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Top 10 considerations

for early phase discovery and development.

Early phase API discovery and development is exceedingly challenging, requiring careful consideration of many complex variables, some of which will only come into play in latter stages of the pharmaceutical lifecycle. As new therapeutics continue to rise in complexity, more pharmaceutical and biotechnology organisations are outsourcing early phase projects than ever before. **In fact, large pharmaceutical organisations outsource 45% of their research and development activities to CROs and CDMOs, while that number can reach up to 100% for smaller organisations.[1]**

To streamline early phase discovery and development and set their projects up for long-term success, organisations must carefully select an outsourcing partner with extensive early phase expertise. Discover how the right partner can help you address ten key challenges organisations face during their projects' early stages.

1

Project continuity

As outsourcing continues to gain prevalence, many organisations transition projects between partners for different aspects of the work required, from research, to preclinical development, through to commercial manufacture. **By engaging a partner who has extensive expertise spanning the lifecycle of the molecule, organisations can benefit from continuity throughout their projects, mitigating the added costs and delays that come with an excess of external project transfers.**

On average, external tech transfers take **5.8 months more** than internal transfers.[2]

2

Full-lifecycle perspective

Even in a project's earliest stages, it is important to design processes that are safe, scalable, and repeatable to avoid unanticipated challenges in the long run. **Beyond ensuring continuity, a partner who offers end-to-end capabilities will look at early stage development in the context of the entire molecule lifecycle.** In turn, they will proactively anticipate and avoid pitfalls that could surface as the project scales.

Nearly 40% of pharmaceutical and biotechnology organisations prefer a full-service outsourced partner. [3]

3

Funding guidance

Securing the necessary funding can present a major hurdle during the early stages of a project, particularly for emerging biotechnology organisations who may have only one molecule in the pipeline. **A partner with deep knowledge of the global funding landscape and credibility among investors can enhance an organisation's chances of securing the funding it requires, and optimise allocation of funds once they are obtained.**

The average cost of developing a new therapeutic is nearly **$4 billion.**[4]

4

Timeliness

Timeliness is critical throughout the entire lifecycle of a project, but especially so as an organisation works to get their product to clinical trials. **An outsourced partner should have a strong track record of timely delivery, taking care to adhere to the customer's desired timeline while balancing costs.** A partner should assist in developing a fit-for-purpose approach that ensures all of the necessary steps are taken early on while prioritising speed.

By optimising preclinical development, pharmaceutical organisations have the potential to get products to clinical trials **40% faster.**[5]

5

Analytical chemistry

Early phase projects are characterised by extensive research and development work, particularly as regulatory agencies require detailed data around the product's physical properties, safety and efficacy. **A partner should have specialised equipment to perform the full range of analytical testing as well as a team of skilled analysts committed to understanding the customer's specific priorities.** The right partner will develop a tailored analytical approach that adheres to budget and time constraints while affirming quality and strengthening the molecule's chance of success.

87% of biopharmaceutical organisations outsource parts of analytical testing.[6]

6

Solid state expertise

Selecting a product's target solid form is a critical part of early phase development. **The right outsourced partner will possess extensive solid state expertise, conducting a variety of investigations to help identify and develop a molecule's optimal solid form with the desired properties.** Its solid state capabilities should be supported by state-of-the-art equipment and an expert team of material scientists.

Up to 90% of drugs in the pipeline display poor solubility.[7]

7

Hazard evaluation

Early phase hazard evaluation is important to ensure ongoing safety as a project progresses. **A partner should take care to eliminate or mitigate hazardous processes or materials, assessing the potential for explosion, ignition and heat release that could pose safety concerns now or in the later stages of the project.** In addition, it is critical that a partner protects employees by evaluating the occupational exposure limit (OEL) of hazardous materials. Choosing a partner with proven expertise in hazard evaluation will ensure safety is prioritised when designing processes.

50% of pharmaceutical organisations are very or extremely likely to outsource safety analysis.[8]

8

IND application

As organisations prepare to begin clinical trials, they must file an Investigational New Drug (IND) application or similar. This requires appropriate information and data around preclinical studies, the product's structure and properties, manufacturing information and more.[9] **By combining its chemistry, regulatory and analytical expertise, the right partner will help to compile supporting evidence and ensure that the full range of IND requirements are satisfied.**

43% of pharmaceutical organisations are likely to outsource regulatory consulting.[8]

9

Emerging technologies

As molecule complexity continues to rise, organisations are increasingly seeking to apply innovative technologies like biocatalysis, continuous manufacturing, high potency APIs, controlled substances and more in their projects. **It is important to identify these technologies early on, and to select a partner with the specialised expertise and equipment needed to deliver such capabilities with a high degree of quality and competence.**

Over 50% of professionals cite capabilities in innovative technologies as a key attribute in an outsourced partner.[10]

10

Collaboration and transparency

When engaging an outsourced partner for early phase development, it is important that they have a strong track record of transparency and partnership. Consistent communication is key to understanding the customer's expectations, developing tailored processes and maximising the project's chance of success. **An outsourced partner should maintain close alignment with customers at all times, working closely with them to adhere to budget and time constraints while treating the customer's molecule as its own.**

59% of pharmaceutical organisations have worked with the same outsourced partner for 5 years or more.[11]

Early phase expertise to maximise long-term success

Navigating the complexities of the molecule lifecycle's early phases while carefully balancing speed, cost and quality requires an experienced and collaborative partner. **As a full service PDMO, or partnership development and manufacturing organisation, we at Sterling have a strong track record of setting early phase projects up for long-term success.** With robust capabilities in analytical chemistry, material science, hazard evaluation, regulatory support, funding guidance and much more, we work closely with our customers to overcome their most pressing early phase challenges as they progress their molecule's journey to market.

Are you ready to set
your project up for
full lifecycle success?

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