7 Golden rules of drug development for emerging pharma

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One. Create a business plan

As of 2021, there are currently around 10,223 drug products in development[1] – many of which have a low chance of reaching commercialisation. All development risks must be understood and mitigated as much as possible to increase the likelihood of success. This is especially true if you are an emerging pharma business – the stakes are higher for smaller businesses as they have limited extra capital to mitigate against the impact of project delays.

Even if you plan to out-license the project after proof of concept, you need to have a regulatory strategy and a plan for late-stage development already in place. This is because if it is too costly and time-consuming to perform the final development and to register a product, or to scale up efficiently, it will not be possible to sell the project.

Key things that you need to think about when creating any business plan include:

- What are the intended properties of your product? This should be summarised in a **Target Product Profile (TPP**)
- What does the market look like, and how much of your product do you think you can sell?
- Are there any competitive products and what are they?
- How much will the development project cost and how will you finance it?
- How long will the development take and what clinical trials do you need to perform?
- How will you register the product?

1. https://www.statista.com/statistics/791288/r-and-d-pipeline-drugs-worldwide-by-phase-development/

Two. Remember that drug development requires teamwork

Drug development is extremely complex – not only does development require detailed expert knowledge, but many project activities are interdependent too. Clinical trials can't begin without the drug product being ready, and drug products can't be developed without a supply of the drug substance. Coordination is needed to meet timelines.

When planning any new project, it is important to remember to:

- Have the experts you need already in place. It is often difficult for an emerging pharma business to have the needed expertise in-house. Engaging an external partner, however, can complement internal competences to ensure there is full support for the project from the beginning
- Make sure everyone – including external partners – understands the goals of the project
- Have the processes and communications channels in place to ensure everyone can work as a team

Three. Keep time and cost down

It is important to ensure that no time or expense is wasted unnecessarily. Trying to keep plans simple can help, especially in early phases, as introducing complexity into the process lengthens timeframes and increases the risk of delays or errors. At the same time, though, too much simplicity may result in saving time and money on the wrong things, which can create problems downstream that need to be addressed.

To strike the right balance between simplicity and complexity, it's important to remember to:

- Try and ensure your early-phase project plan can provide a solid foundation for late-stage development before you embark on development
- Work with expert partners from the beginning to achieve the above and to select the right package for safety studies, chemical process development and other aspects of the development process

Four. Ensure the right quality and quantity of drug substance

Clearly the drug substance is vital to any drug development project, but it is not only about identifying the right molecule. It is of fundamental importance to secure the right amount of drug substance of adequate quality. This is a very different process from manufacturing gram amounts in a drug discovery laboratory.

Things to consider to achieve this goal include:

- Allow enough time for **route scouting.** Larger process changes may lead to new impurities, which can affect the relevance of any safety studies, so it's important to use a process that is suitable for large-scale manufacture
- Characterise your drug substance carefully. You want to be sure of what you are using
- Plan how much drug substance will be needed. This will vary from project to project, depending on dose size and other factors. Having to manufacture additional batches of drug substance is costly and likely to cause significant delays

Five. Understand that a medicine is more than a drug substance

Even though the drug substance is of paramount importance, it is not the only part of the drug product to have an impact on therapeutic effect. The drug formulation and the chosen dosage form play a vital role too.

Placing strong emphasis on the final drug product from the beginning is key. Drug delivery can, in many cases, significantly improve the performance of a drug substance, so it is crucial to consider the delivery mechanism from the beginning of active pharmaceutical ingredient (API) development.

To ensure project success, it's important to keep the following in mind:

- Use simple drug formulations in early-phase development. This allows a faster, more streamlined path to obtaining data via human trials. A more advanced formulation can be introduced in phase II
- Use established processes and excipients whenever possible, as this will reduce the cost of goods, as well as development time
- Time can also be saved by starting formulation development with small quantities of **non-GMP (Good Manufacturing Practice)** material. The impurity profile and physical characteristics may differ between batches at this stage, but this material can still contribute valuable information that can benefit the project in the long run
- Do not forget about placebos and blinding. This may appear obvious and straightforward, but in many cases, it can be challenging to provide matching test products
- Plan well ahead – GMP manufacture is time consuming, so it's important to have the materials and infrastructure already in place before it is needed

Six. Execute

It is impossible to plan for every eventuality that may occur during a development project. It is important to have the flexibility to adjust your plan when necessary.

There are a few key factors that are essential to ensuring you have the flexibility you need. These include:

- Have a proficient and experienced project manager in place from the beginning to run and direct the development. This person will be responsible for controlling the entire project team – both in-house and external partners – so it's important to have the right person in the position
- Schedule in enough time for each activity within the development project, particularly for clinical trials to provide a buffer, should you experience delays. Anticipate at least one year for the development and manufacture of drug product for trial, and a further 12 months for the manufacture of GMP API

Seven. Collaborate with a CDMO

Engaging with an expert CDMO partner can go a long way towards maximising the chance of success, by mitigating risk and supporting with all the work that is outlined above.

An experienced CDMO will have expertise in the most fundamental parts of any drug development project: the drug substance and the drug product. This can further streamline processes helping you deliver your project as quickly as possible.

Contact the CDMO early and use its experience in planning the project. Collaboration from the very beginning is essential for project success.

Want to find out more about how Recipharm can help you successfully bring your innovation to trial/commercialisation? Contact us today.

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