Making sense of

early phase research and development

The pharmaceutical industry's spending on R&D has increased tenfold in the past 40 years.[1]

Streamlining processes and balancing considerations with an experienced partner.

Early phase research and development (R&D) is a critical component of any API development project. However, the process can quickly become costly and time consuming, and it is important to strike the right balance while obtaining high-quality data and results. **An experienced outsourced partner will carefully consider budget, time constraints and data requirements to streamline early phase R&D and set your project up for long-term success.**

The challenges of early phase R&D and the importance of balance.

As the pharmaceutical industry continuously evolves, organisations increasingly aim to ensure that their API is ready for scale-up early in the development process. This typically requires robust process understanding, analytical method validation, and comprehensive supporting documentation that adheres to regulatory requirements from the start, as well as additional solid state investigations to identify the target solid form. However, costs can quickly add up, and with only 1 in 5,000 products that enter preclinical testing ultimately making it to market,[2] organisations want to avoid unnecessary spending early in their projects when approval is so uncertain. Finding an appropriate balance between necessary work and costs is therefore a challenge.

How can the right partner elevate early phase R&D?

With many considerations to juggle during a project's early stages, working with an outsourced partner can provide significant advantages. An experienced and collaborative partner can help to ensure that an API is prepared for scale-up during the early phases of a project, while carefully accounting for cost and time requirements. **Here are some of the key benefits the right partner can bring to early phase R&D.**

Collaboration

Collaboration is crucial during early phase R&D for fully understanding project requirements and strategically planning. An outsourced partner should not only maintain consistent communication with the customer, but also regularly collaborate across internal teams to share project information, proactively solve problems, develop process understanding and address the customer's requirements across different areas.

Integrated service offering

The most successful early phase projects account for considerations that may arise later on. **A partner with expertise across the whole lifecycle will help to identify what data and documentation are necessary in the early stages, and what work can be reserved until later phases in the project, in order to contain costs.** In addition, they will offer expertise in new technologies that have the potential to meet the requirements of their project.

Regulatory expertise

A partner who has extensive experience working with customers around the world will possess a strong understanding of regulatory requirements in different regions. By coupling R&D expertise with strong regulatory knowledge, the right partner will compile all necessary documentation and ensure that initial data is placed in a report-ready format in preparation for scale-up.

Solid state capabilities

Solid state chemistry has become increasingly important in a project's early phases, as customers aim to advance the ideal version of their API with the desired characteristics. **The right partner will have a dedicated solid state team to help customers select the optimal target solid form and ensure its suitability for manufacture and commercialisation.** Every molecule is different, so customer and data led chemistry is key to developing a future proof candidate.

Did you know?

On average, pharmaceutical organisations spend **25% of their revenue** on R&D.[3]

Comprehensive capabilities for early phase R&D

At Sterling, we closely collaborate with customers to help them find the right balance between costs, time and documentation requirements for their early phase projects. With full-lifecycle expertise, extensive regulatory experience, robust solid state capabilities, a team of enthusiastic scientists and support for specialised technologies like biocatalysis and flow chemistry, we help our customers to meet all early phase requirements while preparing their project for scale-up and proactively considering long-term project implications. By developing strong relationships with our customers, we serve as true scientific partners in order to maximise value.

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 our 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.

Are you ready to set your early phase project up for success?
Visit www.sterlingpharmasolutions.com to learn more.

1. Research and Development in the Pharmaceutical Industry. 2021. Congressional Budget Office. https://www.cbo.gov/publication/57126 (accessed June 29, 2022).
2. Griffiths, B. Speed, Quality and Cost - Leveraging Australia to Expedite Clinical Development. 2019. Pharmaceutical Outsourcing. https://www.pharmoutsourcing.com/Featured-Articles/361330-Speed-Quality-and-Cost-Leveraging-Australia-to-Expedite-Clinical-Development/ (accessed June 29, 2022).
3. What Are the Average Research and Development Costs for Pharmaceutical Companies?, 2022. Investopedia. https://www.investopedia.com/ask/answers/060115/how-much-drug-companys-spending-allocated-research-and-development-average.asp (accessed June 29, 2022).