations at any time. Our customers visit us on a regular basis to audit our facilities and quality systems. We are proud of our outstanding track record of inspections from European and US authorities: We have never received a critical observation in the company's history!

But there is more to your product than ensuring the best possible product quality. Our quality assurance and regulatory affairs team attends your project with comprehensive regulatory support. For example, we can help you to file regional dossiers or execute the filing on your behalf.





## COMPREHENSIVE SERVICES

### The story of ChemCon

- 1992:** ChemCon's roots date back to one of the founders' synthesis development of APIs at the University of Freiburg
- 1997:** Dr. Raphael Vogler & Dr. Peter Gockel found ChemCon
- 1998:** First API production service in own cleanroom facilities
- 1999:** Development services are added
- 2000:** ChemCon becomes Germany's youngest company to pass the first FDA inspection and facility approval without deficiency and receives the fastest NDA approval for an anti-cancer agent in the FDA history
- 2001:** In-house analytical services are established
- 2004:** Baden-Wuerttemberg L-Bank Award, demonstrating excellent management skills
- 2006:** First cGMP inspection by regional German authorities without deficiency
- 2009:** STEP Award for "dedicated-equipment-strategy"  
First ISO 9001 certification
- 2013:** Approval to manufacture drug products for clinical phases
- 2014:** New cleanroom facilities including isolator to handle highly potent material
- 2016:** Expansion of production capacities to 400 L  
ChemCon starts offering external analytical services
- 2017:** Additional cleanroom and development laboratories
- 2018:** Most recent and successful FDA inspection



## Individual customer service

*from your inquiry to the shipment of your product and beyond...*

**...is our main ambition besides the manufacturing of top-quality products with professional documentation.**

A few more reasons to partner with us:

### Customized response to your inquiry

We evaluate each inquiry individually and compile detailed, tailor-made offers. Chronological development modules that can be flexibly adjusted to your requirements give you a transparent overview over expected timelines and costs. We are very happy to discuss the details of complex offers in person to fine-tune our proposal to your precise needs, for example combined with a visit to our facilities, at your site, or over the phone.

### Development modules keep your project flexible

The course of a development project, in particular for new chemical entities, is sometimes difficult to predict. Requirements, both by yourself and/or regulatory authorities in different geographic areas can change fast and suddenly. You are free to order your development modules subsequently, allowing flexible changes to the modules at any stage of the process.

### Finding solutions to chemical challenges

Two decades with a clear focus on small-molecule API production in small to medium quantities allowed us to build up extensive experience in cGMP process development for an exceptionally broad variety of chemical reactions in organic, inorganic, and polymer chemistry. We will not just produce your compound - we will find the best way to do so!

### Help and advice regarding analytical and regulatory demands

Recently, the regulatory pressure on the supply chain has increased significantly. We ensure that your project will comply with any current regulatory standard, from the sourcing of the starting material to the correct regulated shipment. Another tricky decision can be the selection of the most efficient analytical methods. You can rely on our experienced quality control and quality assurance managers to help your decision for covering regulatory necessities whilst avoiding unnecessary expenses.

### Communication – the key to mutual success

Overall, we are convinced that a close partnership is the key to overcome any challenges. We will assign a designated project manager to your project, who will be your personal contact from day one in the lab all the way to your goal. Weekly updates give you the opportunity to discuss potential challenges at any time and you benefit from a transparent, cost- and time-efficient progress.

***We are proud of what we can achieve with you and for you and look forward to learning more about your project!***

## CURIOUS?

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