

An Overview of Almac

A Closer Look at Almac Group's Expertise

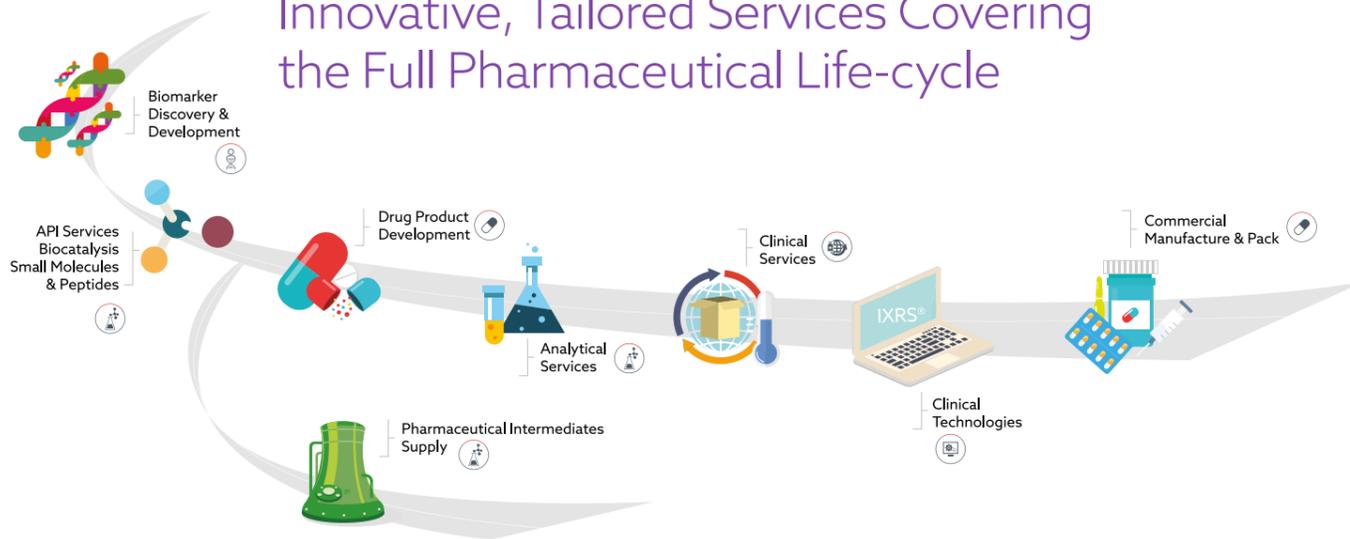


The Almac Group is an established contract development and manufacturing organisation that provides an extensive range of integrated services to the pharmaceutical and biotech sectors globally. The services range from R&D, biomarker discovery development and commercialisation, API manufacture, formulation development, clinical trial supply, IXRS® technology (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation that has organically grown over 50 years and now employs in excess of 5,000 highly skilled personnel. Almac is headquartered in Craigavon, Northern Ireland with additional operations in the UK, Ireland, across the US (Pennsylvania, North Carolina and California) and in Asia (Singapore and Tokyo).



Innovative, Tailored Services Covering the Full Pharmaceutical Life-cycle



Specialised Services



Leadership

Board of Directors



Alan Armstrong
Chairman & CEO



Kevin Stephens
Executive Director



Colin Hayburn
Executive Director



Stephen Campbell
Executive Director

Diagnostics

Tailored companion diagnostic solutions, utilising complex biology, to help differentiate your drug in the marketplace

Almac Diagnostics is a precision medicine company, focused on the discovery, development and commercialization of complex diagnostic tests.

The company, based in Craigavon, UK and Durham, USA has been in existence for over 15 years. We have a strong and stable leadership team who have worked together for over a decade and are extremely well networked within industry and academia.

Our diagnostic experience spans oncology, immunology, CNS and infective diseases.

In addition to supporting clients with their biomarker projects, Almac also has a portfolio of internally developed, novel biomarkers with predictive or prognostic utilities.

Our Range of Services:

- CDx Development & Commercialisation
- Clinical Trial Assay Development
- RUO Assay Development
- Clinical Testing
- Biomarker Discovery

Our Customised CDx Approach

We know that when it comes to the discovery, development & commercialisation of companion diagnostics for future precision medicines, no two pharmaceutical or biotech companies will ever have the same needs.

Our Customised CDx approach has been designed to offer you an intuitive partnership, with a range of flexible options and specialist supporting services tailored to your specific drug and companion diagnostic requirements.



Professor Paul Harkin
President & Managing Director,
Almac Diagnostics

Professor Paul Harkin is founder of Almac Diagnostics. As President and Managing Director, he has overall responsibility for the strategic, financial and operational leadership of the company.

Leadership & Events

- 10th Annual Next Generation DX Summit
Aug 20-24, 2018
Washington, DC
- 9th Clinical Biomarkers & World CDx Boston 2018
Oct 4-5, 2018
Boston, MA
- 5th Precision Medicine & Biomarkers Leader Summit: Europe
Sep13-14, 2018
Munich, Germany
- ESMO 2018 Congress
Oct 19-23, 2018
Munich, Germany



166+
Clinical Sites

Received samples from 166+ clinical sites globally in last 12 months



5,000+
Clinical Samples

Processed 5,000+ clinical trial samples in the same period



almacgroup.com

<https://www.linkedin.com/company/almac-diagnostics>



Sciences

API Services and Chemical Development: your molecule, our expertise

Almac Sciences is a provider of integrated services from development to commercial scale of advanced intermediates and Active Pharmaceutical Ingredients (API). We provide a range of services for small molecules (including highly potent) and peptides. We have a proven track record of saving time and costs through the integration of our services and application of innovative biocatalysis and technology solutions.

Complementing Almac Sciences' range of services is its Arran Chemical Company Business unit. Arran manufactures products for diverse industrial applications, featuring a range of alkylamines, pharmaceutical intermediates, flavour & fragrance and other specialties. The combination of our exclusive biocatalysis technology platform with our large scale manufacturing asset allows fast supply of advanced intermediates from kg to multi-tonne scale.

We have responded to our clients' needs of leading their molecules through clinical development faster, smarter and cost effectively, ensuring projects are completed to the highest quality, on time and in full.

- API Development & GMP Manufacture
- Small Molecules and Peptides
- Biocatalysis Solutions
- ¹⁴C Radiolabelling
- Analytical & Solid State Services



Pharma Services

Development to Commercialisation

Almac Pharma Services provide scalable drug product development to commercial manufacturing solutions, supporting all phases of clinical trials, through product launch and ongoing supply.

- Non-GMP and GMP pharmaceutical development
- Scalable development & manufacturing solutions
- Comprehensive analytical support
- High potent processing

Pharmaceutical Development

Addressing the increasing pressure to bring clinical candidates through the pipeline faster and with greater efficiency, we provide expert development solutions. From developing a fit-for-purpose formulation for First-in-Human trials, to developing a more robust formulation and scaling up for late phase trials and ultimately commercialisation.

Product Launch & Distribution

Having supported 15 orphan drug launches in the past 3 years, we pride ourselves on being the leader in understanding market requirements from product import analysis and country specific packaging to in-country distribution. Our expert product supply team ensure your launch dates are met and ongoing commercial supply is delivered on time in full.

Commercial Manufacture & Pack

Whether we are scaling up from our development services to full scale commercial supply or transferring existing commercial products, we can meet your commercial solid oral dose manufacturing requirements.

With UK and US commercial packaging operations, we provide customised quality driven packaging solutions supporting both high volume marketed products and orphan drug launches.

Leadership & Events



Dr. Stephen Barr
President & Managing Director,
Almac Sciences

Dr. Barr has been Managing Director and President of Almac Sciences since 2001, with full responsibility for all technical operations and strategic direction.

- **ChemOutsourcing 2018**
Sep 17-19, 2018
Long Branch, NJ
- **17th Annual Contract Pharma Conference**
Sep 27-28, 2018
New Brunswick, NJ
- **CPhI Worldwide 2018**
Oct 9-11, 2018
Madrid, Spain
- **2018 AAPS PHARMSCI 360**
Nov 5-7, 2018
Washington, DC



Graeme McBurney
President & Managing Director,
Almac Pharma Services

Graeme oversees the operations and long-term strategy for the Pharma Services' development and has over 20 years' experience in the manufacturing and distribution of pharmaceutical products.

Leadership & Events

- **2018 PDA Universe of Pre-Filled Syringes and Injection Devices**
Oct 8-9, 2018
Orlando, FL
- **17th Annual Contract Pharma Conference**
Sep 27-28, 2018
- **CPhI Worldwide 2018**
Oct 9-11, 2018
Madrid, Spain
- **2018 AAPS PHARMSCI 360**
Nov 5-7, 2018
Washington, DC

5,000+
Almac Group employees

5,400+
Client locations across the globe



almacgroup.com

<https://www.linkedin.com/company/almac-sciences-limited>

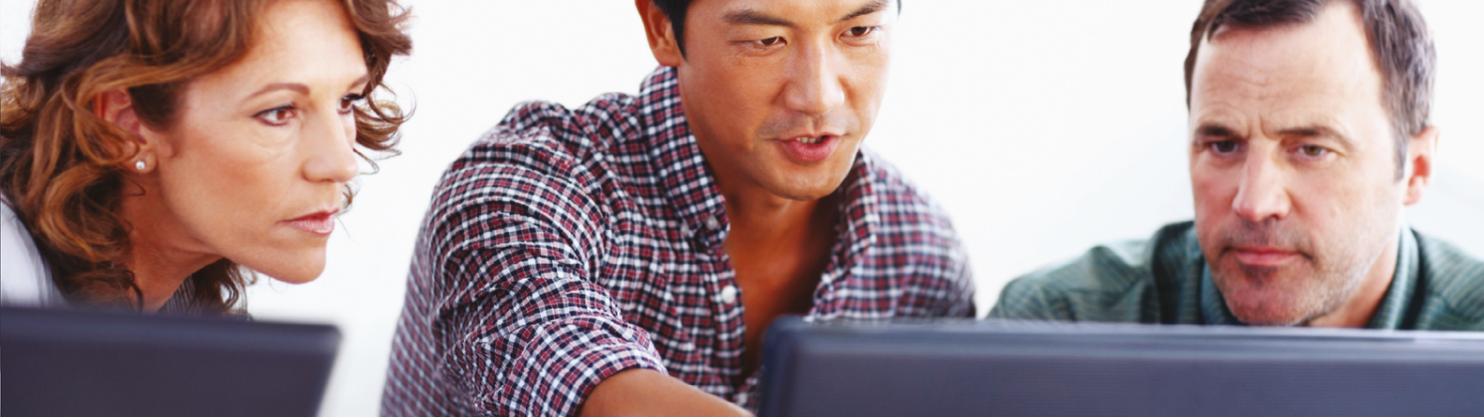
25/25
Worked with all 25 of the
top Biotechs

Phases I-IV
Experienced in phases one through four
of pharmaceutical development



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<https://www.linkedin.com/company/almac-pharma-services>



Clinical Services

Understanding and Delivering your Global Clinical Supply Chain

Almac provides the most comprehensive global clinical supply chain solution in the marketplace. Guided by our extensive clinical supply experience, we provide the physical resources and supportive technologies that ensure your clinical supply chain continually delivers across the globe. Clinical trial supply chains are becoming longer and more complex, while costs are rising and sponsors face additional challenges to reduce waste, cost and timelines. As trials become truly global, sponsors require partners that can provide the physical means of packaging and distributing their supplies, as well as providing the data to facilitate planning and enable decision-making.

- Commercial Drug Procurement
- Clinical Supply Chain Management
- Blinding of Clinical Trials
- Clinical Supply Packaging (Primary and Secondary)
- Clinical Storage & Distribution
- Next Generation Temperature Management

With over 25 years' experience, a history of innovation and a record of delivering 30,000 protocols for over 600 global clients, we have the experience to support you in your trial from beginning to end - with the ability to foresee any potential issues before they arise.



Clinical Technologies

Real-Time Control of the Most Critical Elements in Protocol Execution

Almac Clinical Technologies is here to help the biopharmaceutical industry bring new therapies to those in need by empowering trial sponsors to proactively manage sites, patients, and clinical supplies through our industry-leading technology and expert consultancy.

The solutions we offer facilitate more than simplifying patient and trial material management - they engineer quality into the clinical trial process. Our technology provides sponsors and CROs with the visibility and control needed to make data-driven decisions by leveraging advanced supply management functionality coupled with real-time site and patient data in a closed-loop environment.

We employ more than 500 professionals dedicated to delivering high-quality solutions and reliable customer service. For nearly two decades, our expertise, energy, and commitment have earned us a reputation as a trusted ally in the drug development process.

By the Numbers:

- 2,000 clinical trials performed with IXRS®
- Over 2 million patients supported
- Trials conducted in over 85 countries
- 65+ Language
- 10+ Rescue Studies

Mega-Trial Experience:

- 510 studies lasting 5+ years
- 115 studies lasting 4+ years
- 44 studies with over 500 sites
- 170 studies with 200 sites
- 55 studies with more than 5,000 patients
- 34 trials with 10,000+ patients

Leadership & Events



Dr. Robert Dunlop
President & Managing Director,
Almac Clinical Services

Dr. Dunlop is responsible for the strategic, financial and operational leadership of Almac Clinical Services in the UK, US and APAC and has over 25 years' experience in the pharmaceutical industry.

- **2018 ARCS Annual Conference**
Aug 21-23, 2018
Sydney, Australia
- **CRISP Fall Meeting 2018**
Oct 25, 2018
San Francisco, CA
- **GCSG 2018 European Knowledge Forum**
Oct 23-25, 2018
Barcelona, Spain
- **Clinical Trial Supply East Asia 2018**
Dec 5-6, 2018
Seoul, Korea



Valarie Higgins
President & Managing Director,
Almac Clinical Technologies

Valarie directs Clinical Technologies' long-term commercial and operational growth strategies and has over 20 years' experience in the biopharmaceutical development industry.

Leadership & Events

- **Clinical Innovation Partnership**
Sep 11-12, 2018
Zurich, Switzerland
- **Outsourcing in Clinical Trials New England 2018**
Nov 6-7, 2018
Boston, MA
- **8th Annual IRT 2018**
Oct 22-23, 2018
Philadelphia, PA



60+

Network of 60+ in-country depots for clinical supply



50%

Contributed to 50% of the FDA approved NMEs last year



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<https://www.linkedin.com/company/almac-clinical-services>



2,000,000+

Patients in 2,000,000+ clinical trials supported with Almac's IXRS™ Interactive Response Technology platform



20+

Years' experience offering technology support for clinical trials



almacgroup.com

<https://www.linkedin.com/company/almac-clinical-technologies>

Almac: A Global Presence



ALMAC GROUP
US HEADQUARTERS,
PENNSYLVANIA



ALMAC GROUP
GLOBAL HEADQUARTERS,
UNITED KINGDOM



ALMAC GROUP
ASIA PACIFIC HEADQUARTERS,
SINGAPORE



Countries we have provided services to in the last 50 years



Our 60+ depots



Our locations

Get in touch

US

Almac Group
(US Headquarters)
25 Fretz Road
Souderton, PA 18964
United States of America

+1 215 660 8500

UK

Almac House
(Global Headquarters)
20 Seagoe Industrial Estate
Craigavon BT63 5QD
United Kingdom

+44 28 3839 5815

EUROPE

Almac Group Ireland
Finnabair Industrial Estate
Dundalk
Co. Louth
Ireland

+44 28 3833 2200

SINGAPORE

Almac Pharmaceutical
Services Pte. Ltd.
9 Changi South Street 3
Unit 01-01 Singapore 486361

+44 28 3839 5815



twitter.com/AlmacGroup



www.linkedin.com/company/almac-group

For Media/Press or Public Affairs inquiries, please contact: media@almacgroup.com