BUCHS FACILITY OVERVIEW
COMPLEX SMALL MOLECULE MANUFACTURING

SAFC Buchs, Switzerland specializes in complex, multi-step, organic custom synthesis of excipients, critical raw materials, intermediates and APIs from preclinical to commercial scale manufacturing. This FDA inspected and ISO certified site provides a wide range of development and production capabilities, including biocatalysis and flow chemistry technology. Working in close alignment with other SAFC global facilities, SAFC Buchs offers its customers the quality, dependability and flexibility to move their products to market quickly and efficiently.

CHEMISTRY DEVELOPMENT SERVICES

Comprehensive chemistry development services at Buchs include:

- Route finding
- Scaling and optimizing processes for lab & plant-scale (100 steps p.a.)
- Process validation support (DoE)
- Qualification run
- Analytical Development: LC, GC, LC/MS, GC/MS, NMR, In-situ monitoring (FTIR)
- Specialized in technologies like: Continuous flow chemistry, Transition Metal Catalysis*, Biocatalysis
- Hazard evaluation lab: calorimeter, gasflow, DSC, ARC, Fall hammer, etc.

*Collaboration with CatSci Ltd.

ANALYTICAL SERVICES

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

- Impurity identification and characterization
- Method validation and stability testing
- Analytical instrumentation:
  - Physical data: mp, bp, n, d, viscosity, opt. rotation, etc.
  - Titration: variety of titration methods, KF
  - Spectroscopy: IR, NIR, UV, NMR (H,C,P,F)
  - Chromatography: GC, GC-MS, GC-HS, HPLC, UPLC, HPLC-MS, MALDI-TOF, GPC, TLC
  - Elemental analysis: C, H, N, S
  - Trace analysis: AAS, ICP-OES, ICP-MS, IC
  - Biochemical analysis: CE, gel electrophoresis, fluorescence, enzymatic tests, bio-tests in vitro AAA, enzymatic traces for molecular biology, peptide analysis, endotoxin testing

SAFC®

MANUFACTURING

Buchs offers a broad range of manufacturing areas including cGMP kilolabs and pilot plant facilities.

- Three laminar flow cabins at ISO 8 classification
- Closed solid charging and discharging
  - Purified water plant: USP & Ph. Eur. Grade
  - GMP compliant quarantine and storage areas

Equipment overview:

QTY	Equipment	Capacity	Temp. Range
7	Glass lined reactors	1,000-1,600 L	-20° to +180° C
5	Glass lined reactors	400-630 L	-50° to +180° C
21	Glass lined reactors	63-250 L	-40° to +180° C
5	Centrifuges	100 KG	
2	Agitated filter dryers	50 KG	
6	Vacuum shelf dryers	50 KG	
2	Spherical/Tumble dryer	200 KG	
3	Fractional distillation stills	250 L	
1	Thin fill evaporator	50 L / day	
8	Rotavaps	20-50 L	

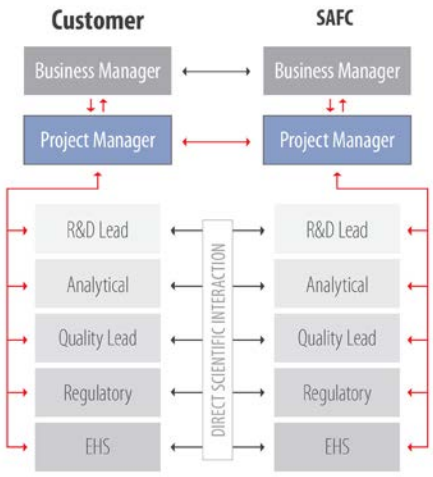
COMPLIANCE, REGULATORY & EHS

A dedicated team of experts ensures:

- Proven track record of successful DMF submissions
  - Preparation of regulatory filings (NDAs)
  - Vendor audits
- Regular inspections and audits by authorities and customers
  - Control documentation and testing
  - ISO 9001: 2008 management system
  - ISO 13485 (Medical devices)
  - ICH Q7 compliance (APIs)
  - IPEC PQG compliance (Excipients)
  - OHSAS 18001 certification
- GMP compliant
- FDA and South Korea MFDS inspected

PROJECT MANAGEMENT

From evaluation to execution, SAFC's dedicated project managers are coordinating multi- disciplinary teams, international site activities and timelines throughout the lifecyle of your program. They consolidate and facilitate direct communication by technical leads:



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