LIFECYCLE BRIEF

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Preclinical

Proactively anticipating challenges to enhance project success

Preclinical development typically takes **between three and six years.**[1]

An integrated and efficient approach to preclinical development is critical to position an API for long-term success. Comprehensive planning, process development and data generation are all necessary for developing a safe and effective product that is prepared to enter clinical trials.

As the preclinical phase is among the most important in the product lifecycle, it is also among the most challenging. The research and planning necessary to prepare a candidate for clinical trials, especially with the complexity of drug products today, requires significant time, expertise and financial resources. Your outsourced partner can make or break your ability to address scientific hurdles in a timely fashion, adhere to product budgets and timelines, and position your product for long-term success.

Below are some key areas that can present challenges for pharmaceutical and biotechnology organisations during the preclinical phase.

Project continuity

Around 50% of organisations outsource at least part of preclinical research and development to contract research organisations (CROs),[2] as outsourcing can help them to streamline their projects and access necessary expertise. Outsourcing to organisations who lack full-lifecycle capabilities, however, can impede continuity and extend project timelines. **It is critical, therefore, to keep project continuity in mind from the earliest stages, selecting a partner that can ensure seamless scale-up.**

Hazard evaluation

In early phase development, comprehensive hazard evaluation is critical. To anticipate hazards and mitigate risk, organisations must consider the potential for heat release, explosion and ignition, as well as identify ways to minimise hazardous materials and processes. Effectively overcoming such challenges requires an integrated approach and specialised expertise. **To ensure hazards are appropriately handled from day one, identify an outsourced partner that is known for its hazardous chemistry expertise.**

Data generation and analysis

Applications for investigational drug products require robust supporting evidence to ensure that the product is safe to enter human trials, provide critical manufacturing details and offer clinical protocols.[3] This calls for comprehensive research and analysis, which can be costly and time-consuming. **A partner with significant regulatory expertise, one that has successfully supported data requirements for many drug candidates, can streamline this complex process**.

Regulatory nuances

Regulatory success requires proactive, early phase planning and a CMC (Chemistry, Manufacturing and Controls) strategy that will stand up to scrutiny. In a highly regulated industry, it proves challenging to satisfy regulatory requirements while maintaining an efficient path to market. **Look for a partner that understands the importance of efficiency, cost control and scientific rigour; one that is adept at balancing these variables throughout a molecule's journey to market.**

At Sterling, we have the specialised teams, state-of-the-art facilities and equipment, and extensive expertise to support our customers' molecules through every stage of their journey to market, from early phase development through to full commercial manufacturing. In addition, we provide comprehensive discovery and preclinical support for our customers' ADC projects.

Here's how we support our customers through preclinical development:

Full-lifecycle capabilities

In a project's earliest stages, we offer a range of research and development capabilities to set our customers up for success. In addition, as a full-service partner, we deliver the robust capabilities and expertise needed to support projects at every stage while ensuring critical continuity and accelerating path to market. Our full-lifecycle perspective enables us to anticipate and prepare for later stage challenges from day one.

Integrated hazard evaluation approach

With a track record of more than 50 years safely handling hazardous processes, we perform extensive hazard evaluation work at the onset of every project. Our comprehensive and collaborative approach to hazard evaluation enables us to proactively overcome risks and ensure ongoing safety. This work is not isolated to a project's early phases, though. We consistently reassess and adjust processes to mitigate risk at every stage.

Analytical expertise

Our team of skilled analysts and state-of-the-art equipment enables us to perform comprehensive analytical chemistry work on behalf of our customers. By pairing our analytical expertise with regulatory knowledge, we deliver the data our customers require to affirm the safety, quality and efficacy of their products as they prepare to enter clinical trials. We also offer specialised analytical services for ADC discovery and development, supported by the expert analytical team at our dedicated bioconjugation facility.

CMC support

In addition to conducting comprehensive analyses and gathering critical supporting data, we offer CMC guidance to help our customers pursue and receive regulatory approval. For more than 50 years, we have supported customers around the world through successful regulatory submissions. By offering CMC advice and shaping a strategy tailored to each programme's requirements, we support customers in finding an optimal balance between speed, cost and regulatory success.

Delivering early phase expertise to maximise full-lifecycle success

At Sterling, we deliver research and development, and regulatory expertise to support our customers from the earliest stages of their projects. But that's not all. As a PDMO®, or partnership development and manufacturing organisation, we offer the capabilities and collaboration needed to serve as true scientific partners to our customers throughout the entire lifecycle of their products, from grams to tonnes.

Service

We pride ourselves on being easy to do business with, removing layers of complexity, maximising flexibility and adaptability to your requirements, and doing what we say we will do, again and again.

Passion

We promise to treat your molecule as our own, drive progress by continually exploring new and emerging capabilities, and do the right thing for people and planet.

Science

We combine our expertise in complex and hazardous chemistry, our world-class facilities and our full-lifecycle capabilities to place scientific excellence at the core of every solution we deliver.

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1. Biopharmaceutical Research & Development: The Process Behind New Medicines, 2015. Pharmaceutical Research and Manufacturers of America. http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf (accessed May 20, 2021).
2. Pharmaceutical Development: The Safety Hurdle Prior to Human Trials. American Pharmaceutical Review, April 30, 2016. Retrieved from https://www.americanpharmaceuticalreview.com/Featured-Articles/187349-Preclinical-Development-The-Safety-Hurdle-Prior-to-Human-Trials/
3. US Food & Drug Administration. Investigational New Drug Application. https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application (accessed May 13, 2021).