Recipharm

ReciPredict

Understanding how value by design can bring your drug to market faster

Introduction

Today's pharmaceutical companies face significant hurdles in bringing new medicines to patients. The pressure to accelerate time-to-market is intense, while simultaneously managing substantial development and manufacturing costs. Ensuring consistently high product quality remains paramount for patient safety and regulatory compliance in this demanding environment.

Quality by Design (QbD) offers a strategic solution to these challenges by proactively building quality into the development process. This systematic approach focuses on understanding and controlling critical product and process parameters. While QbD promises enhanced quality and efficiency, its implementation can present obstacles, including initial investment, cross-functional integration complexities, and organisational change management.

ReciPredict™ is a cutting-edge platform designed to support the effective implementation of QbD. It harnesses the power of automation and data science to enable data-driven, informed decisions in the development and manufacturing of drug products and can be applied across all products and projects.

With ReciPredict, you can:

- Fully understand your materials and processes and how they interact
- Streamline the clinical stage by up to 6 months
- Reduce active pharmaceutical ingredient (API) and material consumption by up to 70%
- Optimise formulation and process robustness, even in commercial manufacturing
- Support and structure quality risk management (QRM).

In this eBook, we will explore how ReciPredict works in the context of a real project to achieve these goals.

Readers will gain a comprehensive understanding of:

- How ReciPredict leverages advanced statistical modelling to facilitate QbD.
- How the platform connects critical process parameters and material attributes with drug product quality attributes.
- How data science and human expertise are integrated to drive informed decisions.
- How ReciPredict can be effectively implemented into a project.
- The practical benefits of harnessing ReciPredict for pharmaceutical companies.

Sections

1. ReciPredict fundamentals: Understanding the core technology

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Section 1
ReciPredict fundamentals: Understanding the core technology

ReciPredict enhances pharmaceutical development and manufacturing through predictive modelling. It serves as a central hub for integrating diverse data sets and applying advanced statistical techniques. At its core, ReciPredict aims to provide a deeper understanding of the relationships between a drug product's:

- Critical material attributes (CMAs)
- Critical process parameters (CPPs)
- Critical quality attributes (CQAs)

By establishing these connections in quantitatively well-fitted models for value and variability, ReciPredict empowers pharmaceutical scientists and engineers to make more informed decisions throughout the product lifecycle.

Key features and capabilities

ReciPredict offers a range of powerful analytical tools, including:

- **Advanced statistical modelling:** Employing sophisticated techniques to uncover complex relationships in manufacturing data, for expected value and expected variability.
- **Connecting CPPs and CMAs to CQAs:** Providing direct insights into how input variables influence final product quality.
- **Data integration and analysis:** Facilitating seamless data integration from various sources with comprehensive analysis and visualisation tools.
- **Prediction capabilities:** Allowing users to explore different scenarios and anticipate potential outcomes.
- **Simulation:** In-silico-simulation (modelling) as well as micro-scale production simulation.

How ReciPredict enables QbD

ReciPredict can transform the implementation of QbD principles by supporting:

- **Design of experiments (DoE):** Helping identify the most impactful factors to study.
- **Risk assessment and mitigation:** Enabling proactive identification and mitigation of potential quality issues through data-driven insights.
- **Understanding the variability of materials and process**
- **Knowing the design space.**

This systematic approach, guided by ReciPredict's analytical power, leads to more robust and reliable manufacturing processes.

Section 1. ReciPredict fundamentals: Understanding the core technology

Integrating human expertise

ReciPredict is designed to work in synergy with pharmaceutical professionals by:

- **Complementing expertise:** Providing powerful analytical tools and data-driven insights that enhance existing knowledge and experience.
- **Enhancing decision-making:** Empowering scientists and engineers to make more informed choices, leading to accelerated development timelines, improved product quality, and greater process understanding.

Analysing all CPPs, CMAs and CQAs together and their impact on each other and the overall process is not possible with traditional troubleshooting methods. By enabling this, ReciPredict makes it possible to identify the exact parameter causing issues so that methods can be developed to solve it, resulting in significant time and cost savings. Ultimately, this collaboration between human expertise and ReciPredict's capabilities results in more efficient and effective drug development and manufacturing.

Section 2
The impact of implementing ReciPredict throughout the development journey

ReciPredict offers practical applications for projects at any stage of the drug development journey, by helping to identify and understand all relevant sources of variability, including materials and processes. The outcome of ReciPredict is a mathematical formula for quality attributes, allowing for a complete understanding of the origin of variability and of the interrelation between materials, processes and product quality.

Project introduction

ReciPredict helps define precise expectation values by applying scientific & mathematical models. It translates customer expectations (QTPP) into measurable CQAs. Before starting trials, ReciPredict identifies & describes the formulation & manufacturing process mathematically, predicting the distribution of quality for each quality attribute. This model is then verified with real trial data, ensuring that measured results match predicted outcomes.

Material & process characterisation

Using statistical tools & equipment, ReciPredict can investigate CMAs & CPPs, evaluating their impact on quality attributes. It helps understand the interrelation between materials, processes, & product quality, even with variations in materials or processes. By building models, ReciPredict allows for the calculation of predicted values, which are then compared with real values to confirm the understanding of the system. With this, it is possible to be prepared in the event of change of material source or changes in manufacturing process.

Formulation & process optimisation

Employing a model-based approach, ReciPredict pinpoints & comprehends all pertinent sources of variability & their influence on processes & materials. This facilitates the enhancement of formulations & procedures, yielding resilient products that reliably adhere to specified limits. The tool is capable of simulating commercial production environments, enabling the refinement of process parameters & decreased API consumption. For example, a process change, such as a new line or site, can be simulated & compensated before first tech trials.

Clinical stage streamlining

ReciPredict accelerates drug development timelines by shortening supply for clinical trials. It can significantly reduce the time required for defining a robust design space & conducting failure mode & effects analysis (FMEAs). By providing a clear understanding of process variability, ReciPredict helps ensure a smoother transition to capable manufacturing.

Technology transfer optimisation

This is the main area where issues, such as quality challenges, can occur. By providing a mathematical description of the product quality as a function of materials & processes, ReciPredict streamlines technology transfer. The model uses historic data from the transferring site. This model-based approach facilitates the transfer of knowledge, ensuring a smoother transition to manufacturing & reducing the time & resources required for successful scale-up. It allows for the simulation of process performance & the identification of potential issues before they arise.

Manufacturing robustness

In identifying & controlling sources of variability, ReciPredict establishes process robustness & ensures consistent product quality. It allows for the prediction of process outcomes & the optimisation of process parameters to minimise deviations from specifications. This leads to more reliable & incident-free commercial manufacturing.

Post-approval changes:

ReciPredict helps manage post-approval changes by assessing their impact on product quality & regulatory compliance. It allows for the evaluation of proposed changes & the demonstration of their impact on product quality, facilitating regulatory approval. By providing a database of rationales for changes, ReciPredict can significantly reduce the time required for change control processes.

Routine manufacturing

From routine manufacturing to monitoring process performance to identifying potential issues, ReciPredict has multiple production uses. It allows for the ongoing improvement of process robustness & the maintenance of consistent product quality. The tool can also be used to investigate deviations from specifications & identify their root causes.

Section 3
Practical benefits

ReciPredict offers tangible advantages that significantly improve the efficiency and success of drug development and manufacturing, compared with traditional methods, due to its revolutionary systematic, data-based approach. This radical strategy minimises uncertainties and optimises processes from the outset, maximising chances of successful project execution.

Key benefits include:

- **Accelerated time to market:** Scale-up is streamlined, and technology transfer to different manufacturing lines can be delivered more smoothly, informed by comprehensive data analysis. This contrasts with traditional methods, which can be time-consuming and prone to delays due to unforeseen challenges during scale-up. By quantifying potential time savings, ReciPredict enables faster product launches, directly impacting revenue generation and bolstering market share.
- **Cost reduction:** The platform optimises processes, leading to reduced consumption of expensive APIs and other materials. This contrasts with traditional approaches, where material usage might be less efficient due to a lack of precise process control. By minimising the need for extensive experimentation and troubleshooting, ReciPredict significantly lowers development and manufacturing costs, promoting more sustainable resource utilisation.
- **Enhanced quality and reliability:** The development of processes can be facilitated that ensure consistent product quality, reducing and understanding out-of-specification (OOS) results and allowing a more straightforward assessment of deviations. Traditional methods may struggle to achieve the same level of consistency, resulting in more frequent OOS investigations and potential product failures. This proactive approach significantly reduces the risk of costly recalls and protects both patient safety and brand reputation.
- **Improved process robustness:** Technology transfers are de-risked by providing a clear understanding of CPPs and their impact on product quality, reducing process variability across different manufacturing sites. Traditional technology transfer processes can be challenging and are a main cause of inconsistencies between sites and quality issues. ReciPredict's model-based approach ensures a smoother and more reliable transfer.
- **Regulatory compliance:** ReciPredict directly supports QbD principles by providing the data-driven insights necessary for robust process understanding and control strategies. This contrasts with traditional methods, which may not fully align with QbD principles, potentially leading to challenges during regulatory submissions. By streamlining regulatory submissions and increasing the likelihood of successful approvals, ReciPredict simplifies the path to market.

Section 4
Implementing ReciPredict

Recipharm works in close collaboration with drug development customers, ensuring a smooth and effective integration of the ReciPredict platform into their specific drug product development or manufacturing projects. Recognising that a one-size-fits-all solution is rarely optimal, our approach is tailored to meet the unique needs and existing infrastructure of each customer. Recipharm's experienced team acts as a strategic partner, providing comprehensive support throughout the entire integration process, from initial consultation and system set-up to ongoing training and application guidance. This collaborative model empowers companies to harness the full potential of ReciPredict to achieve their project goals.

Phased implementation strategy
Recipharm starts with a thorough assessment of the client's current workflows, data landscape, and specific objectives for using ReciPredict. Based on this analysis, a bespoke implementation plan is developed, outlining the necessary steps, timelines, and resource allocation. Recipharm's experts provide hands-on assistance with data integration, ensuring seamless connectivity between existing data sources and the ReciPredict platform.

Ongoing support and expertise
Recipharm extends long-term guidance to help drug developers leverage ReciPredict for specific applications within their projects. This includes:

- Designing and analysing DoE
- Building quantitative predictive models for critical quality attributes
- Utilising the platform for risk assessment and mitigation strategies.

Recipharm's team brings a wealth of pharmaceutical development and manufacturing knowledge, enabling them to provide valuable insights and best practices for applying ReciPredict to address real-world challenges. This continuous support ensures that clients can maximise the value derived from the platform over the long term. ReciPredict's implementation is centred on partnership and knowledge transfer. We don't just provide the method; we empower our clients to become proficient users who can independently leverage the platform's capabilities. This commitment to comprehensive support, coupled with the power of ReciPredict, enables drug developers to accelerate their timelines, enhance product quality, and achieve greater efficiency in their drug product development and manufacturing endeavours.

Conclusion
The future of drug development with ReciPredict

The pharmaceutical industry is rapidly transforming, with data-driven approaches now essential for accelerating drug development, reducing costs, and ensuring consistent quality.

Services such as ReciPredict exemplify this shift, providing the tools and insights necessary to optimise drug development and manufacturing processes. By embracing QbD principles and leveraging ReciPredict's advanced predictive modelling, companies can achieve greater efficiency, reduce overall lifecycle costs, and ensure the consistent delivery of high-quality medicines. This evolution promises to accelerate innovation, ultimately benefiting patients and driving the future of healthcare.

About Recipharm

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.

Value by design

ReciPredict harnesses our years of expertise to accelerate the journey of new drugs to the clinical stage by reducing the number of test cycles, substantially expediting the drug development process. It offers cost savings by reducing API consumption, and de-risks technology transfers by identifying the ideal parameters for optimum process robustness, achieving high-quality results, each and every time.

Interconnected intelligence

By combining our expert data science and statistics team with a careful selection of tools, such as advanced modelling tools, comprehensive statistical tools, powder characterisation (FT4, Accupyc, BET, and more) and Style One Evo compression and compaction simulator, ReciPredict stands out as a robust and reliable platform, offering unmatched results to transform your drug development journey.

Talk to us

Discover how ReciPredict can revolutionise your QbD implementation and propel your drug development forward. Contact us today for a personalised consultation and a demonstration of ReciPredict's transformative capabilities.

Contact us


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