ChemCon
Good Manufacturing Partner

cGMP Polymers

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

Your partner to meet regulatory requirements

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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
- polymer chemistry
- purification/derivatization of natural products

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

+ GMP polymers

In response to the increasing regulatory demand for polymers used in medical applications, we have extended our team with polymer experts and offer polymer chemistry to full cGMP standards. Customized offers allow us to match material specifications exactly to your needs and regulatory requirements. Polymer projects at ChemCon include, for example, the cleanroom production of synthetic polymers and/or monomeric starting materials as well as the derivatization and purification of natural polymers to obtain cGMP material. Our polymer expertise is complemented in-house with state-of-the-art techniques, such as ultrafiltration, DOSY NMR spectroscopy, GPC, or rheometry.

+ 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.

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

+ 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 regualtory 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.

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