



Sanofi Pasteur improves the reliability and economic performance of its processes with **Process Rules Discovery™**

Sanofi Pasteur

- Subsidiary of Sanofi Aventis, the world leader in the pharmaceutical industry
- Revenue: 2.11 billion €
- Personnel: 8,500
- 1.4 billion doses of vaccine produced to protect more than 500 million people worldwide.

Location

- Headquarters in Lyon, France
- Located in more than 150 countries

The Challenge

- Improve the profitability of production processes whose biological parameters behave in ways that are not well understood.
- Explain the variability of these processes when classic analysis tools have failed
- To launch the product on time and on budget

The Solution

- Process Rules Discovery™ to create rules that govern complex vaccination production processes

The Benefits

- Elimination of 50% drop in yield due to process change
- Improvement of over 10% in the best-case yield of a production process
- Resolution of a blocking profitability problem for a critical vaccine
- Optimization of quality/yield ratio for the production process of a vaccine in development

“Because it is inherently more user-friendly and flexible than other artificial intelligence tools, Process Rules Discovery™ is particularly successful where other, more classic analysis tools fail. By producing simple and explicit rules that explain the functioning of our vaccine production processes and by highlighting the parameter correlations that may cause these processes to deteriorate, Process Rules Discovery™ helps us to improve process quality, security, and profitability. In an industry such as ours where investment is extremely high, this tool is a very welcome addition!” - René Labatut, Vice President, Global Manufacturing Technology, Sanofi Pasteur

Sanofi Pasteur is the world's leading producer of vaccines and owes its success to its ability to innovate and evolve. “This does, however, come at a price: a high level of investment” says René Labatut. “In addition, once the product problems – i.e.: vaccine effectiveness levels, safety for human use and conformity with current world health norms – are solved, our priority is the quality and economic viability of our production processes. In fact, our ability to meet the vaccination requirements of low-income populations (in particular through WHO/UNICEF programs) and our return on investment directly depends on the profitability of these processes. However, because our processes are biological in origin, they have an enormous number of parameters whose behavior is often not well known. Their variability and thus their reliability and economic performance (production rate for products in accordance with the required standard) is thus all the more difficult to control.”

At the start of 2001, the statistics software available on the market reached the limits of what it could offer Sanofi Pasteur in terms of process results analysis (results that are often inferior in quality). As a result, the company turned to Intercim for more powerful, innovative software.

Leveraging Process Rules Discovery™

“While researching statistical software, we discovered Process Rules Discovery™. We were attracted by the innovative approach and decided to test the software solution on a blocking problem we had with the yield of a particular vaccine,” remembers René Labatut. During one month of “testing” by the Sanofi Pasteur data analysis team, Process Rules Discovery™ was able to generate rules that clearly identified the process parameters that were critical in determining process outcome. The software was also able to refine the vaccine production rules by identifying which parameter interactions were responsible for the deterioration in process results. In 2003, at the end of this convincing test period, Sanofi Pasteur engaged with Intercim with a goal to equip all its Production and Engineering Technology sites (four in France, one each in Canada and the US).

The objective: to assist production and development organizations to implement a Six Sigma quality program by helping decision making and problem resolution, particularly where the classic tools failed.



Intercim *i*

SUCCESS STORY

OPERATIONAL EXCELLENCE FOR ALL

“...We had a reduction of nearly 50% in a vaccine yield. With Intercim we solved the issue and improved the yield...”

About Intercim

Intercim is a global leader in Manufacturing Operations Management (MOM) solutions for the aerospace & defense, automotive, pharmaceutical and semiconductor industries. Our flagship product, the Pertinence Suite powered by Velocity, is a truly innovative software solution that bridges the gap between product design and supply chain. Our unique technology empowers distributed teams to collaborate on process planning, execution and quality to reduce manufacturing costs, time to market and cycle time. With 25 years experience, Intercim operates from offices throughout the US and in Europe. Its customers include industry leaders like Airbus, BMW, Boeing, Intel, Ipsen, Sanofi Pasteur. Partnerships with SAP and Microsoft support the company in its mission to provide operational excellence for all.

■ Corporate Headquarters

Intercim, LLC
1915 Plaza Drive
Eagan, MN 55122 USA
Phone +1 651-289-5700

■ European Headquarters

Intercim
32, Rue des Jeuneurs
75002 Paris, France
Phone: +33 1 44 76 81 81
www.intercim.com

The testing: Five data analysts were trained on Process Rules Discovery™ and their goal was to use it in collaboration with the group's process experts. Sanofi Pasteur used the following approach: In order to take full advantage of the power of Process Rules Discovery™, each problem or question was first entered into the system by the analysts – without any bias. The results were then studied by the experts who combined their individual skills with Process Rules Discovery's™ optimization capabilities to further refine the analysis (for example through the withdrawal of certain process parameters that are not considered critical).

Critical vaccine yield increases from 45 to 100 units

The results: After 12 months of usage, these two groups (analysts and process experts) acknowledged that they particularly appreciated the software's user-friendliness, the ease with which projects were organized, and the expressive simplicity of the proposed rules. Sanofi Pasteur was particularly pleased with the results achieved by the software in improving the production processes for four vaccines.

“With regard to the first vaccine, we had a reduction of nearly 50% in its yield due to a change in the raw material (of animal origin) – a change imposed by new regulations,” explains René Labatut.

“This reduction in the yield was deteriorating and sooner or later we were going to find ourselves having to stop production on a product that annually generates several million euros in turnover! However, Intercim has not only enabled us to solve this problem, but it has also contributed to an improvement in the starting yield. In other words, the yield fell from 90 to 45 (international units) but today it stands at over 100. Even if we haven't calculated it precisely yet, the return on investment for our solution is easily covered by the losses we have managed to avoid.”

For the second vaccine of which stocks were running low, Intercim managed to solve a quality problem – just at the right time – that was preventing newly produced batches from being put on the market. The production quality of the third vaccine was also improved through Intercim. For the fourth vaccine, Process Rules Discovery™ was used in the early process development stage and contributed to maximizing the quality/yield ratio of the production process.

Intercim manages continuous control of process stability

These excellent results have today led Sanofi Pasteur to expand the use (over successive stages) of Process Rules Discovery™ throughout the production and development organizations in order to increase the sharing of knowledge and understanding.

Adds Labatut, “In fact, Process Rules Discovery™ can describe very simply and explicitly the behavior of our processes – in a sense, it is driving a very beneficial change in the established culture, by ensuring that knowledge is no longer limited to a handful of experts. It therefore seems sensible to use this ability to distribute – by means of competent users – our process best practices to a large number of people.

It's a simple yet effective way, first of all, of ensuring continuous control of process stability and preventing rapid deterioration, which could harm our ability to meet our clients' vaccination requirements and the economic performance of the whole company. Last but not least, Intercim helps our personnel to make better use of production tools. It is thus also a means to strengthen their personal safety and security as the processes they handle can sometimes involve dangerous components.”