

cGMP API Manufacturing SAFC Pharma™ – Buchs

SAFC Pharma's Buchs, Switzerland facility specializes in complex, multi-step, organic custom synthesis of pre-registered APIs and key intermediates from Phase I to Phase III clinical trials. This cGMP, ISO certified site provides a wide range of development and production capabilities, including Simulated Moving Bed (SMB) chromatography and micro-reactors technology.

Working in close alignment with other SAFC global facilities, SAFC Pharma-Buchs offers its customers the quality, dependability and flexibility to move their products to market quickly and efficiently.



Manufacturing

Buchs offers a broad range of multi-purpose manufacturing capabilities and is a proven contract manufacturing partner that accelerates the development process.

- Over 30 vessels, up to 1,600 L capacity
- Temperature range: -65 to +200 °C
- Three rotary evaporators (50 L)
- Two distillation stills (100 and 250 L)
- Two thin-film evaporators
- Small-scale chiral (SMB) separation unit

Chemistry Development Services

Buchs chemists are known for their ability to solve chemistry challenges and developing efficient chemical processes that support customers' programs. Comprehensive development services include:

- Seven Ph.D. process development chemists
- Specialized technologies proven to reduce development times
 - Chem-EYE (FT-IR in-line monitoring system)
 - Automated lab reactors
 - Micro-reactor technology
 - SMB capabilities
- Proficiency in scaling-up processes targeted for large-scale manufacturing

SAFC® Pipeline Partners

Facility Focus

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Analytical Services

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

Comprehensive array of analytical capabilities including:

- NMR
- Polarimetry
- KF
- GC
- AAS, ICP-MS
- LCMS
- FT-IR
- ROI
- UV-VIS
- DSC
- GCMS
- CE

- Raw material, intermediate and final product testing methods
- Impurity identification and characterization
- Method validation and stability testing



Regulatory Compliance

Our experienced team of regulatory compliance experts have a proven track record of successful DMF submissions and can support:

- Preparation of regulatory filings (NDAs)
- Vendor audits
- Control documentation and testing
- ICH and cGMP compliance
- Scientific and technical writing

Project management

All project managers are integrated into SAFC Pharma's worldwide project management team and serve as the single point of contact for customers.

Project managers are assigned and responsible for all activities, communications and milestones:

- Work with chemistry team leader, analytical, manufacturing and regulatory affairs
- Provide weekly summary reports
- Use Gantt Chart tracking
- Provide business development support



SAFC Pharma–Buchs specializes in complex-multi-step synthesis of APIs from Phase I to III.

SAFC Pharma™
Inspiring Science

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