

Custom Synthesis

GEO Specialty Chemicals – Hythe Development Group

We are a high-level chemical development and scale-up group, offering a palette (or wide range) of specialised chemistries and chemical technologies and representing a scientific and technological centre of excellence within the wider GEO Specialty Chemicals organisation.

We partner with pharma services (and animal health) clients typically in the preclinical and early development space, providing (or offering) flexible solutions and applying enabling chemical technologies for the custom development and manufacturing of small molecule intermediates and API.

Our rich site history and culture of partnering has reinforced the ability of Hythe Development Group to deliver in three key industry areas:

- Fine Chemicals
- Pharma intermediates
- Specialty Chemicals

In addition to our access to scientific expertise and technology assets both within the wider GEO Specialty Chemicals organisation and through our international network, we are ideally located in the Southampton area, taking advantage of high level university facilities, and proximity to Southampton and Heathrow airports for connections both within the UK and internationally.

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Custom Synthesis Overview

HYPHE SITE - OVERVIEW

GEO Specialty Chemicals Hythe is a modern chemical facility with a rich background in Specialty and Fine Chemicals, and from its initial construction/commissioning by Union Carbide has demonstrated sustained success and a strong track record in bringing processes and products to market.

GEO Specialty Chemicals Hythe comprises high level development, pilot plant, production and distillation facilities, supporting the following areas of activity and products:

- High purity contact lens materials and blends
- Specialty alkoxyates for lubricants, food & pharmaceuticals
- Acrylic Monomers for coatings, adhesives & specialty polymers

Hythe is the leading European producer of industrial grade HEMA, Methacrylate monomers and Polyalkylene Glycols.

The Hythe site has been subject to intensive and sustained investment and modernisation since its inception. Significant investment by GEO Specialty Chemicals in recent years has included €13 m infrastructure spending since September 2011 and €10 m investment in specialized chemical manufacturing (contact lens monomer) facilities in 2016/2017.

Our activities are conducted by a highly-skilled and experienced workforce of 160 employees, having an average of 14 years service; over 30% are qualified to degree level. We are keenly aware that our people are a key asset in meeting client expectations and ensuring success in our business activities, and this has driven our sustained focus on attracting, retaining and developing high-level talent. In this respect, Hythe is also proud to hold an Investors in People accreditation (Silver Award)

The Hythe site has an excellent track record in the areas of Health, Safety and Environment*, meeting and exceeding industry expectations for a chemical development & production site of this type. GEO Specialty Chemicals continually strives to ensure full compliance with all regulatory requirements in connection with its Hythe business activities and this strong HSE culture has been recognised within a framework of internationally recognised accreditations.

All information and data, including the formulations and procedures discussed herein, are believed to be correct. However, this should not be accepted as a guarantee of their accuracy, and confirming tests should be run in your laboratory or plant. No statement should be construed as a recommendation for any use which would violate any patent rights. Sales of all products are pursuant to terms and conditions included in GEO Specialty Chemicals sales documents. Nothing contained therein shall constitute a guarantee or warranty with respect to the products described or their use. Safety information regarding these products is contained in their Safety Data Sheets. Users of these products are urged to review and use this information.

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OUR PEOPLE/ OUR TEAM

The activities of our Hythe Development Group are conducted by an experienced team of scientists (chemists and analysts), engineers, scale-up, production and quality assurance* personnel. The high level scientific and technological capabilities of our staff are complemented by diverse backgrounds in the following industry sectors:

- Custom Manufacturing and Development
- Fine Chemicals and Pharma Intermediates
- Pharmaceutical industry
- Specialty Chemicals

This broad palette of experience and capabilities is enhanced by a strong industry & academic network and has allowed the team to establish a strong track record in developing and scaling up cost-effective, safe and industrially viable chemical processes.

In addition to this we invest actively in the ongoing professional development of our team members extending beyond the scientific and technical dimension with an emphasis on developing strong problem solving capabilities, project management and client focus.

OUR CULTURE AND VALUES

Customer Focus: We believe that the key to our business success is the prioritization of customers' needs to meet and exceed their expectations. Our strong client orientation is underpinned by our ability to listen to and engage with diverse partners.

Integrity: We are committed to building our solid industry reputation through transparent & open interactions, building a shared understanding of expectations with our partners and ensuring rapid and direct communication in the event of issues and scope changes arising during the course of an engagement. Respect for client confidentiality and the protection of client intellectual property is also central to our way of doing business.

Innovation: We are a science and technology-based organisation, and as such we value and promote innovation and the flexible application of scientific and technological solutions to address client needs. This is reinforced by:

- Strong scientific and technical leadership
- High level internal scientific expertise
- A broad external network

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G E O[®]
SPECIALTY CHEMICALS

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PARTNERING TO INNOVATE

Hythe Development Group has continued to build on a rich history of partnering across academia & industry, supported by a strong scientific network. In many cases, our ability to identify and implement innovative solutions to address complex challenges has been enabled through actively seeking and engaging with relevant external expertise. Some examples of these interactions and partnerships would include:

- University of Sheffield, (Steve Armes)
- Cambridge University (S. Ley),
- University of Hull (Flow chemistry/Chemtrix)
- University of Warwick (GPC),
- Southampton University (NMR Interpretation)
- Aston University
- University of Leicester (fluorination)
- University of Durham (fluorination)

In addition to academic and industrial partnering, Hythe Development Group benefits from access to a network of leading industry consultants, bringing specific expertise as needed to address scientific challenges linked to its business activities.

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SERVICES

We provide high impact and customized solutions in the pharma services and custom synthesis space to facilitate progression of projects through development.

Our main areas of activity are:

- Synthesis of intermediates and API for preclinical requirements
- Non-GMP intermediates for early development API needs
- Early scale-up and industrialization of chemical processes

We aim to address our partners' needs in terms of:

- Developing and scaling up safe, viable and cost-effective chemical processes from laboratory or kilolab to a production environment.
- Providing customised solutions in terms of specific and niche chemistries and enabling chemical technologies
- Addressing capability gaps in terms of chemistries, technologies and range of scale
- Driving/enabling/facilitating the progression of client processes from laboratory through development

CHEMISTRIES AND CHEMICAL TECHNOLOGIES

The Hythe site has long experience in introducing and implementing a wide range of specialist and niche technologies to address customer needs in the areas Specialty and Fine Chemicals and pharma services sectors. Our expertise in this area is underpinned by world-class engineering support, scientific network and close connectivity with the wider GEO organisation. These capabilities include:

| | |
|--------------------------|-------------------------|
| Alkoxylation | High pressure reactions |
| Hydrogenation | Photochemistry |
| Alkyl lithium reactions | Flow Chemistry |
| Metal hydride reductions | Advanced distillation |
| Friedel-Crafts | Short path |
| Reductive amination | Wiped film |
| Ammonolysis | Fraction splitting |
| Bromination* | |
| Biotransformation | |

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MATERIALS HANDLING CAPABILITIES

Handling, containment and use of an impressive range of challenging materials has been a feature of Hythe activities for many years. Key classes of material where we have experience, supported by world-class chemical engineering expertise, would include:

Pyrophoric and air/moisture-sensitive materials

- Organolithium reagents
- Phosphines
- Highly flammable reagents and solvents
- Ethylene oxide
- Propylene oxide
- Sensitive & reactive acrylate monomers (handling/distillation)

Hazardous and corrosive materials:

- Hydrogen Fluoride
- Bromine
- Aluminium Chloride
- Lithium aluminium hydride
- Boron trifluoride
- Dimethylamine borane
- Epichlorohydrin
- Formaldehyde
- Allyl chloride

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OUR SCALE-UP AND PRODUCTION FACILITIES

The Hythe development group utilises a range of pilot and production units to conduct piloting and scale-up of laboratory processes, and the eventual production of non-GMP intermediates and API.

Flexibility in implementing a wide variety of chemistries is assured by a variety of materials of construction for reactors and ancillary vessels (Glass, Glass-Lined, Stainless Steel and Hastalloy).

Autoclave units (Parr & Buchi, 2-10 litre, SS & Glass)

5 litre 316 SS reactor

10 litre 316 SS reactor

100 litre 316 SS reactor

100 litre 316 SS reactor

50 litre Hastalloy reactor & filter dryer

50 litre Glass reactor

400L Glass-lined reactor & 600L wash vessel

Distillation units (listing of specifications for HEMA units)

Operating ranges:

-40 to + 200°C

< 8 barg (pilot reactors)

< 300 barg (2-10 l autoclaves)

Automation & Control systems: Siemens S7200 & DeltaV

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ANALYTICAL CAPABILITIES

Our analytical activities in support of chemical process development and production are supported by capabilities and expertise in the key areas of analytical method development, analytical transfer, stability studies, fate of impurities studies (check this).

Analytical technologies available in-house include:

| | |
|-------|------------------------------|
| GC | Flashpoint |
| GC-MS | OH Number |
| HPLC | Acidity Number |
| GPC | Viscosity |
| IR | NMR (Southampton University) |
| UV | AAS |

QUALITY, SAFETY, ENVIRONMENT

The Hythe site has demonstrated an impressive safety record in its handling of challenging reagents and starting materials during over 50 years of business activity in the specialty and fine chemical sectors. In addition to meeting or exceeding all relevant safety requirements linked to its business activities, Hythe's safety philosophy is underpinned by its adoption of the ISRS HSEQ systems and best practices, and adherence to other internationally recognised standards and regulations as noted below:

Site accreditations:

- ISO 14001 (environmental safety standard)
- ISRS compliant management system
- ISO 9000 : 2008 (quality standard)
- COMAH / IPPC regulated
- ISRS International Safety Rating System – Integrated SHEQ best practice system
- COMAH – Control of Major Accident Hazards
- IPPC – Integrated Pollution Prevention and Control

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