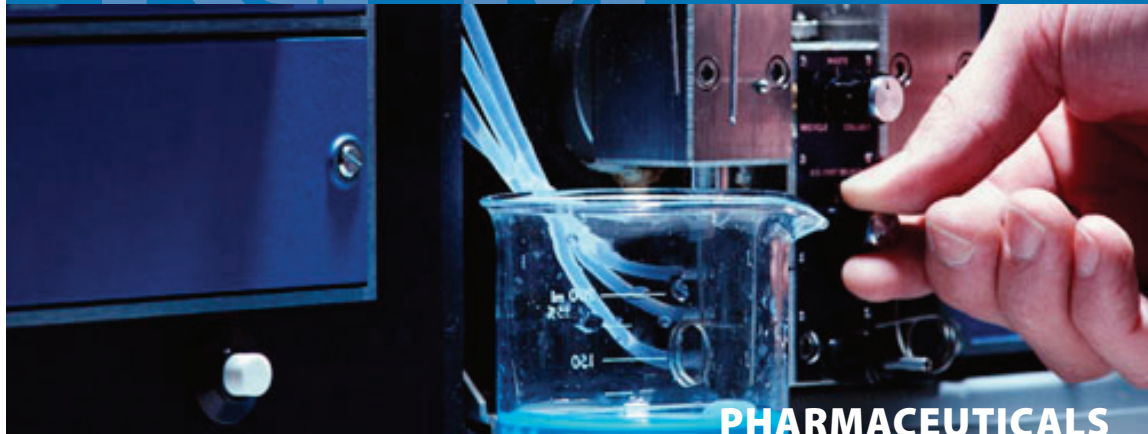




Headquarters: Basel, Switzerland

Technical Environment:

Intel; Microsoft; Cisco; SAP

Challenge: To sustain a world leadership position, The Roche Group sought an information platform to help employees improve operation and batch efficiencies, accurately report on Good Manufacturing Practices, and collaborate across the enterprise. The company needed a solution that would unify massive amounts of information and reliably deliver data for root-cause analysis, reporting, and continuous improvement.

Why OSIsoft Won: Choosing OSIsoft's Platform offered Roche a more affordable operations infrastructure and a complete, off-the-shelf product line. OSIsoft products require little, if any, engineering to provide true enterprise-level power and capacity.

Applications:

- Automated Reports
- Batch Quality Monitoring
- Downtime Monitoring
- Key Performance Indicators (KPIs)
- Process Performance Analysis
- Product Compliance Reporting
- Root-Cause Analysis

Benefits:

- Unified, real-time information accessible enterprise wide
- Real-time and historical data analysis not possible before RtPM
- Dramatically improved root-cause analysis and problem-solving
- Identification of real KPIs
- Improved quality due to ability to display trending and deviations from batch to batch
- Enhanced efficiency and performance
- Improved yield, cost efficiencies, cycle time, and equipment effectiveness
- Real-time costing
- Simplified production of GMP-compliant batch reports

OSIsoft helps The Roche Group employ real-time performance management as a global initiative and increase operational efficiencies

The Roche Group maintains three types of manufacturing facilities: chemical, biotech, and galenical. To sustain growth in an increasingly competitive global business environment, the company sought a technically superior information platform that would enable operational improvements in efficiency, performance, quality, and compliance with Good Manufacturing Practices (GMP).

Roche considered the Real-time Performance Management™ (RtPM™) Platform and its PI System™ (PI™) real-time data engine to be the best foundation to gain visibility into operational performance and enable faster response time and analysis for more cost-effective actions. As a successful global initiative, RtPM allows management to make more effective business decisions based on reliable and current information. Local plant management can optimize process operations to respond to real-world product demand. Operators, engineers, chemists, and managers can now plan better, improve production, and increase efficiency. Throughput is up; and for one product cycle time fell from eleven hours to eight. Roche is now able to produce 10 percent more batches per week. And, since the Platform has been installed, Roche has moved to more electronic batch reporting, virtually eliminating compliance complaints.



Robert Fretz

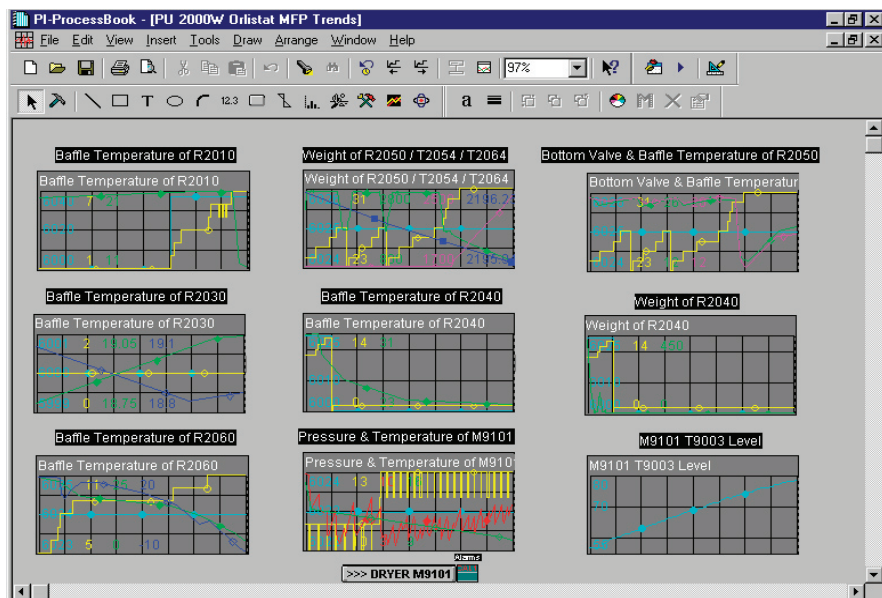
Head of Process Automation & MES
Roche Pharmaceuticals Global Engineering
and Technologies Group

"Using OSIsoft's Platform is a global initiative both as an operational improvement solution and as a solid infrastructure. The power of having real-time data so pervasive across the organization is a great advantage. Making operations data available to every employee and providing the environment to make use of the data correlates with our belief that our success depends on our employees' capabilities. OSIsoft's Platform helps create those capabilities."

Headquartered in Basel, Switzerland, **The Roche Group** is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis, and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.

Seeing operations is believing – and improved business results

The PI System was initially deployed at the Roche chemical production plant in Clarecastle, Ireland. There, PI was used primarily as an engineering tool, connected to control systems to gather production data in real time and reliably store it indefinitely. However, it was soon apparent that RtPM Platform offered many more major benefits in terms of operational visibility, trustworthy data, and the ability to build applications to help users solve operational and business problems.



A batch analysis application helps Roche see a more complete picture of operations with real-time data in a batch context. Displays include: individual unit summary, shift turnover report, quality assurance trend analysis, operational trend, alarm handler, set point calculator, and golden batch comparison.

Previously, it was difficult for plant management, engineers and operators to obtain the necessary information in a timely manner in order to avoid costly problems. Robert Fretz, Head of Process Automation & MES in the Roche Pharmaceuticals Global Engineering and Technologies Group explains, "This lack of data access presented us with many difficulties. Data had to be collected manually, which delayed decisions. People weren't working from the same data because it was often manipulated by different people in different ways, which led to differing sources of data and results. When the data was there, it was difficult to get it in the proper context and work with it."

"What we needed was a common repository that could handle a wide variety and volume of data from multiple systems across the entire enterprise. OSIsoft offers three big advantages for doing that," says Fretz. "The total system cost is much lower because OSIsoft's Platform does not require the massive infrastructure or customization of some solutions. It seamlessly integrates with our other systems, be they plant-level or business-level, for a more complete picture of our entire operation. The PI System allows us to gather more data in a smaller storage footprint, thanks to its compression capabilities. And, PI offers superior performance because an almost limitless number of data points and events can be stored and delivered with the high frequency we require."

The solution is working. Roche Ireland has reduced the number of process alarms and associated review times by 80 percent. This translates into an improved quality of life for the operator because each alarm is now significant. Not wasting time with "noise" alarms allows operators to concentrate on actual operations rather than handling numerous, often unnecessary alarms. Supervisor reviews have been reduced to discussing 50 meaningful alarms, instead of 500 that required time-consuming searches to determine importance.

"We can now guarantee Good Manufacturing Practices (GMP)-compliant handling of all alarms, which was more difficult before," says Fretz. "Since the Platform has been in use, even with the reduced alarm set, we haven't had any regulatory complaints or fines. Is that a dollar ROI? Not exactly, but it certainly is a valuable return."

Based on the initial success in Clarecastle, Roche developed numerous PI applications to fine-tune production and share them with other sites. For example, a cycle time tracking application displays dollar value of time, labor, energy consumption, and other factors, and calculates the cost of each operation in real time. This cost can then be compared with standard company metrics.

"Our engineers came up with something management always wanted – the ability to see dollar values rise or fall and to predict and track comparative costs of one action over another," Fretz says. "We used to do this type of analysis only once or twice a year, but now we can do it even as a batch is running."

"We have developed a project called 'Real-time Performance Measuring' that uses data from PI to optimize and cost operations," said Frank Neville, Assistant Plant Manager at the Clarecastle site. "There are two aspects to the project: the first reports back the Key Performance Indicators (KPIs); the other projects the dollar value of each operation. That information is fed back to the staff before they even go home, informing them whether they've actually made or lost money on that shift. This is incredible, performance-based feedback. In the past, we had no way to provide information to people with a dollar value attached."

Real-time data crosses organizational boundaries, enterprise-wide

"Employing real-time performance management using OSIsoft's infrastructure has now become a global initiative, both as an operational improvement solution and for the enterprise value of its architecture," says Fretz. "The power of having real-time data so pervasive within the organization is a great advantage. Making real-time and historical data available to every employee and providing the environment to make best use of that data is a perfect fit with our rule of high degree of empowerment of our local management. Now they can make the most efficient use of their resources. The improved attitudes and shift in mind-set resulting from the openness that the RtPM Platform has created a more positive environment of collaboration and information sharing. People can see what is wrong, learn from mistakes, and take the proper corrective action."

"OSIsoft's Platform crosses all organizational boundaries between plant, business office, engineering, and IT functions at Roche. We are confident that this connection is safe because of PI's built-in data security and firewall infrastructure," says Fretz. "There's no increased risk of system malfunction, data loss, or virus vulnerability between the control systems and the office world. We have run tests to verify that we can protect all applications from unwanted data intrusions and yet be as open as we need for a truly collaborative environment."

Faster analysis and adjustment saves time and money

"Deploying an infrastructure that allows real-time performance management has made an enormous change in how we work," says Richard Fitzgerald, Project Manager in Process Automation at the Clarecastle site. "Real-time data on every desktop changes staff from data collectors to true knowledge workers who can visualize, analyze, and share data in an instant," says Fitzgerald. "Before using OSIsoft's solution, root causes and problems were often assumed and took a lot of time and talent to resolve. It used to take us up to a week or more to find and fix a problem. Even then, we didn't always exactly know if we had found the real problem. Now, we can take a more scientific and logical approach to problem solving. When someone makes a suggestion, it's based

on real and trustworthy figures. People believe it, and we can move through resolution faster. We can find problems, fix them, and move on, never to see that problem again because next time we'll avoid it altogether."

Two examples illustrate how the Platform works for Roche: A small material leak had been costing an estimated \$50,000 to \$100,000 a year in material loss. Since the loss was not very significant, it went unnoticed until plant management discovered it with real-time PI data. In a similar case, Roche identified another material loss in one process operation. Without utilizing real-time data and analysis tools, the loss of material, along with improper product mix would have caused significant yield losses and increased cost.

Competitive advantages of operational efficiency

Today, PI monitors the operational processes at Roche in chemical and biotech (both batch processes), but the next step will extend RtPM to manage the operational performance in galenical operations. Bringing production efficiency to every plant floor operation has increased Roche's competitiveness in several ways. Using OSIsoft's Platform has enabled users to lower the cost of making products, which then become more competitive on the open market. Roche can now better determine which plants are best suited for manufacturing a particular product. In the case of the plant in Clarecastle, having real-time data and applications, centralizing calculations, trending, and using correlation displays allowed the plant to more profitably manufacture a highly visible, high-demand product under considerable cost pressure.

Roche uses OSIsoft's Advanced Computing Engine for centralized production calculations to achieve greater reusability – dramatically increasing efficiency for better process monitoring. Easy sharing of even the most complex calculations has enabled all personnel to monitor and improve operations at a higher level.

"If we had to re-calculate for each event every time, we wouldn't even bother looking," says Neville. "It would take six or seven chemists sitting around all day to do the volume of calculations that one engineer can create using the Advanced Computing Engine. In fact, we're calculating things we never could before – and discovering things that *should* be calculated!"

Better visualization and analysis have also enhanced Roche batch production. The OSIsoft batch software provides a more uniform view of production, including batch and unit-relative displays. With data shown in context, there is a better understanding of the specifics of a particular operation for more effective decision making. Such visualization with specific context provides

the ability to make batch-to-batch comparisons. Replacing prior manual tasks with the ability to extract and trend values facilitates quicker batch analysis. Even before a batch is complete, Roche can discover if something is amiss.

"Last year, we were five percent below our yield standard, but we've already improved a half percentage point over that standard, thanks to employing more real-time performance management," says Pat Scully, a senior engineer and application developer at the Clarecastle site. "Operators, engineers, chemists, and managers can plan better, improve production, and increase efficiency everywhere. Throughput is up; cycle time fell from eleven hours to eight. We're now able to produce 10 percent more batches per week."

Shorter cycle times and enterprise standards has enhanced The Roche Group's agility in manufacturing, allowing products to be delivered more quickly in response to higher commercial demand. In addition, since cycle times and equipment effectiveness are linked so closely, Roche Ireland is now able to run operations longer and more efficiently, with almost no downtime. As one illustration, three hours were shaved from cycle times and energy costs reduced by about \$30,000 simply by knowing to lower the temperatures of production coolants. Previously, only 50 batches could run before exchanger equipment became too hot and needed flushing. This added four hours to cycle times. Now, 300 batches can run with only a 20 percent decrease in cycle time.

Better compliant reporting ability

Employing an enterprise-level platform has also been integral to Roche's strategy of moving into electronic batch reporting. Since Roche began using the PI System data engine to collect data in 1996, not one record has been discarded – yet the number of batch pages required for validation has been substantially reduced. For example, in one plant, for just one product, batch records were reduced from 70,000 pages to 10,000 per year. Previously, it took as long as 2,000 hours to review 70,000 pages; now it can take as little as 120 hours to review 10,000 pages. This time-saving translates into large decreases in cycle time and time-to-market – and this represents only one-tenth of annual production.

"Applications we've built using OSIsoft's Platform have helped our regulatory reporting as well, by producing clear audit trails to support procedural compliance and back up production records," says Fretz. "Auditors like the data reliability and we even get points for being proactive in reporting. Auditors have come to trust OSIsoft's infrastructure and its data as valid, so there is growing acceptance and standardization of compliance reporting generated from OSIsoft's Platform."

Roche Ireland was an early adopter of OSIsoft's compliant reporting tool, RtReports. The goal was to replace the massive amounts of paper batch sheets used on the production floor with minimal electronic reporting. A team from OSIsoft mapped out the requirements for the reports and designed the pre-defined actions and formatted style sheets. With the initial installation and set of reports completed in three days, RtReports was successfully adopted by operators and managers as a replacement of paper-based reporting systems.

"Quickly delivering safe, high-quality products that comply with complex government approvals is critical to success in the pharmaceutical industry," says Fitzgerald. "However, being compliant can be very expensive. Having a good compliant reporting tool not only reduces the huge paper trail this type of reporting requires, it saves money in avoiding report-generation man hours and out-of-compliance fines. OSIsoft provides the only reporting solution we have found that meets our agile data collection and storage needs to ensure fast, accurate batch-record measurements."

Easy path for future growth

"We are confident that we'll be able to grow our applications to meet whatever our future requirements are," Fretz concluded. "Since we started with OSIsoft's Platform, we've never even had to discuss upward migration or backward compatibility. Migration is seamless; it just works. Time after time, we have started to re-validate after a version change but soon realized that this effort could be minimized since we know the Platform will still behave the same way – except it runs faster and offers more features. Migration is simply 'under the hood'. It requires no effort on our part – which is a major time and cost-saving benefit. This is one system we know will grow smoothly as we grow our company."

