# Process Chemistry R&D Laboratory, Manchester, UK

Accelerating your NCE development programs

Sai

Make it better together

## Overview

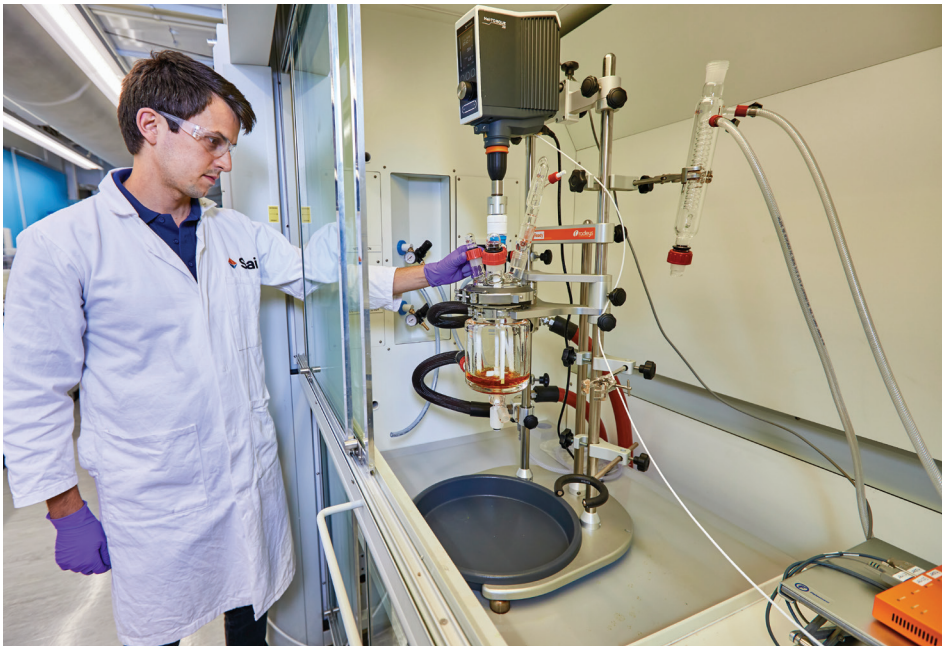
- **20,000 square feet** Process Chemistry R&D, Analytical and Scale up laboratories
- **Leveraging Cutting Edge Technology** to deliver high quality and efficient development and scale-up
- **Seamless technology transfer** to Indian sites
- **Proximity** to UK and EU customers and time zone advantage
- **Understanding your needs** 65+ experienced team across chemistry, analytical and engineering from Pharma and CDMO backgrounds bringing a breadth of experience
- **cGMP facility** with ISO 9001:2015 certification set up to deliver up to 3 kg of clinical grade API

## Key capabilities

1. Route Scouting and Route Ideation
2. Early and Late-Phase Process Development
3. Control Strategy Definition
4. Analytical Method Development
5. Manufacture of non-GMP Tox and cGMP Clinical material
6. Tech Transfer support for larger scale manufacture in India
7. ICH M7 Consultancy
8. CMC Regulatory Consultancy

## Chemical Development experience

- Our team have worked on Projects from the Discovery interface through to commercial file and launch
- A senior leadership team with significant Pharma experience around Quality, compliance and regulatory expectations
- Ability to partner with clients to identify technical Project risks and propose phase appropriate risk mitigation options
- Scientific expertise in DoE, high throughput experimentation, kinetics, modelling, process analytical technologies, analytical method development, structural elucidation and crystallisation
- Expertise in Route innovation and Process development to successfully deliver challenging customer



Projects including speed of delivery, complexity, cost of goods issues, sustainability and scale up

- Ability to enable Phase 1 clinical readiness: route scouting, process development, analytical method development, non-GMP safety assessment batch preparation, GMP clinical batch, ICH stability studies, regulatory support, Genotox risk assessment

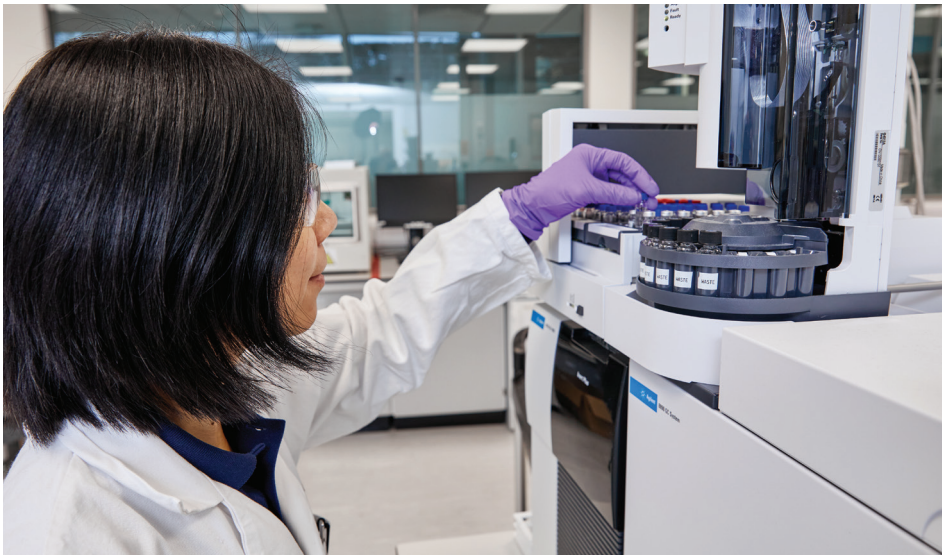
## Well-equipped Chemistry Laboratories

- We use parallel screening tools (Mya 4, Integrity10, Amigochem, Chemscan) to:
  - Perform solvent, reagent, base, catalyst and ligand screening
  - Generate data to support optimisation and robustness Design of Experiments investigations
  - Generate kinetic data to further provide mechanistic insight and build reaction models

- We are building a “high throughput experimentation” platform
  - Designed with flexibility & speed in mind to support synthesis and reaction optimization
  - MBRAUN Glovebox, solid handling using a Mettler Toledo Quantos Chronect
  - Software for batch processing and visualisation of data
- Scale up using controlled jacketed lab reactors (Radleys Reactor Ready) with overhead stirring to 250 mL to 5 L scale
- Teledyne purification flash chromatography capability for rapid purification from mg to multi-hundred gram

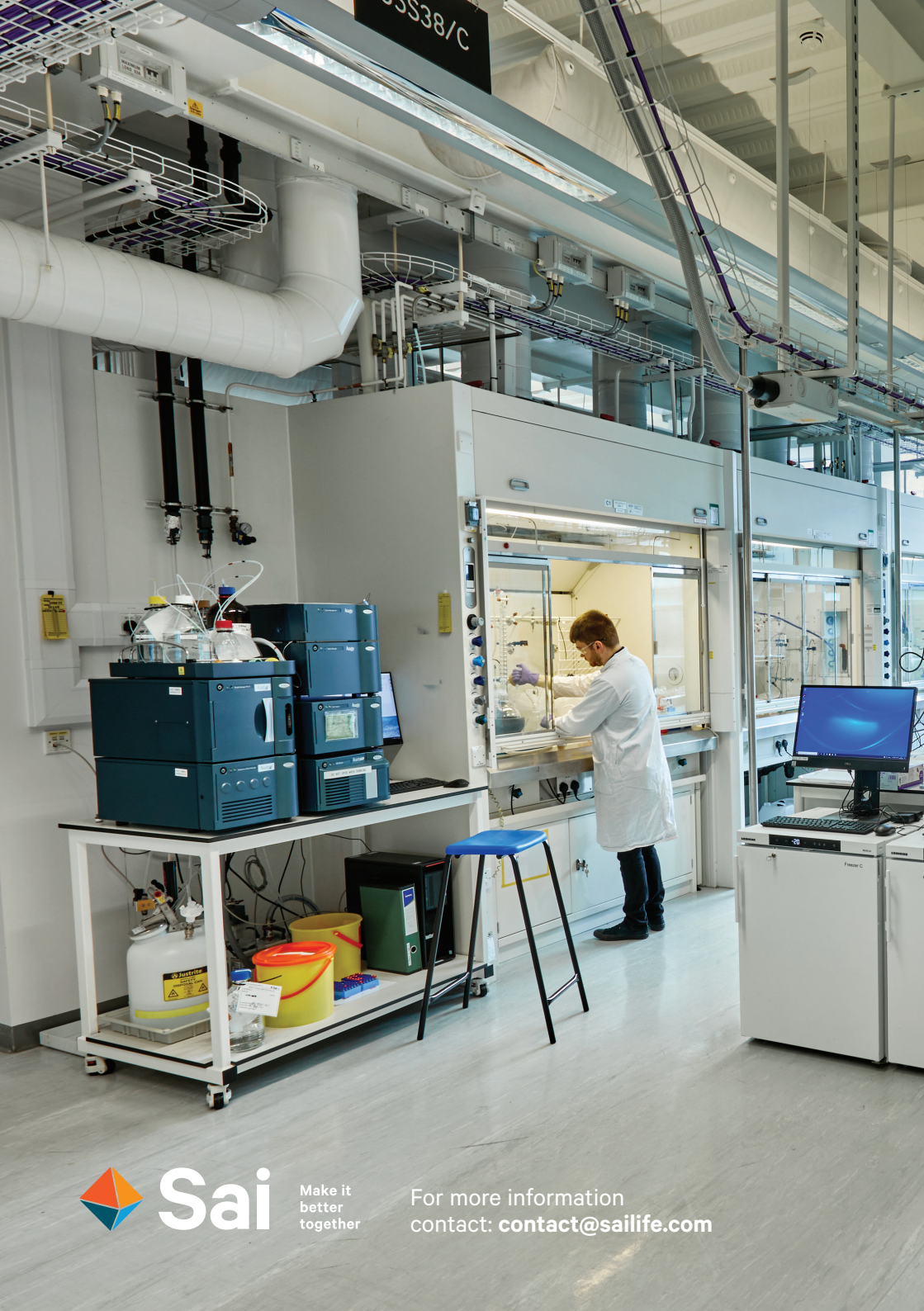
## We generate Scientific Understanding

- We use Process analytical technologies (PAT) to gather real time data
  - React IR for real-time in situ reaction monitoring providing insights to reaction mechanism and kinetics
  - Crystal 16 with turbidity measurement for crystallisation development, automated generation of solubility curves / metastable zone widths
  - Blazemetrics probe to generate simultaneous in situ high resolution microscopy and Raman data via a single PAT probe enabling monitoring of particle size, crystal habit, polymorph, turbidity or oiling during crystallisation
- Range of Analytical techniques and expertise
  - UHPLC and HPLC with UV, diode array, CAD, ELSD and MS detection, High Resolution MS, GC/FID with headspace and GCMS, FTIR, UV, 400 MHz NMR, Karl Fischer, automated titrations and Microwave ash.
  - 21CFR Part 11 compliant equipment to support cGMP activities
  - Physical Properties testing, including DSC, TGA, PSD and XRD
- Open access equipment is available for chemists to generate their own data enabling fast turn around and decision making
- 4 open-access UHPLC-MS, open-access GCMS (EI and CI mode), open-access chiral HPLC, and 400 MHz NMR



## Production capability to deliver low kg quantities of material

- Non-GMP scale-up laboratory: 2 standard process streams with flexible configuration
  - 10-35 L glass reactors, 10 L Hastelloy and 20 L SS hydrogenators (up to 7 bar), Cuno filter, 20 L rotary evaporator, Teledyne Torrent Flash purification (3 kg column / 300 g loading), large vacuum tray drying oven
- cGMP scale up laboratory: 1 standard process stream with flexible configuration
  - 10, 20 or 35 L dissolution / reactor vessel, 10, 20 or 35 L crystalliser, ANFD for closed API isolation operations, Pan filter and tray drier for intermediate isolations
- 3 Stability Chambers capable of controlling both temperature and humidity to support ICH Q1a/b stability studies for either GMP studies or non-GMP (Development) stability studies.
  - Systems are all controlled via 21CFR Part 11 compliant software
- ISO 9001:2015 certified Quality System
- Low-cost supply strategies can be developed by manufacturing earlier intermediates in our Hyderabad facility in India



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For more information
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