SAFC®

Pharma & Biopharma Raw Material Solutions

MilliporeSigma

GMP starting Materials, key intermediates and building blocks

Buchs Facility Overview

Our facility in Buchs, Switzerland specializes in the development and manufacturing of complex small molecules. These include critical raw materials, reagents, advanced intermediates to support API manufacturing and excipients from pre-clinical to commercial scale. This FDA inspected and ISO certified site provides a wide range of scale and cGMP manufacturing capabilities. Working in close alignment with our other global facilities, the site in 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 manufacturing Areas including cGMP kilolabs, batch range size and pilot plant facilities.

Equipment overview:

QTY	Equipment	Capacity	Temp. Range
3	Laminar flow cabins		
7	Glass lined reactors	1,000-1,600 L	-20º to +180º C
5	Glass lined reactors	400-630 L	-50º to +180º C
21	Glass lined reactors	63-250 L	-40º to +180º 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 film evaporator	50 L / day	
8	Rotavaps	20-50 L	
2	Kilo Labs: ISO 8 Clean rooms	g to kg scale	

Process and Analytical Development Services

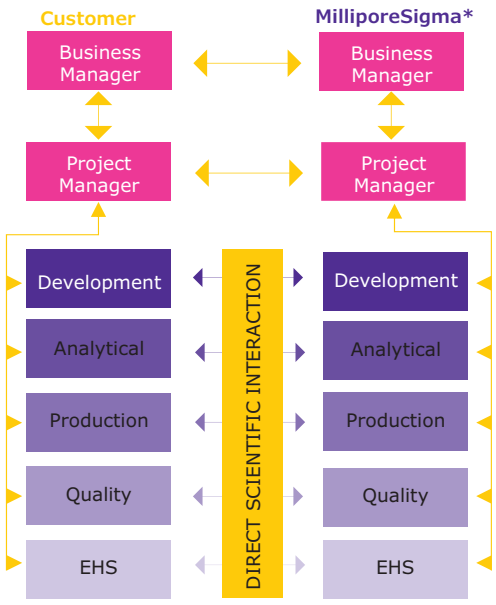
- Scaling and optimizing processes for lab & plant-scale
- Process validation support (QbD with DOE)
- Hazard evaluation lab: calorimeter, gasflow, DSC, ARC, Fall hammer, etc.
- Impurity identification and characterization
- Method validation and stability testing
- Analytical instrumentation:
  - Physical 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
  - Stability Studies per ICH
- Bioburden (TYMC, TAMC), external

Quality and Regulatory Services

- Proven track record of successful DMF submissions
  - Preparation of regulatory filings (NDAs)
- Customer 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, PMDA, 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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