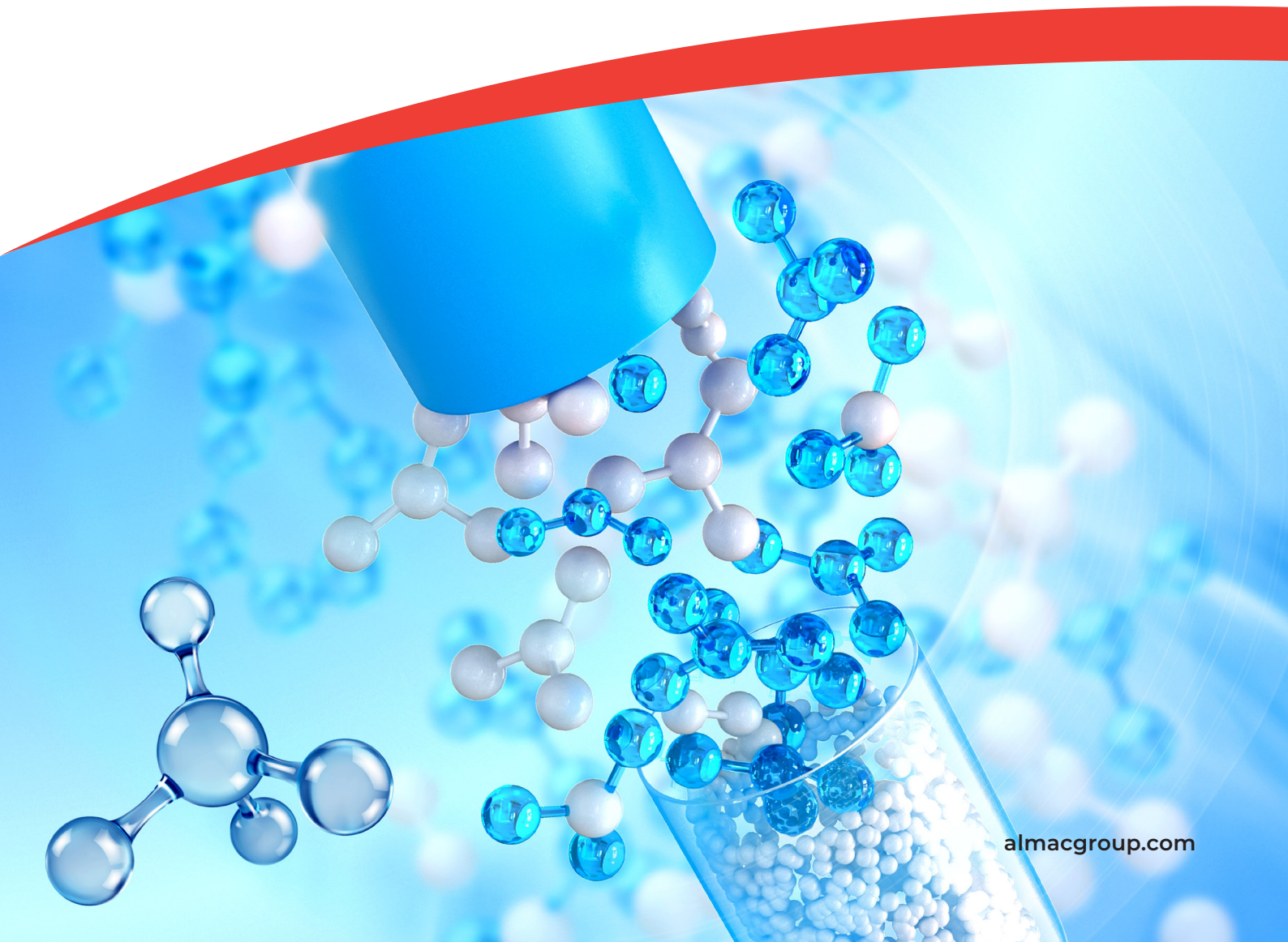
ALMAC

Simplifying CMC: The value of an integrated drug substance and drug product strategy



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Partnering to Advance Human Health

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Simplifying CMC: The value of an integrated drug substance and drug product strategy

Bringing a new therapy from concept to clinic has never been more complex. Developers are under increasing pressure to accelerate timelines, manage technical risk, and generate robust data to support regulatory submissions, all while navigating evolving molecular modalities and increasingly demanding supply chain requirements.

In this environment, Chemistry, Manufacturing and Controls (CMC) is no longer viewed as a series of standalone activities. Instead, successful programmes increasingly depend on integrated strategies that align drug substance and drug product development from the earliest stages.

For many organisations, this shift reflects a simple reality: decisions made during API development can have significant implications for formulation performance, manufacturability, scalability, regulatory strategy, and ultimately, speed to patient.

Why Integration Matters

Historically, drug substance and drug product development have often been managed through separate workstreams, frequently involving multiple vendors and handovers between organisations. While this approach can be effective, it can also introduce communication challenges, duplicate activities, and delays when issues arise.

An integrated CMC model helps remove these barriers by bringing scientific expertise together across the development lifecycle. By connecting process chemistry, analytical development, physical sciences, formulation development, manufacturing, and regulatory support, teams can identify risks earlier and make more informed decisions.

The result is a more coordinated pathway from preclinical development through clinical supply and commercialisation.

This approach becomes increasingly important as molecules become more complex. Emerging APIs often present challenges related to solubility, polymorphism, stability, impurity control, process robustness, and manufacturability. Addressing these issues effectively typically requires collaboration across disciplines rather than sequential problem-solving.

Connecting Drug Substance and Drug Product Development

One of the key advantages of an integrated CMC strategy is the ability to link drug substance attributes with downstream formulation and manufacturing requirements.

Factors such as particle size distribution, solid-state form, residual solvents, impurity profiles, and process parameters can all influence formulation performance and product quality. When teams work collaboratively from the outset, these critical characteristics can be assessed holistically rather than in isolation.

Physical sciences expertise is often central to this process. Detailed solid-form screening and material characterisation provide a deeper understanding of API behaviour, helping inform formulation selection and manufacturing strategies. Analytical scientists also play an important role, ensuring robust methods are established early and evolve alongside process and product development activities.

Together, these capabilities help generate the insights required to reduce development risk and avoid costly surprises later in the programme.

Accelerating Development Through Scientific Alignment

Beyond the technical benefits, integration can deliver significant operational advantages.

When drug substance and drug product teams work within a unified strategy, communication becomes more efficient, knowledge transfer is simplified, and scientific findings can be shared more rapidly. This can reduce delays associated with multiple handovers while supporting faster, more informed decision-making.

For biotechnology companies and emerging innovators with limited internal CMC resources, access to multidisciplinary expertise can be particularly valuable. Support spanning route scouting, process optimisation, analytical development, formulation, clinical manufacturing, and regulatory activities can help streamline programme execution while maintaining scientific rigour.

Importantly, integration is not about applying a standardised template to every project. Every molecule presents unique scientific and development challenges. The most effective CMC strategies are tailored to the specific characteristics of the compound, development objectives, and commercial requirements of the programme.

Building on Expanded Scientific Capabilities
The evolution of integrated CMC services is also being shaped by broader industry trends focused on bringing complementary expertise together to create more seamless development pathways.

Within Almac, this approach is reflected in the continued alignment of scientific and manufacturing capabilities across the organisation. The transition of Arran Chemical Company to Almac Sciences forms part of a wider strategy designed to strengthen connectivity between drug substance and drug product activities, expanding access to expertise, technologies, and manufacturing capabilities through a more integrated development model.

While organisational changes are rarely a primary concern for developers, the practical outcome is highly relevant: fewer internal barriers, greater scientific alignment, and improved continuity throughout the development journey.

Solving Complex CMC Challenges

As therapeutic innovation advances, developers increasingly require partners capable of addressing complex scientific and technical challenges across the CMC lifecycle. Whether overcoming synthetic chemistry obstacles, optimising solid-state properties, mitigating formulation risks, scaling manufacturing processes, or developing robust analytical methods, success depends on bringing the right expertise together at the right stage of development.z

The most effective partnerships are built around collaboration and scientific problem-

solving, with development strategies tailored to the specific needs of each molecule rather than following a standardised approach. By combining deep technical expertise with a practical understanding of development realities, teams can address challenges proactively and maintain progress towards key clinical and commercial milestones.

Looking Ahead

The future of CMC development will increasingly depend on connectivity, both between scientific disciplines and across development stages. As molecules become more sophisticated and timelines remain compressed, developers must find ways to reduce complexity while maintaining quality, efficiency, and regulatory compliance.

Integrated drug substance and drug product development offers a proven route to achieving these goals. By aligning expertise across the CMC continuum, organisations can improve communication, reduce risk, and make more informed development decisions, ultimately advancing human health.

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