Millipore®
CTDMO Services

MERCK

CTDMO Centers of Excellence for PEGs and Lipids

Schaffhausen Facility Overview

As a development, launch, and commercial supply site for APIs and lipids as well as activated PEGs, our cGMP facility in Schaffhausen (Switzerland) offers production capacities for custom synthesis from grams to tons. We have more than 50 years of experience in pre-clinical to commercial supply. Our tailored approach enables our customers to move their products to market quickly and efficiently.

Custom and Portfolio Lipids

We are highly specialized in synthesizing top-quality cGMP lipids for pharmaceutical applications and gene therapy, focusing on tailored manufacturing to meet our client's specific needs.

- High quality synthetic products
- Flexibility with custom and portfolio offering

Activated Polyethylene Glycols (PEGs)

With decades of expertise in activated and functionalized PEGs, we offer the technical, quality, and regulatory support needed to maximize product efficiency through optimized release kinetics and targeted drug delivery.

- Support for both polydisperse and monodisperse PEGs, linear to branched, and all varieties of functionalization.
- Advanced analytical expertise to characterize and quantify PEG

Chemistry Development Services

Specialized in lipids, PEGs, and other APIs, our comprehensive chemistry development services include:

- Route finding
- Chemical feasibility studies
- Process characterization
- Process optimization and full development including QbD and DOE
- Scale-up for kilo lab and commercial scale up to 60 L
- Process Safety evaluation
- Impurity characterization and synthesis

Analytical Services

We offer comprehensive analytical support for all our cGMP operations from raw material quality control (QC) to final product release.

- Thorough chemical analytical testing
- Identification of impurities and by-products
- Microbio lab for bioburden and endotoxin testing
- Development of analytical and microbiological methods
- Method validation according to ICH Q7
- Stability studies according to ICH Q7 with internal storage capacity
- Direct support by our technical teams
- SAP QM as integrated LIMS with automatic data transfer

General applicable methods

- UPLC (UV/RI/ELSD/CAD/MSD)
- GC/GC-MS/MALDI-TOF
- DSC/TG
- IR/UV/Optical rotation
- Wet chemistry (Titrations)
- CE/Ion Chromatography
- TOC
- Microbiological testing

Special methods

- XRPD – differentiation of polymorphic forms
- NMR – structure elucidation
- SEC – Mw distribution

Manufacturing

Schaffhausen provides APIs, lipids and activated PEGs out of state-of-the-art cGMP facilities for use in clinical trials and commercial product applications.

Equipment Overview

QTY	Equipment	Capacity	Temp. Range
10	Glass line reactors	250 – 630 L (nominal vol.)	-40 °C–200 °C
3	Hastelloy® reactors	250 – 630 L	-20 °C – 160 °C
2	Hastelloy® centrifuges	800 mm (diameter)	-25 °C – 100 °C
1	Inverted bag centrifuge	450 mm	-10 °C–100 °C
1	Hastelloy® double cone dryer	750 L (300 L product)	-30 °C – 200 °C
1	Titanium filter dryer	280 L	-20 °C – 135 °C
2	VA Shelf dryers	1150 – 2050 L	25 °C – 100 °C
2	VA centrifuges	800 mm (diameter)	-25 °C – 100 °C
1	VA filter dryer	250 L	-10 °C – 100 °C
2	Mobile vacuum contact dryers	160 L (nominal value)	25 °C – 80 °C

Clean Rooms

- 5 ISO-8 clean rooms for dispensing active materials

Other Features

- Endotoxin controlled purified water system

Technologies

- Aromatic chemistry
- Protected amino acids
- Esterification
- Alkylation
- Heterocyclic chemistry
- Pressure reactions
- Oxidation
- Reduction
- Chiral synthesis
- Chiral resolution
- Hydrogenation

Compliance, Regulatory & EHS

Schaffhausen complies with the quality systems and standards of Merck KGaA, Darmstadt, Germany and has been inspected regularly by various regulatory authorities including the FDA (USA) and our principal regulator, the Swissmedic (Switzerland). A dedicated team of experts ensures full regulatory support/documentation:

- Global expertise in API registration
- Intellectual Property (IP) and Freedom-to-Operate (FTO) evaluation
- Proven track record of successful DMF submissions globally
  - Preparation of regulatory filings (NDAs)
  - 150+ customer audits over the past 10 years
- Excellent FDA inspection track record (no Form 483 issued)
- Quality systems cGMP/ICH Q7
- Compliant with US-FDA generic drug user fee act (GDUFA)
- Annual Kosher inspections
- Annual Halal inspections
- License for handling controlled substances

Dedicated Experts

Research & Development

Our team of dedicated scientists and highly skilled experts support the development of innovative APIs, activated PEGs, PEG-hydrogels and specialty lipids suitable for parenteral use. Our position as a large European manufacturer allows us to offer a full spectrum of services from reaction screening to commercial supply.

Project Management

From evaluation to execution, our dedicated project managers are coordinating multidisciplinary teams, international site activities and timelines throughout the lifecycle of your program.

Learn more about our Millipore® CTDMO services here:
SigmaAldrich.com/MilliporeCTDMOServices

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