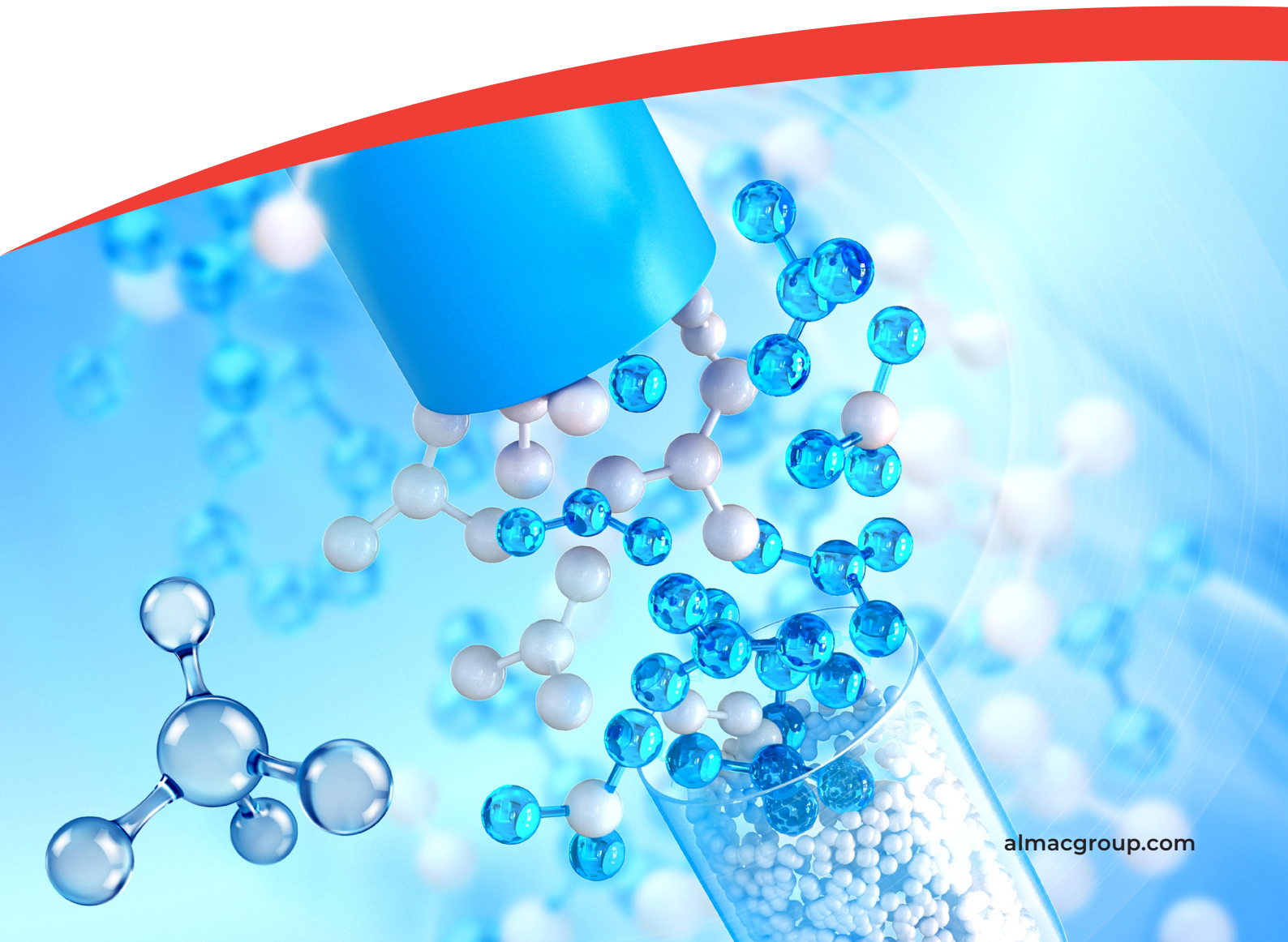
ALMAC

From complex chemistry to patient-ready medicines: The value of integrated drug substance & drug product expertise



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ALMAC
Partnering to Advance Human Health

Almac Voice

From complex chemistry to patient-ready medicines: The value of integrated drug substance & drug product expertise

Some molecules fit established development pathways. Others demand a deeper understanding of chemistry, formulation and analytical science to overcome challenges around bioavailability, manufacturability and performance. In these programmes, collaboration across drug substance and drug product disciplines becomes a critical advantage and can make a meaningful difference.

Almac brings together deep experience in API development and manufacture, alongside extensive drug product development, manufacture, packaging and clinical supply capabilities. Together, this creates a connected approach designed to support programmes from early development through to commercial supply, helping clients reduce complexity, improve decision-making and maintain momentum.

Strength in RSMs, intermediates & API development

A robust API strategy begins before the final drug substance. Reliable access to regulatory starting materials, advanced intermediates and well-understood synthetic routes can have a significant impact on programme resilience, scalability and cost.

The ability to develop and manufacture registered starting materials (RSMs) and intermediates within an integrated scientific environment provides important advantages. It supports improved supply chain control, reduces dependency on fragmented external networks and enables greater visibility of quality-critical parameters earlier in development.

Integration that starts earlier

Drug substance and drug product development are often managed as separate workstreams. However, decisions made at the API stage can have a direct impact on formulation performance, manufacturability, stability, analytical methods and ultimately patient usability.

By bringing these disciplines closer together, Almac helps clients consider the downstream implications of upstream decisions from the outset. This is particularly important for challenging molecules where solubility, stability, polymorphism, particle size, impurity profile or process robustness may influence the final dosage form.

An integrated model enables scientific teams to assess how the properties of the drug substance affect the drug product, and vice versa. This can support better control strategies, more efficient development planning and fewer late-stage surprises.

Rather than viewing API development, formulation and clinical supply as separate milestones, an integrated approach treats them as connected elements of

one programme. For clients, this means clearer communication, stronger technical alignment and a more efficient path from molecule to medicine.

Addressing bioavailability challenges

Bioavailability remains one of the most common and important challenges in drug development. Many promising compounds present difficulties related to poor solubility, permeability, stability or manufacturability. If these challenges are not addressed early, they can lead to delays, reformulation, increased cost and clinical risk.

Almac's integrated expertise supports a more proactive approach to bioavailability enhancement. By combining drug substance knowledge with formulation and analytical capability, teams can evaluate key material attributes and formulation options in parallel.

For clients, this integration can be especially valuable when developing complex or poorly soluble molecules. It allows potential issues to be identified earlier, technical options to be assessed more efficiently and development strategies to be adapted with greater confidence.

Analytical insight across the development pathway

Analytical science sits at the centre of successful integration. It provides the evidence required to understand a molecule, control a process, demonstrate quality and support regulatory progression.

Almac's analytical expertise spans drug substance and drug product development, enabling a joined-up understanding of critical quality attributes from raw materials through to finished product. This includes method development, validation, stability testing, impurity identification, solid-state characterisation and release testing.

For integrated programmes, a connected analytical strategy helps avoid duplication, reduces the risk of method transfer issues and ensures that data generated at each stage supports the next.

This is especially relevant for complex molecules, difficult-to-analyse compounds or products requiring specialised analytical techniques. By applying analytical insight across both drug substance and drug product workstreams, Almac helps clients build a clearer picture of product performance, process control and long-term developability.

A connected path from API to finished product

Once a suitable API route and control strategy are established, the next challenge is translating that material into a finished product that can be manufactured, packaged, supplied and administered effectively.

Almac provides drug product development and manufacturing capabilities, including formulation development, clinical trial material manufacture, packaging, labelling and supply chain solutions. When combined with our API expertise, clients benefit from a more seamless transition between drug substance and drug product activities.

This integrated approach can help address practical questions earlier. Is the API suitable for the intended formulation? Are there stability or compatibility concerns? Do particle attributes need tighter control? Are analytical methods suitable for both API and finished product release? Can development batches be aligned with clinical supply timelines?

By considering these questions across disciplines, Almac helps clients reduce

handover risk and improve programme efficiency.

Serious science, delivered practically

Almac's approach reflects a simple principle: difficult science requires joined-up thinking. While every development programme is different, complex molecules often demand more than standard solutions. They require experience, technical judgement and the ability to bring the right expertise together at the right time.

In the context of integrated drug substance and drug product development, it is not about complexity for its own sake. It is about applying scientific depth, practical experience and disciplined execution to help clients overcome barriers that could otherwise slow or compromise development.

Combined with Almac Pharma Services, this creates a broader service platform that can support clients across API development, RSM and intermediate supply, drug product development, clinical supply and commercialisation.

Reducing complexity for clients

Pharmaceutical development will always involve uncertainty. However, the way programmes are structured can either increase or reduce that uncertainty.

An integrated partner can help simplify the development journey by improving communication, aligning scientific decisions and reducing the number of interfaces a client must manage. This does not remove the need for specialist expertise. Instead, it ensures that specialist expertise is connected, coordinated and focused on the same end goal.

For clients developing challenging molecules, this can mean faster issue resolution, better-informed decisions and a clearer path through development. It can also support stronger regulatory narratives, as data and rationale are generated through a more cohesive scientific strategy.

From molecule to medicine

Bringing a new medicine to patients requires more than technical capability. It requires collaboration, foresight and a practical understanding of how decisions made early in development shape outcomes later.

Through the combined strengths of Almac's drug substance and drug product teams, we offer clients an integrated pathway from complex drug substance development through to finished drug product supply. With expertise spanning RSMs, intermediates, APIs, formulation, analytical testing, manufacturing and clinical supply, Almac is well positioned to support programmes where scientific challenge, speed and quality all matter.

For organisations seeking to progress complex molecules with confidence, this integrated approach offers a clear advantage: one connected partner, combining serious scientific depth with the practical capability to move promising compounds closer to patients.

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