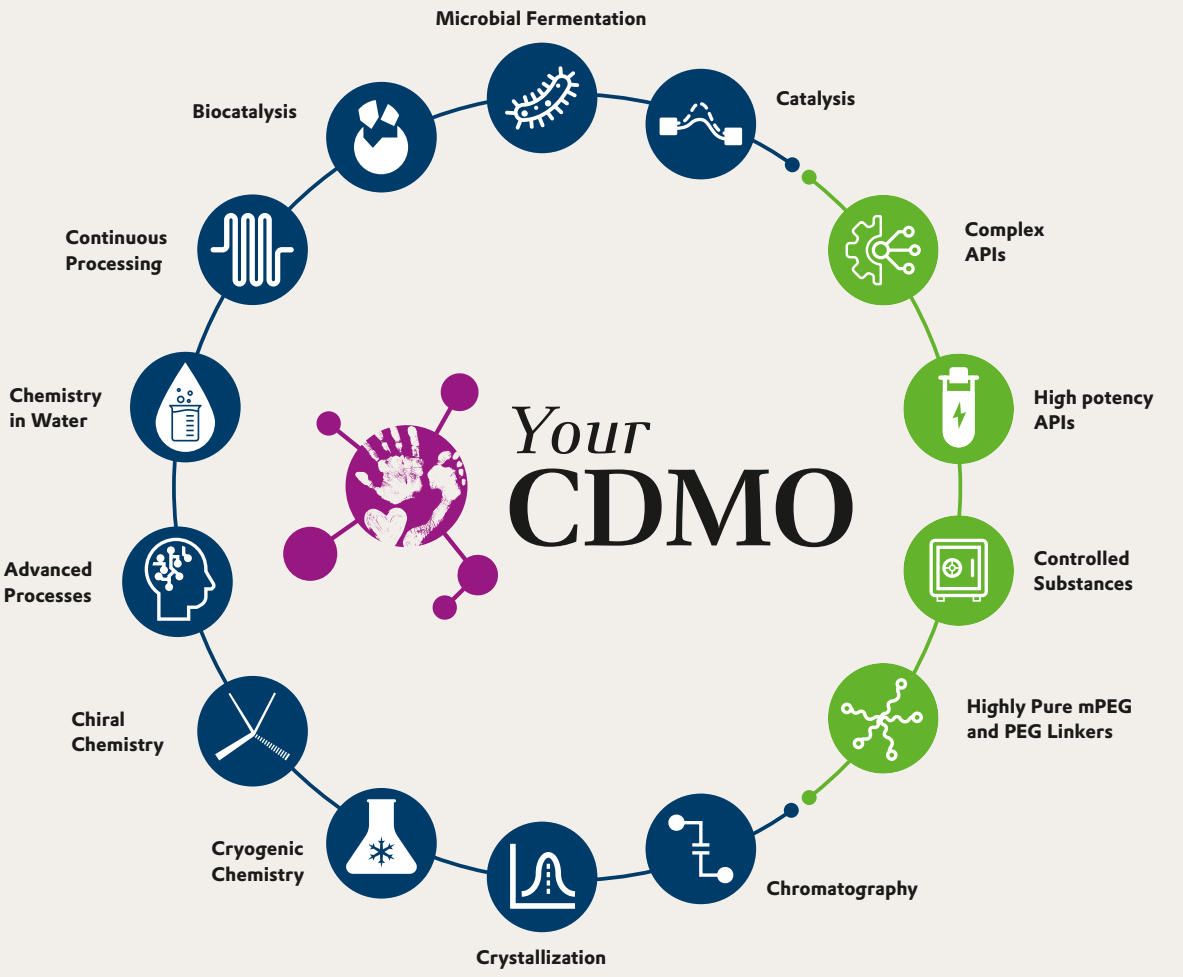
Evonik Drug Substance

Differentiating technologies and scientific expertise
for your pharmaceutical intermediates and APIs



EVONIK
Leading Beyond Chemistry

Great science is built on strong relationships

We are a global CDMO, specialized in complex and high potent drug substance development and manufacturing. With deep chemical expertise, differentiated technology platforms, and proven regulatory and quality track records, we support innovators from clinical development to commercial supply – reliably, flexibly, and at-scale.

Your CDMO – Gain access to our global network of services and deep technical know-how

4 SITES	**> 200** CUSTOMERS ACROSS 40+ COUNTRIES	**8** FDA INSPECTIONS IN A ROW WITH NO 483's FILED
170 m^3 HPAPI CAPACITY	**> 15** DIFFERENTIATED TECHNOLOGIES	**1,200 m^3** COMPLEX API CAPACITY

"Our customers trust us because we take the time to understand their challenges and deliver solutions that stand up to real-world pressure. Your molecule becomes our mission, and we take that responsibility personally."

DANIEL FRICKER – HEAD OF DRUG SUBSTANCE AT EVONIK

From Challenge to Global Supply

CHALLENGE

A customer required rapid development, scale-up and cGMP validation of a complex, multi-stage API-achieving commercial-scale validation within 16 months despite an ambitious timeline and fully remote collaboration conditions.

EVONIK SOLUTION

By integrating differentiated technologies, including high potent API development, in-house catalyst screening and development for catalyst selection and selectivity optimization, and optical process analytical technology for critical in-process-control, with extensive engineering support for specialized unit operations and pilot-to-commercial manufacturing capabilities, Evonik accelerated the path from process transfer to production. In parallel, the establishment of a robust, cost-aware starting material supply chain prepared the project for reliable global supply.

CUSTOMER BENEFIT

- Onboarding, transfer and validation of > 30 analytical methods within less than 6 months.
- Efficient process development for complex chemistries including a challenging heterogeneous catalysis step and PAT.
- Reliable scale-up execution in less than 9 months.
- Cost contributed by key raw materials reduced by over 60 %.
- Seamless collaboration across functions, multiple organizations and three Evonik sites.
- Supply security through commercial manufacturing from two geographic regions.

RESULT

Evonik delivered a 40 kg GMP meeting all specifications, completed validation and process filing support on time, and established commercial supply on > 5 MT scale from two geographic regions – providing the customer with a resilient globally diversified supply setup

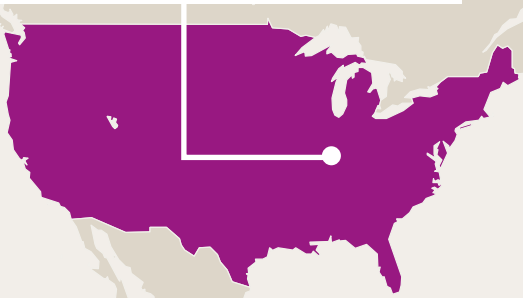
Our locations

Evonik's Drug Substance sites in Europe and the USA have capacities from lab-scale through to small, medium or large-scale production

Tippecanoe, IN, USA

Our fully self-sustained large-scale cGMP USA hub

- Mid to large volume cGMP production, a total of 860 m^3 small molecule plant capacity
- Three HPAPI plants, extensive cryogenic capabilities, up to 16 m^3 reactor volume
- Large scale fermentation (2500 m^2)



Dossenheim, Germany

Controlled substance and complex API manufacturing in the heart of Europe

- A total of 180 m^3 small molecule plant capacity
- Intermediates and API production, up to 8 m^3 reactor volume
- Controlled Substances Schedules III-V

Hanau, Germany

Our R&D and technology center of excellence

- R&D center for process development and differentiated technologies
- Small scale GMP production facility for highly potent APIs
- Pharma PEGs and modified PEGs

Slovenská Ľupča, Slovakia

Your Precision Fermentation CDMO

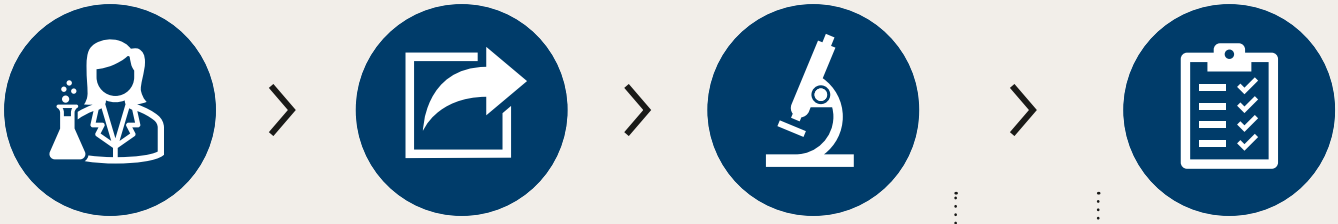
- Over 30 years of experience in fermentation
- 1200 m^3 capacity up to 50 m^3, flexible downstream including protein purification
- Biomaterials, bio-polymers, cosmetics, collagens, proteins, APIs, amino acids and advanced food ingredients

End-to-end drug substance services

Successful drug substance CDMO programs require more than chemistry – they demand an integral service model that combines scientific depth, robust processes, regulatory readiness, and operational reliability – from early collaboration to long-term commercial supply.

Our end-to-end service offering brings together all aspects of a successful collaboration into one seamless process flow, ensuring continuity, speed and confidence at every stage.

Bringing together innovation, analytics, manufacturing, and supply chain excellence across the full product life cycle



PROCESS TRANSFER AND DEVELOPMENT

R&D collaboration and innovation excellence

Process development and technology transfer

Analytical method development, transfer and validation services

Process validation and regulatory support

LAUNCH, COMMERCIAL SUPPLY AND LIFE CYCLE MANAGEMENT

Sustainable manufacturing solutions

Manufacturing of complex APIs

Manufacturing of high potent APIs and controlled substances

Supply chain and operational excellence

Your Technology Experts for API &

FOOTPRINT

1 Catalysis

- From first lead to scale up: End-to-end service for catalytic reactions
- Over 30 years of experience in developing, tailoring and commercializing catalysts
- Global cGMP API production sites; up to 25 bar and up to 16,000 liters

2 Microbial Fermentation

- From in-house strain development to commercial production
- Six fermentation sites across Asia, Europe and the US with pilot to full scale capacity
- Pharma, advanced food ingredients and nature-identical materials

3 Biocatalysis

- Inhouse enzyme development and technology platform
- >20 different enzymes applied at production scale
- Combined biotransformations through whole cell catalysis

4 Continuous Processing

- Decades of experience and track record in continuous processing
- Flow chemistry and continuous downstream including crystallizations and chromatography
- Development, pilot and manufacturing capabilities

5 Chemistry in Water

- Micellar catalysis enables a broad range of reaction types
- Reduces need for organic solvents and carbon footprint
- Improved reaction performance, higher yields, increased selectivity, and reduction of catalyst loading

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6 Advanced Processes

- State of the art digital solutions for process development and execution
- AI supported, expedited development, optimization, implementation
- Process analytical technology

7 Chiral Chemistry

- 40 years in development, scale-up and production of chiral compounds
- Established production of over 100 chiral products including natural and non-natural amino acids
- Chemo-catalytic and chiral pool synthesis and chiral resolution and separation technology

8 Cryog

- 200 m^3 weste capacity (steel,
- Organometalli lihtiations, Gri
- Batch and cont

& Intermediate Manufacturing

our
DMO

1 Complex APIs

- Western based manufacturing capacity for even the most complex projects
- Broad portfolio of differentiating technologies
- Sustainable, flexible and scalable solutions for end-to-end reliability

2 High potency APIs

- 170 m^3 total capacity
- Reactor volumes from lab scale up to 7,600 l
- OEL down to 5 ng/m^3 for small scale and 0.1 $\mu g/m^3$ for medium and large-scale production

3 Controlled Substances

- Western based manufacturing hub for scheduled drugs and intermediates
- On-site development and analytical capabilities
- Generic APIs as well as CDMO services

4 Highly Pure mPEG and PEG Linkers

- Highly pure PEGs and mPEGs for PEGylation and linker conjugates
- From 2000 kDA to 50000 kDA with narrow PDIs and high purities
- Off-the shelve grades and custom solutions available

HANDPRINT

enic Chemistry

rn based cryogenic reactor
Hastelloy and glass lined)
c reactions including
gnards and complex hydrides
inuous processing

9 Crystallization

- Particle technology laboratories in Europe and the U.S.
- Crystallization, solid-liquid separations, drying and milling development
- End-to-end service from solid form screening to production support

10 Chromatography

- Dedicated expert team for chromatographic separation development
- Low and high-pressure separations at scale across Europe and the U.S.
- Batch and continuous (SMB) operations

CONTACT US
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