



## Cytotoxic and Highly Potent APIs

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Specific process design  
Dedicated SHE experts  
Analytical services  
Documentation and release certificates

*Your high potent in safe hands*

## About ChemCon

ChemCon is a custom research and manufacturing partner to produce APIs and specialty chemicals for various different applications on demand. ChemCon offers high containment operations for the manufacturing of cytotoxic and highly potent substances. Our services include HPAPI manufacturing under cGMP conditions, utilizing cutting-edge technology, comprehensive product experience, and rigid training procedures. ChemCon is able to manufacture HPAPIs from gram to kilogram quantities.

### + *In safe hands*

With a multi-product track record of 19 years, ChemCon is experienced in the process development and manufacturing of numerous cytotoxic substances and HPAPIs.

ChemCon's facilities allow for cGMP manufacturing (OEL down to 1 µg/cbm by use of containment and special handling procedures, comparable to SafeBridge class III).

- cleanroom: class 100,000 (can also be operated as class 10,000)
- cross-contamination prevention by use of dedicated equipment
- dedicated SHE experts to assess compound potency and evaluate and monitor processes
- Quality control laboratories equipped with laminar flow safety, benches for HPAPI testing
- validated cleaning procedures
- certified hazardous waste disposal

### + *Isolator train*

ChemCon's facilities include an isolator train class 10,000 with the following specifications:

- reactor capacities in isolator train: two 100 L reactors or one 200 L reactor; -60 °C to + 200 °C.
- clean in place (CIP) for isolator train, decontamination unit
- vacuum drying oven in isolator train
- tray lyophilization option in isolator train
- the incoming air for cleanrooms is filtered by a pre-filter, a main-filter, and a HEPA filter

- the incoming air for the isolator train is filtered by a second HEPA filter stage
- the exhaust air of the isolator is filtered by push-push HEPA filters that can be exchanged and disposed while the isolator is completely sealed

### + *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 European authorities numerous times without deficiency.

#### **ChemCon GmbH**

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