Symeres

Making Molecules Matter. Together.

DRUG DISCOVERY, DRUG DEVELOPMENT, ADME-TOX, SOLID STATE

IND/IMPD Enabling Developability Roadmap

PAUL O'SHEA

Drug discovery and development is a complex and iterative process that involves the identification, design, development, testing, and approval of new pharmaceutical drugs for use in patients. It encompasses a series of scientific, regulatory, and commercial activities aimed at discovering and bringing safe and effective medicines to the market. A key milestone in this process is candidate selection when a decision is taken to invest in a single molecule and transition the program from discovery into development. This transition prompts a number of activities to facilitate drug development, one of which is an assessment of potential sources of issues or delays in subsequent development. At Symeres, we designed our proprietary Developability Roadmap package to provide you with the information you need to enter development with a clear plan of action.

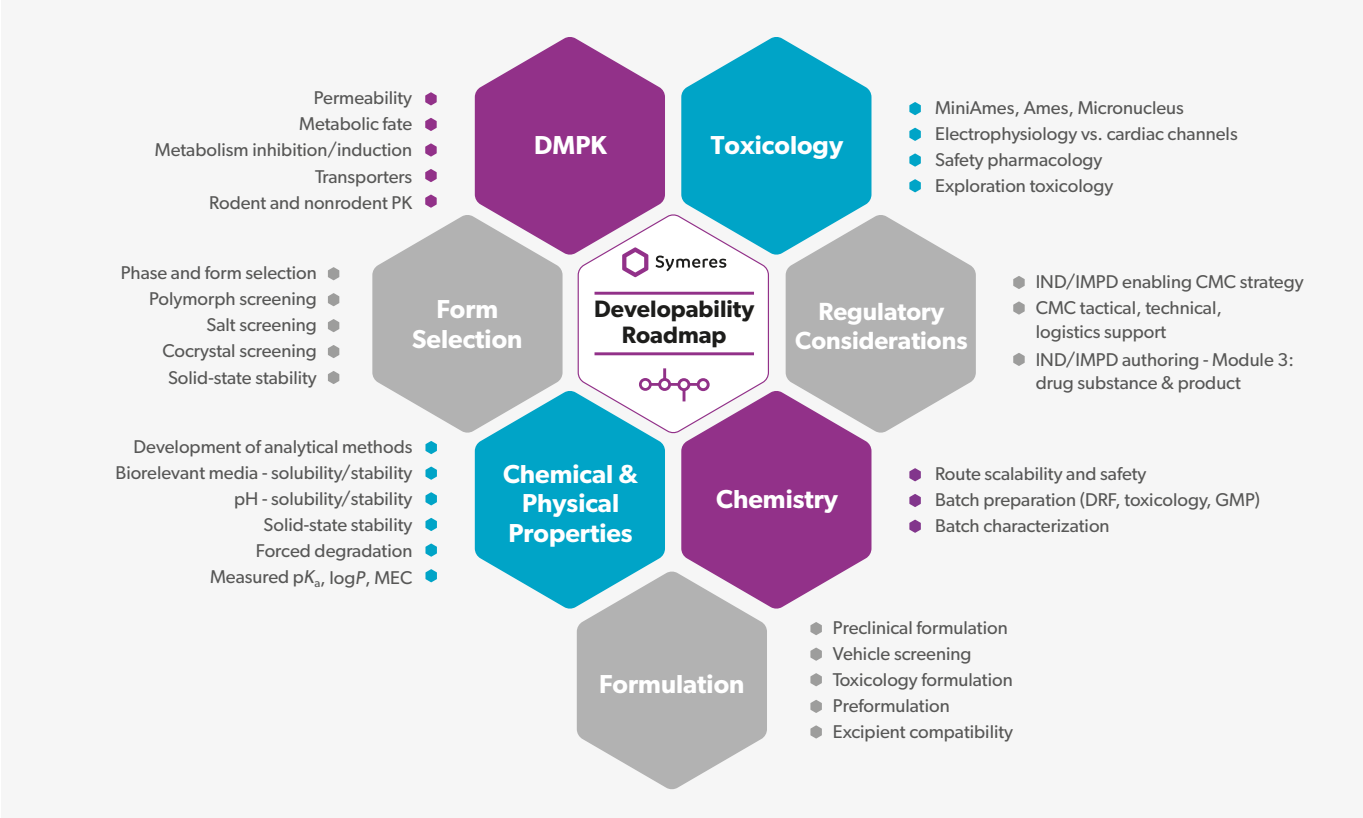


Figure 1. Developability Roadmap

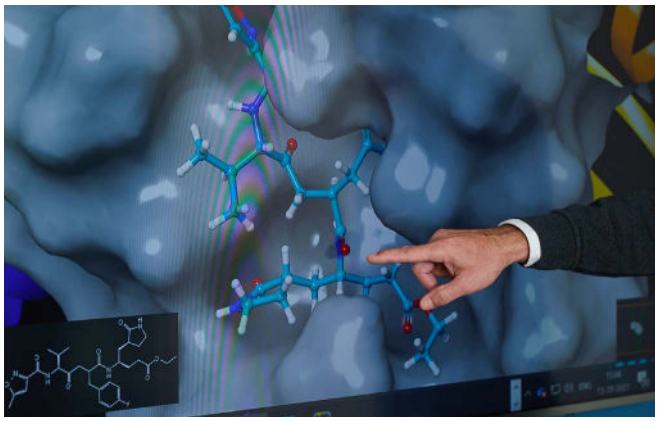
Symeres can provide you with a comprehensive evaluation of the potential of a drug candidate or candidates to be developed into a safe, effective, and marketable medication. The Roadmap typically involves the analysis of various factors, including chemistry; selection of phase/form; chemical and physical properties; formulation; pharmacokinetics; toxicity; and, if required, assistance with planning and authoring your IND/IMPD.

Key topics covered for IND/IMPD filing

Identification and mitigation of potential risks and challenges associated with the development of a new drug candidate are covered by a drug developability assessment. This is essential for the following reasons:

1. determine whether a drug candidate has the critical requisites to progress into drug development;

2. identify potential issues with a drug candidate, such as poor pharmacokinetics, low solubility, or toxicity, and enable researchers to address them early in the drug development process and avoid alterations to timelines and budget at later stages;
3. optimize key properties of the drug candidate to improve study outcomes and potential IP position;
4. provide a robust, homogeneous data and knowledge package, for example, solubility and compound characterization, for successful IND or IMPD filing on a single batch and form.



When's the right moment to contact us?

Our Developability Roadmaps are typically performed early in the drug development process, often just before, or immediately after the clinical candidate selection. They are conducted by multidisciplinary teams of experts, including medicinal chemists, toxicologists, synthetic chemists, analysts, materials and formulation scientists, and regulatory experts.

A systematic, well-thought-out drug developability assessment, such as the Symeres Developability Roadmap, is critical for the efficient development of new drugs. It helps biotech and pharmaceutical companies make informed decisions about which drug candidates to prioritize. It also enables the early identification of potential development risks that should be addressed with the highest priority to avoid delays and unnecessary costs.

Vital components of success

Our Developability Roadmap involves the evaluation of various components related to a drug candidate's ability to be developed into a safe, effective, and marketable medication. The specific components can vary according to the compound, therapeutic indication, and target product profile. However, some common components include the following:

1. **Chemistry:** Whether the current synthetic route is amenable and cost-efficient for scale-up, including sourcing of key raw materials, length and yield of the synthesis, purification methods, chirality, and safety aspects.
2. **Chemical and physical properties:** Assessment of the drug candidate's chemical and physical properties, such as solubility, chemical stability, and experimentally determined pK_a, log*P* and log*D*, as well as ensuring appropriate analytical methods are available for the coming studies.
3. **DMPK:** Assessment of the drug candidate's pharmacokinetic properties, such as *in vivo* absorption, distribution, metabolism, and excretion; DDI potential; as well as nonregulatory rodent and nonrodent pharmacokinetic studies.
4. **Toxicology:** Carrying out non-regulatory genotoxicity studies, cardiac channel electrophysiology, safety pharmacology, and exploratory tox studies.
5. **Form selection:** Investigation of the polymorph landscape, salts, or cocrystals; drug–excipient compatibility; ease of manufacture; and stability is essential. This ensures that the drug can be manufactured consistently and efficiently.
6. **Formulation:** Studying preclinical and toxicology formulations for early phases involves thorough preformulation studies, including excipient compatibility and vehicle screening.
7. **Regulatory considerations:** Assessment of regulatory requirements and guidelines for drug development is necessary to ensure that the drug can be developed in compliance with applicable laws and regulations. This can also be extended to assistance in authoring the Module 3 content of the IND/IMPD.

Symeres services

The Developability Roadmap is composed of data and information from several technical disciplines, including chemistry, materials science, formulation, ADME, and toxicology groups. The majority of these studies are conducted at Symeres, with some specific aspects, such as electrophysiology and in vivo toxicology, conducted under Symeres' control at trusted third parties located in Europe and the USA. The results are reported in a single document containing the relevant data in a format that will greatly facilitate your IND/IMPD filing. We provide more than just data and will work with your team to identify program risks, propose mitigation strategies, and coordinate future activities.

With Symeres managing the entire Developability Roadmap for you, you will save the most important asset – time. We achieve extremely efficient project management and execution via effective communication between our departments. This can be easily tracked by our extensive track record, with over 30 years of experience in the market.

Material quantities and general timelines

We will work with you to tailor a package best suited to your project and target product profile, aiming to minimize both the overall timelines and the material that we prepare. We would recommend that the package be created around a single batch of a defined polymorph and/or salt form to maximize robustness and remove a significant source of interstudy variability.

For further inquiries or collaboration opportunities,
please contact us via: science@symeres.com
www.symeres.com

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