SCENARIO SHEET

Sterling

# Transitioning projects from the laboratory to the plant

## THE SITUATION

Process scale-up is one of the most important elements of API manufacturing, but with it comes a number of key considerations that must be carefully balanced. To add to the complexity, different process requirements and priorities necessitate a tailored approach for every project.

Regulatory considerations, costs, timelines and technology transfer are just a few of the factors that can make transitioning a project from the lab scale to the plant scale exceedingly difficult. By taking a pragmatic approach to scale-up, pharmaceutical organisations can adhere to high quality and safety standards while also accounting for key project realities.

## THE CHALLENGES

### Balancing risk and results

**With more complex molecules in the pipeline comes longer drug development cycles.** Today, it can take up to 15 years for a drug to reach the market,[1] and only around 10% of drugs that enter clinical trials ultimately go on to receive commercial approval.[2] So, reaching scale-up quickly while containing costs is a top priority for many organisations, yet, there can be tension between these factors if the right processes are not in place. In particular, greater speed could introduce risk related to quality and yield. Navigating this balancing act requires an understanding of the many considerations that matter, as well as the relationship between them.

### Affirming safety

**Safety is another key consideration as a process scales, and unlike factors like speed, cost and yield, safety provides zero room for compromise.** Hazard naturally increases along with scale, with a higher volume of hazardous materials leading to potentially dangerous changes in heat and mass transfer.[3] Processes that involve exothermic reactions or that produce a non-condensable gas can be particularly hazardous on a larger scale.[3] To mitigate these issues, thorough hazard evaluation should occur before any process scales up, inclusive of thermal stability testing, reaction calorimetry and other assessments.

### Mitigating knowledge gaps

**When a project moves from a lab scale to a plant scale, it comes with new people to add to the team that will naturally not possess the same level of knowledge.** The World Health Organisation recommends a thorough, well-documented technology transfer approach that is inclusive of specific information around particle size distribution, physical properties, solubility and more to maximise continuity.[4] And yet, proper documentation is not always readily available, driving avoidable complexity and cost for pharmaceutical organisations.

# The Sterling solution

At Sterling, our integrated global facilities, experienced teams, flexible approach, and robust risk assessment and hazard evaluation capabilities enable us to successfully scale customers' projects.

## Connected facilities for seamless tech transfer

**Our five global facilities deliver a breadth of expertise spanning every stage of the lifecycle.** While located in various regions of the world, our facilities adhere to the same standards for documentation, communication and transfer of critical project knowledge. In addition, our global teams do not work in silos, instead maintaining consistent communication to maximise project continuity. At each facility, our technical teams provide deep expertise in process chemistry and process engineering to minimise risk, instill confidence in our customers and ensure success at every stage. As a result, we are able to seamlessly transition projects across sites based on their stage in the lifecycle and the technologies they require.

**Our approach to tech transfer enables our customers to virtually eliminate knowledge gaps and radically reduce time and resource requirements during scale-up.** With all critical project data contained in our global network from the very start, we mitigate avoidable loss of information that may cause of project delays and missing regulatory documentation.

## Flexible approaches to scale-up in stride

**With experience supporting a broad range of projects at different stages of development, we understand the natural tension between project timelines and other variables like quality, yield and compliance.** We focus on understanding each customer's order of priorities, with a pragmatic approach that masters the complex balancing act involved in scale-up.

These variables are not always in our control. **In cases where we are not afforded the benefit of an internal knowledge transfer, we are adept at identifying and acquiring the necessary information from external organisations quickly and comprehensively.** A key pillar of our ability to streamline external knowledge transfer is our robust analytical approach.

For example, a customer may transition a project from one manufacturer to Sterling as volume requirements increase. When conducting this transfer, we may discover gaps in method development and validation. Our full-lifecycle perspective proves invaluable as the Sterling analytical team quickly familiarises itself with the project, develops and validates all necessary analytical methods and optimises the process for manufacture, all while maintaining high standards of efficiency and quality. The project team and production chemists continue to closely monitor manufacturing batches after a project transitions to the plant to quickly respond to any challenges that may arise.

## Comprehensive risk assessment for scalable success

**In the complex pharmaceutical manufacturing process, risk is a moving target that shifts as volume increases. When it comes to hazard evaluation, our philosophy is that earlier is better.** From the earliest stages of the project, we conduct a thorough hazard evaluation that not only considers safety concerns at a project's current stage, but also anticipates hazards later on in its lifecycle. We leverage a range of tests to assess the potential for heat release, ignition, explosion and other hazards that may surface at a large scale, proactively addressing these hazards before they emerge.

**We also conduct scale-up risk assessments to identify possible areas of failure when a product is manufactured at a larger scale, including issues with purity, yield and other key factors.** This includes demonstration runs later in the development process that can anticipate potential issues at the largest scale possible in the lab. Many customers aim to scale quickly to contain costs and enhance speed. By conducting thorough risk assessments early, we can meet customers' priorities while avoiding setbacks down the line.

> "Projects come into Sterling at different stages of development, and our standardised, yet tailored, approach allows us to adapt to our customers' priorities. We take care to advise customers on scaling in a way that will adhere to desired timelines without compromising on other factors."
>
> **- Jamie Wolstenhulme,**
> *NPI Manager,*
> *Sterling Pharma Solutions*

# Are you ready to seamlessly scale your project?

Visit **sterlingpharmasolutions.com** to learn more.


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