



## Trusted Scalability

### Large scale API production services

Delivering commercial success every step of the way through a consultative and phase appropriate approach. Benefit from decades of experience of a small molecule CTDMO. Our trusted network has the development, scale up, and manufacturing expertise to meet small molecule API project needs no matter the batch size. Our pilot plant and production suites produce batches ranging from kilos to hundreds of kilos, down to potencies of 1 µg/m<sup>3</sup>.

### Specialized in Small Molecule Synthesis

#### Darmstadt, Germany

##### 2 Large scale production suites

- 4000 L reactors, -35 to 190 °C, 6 bar pressure
- Capable of handling compounds down to 1 µg/m<sup>3</sup> OEL
- Glass-lined and Hastelloy construction
- Cleanroom down-filling
- Batch sizes from 100 kg to 400 kg

##### Cryogenic reactor suite

- 1000 L, 1600 L and 2500 L reactors, down to -100 °C
- 4000 L reactor down to -80 °C
- Hydrogenation reactor suite, 6 bar pressure
- 2500 L reactor, Stainless steel construction, 6 bar pressure
- 1000 L reactor, Glass-lined construction, 6 bar pressure

#### Verona, Wisconsin, USA

##### 2 Large scale production suites

- 2000 and 4000 L reactors, -30 to 180 °C, 6 bar pressure
- 2000 L Hastelloy cryogenic reactor, -80 to 180 °C
- Capable of handling compounds down to 1 µg/m<sup>3</sup> OEL
- Glass-lined and Hastelloy construction
- Batch sizes from 50 kg to 350 kg



## Pilot Plant Manufacturing

Our pilot plant manufacturing suites support early phase clinical batches through commercialization.

### Facilities in Darmstadt and Verona

- 34 reaction vessels (63 – 2500 L)
- 1 to 200 kg batches
- Support tech transfer, scale up and clinical batches
- Capable of commercial manufacturing for 1 kg to 35 kg batches
- Potency capability down to 50 ng/m<sup>3</sup>
- Glass-lined and Hastelloy construction

## Quality and Regulatory

Built upon a longstanding reputation for providing high quality chemicals and comprehensive regulatory support, our small molecule CDMO services portfolio and network has deep expertise in quality, compliance, and regulatory with:

- ICH Q7 GMP facilities
- ISO 13485 Certification\*
- Active DMFs filed in more than 35 countries
- Development activities support with:
  - Regulatory filings (CMC sections) preparation
  - Vendor audits
  - Control documentation and testing

Contact us for Large scale API production services:

[SigmaAldrich.com/adc-api-ctdmo-contact](https://www.sigmaaldrich.com/adc-api-ctdmo-contact)

Learn more about our Millipore® CTDMO services here:

[SigmaAldrich.com/MilliporeCTDMOServices](https://www.sigmaaldrich.com/MilliporeCTDMOServices)

\*Darmstadt, Germany

## Critical Raw Materials and Key Intermediates

A global supply chain network and non-GMP contract manufacturing sites support programs with critical starting materials and intermediates.

- Air and moisture sensitive chemistry
- Phosgenations, ozololysis, and hydrogenations
- Cryogenic and high temperature reactions
- Non-GMP continuous flow facilities
- Gram to multi-metric ton capacity for custom materials

## Analytical Development and Quality Control

Analytical technologies for small molecule development and manufacturing are key to success:

- Extensive chromatographic expertise: GC, HPLC, UPLC, IC
- Compound identification by NMR, MS, FTIR,
- Elemental analysis: ICP/MS
- Solid state characterization: XRPD, DSC, TGA
- In-house stability testing (ICH guidelines)

## Project Management

From evaluation to execution, dedicated project managers focus on direct, transparent communication and coordinate multi-disciplinary teams for a streamlined experience to meet project milestones and critical success targets.

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