



Creative Carbohydrate Chemistry



Our Company



Dextra was founded in 1989 to provide carbohydrate synthesis and analytical services to the scientific research community

Providing world leading, innovative solutions for the total synthesis of challenging complex carbohydrates, Dextra typically simplify routes and reduce the number of synthetic steps required to achieve the target compound.

From a few milligrams to multi kilogram scale our chemists offer unparalleled expertise in oligosaccharide and chiral chemistry taking your project from discovery to clinical trial.

Your partner of choice for Carbohydrate products and CDMO services

Our Approach

We offer a comprehensive custom synthesis service to take your project from discovery to clinical trial

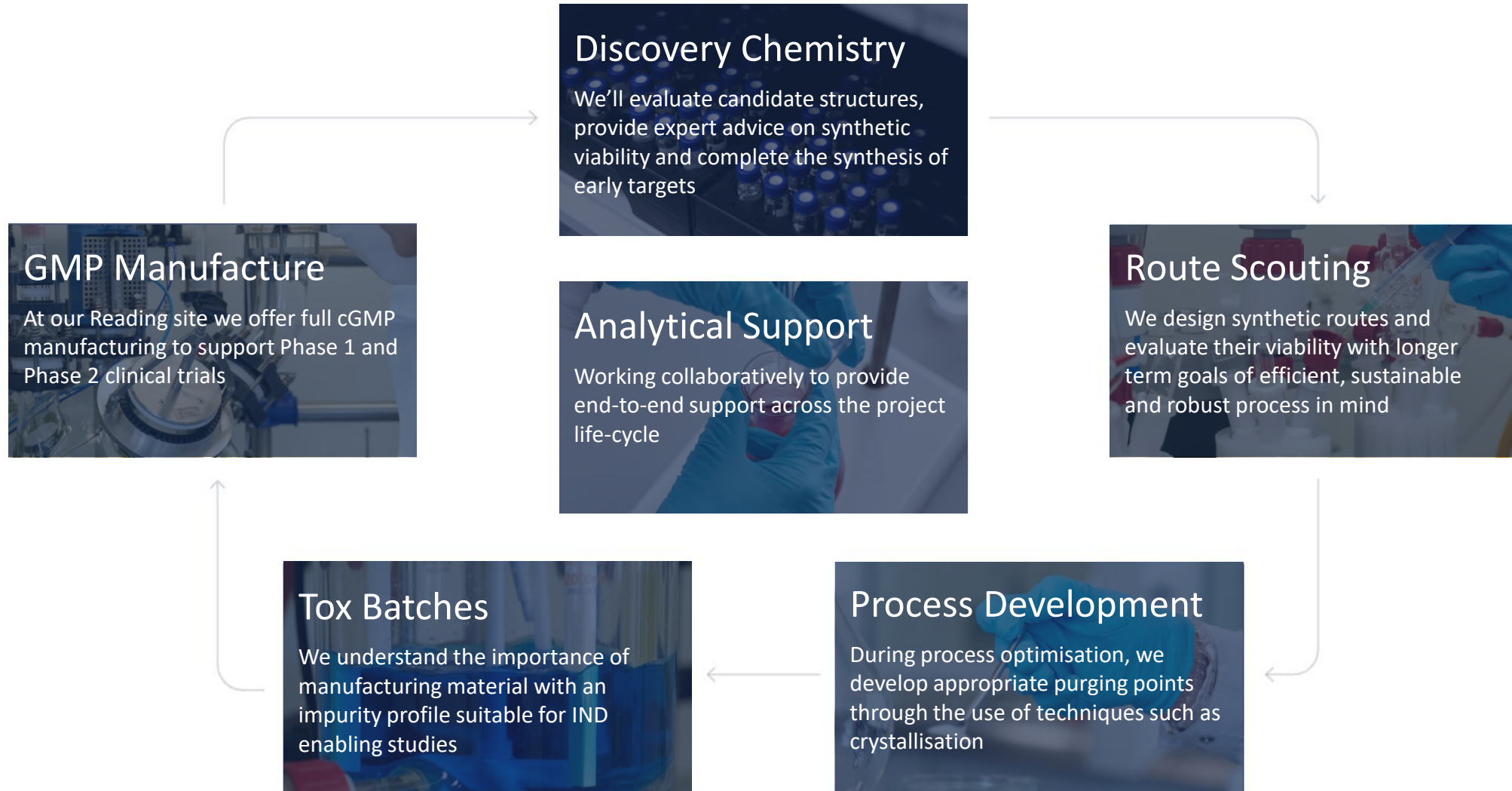
Our core competencies include complex oligosaccharide chemistry, route design, process development, optimisation and scale-up, process validation, technology transfer and GMP manufacture for Phase 1 and Phase 2 clinical trials.

Our fully equipped analytical laboratories offer expert support with a comprehensive range of analytical techniques available. All activities are fully supported by a strong Quality Management System and Health & Safety framework and we have successfully achieved ISO9001:2015 registration.

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Services we offer



Our expert team manage the life cycle of your project from discovery to clinical trial

Discovery Chemistry

- We understand drug development programs are complex, challenging and that it all begins with an effective discovery phase.
- Dextra Offers a bespoke service to support discovery chemistry including:
 - evaluation of candidate structures
 - expert advice on synthetic viability
 - synthesis of early targets
- Parallel synthesis and automated purification equipment is available to support the rapid synthesis of candidate analogues.
- We can quickly action our scale up team to provide larger scale quantities of a target compounds as required.
- Our proven team of PhD qualified chemists has specialist knowledge of carbohydrate chemistry and a wealth of knowledge in the synthesis of a wide range of molecules.



Route Scouting



Our research and development team look for creative ways to prepare your compounds, working with you to deliver the solution that you need.

Design of efficient, sustainable and robust processes.

Consideration of:

- Safety

- Raw material availability

- Economic viability

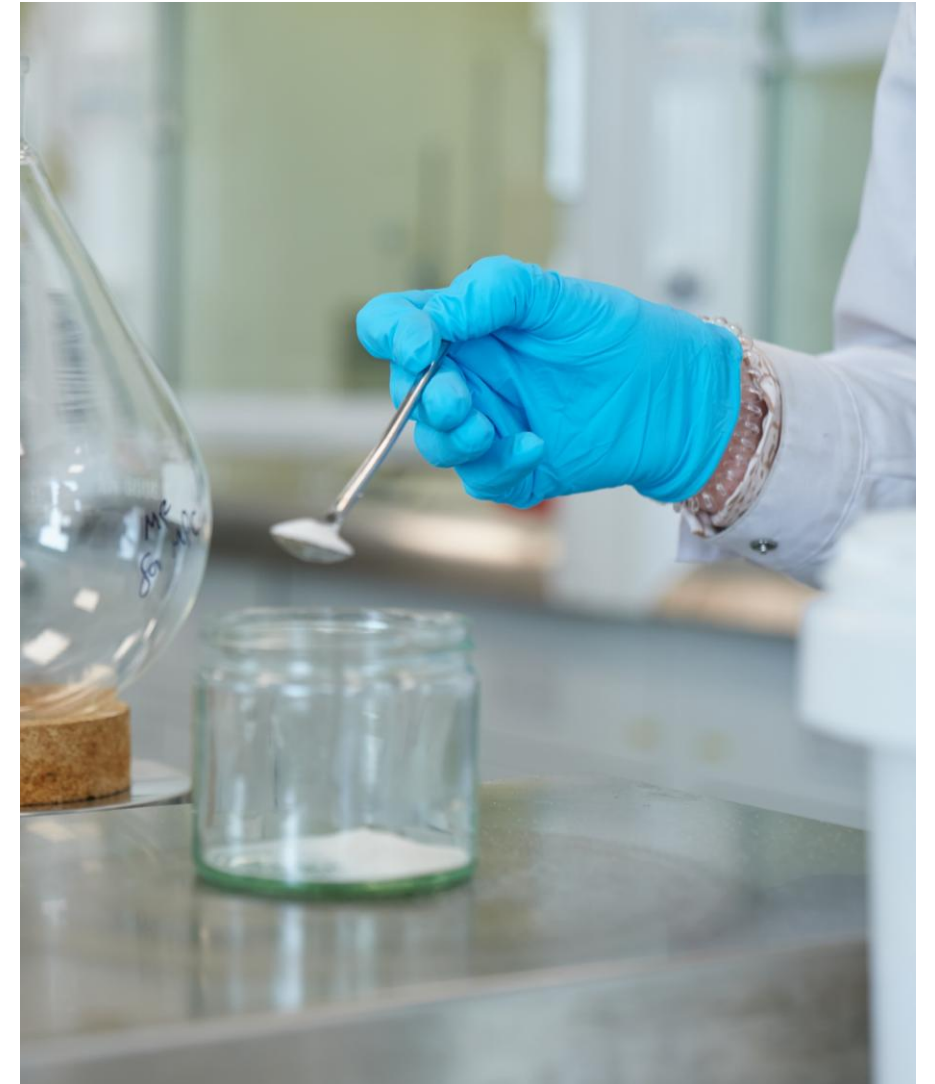
- Waste generation

- IP

Reduction of the number of synthetic steps.

Process Development

- ▶ We are experts in process development, problem-solving, optimisation and scale-up
- ▶ We look for innovative solutions to provide simplified processes and build in robustness
- ▶ Development of appropriate purging points through the use of techniques such as crystallisation to ensure product quality
- ▶ Jacketed vessels from 250 mL up to 50 L, mimicking stirring and reaction kinetics to ensure processes readily transfers to plant manufacture
- ▶ Impurity tracking
- ▶ Development reports
- ▶ Technology transfer



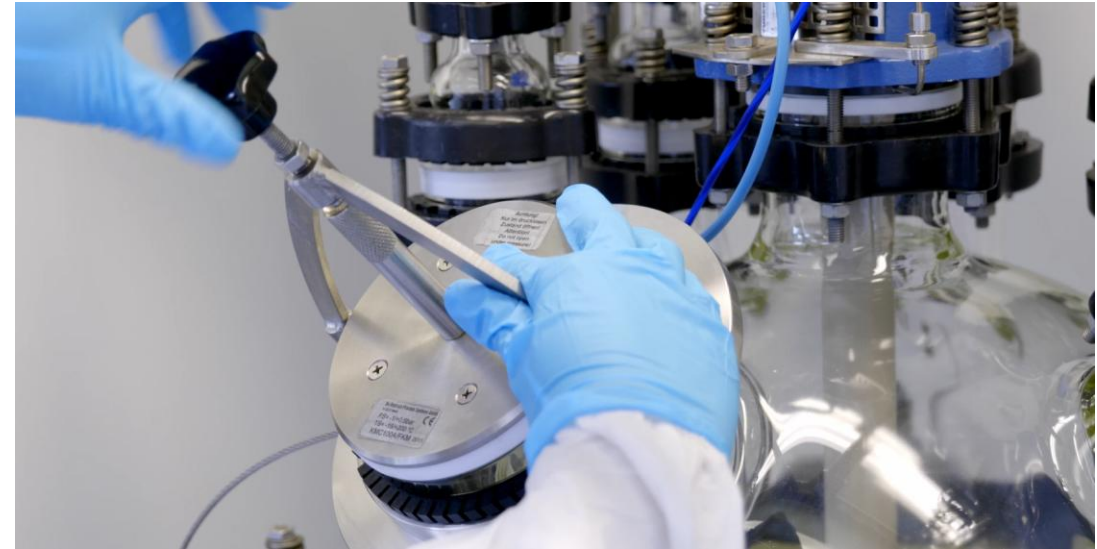
Tox Batches



- ▶ We understand the importance of manufacturing material with an impurity profile suitable for IND enabling studies.
- ▶ Production of multi-kilogram scale non-GMP batches of APIs for your preclinical studies, including dose range finding and tox batch requirements.
- ▶ Efficient supply of material with appropriate control over the impurity profile.
- ▶ Our integrated approach means early development batches can offer reliable information regarding the performance of later stage manufacture and materials.

cGMP Capabilities

- cGMP manufacturing to support phase I and phase II clinical trials
- Late-stage clinical trial manufacture and commercial manufacture available at other ICE Pharma sites worldwide.
- Two dedicated class 100,000 (ISO 8) laboratory cleanrooms.
- Quarantine areas and equipment store.
- 50 L fixed vessel operating from -90 °C to +200 °C; 20 L rotary evaporator.
- cGMP manufacture is supported by a full analytical capability:
 - method development
 - qualification and validation
 - degradation and stability studies
 - specification development
 - raw materials and intermediates testing.



Analytical Facilities and Regulatory Support

Services include:

- Material characterisation
- Product certification and release
- Method development
- Method validation (ICH guidelines)
- Method transfer
- Specification development
- Forced degradation studies (ICH guidelines)
- Impurity profiling
- Stability studies (ICH guidelines)
- Preparation of CMC documentation



Contract Laboratory Analytical Service

As well as supporting our catalogue offering, R&D activities and client-based synthesis activities, we also offer Contract Laboratory Analytical Services to clients. Our on-site techniques in the UK include:

Separation sciences

- HPLC (UV, RID, DAD, ELSD)
- UHPLC (DAD, RID)
- Ion Chromatography (PAD)
- Gas Chromatography (Direct & Head Space)
- TLC
- Gel Electrophoresis

Spectrometric & Spectroscopic characterisation

- NMR (^1H , ^{13}C , ^{19}F , ^{31}P , COSY, HMBC, DEPT, DEPT135, DEPTQ, HMQC)
- FTIR
- UV
- Mass spectrometry

Elemental & Microanalysis

- Karl-Fischer
- Titrations
- Residue on ignition
- Loss on drying

Physical Chemistry

- Melting point
- Polarimetry

A wealth of additional techniques are available on request through our third-party analytical service provision

Reading Site at a Glance

■ Dextra Laboratories (NZP UK) operate from the Gateway Building at Thames Valley Science Park

- Dextra Laboratories has over 35 years experience and specialises in carbohydrate chemistry
- Acquired by ICE Pharma in August 2020

■ Dextra can provide a complete solution from discovery chemistry to GMP manufacturing for early phase clinical trials

- The site has well equipped research and analytical laboratories in addition to two ISO 8 clean rooms for production of material for early phase clinical trials
- Reading site offers cGMP manufacturing to support Phase 1 and Phase 2 clinical trials in reactors up to 50 L, operating at temperatures from -30 to 200 °C.

■ Regulated site

- BS EN ISO 9001:2015 accredited
- QMS system compliant with ICH Q7 section 19

■ Safety, Health & Environment

- SH&E Committee
- Incident Management Team



The Dextra Catalogue

Our Catalogue showcases a comprehensive range of over 800 carbohydrate products, exploiting the complexity and diversity of glycobiology.

Products groups include:

- ▶ Blood Group Products
- ▶ Glycoconjugates
- ▶ Oligosaccharides
- ▶ Monosaccharides
- ▶ Nucleosides & Nucleotides
- ▶ Polysaccharides



In Summary



- Over 35 years of experience.
- Specialists in carbohydrate chemistry.
- World leading innovative synthetic solutions for the synthesis of complex carbohydrates.
- Comprehensive custom synthesis service to take your project from discovery chemistry to GMP manufacturing.
- Project management, including access to highly qualified and experienced organic chemists.
- Fully compliant cGMP manufacture for Phase I and Phase II clinical trials.
- Well resourced analytical laboratories provide expert support to all phases of our projects
- Extensive catalogue showcases a wide range of carbohydrate products.

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