ALMAC

Partnering to Advance Human Health

Brochure

Think Almac... Sciences

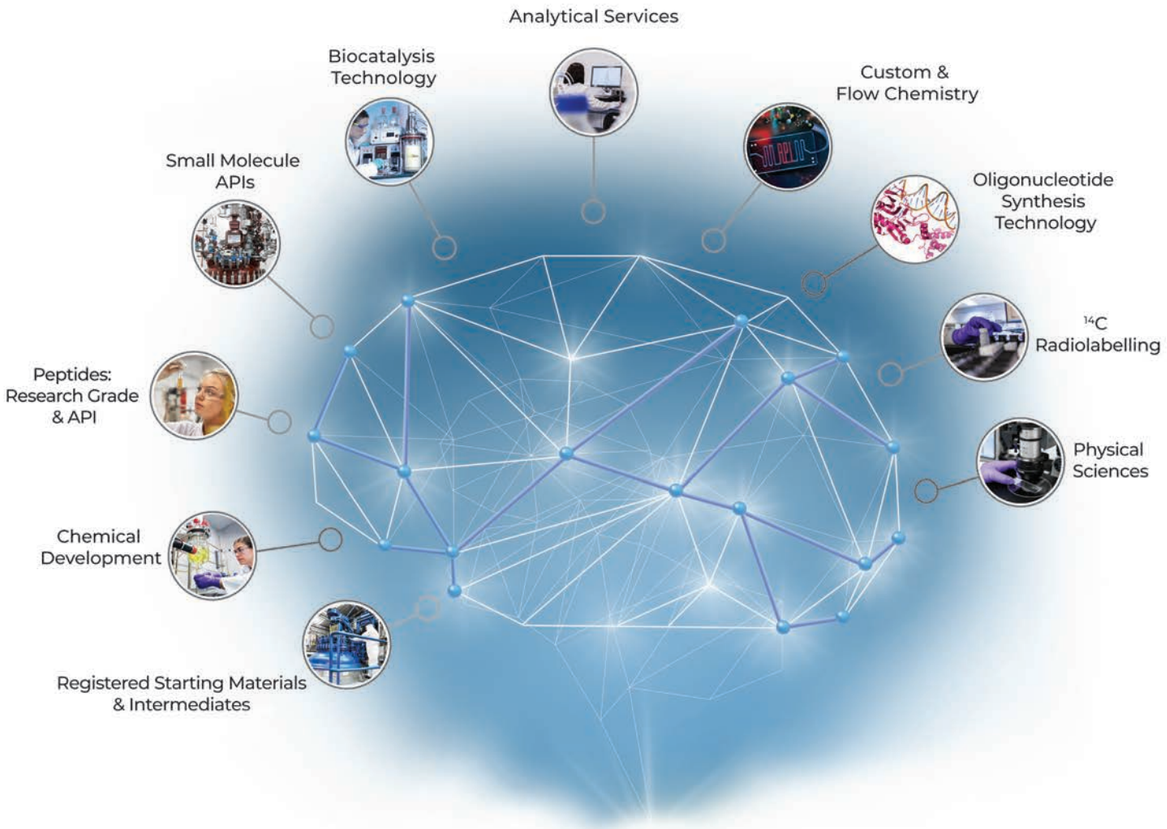
Your integrated API and analytical services provider

Your integrated API & analytical services provider

Almac Sciences provides services from development to commercial scale of advanced intermediates & Active Pharmaceutical Ingredients (API) for small molecules (including highly potent) and peptides. We have a proven track record of saving time & costs through the integration of our services & application of innovative technology solutions including biocatalysis & flow chemistry. Supported by our radiolabelling, physical sciences and global analytical services teams, think Almac for your drug development outsourcing solutions.

As part of the wider Almac Group, we are a stable, privately owned business that is growing globally in line with increased customer demand.

Think Almac...



API development & manufacture

Specialising in small molecule and peptide API development and manufacturing from pre-clinical to commercial scale, we offer comprehensive end-to-end solutions.

Chemical and analytical development

We have significant experience in the first-time scale-up of APIs. Starting with the medicinal chemistry route, our knowledgeable chemists can quickly identify the most pressing parts of the chemistry to develop.

Our chemists work closely with our development analysts and production teams to ensure that controls are appropriately embedded into the process IPCs, intermediate specifications and processing instructions. The salt form and polymorph landscape are explored within our physical sciences teams and drive the development of the API isolation process. Particle size manipulation can be developed into the process either via the crystallisation or end of line milling solutions.

We have an established reputation for developing processes for late clinical stage. Our extensive experience lies in taking processes from inception through to process validation, both in small molecule chemistry and peptides.

As an API moves from early clinical phase towards late clinical phase, the emphasis of the project changes. Whereas in early clinical supply, a lean fit-for-purpose approach is appropriate, other factors start to dominate when moving towards late phase, particularly process efficiency and knowledge.

We strategically integrate the principles from regulatory guidelines (FDA, ICH, USP), such as risk management and quality by design, as a basis for development and manufacturing strategies.

API manufacture

Once we are satisfied with the development of the process, we utilise our kilo lab to undertake proof of concept studies. The lab, with 50 – 100 L reactor capacity, is also used for API synthesis for pre-clinical testing.

Our API manufacturing facility with current reactor capacity of 100 - 1000 L is currently undergoing major expansion. Our ongoing investment programme is underway with construction to incorporate 4000 L reactors in the near future, creating a manufacturing centre of excellence to support small molecule API late phase and commercial production at up to 200 – 300 kg scale.

Highly potent manufacture

Almac facilities are designed to allow handling of High Potent APIs down to an OEL of 0.05 µg/m^3, using a variety of closed charging systems and glovebox isolators.

Custom synthesis

Almac has significant experience with complex chemical synthesis providing bespoke custom synthesis services from proof of concept to supply of key registered starting materials (RSM) and building blocks at tonne scale.

Think Almac... for API development & manufacture

Our reputation and expertise in API development and manufacture precedes us within pharma and biotech companies who seek integrated drug development solutions from molecule to market. Our technical expertise and extensive facilities enable us to offer integrated API contract manufacturing, on one site through all stages of the drug development lifecycle.

A key benefit to partnering with Almac is access to our innovative technology services. Our dynamic team successfully addresses many complex project challenges and offers responsive solutions when technical challenges arise, ensuring the needs of your drug development programme are fully met whilst maintaining time and cost efficiences. Supporting capabilities include:

- Rapid implementation of chromatography for purification
- Containment equipment for potent compounds
- Milling techniques to control particle size
- Crystallisation development
- Biocatalysis platform
- Flow chemistry
- Stability studies

Peptide & protein technology

Almac's Peptide and Protein Technology (PPT) group has been manufacturing peptides for the research community and clinical trials since 1994. We place significant emphasis on peptide synthesis methodology and have manufactured well over 10,000 peptides. Focussing on the delivery of high quality products, we have developed a highly differentiated skill set allowing us to tackle challenging projects such as long peptides (>100mers), macrocyclics and conjugates.

Almac has two UK-based sites. Our site in Edinburgh, Scotland focuses on high throughput manufacture, both for non-cGMP research use, and for cGMP personalised cancer vaccines. Our global HQ site in Craigavon, Northern Ireland, UK, manufactures cGMP peptides on larger scales.

Non-cGMP custom synthesis

Our high throughput, non-cGMP group uses the latest peptide manufacturing methodology and equipment for the rapid custom manufacture of peptides for researchers across the globe. Whether the supply of a single peptide for a one-off experiment, the manufacture of hundreds of peptides for protein mapping, or a clinical lead generation programme, Almac can deliver. Our service is totally customised, and we can manufacture linear or cyclised, standard or modified peptides, and their conjugates, on the milligram to gram scale.

We can incorporate the full range of modifications to your peptide sequence:

- Probes such as biotin or fluorophores
- Cyclised peptides: macrocyclic, side-chain stapling, single or multiple disulphide bridges
- Post-translational modifications such as methylations, phosphorylation and glycosylation

Conjugation expertise
Increasingly, chemistry is called upon to join peptides to proteins or other moieties such as fatty acids or PEGs to impart favourable qualities such as stability, receptor targeting or half-life extension.

Almac has experience in a wide variety of conjugation chemistries to ensure control and selectivity, including thiol / maleimide, haloalkyl, or thioester (NCL) conjugations: NHS, oxime, hydrazide linkers, or azide-alkyne 'click' chemistries.

Specialist catalogue reagents
Almac also provides a range of specialist catalogue products for use in basic research. These reagents are available from stock and shipped within 24 hours of ordering.

Chemokines
- Chemokines
- Histones
- Ubiquitins

cGMP peptide manufacture

Almac has been manufacturing cGMP peptides since 2007 and has a strong reputation for expertise and service delivery. All our cGMP projects benefit from support from our experienced project management, analytical and quality assurance functions.

First in human
We have manufactured numerous peptide drug substances for First in Human trials. Packages can be tailored according to the experiences and needs of the client. Whatever the content, the aim is to ensure that material is provided for the first patients quickly, and under cGMP control. We ensure robust process development techniques are used to define an appropriate manufacturing process for each peptide and we are experienced in defining new processes, or in transferring in existing ones. We have helped multiple SME clients who have since licensed their projects to large pharma, with Almac continuing supply.

Peptide vaccine cocktails
An increasingly popular approach is to use multiple peptides in therapeutic vaccines in fields such as oncology and anti-allergy. These approaches involve the manufacture of multiple peptide drug substances which are combined in a drug product cocktail for use as a vaccine. Cocktails present multiple technical and logistical challenges which Almac is experienced in overcoming through the delivery of multiple projects.

Late phase and commercial
We ensure a strong understanding of the parameters influencing variation within a manufacturing process and in delivering cost of goods targets. We follow industry guidelines on process validation, utilising modern Quality by Design methods. The key here is to build a full understanding of the manufacturing process, analytical methods, facilities qualification and cleaning procedures.

We achieve this through our bespoke Process Validation Roadmap. In 2023, Almac has successfully transitioned two of these programs into commercial manufacturing.

Radiopharmaceutical precursors

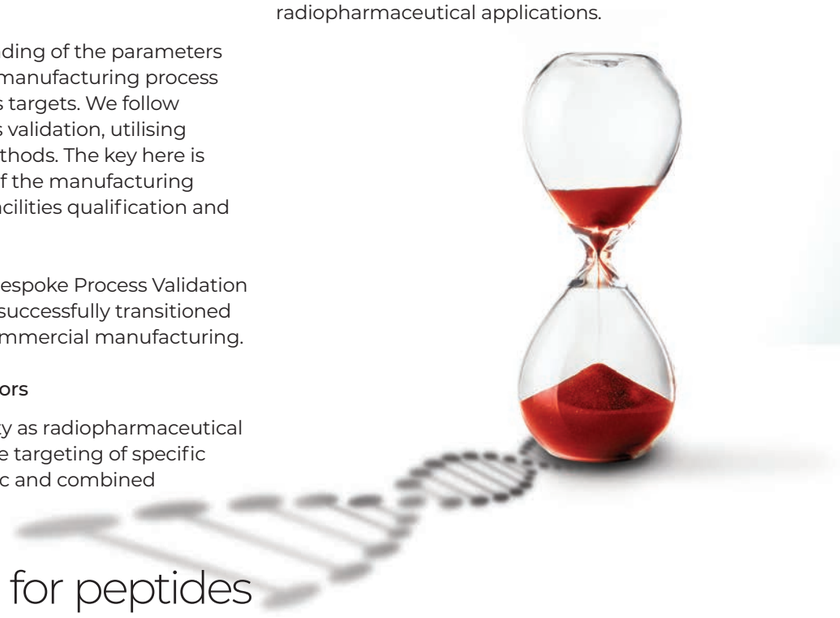
Peptides are gaining popularity as radiopharmaceutical platforms, as they allow precise targeting of specific tissues. Diagnostic, therapeutic and combined theranostic peptide programs are gaining momentum and Almac has accompanied several clients on 'cold' precursor projects in this field. We offer a wealth of experience in the development, analysis, and manufacture of these often heavily customised peptides, with an excellent understanding of CMC and regulatory requirements throughout their clinical journey.

NeoPeptides™ – High-throughput cGMP personalised cancer vaccines

NeoPeptides™ are peptides which originate from tumour derived mutations (neoantigens) and are manufactured for incorporation into personalised cancer vaccines. We have used our experience as leaders in this field to establish and refine robust manufacturing methods designed specifically for NeoPeptides™. These processes have successfully enabled the manufacture of a large number of patient-sets to date for use in clinical trials.

An entirely bespoke quality system has been written to support our dedicated cGMP facility for NeoPeptide™ manufacture. The requirements for each client are different, and Almac has experience of operating within a wide range of parameters to a range of regulatory authorities across the globe.

More recently, this platform approach has been leveraged to quickly manufacture low gram quantities of a single cGMP peptide, for example in radiopharmaceutical applications.



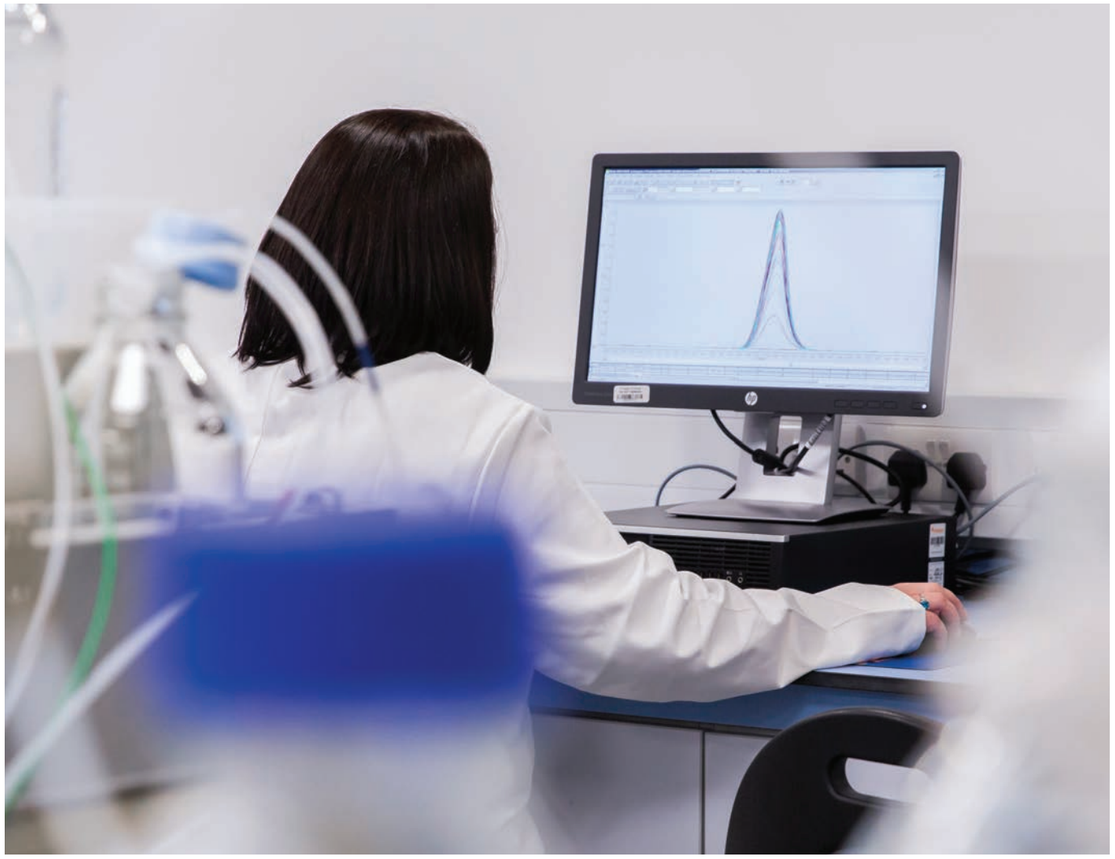
Think Almac... for peptides

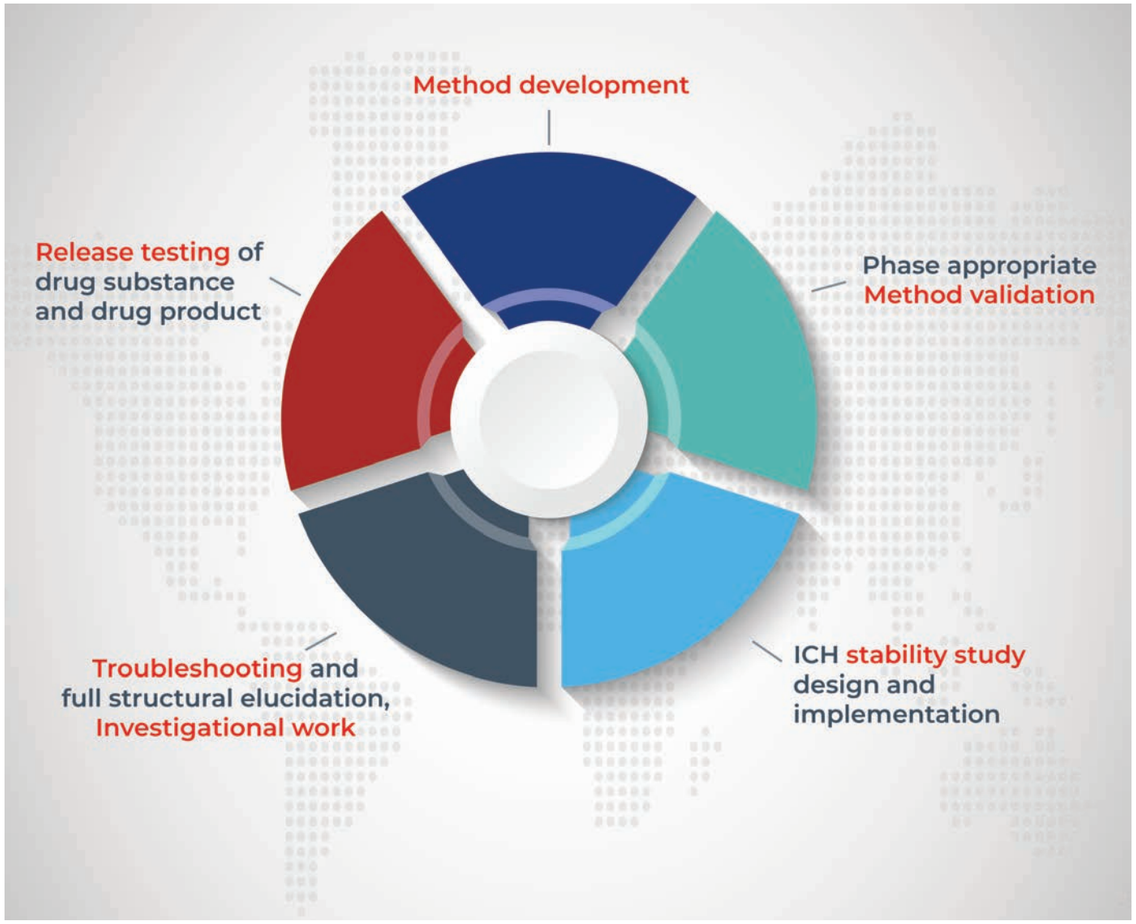
Almac has developed a reputation for sound technical capability and excellent customer relations skills. We achieve these capabilities through structured knowledge management and a culturally embedded project management philosophy bringing together multidisciplinary teams for drug substance manufacturing programmes. Our highly motivated teams work tirelessly to deliver projects to customer requirements.

Analytical services

From our MHRA, HPRA and FDA audited laboratories in the UK, EU and US, we employ over 250 highly trained analytical scientists with expertise in all areas of drug development, including small molecules, peptides, conjugates and biologics, with capability to handle controlled and highly potent materials. Drawing upon our vast pool of scientific knowledge, we can greatly reduce the analytical challenges that typically arise during drug development supporting pre-clinical, clinical and commercial projects.

Almac's labs offer a wide range of diverse analytical techniques to cover all the major analytical tests required for development and commercial release of both small and large molecule therapeutics. Furthermore our scientists are highly skilled in method development and validation as well as troubleshooting techniques to combat any issues that arise. The integration of a diverse suite of orthogonal technologies across multiple geographies allows clients access to a one-stop-shop for all analytical needs.





Think Almac... for analytical services

Communication and scientific continuity are key, whether your analytical requirements are stand-alone or form part of a drug development or commercial manufacture project. Our analytical scientists work with our drug substance and drug product formulation scientists, forming an integral part of the project team. This means they can share data, easily coordinate planning and scheduling and deliver maximum efficiency.

Almac has the capacity and capability to assist with all of your analytical contract testing needs with flexibility across 3 global sites

Physical sciences

Sitting at the interface between drug substance and drug product manufacture, Almac Sciences' Physical Sciences team supports solid form screening studies, crystallisation process development, preformulation development, physicochemical characterisation, and powder property modification / particle engineering

Solid form screening

Focussed on identifying and crystallising novel forms of small molecules and peptides. Whether this is the first time the API has been crystallised or if we are screening for novel polymorphs, salts, or co-crystals, Almac's Physical Sciences team will be able to help.

- Polymorph screens
- Salt screens
- Co-crystal screens
- Crystallisation and 'difficult to crystallise' screens
- *in silico* crystal structure prediction
- Chiral resolution (enantiomeric) screens
- Hydrate mapping
- Single crystal growth for structural elucidation studies
- Powder X-ray diffraction (PXRD) method development
- Broad scope intellectual property (IP) screens
- Amorphous solid dispersion development
- Comprehensive physical and chemical analysis
- Developability assessment for novel forms

Preformulation development

By collaborating closely with Almac's in-house drug substance and drug product teams, our Preformulation team are world leaders in performing rapid early and enabling formulation screening work programs in instances where material is limited.

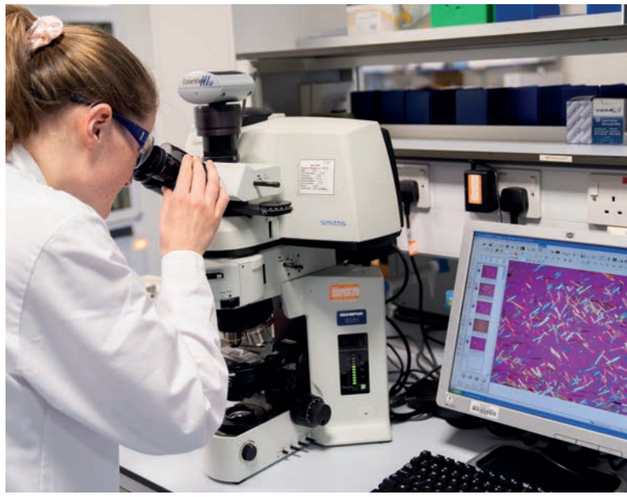
Generally performed as soon as the stable form of an API (free form, salt, or co-crystal) has been determined by polymorph screening, the early / enabling formulation screens perform the following assessments:

- Biopharmaceutical profiling (pKa / logP / logD determination) and permeability (Caco-2)
- Indicative stability testing using ICH conditions (including temperature, humidity, light, oxidative conditions, Cu^{2+}, and Fe^{3+})
- Excipient compatibility assessments (solid excipients and lipids) for pre-clinical / toxicological profiling of oral and parenteral doses
- API solubility testing in common buffers, biorelevant media, and across a simulated GI tract pH range
- Assessment of the drug intrinsic dissolution rate (IDR) in biorelevant media systems
- Amorphous solid dispersions / amorphous API assessment
- Drug Classification System (DCS) assessment
- ***formufast***™ drug development – delivering a stable formulation using as little as 25mg of API

Crystallisation process development

Almac offers a bespoke crystallisation development work packages tailored to material availability or development phase, allowing a wealth of crucial data to be delivered within tight timelines. The goals of typical studies include:

- Impurity rejection / purge studies
- Kinetics of nucleation and growth
- Polymorphic form control
- Maximising yield
- Morphology engineering studies
- Particle size control
- Bulk density and powder flow improvement
- Milling and micronisation studies
- Isolation and drying processes
- Control over residual solvent
- Seeding protocol
- Robustness testing via DoE and response surfaces



Think Almac... for physical sciences

Through the creation of synergy between solid state chemistry and formulation development, our experienced scientists have the ability to add great value to your pre-clinical project, while decreasing timelines.

Continuous flow chemistry

Continuous Flow Chemistry opens up the possibility to access new synthetic routes to a given intermediate or API often not achievable in conventional batch mode due to issues around safety, impurity formation and the instability of reactive intermediates.

Our award winning continuous flow technology platform enables access to better synthetic strategies which are shorter, offer assured safety, reduce environmental impact and control by-products. In addition, improved yields and reaction selectivity is achievable. With the reaction under tight control, product isolation can be streamlined due to reduced requirement for downstream purification.

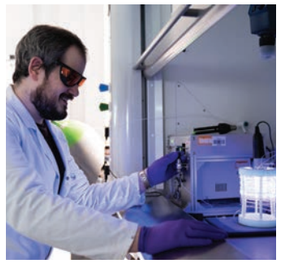
We offer the following:

- Route invention using continuous flow technology
- Proof of concept studies and process demonstration
- Flow as enabling technology for suitable reactions in multi-step synthetic routes
- Reaction validity in flow and process robustness within microreactors
- Access to challenging reaction classes that are inherently difficult to scale in batch
- Process TT and product delivery to 100's kg scale
- Process Analytical Technologies

High pressure
- Custom built packed bed hydrogenation rig
- Pilot Flow H_2 rig capable of up to 300 °C/100 bar
- Hcube® for screening
- Rapid catalyst screening of pelletised Almac's catalyst library in custom flow rig
- FAST hydrogenation process development and direct route to scale up for multi kg's

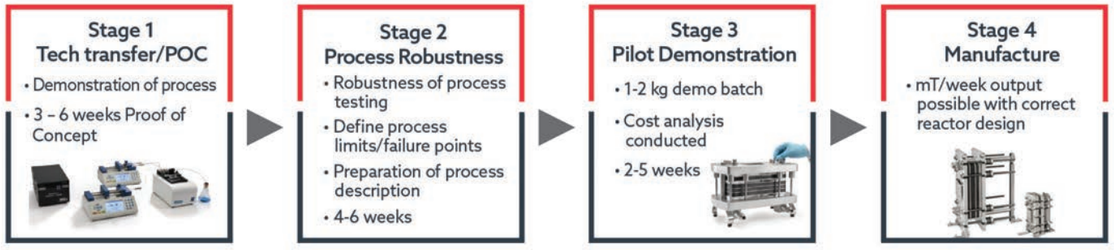
High energy / oxidations
- Chemtrix Labtrix® – microreactor -20 to 195 °C
- Protrix® – SiC reactor up to 20 bar pressure and 195 °C
- Custom built Syrris Asia/PTFE tubing/multiple mixers for low kg delivery
- Microbubble technology
- CSTR
- Liquid-liquid separators

Photochemical
- cGMP medium pressure mercury flow cell for multi kg delivery
- Vapourtec E series with LED reactor
- UV-Photochemical, photoredox flow cell and LED's



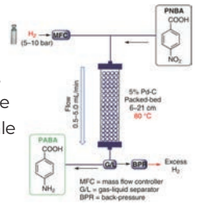
Almac's flow chemistry team has implemented a four stage project workflow to ensure successful delivery of projects for our clients in acceptable timelines and at a competitive price.

Defined workflows ensure the development of robust, safe and scalable processes for multi-kg manufacture.

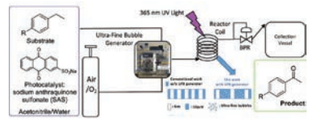


Core expertise

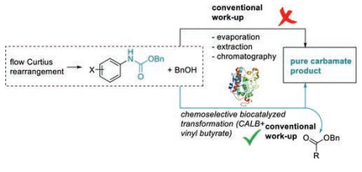
High Pressure
- For example, nitroreductions, reductive deuterations, alkene saturation - up to 100's kg scale



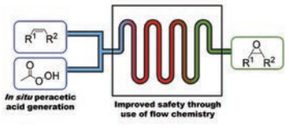
Photochemical
- For example, selective photooxidation of alkylbenzenes using ultrafine bubble technology, brominations, [2+2] -cycloadditions.



High energy
- For example, Curtius rearrangement with BnOH coupled with chemoselective bioremediation for purification.



Oxidations
- For example, peracetic acid is generated *in situ* and telescoped directly into the epoxidation reaction, thus reducing the risks associated with its handling and storage, which often limit its use at scale.



Think Almac... for continuous flow chemistry

Almac's integrated flow technology platform can be applied throughout your product lifecycle to guide your synthesis project from conception to manufacture.

Biocatalysis solutions

Biocatalysts / enzymes are essential tools in chemical synthesis, particularly in the synthesis of pharmaceutical and fine chemical targets. Almac has invested significantly in their selectAZyme™ technology to build expertise ranging from enzyme discovery, enzyme engineering and enzyme production to produce robust, best-in-class enzymes for the synthesis of complex chiral intermediates and active ingredients.

selectAZyme™

Screening of existing Almac libraries of enzymes with your substrate of interest

- Biocatalytic route invention and process development
- Tech transfer and ongoing support through all the manufacturing steps, including the training of personnel, if required
- Supply of chiral intermediates
- Microbial screening and molecular biology for development of novel biocatalysts
- Fermentation development and scale-up from mg to tonne scale
- Metabolite synthesis
- FTE or FFS contracts

Smart enzyme discovery (INSIGHT)

- Use of molecular modelling and Almac's bioinformatic algorithms to discover new enzymes from public databases and Almac unique metagenomic databases
- Machine learning / deep learning to assist in the selection of the best enzymes for the desired reaction.
- Experience in the querying, annotating and building of synthetic biological pathways
- Expertise in the study of protein structure / function using computational chemistry methods and bioinformatics tools

These capabilities enable us to provide unique panels of enzymes built around your specific biotransformation within weeks.

Enzyme engineering

- An established track record of improving enzyme performance (activity, selectivity, specificity, solvent tolerance and process stability) across all major enzyme classes
- Rational enzyme design using molecular modelling, docking and molecular dynamic calculations to engineer enzymes
- Use of computational tools to rationally identify mutational 'hot spots' for site saturation mutagenesis
- Smart site mutagenesis using computational tools to intelligently target specific sequence space
- Directed evolution using random mutagenesis and high throughput screening
- Machine learning guided selection of beneficial mutant combinations

Enzyme manufacture

- Fermentation development from shake flask to high performance fed batch fermentation in weeks
- High level of expertise in optimisation of fermentation and downstream processing
- Fermentation capabilities from 1 L to 15 m^3
- Ability to generate and test multiple physical biocatalyst formulations
- Supply of biocatalyst from mg to tonne scale on a simple price per kg basis

Biocatalytic OligOnucleotide Synthesis Technology (BOOST)

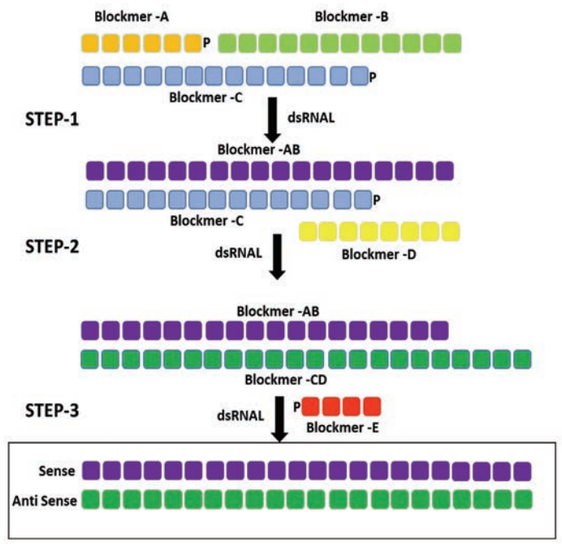
Almac has developed a range of biocatalytic products and services to facilitate the challenges posed in biocatalytic oligonucleotide synthesis. Building upon the strong biocatalytic technology base already available at Almac we have successfully applied this technology to oligonucleotide synthesis using Almac's selectAZyme™ panels for production of both single stranded and double stranded products. The technology can be applied to synthesis of siRNA duplexes and other therapeutic oligonucleotides.

Almac's '3-2-3-2' hybrid approach for double stranded oligonucleotide synthesis ensures that only 3 blockmers are available in the reaction sequence, allowing for IPC testing to ensure reaction completion at each ligation step. Our biocatalytic oligonucleotide synthesis technology (BOOST) can reduce solvent usage and provides a convergent synthesis option compared to linear SPOS synthesis, widening supply chain opportunities.

As the blockmers are short, the levels of impurities are lower and combined with the self-templating of the complementary blockmer sequences a higher purity product can be achieved compared to traditional SPOS synthesis. Furthermore, the natural selectivity of the ligase enzymes also provides the opportunity to synthesize optically pure oligonucleotides.

We offer the following:

- Screening of enzyme panels to identify enzymes specific for your oligonucleotides
- Alternative strategies to allow enzymatic production of single and double stranded RNA oligonucleotides
- Development of cost effective processes using enzymes where single and double stranded oligonucleotides are assembled from blockmers using RNA ligase enzymes
- Utilise blockmer self-assembly or templating followed by enzyme mediated ligation
- Enzyme engineering of Ligase enzymes to further improve your synthesis
- Scale up of the ligase reaction to multigram scale



Almac's '3-2-3-2' hybrid approach

Step 1 3 blockmers are annealed followed by ligation to form 2 RNA pieces

Step 2 Another blockmer is added, annealed and ligated

Step 3 Sequential addition of blockmers followed by annealing and ligation to allow formation of target duplex

Think Almac... for biocatalysis solutions

Our team of molecular, microbiologists, enzymologists, organic chemists and analysts, has demonstrated expertise in gene identification, expression, enzyme engineering, fermentation, enzyme production, process development and biotransformation scale-up. Each member of the team bringing their unique skill set to complex enzymatic and chemical processes. Our biocatalysis group works closely with the process chemistry and manufacturing chemistry groups at Almac, resulting in a facile implementation of an enzymatic process to significantly improve the yield and timelines of multi-step synthesis processes.

^{14}C radiolabelling

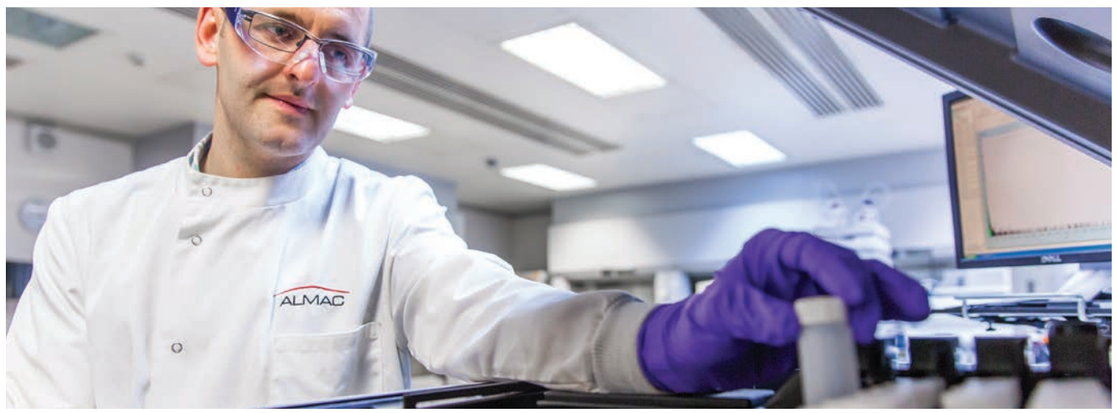
We provide industry-leading ^{14}C labelled drug substance services to meet your quality, cost and delivery expectations. With our extensive experience in the synthesis and analysis of stable and ^{14}C isotope labelled compounds, we can label any compound from simple small molecules to complex structures including peptides and bio-conjugates.

^{14}C is the radioisotope of choice in pre-clinical and clinical ADME studies, avoiding the challenges encountered with tritium labelling such as label exchange and label loss due to radioactive decay. Isotopic labelling imposes many synthetic challenges beyond those found in normal chemical synthesis, and when the isotope is radioactive this adds further safety and regulatory requirements. By choosing Almac as your isotope labelling provider you will have access to our wealth of experience in both stable-and radio-labelled synthesis.

We provide a complete suite of solutions for your needs, including non-cGMP and cGMP radiolabelling / stable labelling, bio-conjugate labelling, quality control and analytical support (including method development, validation / transfer and stability studies), storage and repurification. Our highly skilled team is able to provide custom radiolabelling services from a dedicated, access-controlled cGMP facility using validated quality-critical equipment including:

- NMR and mass spectrometers
- Semi-prep HPLC and automated chromatographic purification systems
- Cyclone Radio-TLC scanner
- Stromboli KF equipment
- Multiple Agilent HPLCs with radioflow, UV and fluorescence detectors
- Tri-Carb 2900, 4900 and Topcount 12 channel scintillation analysers
- 2-8°C, -20°C and -80°C fridges and freezers
- Agilent GC
- 3-, 5-, and 6-point analytical balances
- X-ray powder diffractometer (XRPD)
- Particle size by microscopy

Our strong quality culture will ensure the material manufactured will satisfy the requirements of the relevant regulatory authority; our well-equipped facilities are approved by the MHRA, and with our Almac Regulatory Affairs colleagues we are experienced in providing support for both IND and IMPD preparation.



Think Almac... for ^{14}C radiolabelling

Our proven track record in synthesis and purification, coupled with our seamless analytical and QC integration, ensures your labelled product will be manufactured with the desired chemical and radiochemical purity and rigorously analysed using validated equipment.

arran
CHEMICAL COMPANY LTD
A Member of the Almac Group

Arran Chemical Company (“Arran”) specialises in the manufacture (kg to 100 tonne scale) of fine chemicals for pharmaceutical, flavour & fragrance and personal care industries as well as for other specialised chemical and industrial applications. Arran has over 30 years of experience in chemical processing and was acquired by the Almac Group in 2015.

Arran has a reputation for flexibility and can adapt its equipment to suit many processes. This includes operation of hazardous chemistry and controlled material handling. Arran applies advanced chemistry technologies (such as biocatalysis, flow chemistry, protein purification and falling film distillation) and brings these into routine production in relatively short timelines to meet the supply chain requirements of our multi-national customers. The speed of progression from development to bulk production is one of Arran’s key differentiators.

Arran’s quality systems are routinely audited by top pharma companies. Arran is registered on over 30 regulatory filings as the key supplier of drug substance intermediate destined for commercial API manufacture. Arran is ISO compliant and approved by the US FDA Food Division. We operate excellent health & safety and environmental standards. Arran welcomes site visits and customer audits at our Athlone (Ireland, European Union) headquarters.

Expert supporting services

Project Management

We understand every molecule is unique, and the need to progress projects smarter, faster and cost effectively is paramount to drug developers. That is why our Project Management team works in partnership with our clients throughout their projects to provide a comprehensive service from initial planning through to execution of all agreed deliverables. Our team comprises experienced scientists with significant industry experience who work closely with our clients to anticipate and respond to project priorities.

A dedicated Project Manager is assigned at contract acceptance and acts as a single point of contact with regular communication to navigate through the project as efficiently as possible. Each Project Manager utilises their skills and experience to ensure they fully understand each client's individual programme milestones and needs, providing insight and trusted advice with transparency and flexibility to achieve shared goals.

Our service is tailored around clients' specific needs and we act as a trusted advisor to many of the Pharma and Biotech companies we partner with.

Supply Chain Management

Having a resilient and robust supply chain is critical to the effective management of any drug development program. Almac's Supply Chain Management team efficiently handles the entire manufacturing flow; from sourcing of critical raw materials, management of import and export permits in line with specific legislation and providing the finished product to our clients across a variety of shipping conditions, all of which are fully traceable.

Our expert team offers flexible solutions to balance risk and cost by utilising back-integration and dual sourcing models to mitigate unforeseen delays and ensure the security of supply. Our strategic sourcing solutions support global sourcing of materials with a highly qualified and high quality supply base.

Local, regional and global challenges have caused supply chains obstacles, particularly in the last few years, but our team is committed to delivering continuous improvement and clear communication.

Quality and Regulatory Assurance

Our Global Quality Unit comprises Quality Compliance, Quality Assurance, Quality Control & Quality Validation teams located at our global Sciences' sites. Chemistry, manufacturing and controls (CMC) is an integral part of the drug development cycle and the Almac teams act in both a compliance and supportive/advisory role to inspect and verify all processes and material / data generated to achieve the required regulatory standards.

We pride ourselves on meeting the highest standards of quality and safety. Our FDA, HPRA, ISO and MHRA certified facilities are routinely audited, and our quality accreditations demonstrate that we meet these standards, providing complete confidence to our clients. Our experienced, on-site teams ensure regulatory compliance by preparing and maintaining regulatory documentation, including CMC submission support for IND dossiers.

almacgroup.com

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