DELMIA

SOLUTIONS FOR PHARMA & BIOTECH

Improve process understanding

Understand and optimize your production process

Today's biotech and pharmaceutical industries are under increased pressure to optimize manufacturing operations and reduce time to market when introducing new chemical and biological products. To fulfill this demand, the gap between pharmaceutical development and manufacturing has to be reduced.

PLM brings Quality by Design (QbD) to life

Quality by Design (QbD) is changing the way pharmaceutical companies think about their product and manufacturing processes.

Product Lifecycle Management (PLM) can significantly improve business processes and the information exchange between Engineering, Manufacturing and the Supply Chain.

Minimizing process variation with QbD can improve both productivity and quality, which addresses the timeliness, cost and risk problems that plague the industry today.

Understand your Production Process

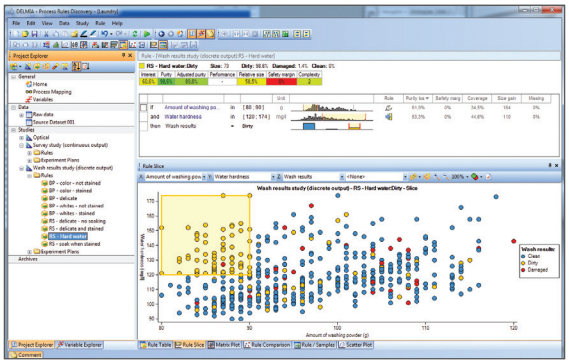
DELMIA Operations for Pharma & Biotech helps to optimize the pharmaceutical production process by streamlining the collection of real-life product and production data during pharmaceutical development. Quality specialists can rapidly identify Critical Process Parameters (CPP), Design Space and build control strategies to reduce Critical Quality Attribute (CQA) variability.

Upon experiment completion, **Process Rules Discovery** uses historical facts and prior scientific expertise to formalize process knowledge. It explains which process patterns lead to "good" and "bad" performance (yield or quality). **Performance Tracker** helps production to gain confidence into these findings. By monitoring the reliability of best practices using new production batches, the rules will be improved by manufacturing operators. **Operations Advisor** monitors real-time shop floor information and analyzes the risk of quality defects and alerts.

DELMIA

Improve process performance

- Notify the operators of possible process variability
- Quantify the level of risk related to deviation from best practices
- Propose preventative or rectifying actions within specifications to improve performance for new campaigns, prior to production



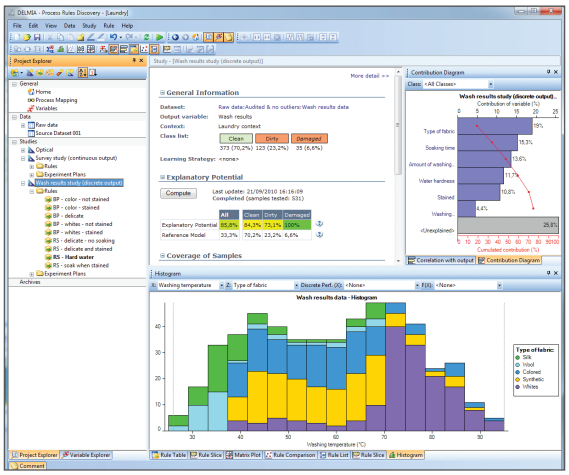
Easily define (top) and visualize rules using scatter plots (bottom)

"The use of **DELMIA Operations** for understanding mechanisms which drive our complex processes **is an asset** to answer to this double requirement (quality & safety) in an efficient manner."

René Labatut,
Vice President Manufacturing Technology
Sanofi-Pasteur

Solution Benefits

- Minimize process variability and reduce risk
- Share process knowledge between development, manufacturing and quality
- Go beyond statistical analysis and Design of Experiment
- Quantify interactions between Critical Process Parameters (CPP)
- Build control strategy to reduce Critical Quality Attribute (CQA) variability



Define and visualize the contribution of each variable (top) and its distribution (bottom)

About Dassault Systèmes

As a world leader in 3D and Product Lifecycle Management (PLM) solutions, Dassault Systèmes brings value to more than 130,000 customers in 80 countries. A pioneer in the 3D software market since 1981, Dassault Systèmes applications provide a 3D vision of the entire lifecycle of products from conception to maintenance to recycling. The Dassault Systèmes portfolio consists of CATIA for designing the virtual product – DELMIA for virtual production – SIMULIA for virtual testing – ENOVIA for global collaborative lifecycle management – EXALEAD for search-based applications SolidWorks for 3D mechanical design and 3DVIA for online 3D

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