Recipharm

Accelerating tablet tech-transfer through predictive modelling

Overcoming tablet quality challenges

Achieving consistent tablet quality during tech-transfer is critical for successful scale-up and commercialisation. Yet many drug developers face persistent challenges during this phase, where small shifts in material behaviour or process conditions can derail performance and trigger failed validations.

This case study explores how a predictive, model-driven approach can help overcome repeated failures in tablet manufacturing and deliver a robust, scalable process in just a few months.

Understanding the challenge of tablet tech-transfer

During the tech-transfer of a solid oral dosage form, development teams can often encounter a series of challenges that can significantly hinder progress. One issue is inconsistency in feeding material to the roller compactor, which directly affects granule quality downstream and compromises the uniformity of the final blend. Even after process adjustments, tablets may still fail to meet critical specifications for hardness and dissolution, indicating deeper, unresolved process variability. These factors frequently lead to validation failures, with no clear root cause in sight, stalling development timelines and increasing operational risk.

Individual issues can signify a lack of underlying process robustness. Interdependent variables, like compaction force, material flow and granule properties, can influence each other in complex ways. However, traditional development approaches, which isolate parameters and rely on incremental adjustments, often fail to provide the insight needed to resolve the problem.

Why conventional troubleshooting falls short

In most tech-transfer scenarios, parameters are investigated one at a time, based on individual judgement or experience. This approach increases the risk of drawing incorrect conclusions. For example, changing tablet press speed or granule size without understanding their joint effect on dissolution can misattribute the cause of variability.

What is needed is a platform that can simulate success and predict performance, not through trial and error, but through data-driven insight.

Results: Applying ReciPredict to identify a robust process

ReciPredict, Recipharm's advanced predictive analytics and Quality by Design (QbD) platform, can be used to break the cycle of conventional tech-transfer troubleshooting. ReciPredict applies a holistic, statistical model-driven method that considers the interconnectedness of quality and process dynamics. By applying material science, data science and digital technologies to drug product development and manufacturing processes, it enables data-driven decisions to help achieve exceptional efficiency and reliability.

Rather than examining variables in isolation, ReciPredict evaluates the material characteristics in the context of the entire process, capturing how formulation and process parameters interact to impact critical quality attributes (CQAs).

ReciPredict

In this tech-transfer, using a minimal number of targeted trials, ReciPredict was able to:

- Map the process landscape and highlight key parameter interactions
- Address the poor flowability of the formulation via an optimised feeding process
- Predict outcomes for tablet hardness and dissolution, even without running the final process
- Identify an optimal set of conditions likely to deliver a successful validation outcome

By leveraging interconnected intelligence, ReciPredict rapidly established a reliable process with high predictive accuracy.

Outcomes: Delivering tangible results in just five months

The predictive model generated using ReciPredict accurately forecasted the CQA outcomes for the new tablet manufacturing process. When the process was executed for the first time, the results closely aligned with the predictions.

> Tablet hardness differed by less than 2 N from the forecasted value, while the deviation in the critical parameter dissolution was under 1.5%.

These outcomes validated both the precision and reliability of the model, showcasing ReciPredict's capability to remove the "error" from trial and error through data-driven foresight.

Beyond resolving the immediate tech-transfer challenge, the project delivered significant wider benefits. A robust and scalable process was successfully identified within just a few weeks, enabling a seamless transition to validation. From the project's initiation to the achievement of validation, only five months had passed, marking a substantial reduction in development time.

Five months from project initiation to validation

Additionally, the approach required far less material than conventional methods, cutting both resource use and associated costs. Importantly, the work also generated a comprehensive data set suitable for regulatory submission, supporting long-term compliance and future manufacturing confidence.

Partnering for a faster, leaner path to validation

These results showcase how Recipharm combines deep development expertise with digital tools to overcome complex formulation and process challenges. By using ReciPredict to guide decision-making, our team transformed a failing process into a validated success, without repeated rework or costly delays.

Through interconnected intelligence, quality by design is simplified. With predictive modelling at the core, development teams can unlock robust outcomes earlier. Less trial and error – more data and confidence.

To learn more about how ReciPredict can accelerate your development timelines, contact us at: www.recipharm.com/contact-us

About us

Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden and the US and are continuing to grow and expand our offering for our customers. We are supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 30 years, we have partnered with our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. We conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do.

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