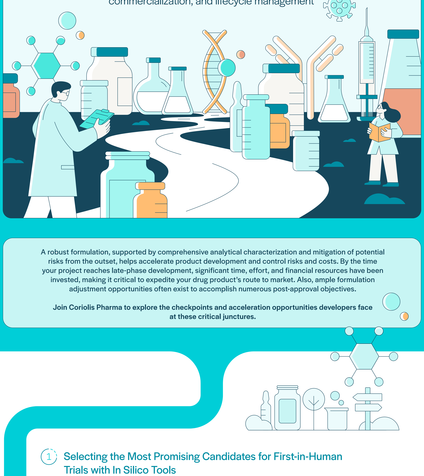
Coriolis Pharma

Driving Success from Preclinical to Commercial Approval & Beyond

A guide for early and late-stage development, commercialization, and lifecycle management



A robust formulation, supported by comprehensive analytical characterization and mitigation of potential risks from the outset, helps accelerate product development and control risks and costs. By the time your project reaches late-phase development, significant time, effort, and financial resources have been invested, making it critical to expedite your drug product's route to market. Also, ample formulation adjustment opportunities often exist to accomplish numerous post-approval objectives.

Join Coriolis Pharma to explore the checkpoints and acceleration opportunities developers face at these critical junctures.

1 Selecting the Most Promising Candidates for First-in-Human Trials with In Silico Tools

Select the most promising candidates with the most favorable biophysical properties.

- Screen early candidates
- Determine self-interactions and predict development risks
- Use in-silico tools to predict the influence of formulation on drug product (DP) stability
- Select lead formulations for clinical studies

In-silico models enable:

- ☑ Early decision-making
- ☑ Later-phase success

Accelerate!

2 Translating In-Silico Insights into Formulation-Ready Candidates

Bridge computational predictions with experimental validation to ensure robust clinical-phase readiness.

- Validate in-silico predictions through targeted wet lab experiments
- Conduct high throughput preformulation studies to assess key physicochemical properties
- Identify and address potential risks impacting developability
- Refine formulation strategy to enable seamless clinical entry

Developability and preformulation studies enable:

- ☑ Rapid progress
- ☑ Fast to the clinic

Accelerate!

3 Setting the Stage for Late-Phase and Commercial Success

Select the correct analytical methods and prepare your program.

- Choose from in-house and validated methods
- Develop new methods under non-GMP
- Validate GMP stability indicating and future QC methods
- Verify compendial methods

Potential timeline shortening opportunities include:

- ☑ Seamless GMP integration
- ☑ Decentralized GMP release methods
- ☑ 200+ analytical methods

Accelerate!

4 Narrowing Product Profile and Quality Attributes

Narrow Critical Quality Attributes (CQAs) and the Quality Target Product Profile (QTPP).

- Review all accumulated data to refine CQAs and provide robust, supportive data
- Lock in and validate control strategies
- Tighten manufacturing specs
- Detail integrations with commercial packaging, storage, distribution, and patient use scenarios

5 Ensuring Comprehensive Drug Product Understanding

Optimize analytical methods to ensure comprehensive product understanding.

- Refine analytical methods for your late-phase DP
- Validate and verify your analytical methods, and ensure they meet regulatory expectations
- Tighten specification limits and confirm product safety and stability for the established shelf life

Timeline shortening through fully integrated services:

- ☑ Science-driven lab partnership
- ☑ Client-centric approach
- ☑ Phase-appropriate services

Accelerate!

6 Refining Formulation

Optimize formulation to support CQA and QTPP refinements and patient-centric clinical strategies.

- Enhance stability and improve manufacturability
- Address viscosity or syringeability issues in high-concentration formulations
- Patient-centric refinements such as formulation concentration for lower injection volume
- Tailored solutions for combination products
- Lyophilization-driven formulation adjustments

7 Solidifying Formulation Format and Dosage Form

Establish final formulation format and dosage form to maximize patient compliance and satisfy supply chain considerations.

- Change from lyophilized to liquid DP or adjust to a high-concentration formulation to accommodate clinic or patient-friendly drug delivery
- Patient-friendly formats like prefilled syringes, autoinjectors, pens, or cartridges
- Switch from frozen liquid to lyophilized DP to extend stability and shelf life
- Clinical in-use compatibility studies to verify handling procedures related to patient administration

8 Prepare for Unexpected Issues

Unexpected late-phase scale-up challenges can occur. Ensure you have the right partner to identify and solve roadblocks quickly and sustainably

- Investigate lot-to-lot variabilities (e.g., between different manufacturing sites)
- Identify particles and understand the root cause of particle formation
- Evaluate scale-up challenges
- Apply specialized methods to address complex issues beyond standard approaches

With analytical expertise front and center, identify and address the root cause(s).

- ☑ AI tools for rapid analysis
- ☑ Fast-Track particle identification
- ☑ State-of-the-art equipment

Accelerate!

9 Lifecycle Management Maximizes Investment

Lifecycle management, DP reformulation and change of primary packaging material can be valuable for extending patent life, improving product performance, and increasing market competitiveness.

- Reformulation and line extensions creating new intellectual property and extending patent life
- Improve patient compliance
- Optimize product stability, handling, and simplify manufacturing
- Support additional indications or patient populations

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