

Outsourcing analytical services...because it's worth it



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Developing a drug is a costly and complex process where purity, safety and efficacy must be continually proven to meet strict regulatory requirements.

Before a drug can enter the trial phase, and more importantly a human, extensive analytical testing must be performed to ensure its safety and effectiveness. It is rare for a drug developer to have all the analytical capabilities to conduct the extensive testing required in-house and is often outsourced. Analytical outsourcing is not uncommon; the global pharmaceutical analytical testing outsourcing market is expected to increase to an estimated value of \$10.42 billion by 2026, attributed to constrained budgets and reduction of R&D expenses and manufacturing costs.¹

Choosing the right provider can be overwhelming, and the challenges of outsourcing are faced by a range of organisations, from first-time biotechnology companies to big pharma. However, irrespective of the nature of the sponsor, the principles remain the same and the rewards for building a successful relationship can be significant.

Almac's state-of-the-art analytical testing labs support drug substance (API) and drug product (finished product) across all phases of clinical development and into commercial release. Key advantages of working with us includes:

- **Experience:** a fully integrated CDMO brings a wealth of experience to drug development, particularly analytical solutions. Through our 20-year history in serving analytical clients, we have generated a great breadth and depth of knowledge through our exposure to a wide range of product types including small molecules, peptides, biologics, conjugates, highly potent and controlled substances. This puts us in a privileged position of utilising our experience across a variety of projects.
- **Regulatory compliance:** a successful CDMO continuously improves not only its technical knowledge and operational practices, but also its regulatory knowledge and adherence. Rigorous procedures need to be in place as well as a comprehensive infrastructure to ensure these principles are adhered to. Almac operates GMP/GLP environments across our facilities in the UK, Europe and US, and have an exemplary regulatory track record at these sites by the appropriate authorities including the FDA, MHRA, EMA, INAB, HPRA.
- **Trouble shooting and technical excellence:** an experienced CDMO anticipates and resolves many problems in advance, however, there will always be anomalies which must be solved rapidly to avoid adversely affecting the clinical programme. With a global team comprising >500 analytical staff across the Almac Group, our vast pool of scientific knowledge can help to overcome the analytical challenges that typically arise during drug development. Almac has a strong project management culture with communication encouraged between scientists on a technical level. There is also excellent communication across different analytical groups, enabling different techniques to be easily and quickly identified to solve any issues.

Almac has served its analytical clients for >20 years with a rich array of fully integrated services available across our global sites. Having invested >\$10M in our analytical services over the last 3 years, with further expansion plans underway, we have the capacity and capability to be your analytical partner of choice.

¹ <https://thedailychronicle.in/news/2443116/pharmaceutical-analytical-testing-outsourcing-market-sees-a-faster-rebound-in-the-era-of-covid-19-leading-players-pharmaceutical-product-development-llc-exova-charles-river-boston-ana/#:~:text=Pharmaceutical%20analytical%20testing%20outsourcing%20is%20the%20constitution%20of,methods%20required%20for%20the%20development%20of%20these%20drugs.>

ALMAC

Non-GMP starting materials / intermediates  **arran**
THE ARRAN CHEMICAL COMPANY
A Member of Almac Group

^{14}C radiolabelling

Biocatalysis and flow technology platforms

Dedicated solid state team

ALMAC

Analytical support

Chemical development

cGMP small molecule API

Non-GMP and cGMP solid phase peptide APIs

Almac Sciences: an integrated chemistry and **analytical services** provider

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

- Serving our analytical clients for >20 years across our UK, US and EU sites
- Superb track record of regulatory compliance
- Continual expansion and investment to meet our clients' requirements

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