

SAP Customer Success Story

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Kai Rothermel, Information Manager SAP QM, Roche Diagnostics



Diagnostics

AT A GLANCE

Roche Diagnostics

Roche Diagnostics, Switzerland
www.roche-diagnostics.com

Industry

Pharmaceuticals

Key Challenges

- Manual, time-consuming, error-prone processes/redundant data
- Mounting regulatory pressures
- Difficulty in managing growing product lines

Implementation Partner

SAP® Consulting

Solution and Services

mySAP™ Product Lifecycle Management (mySAP PLM) for quality management

Existing Environment

A dozen separate, nonintegrated quality management systems

Implementation Highlight

Implemented solution simultaneously with company-wide SAP® R/2® to SAP R/3® migration

Key Benefits

- Transparent laboratory processes/accurate documentation to ensure compliance to regulatory requirements
- Automated, streamlined processes – from laboratory to production
- Reduced IT complexity
- Increased quality of data in a highly integrated system landscape

Hardware

HP/UNIX workstations

ROCHE DIAGNOSTICS

mySAP™ PRODUCT LIFECYCLE MANAGEMENT HELPS ROCHE DIAGNOSTICS UNTANGLE, STREAMLINE ITS LABORATORY INFORMATION MANAGEMENT SYSTEMS

Roche Diagnostics, based in Basel, Switzerland, is one of two divisions of the 100-year-old healthcare company F. Hoffmann-La Roche Ltd.

For Roche Diagnostics, business success comes primarily from manufacturing and selling many of the world's best-known in-vitro diagnostic products. In-vitro products typically consist of chemicals that, when mixed with other substances, cause chemical reactions. These types of tests are highly effective for diagnosing a wide range of medical disorders.

However, Roche Diagnostics realized that to maintain its business success it had to address the challenges presented by a nonintegrated infrastructure of computer systems, used for monitoring and managing the processes of Roche's analytical laboratories. The company turned to SAP® software to help it manage these processes – which in fact are quite complex.

STRINGENT QUALITY TESTS

For instance, every batch of chemicals (or “reagents,” as they are called) must undergo a series of stringent quality tests before being released to production. With the old IT infrastructure, which was made up of a dozen, separate quality management systems, Roche technicians and scientists were required to communicate with one another, and with production, manually – usually by sending faxes to one another.



“Eventually, we were able to send our data into our main ERP system,” says Kai Rothermel, information manager SAP QM at Roche Diagnostics. “But it was a slow process, since we had a dozen different interfaces between the quality management systems and our central ERP system.”

As a result, redundant and sometimes conflicting data populated the different systems, so laboratory personnel frequently had to check their data, and communicate their results manually.

GROWING COMPLEXITY

At the same time, quality testing itself was becoming increasingly complex. Roche was growing, capturing about twice the in-vitro diagnostics market share as its competitors, and was introducing a variety of new products, each of which required its own testing regimen.

Furthermore, public regulatory requirements – from the Food and Drug Administration (FDA) in the United States and from legal authorities in Europe, as part of the Good Manufacturing Practices (GMP) program – were becoming more demanding.

“This industry has always been closely regulated for quality compliance,” says Rothermel. “But as the processes become more complex, the regulations get more complicated. For instance, for the last three years, the regular government inspections have covered our IT systems as well as our actual test and production processes.”

Because of these pressures, Roche installed mySAP™ Product Lifecycle Management (mySAP PLM) and its quality management (QM) capabilities in its diagnostics processing plants in Mannheim and Penzberg, Germany. The solution went live in August of 2002, as part of the company-wide systems upgrade.

NUMEROUS BENEFITS

“Quality management with mySAP PLM benefits us in two ways,” says Rothermel. “First, it performs a full range of laboratory management processes, and produces accurate, consistent documentation that can satisfy the government audits.

“Second, because it is seamlessly integrated with our ERP and production system, it has let us turn what was an IT bottleneck into a highly automated laboratory-to-production system.”

In the laboratory, the SAP solution acts as an enterprise laboratory information management system (LIMS) to cover wide-ranging analyses, including audit-trail and problem management. Also, it produces system and process-control documentation, both for audit purposes and for user training.

“Most important, it gives us full, auditable validation that our processes and our laboratory management systems are working as they should,” says Rothermel.

And thanks to the integration of mySAP PLM with Roche’s IT system, all appropriate QM information now flows directly – and immediately – into the company’s material- and batch-management and production-planning modules.

“For instance, once a new batch of reagent passes the QM testing, the status of that batch is automatically posted as ‘free stock’ in the materials management system,” says Rothermel. “And if it doesn’t pass, then it’s automatically blocked from production.”

As a result, Roche now gets products to market more quickly than before, because staffers don’t have to take the time to manually check and double-check one another’s test data.

ROOM FOR GROWTH, PRODUCT SAFETY

The SAP solution for quality management has helped Roche Diagnostics streamline its IT infrastructure, too, by eliminating the dozen IT interfaces that connected the laboratory and production systems.

And this has cleared the way for Roche to continue growing and introducing new products well into the future.

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Kai Rothermel, Quality Management Information Manager
Roche Diagnostics

The QM solution has also brought a new level of safety both to its customers and to Roche, according to Rothermel.

“We now know we can rely on our QM data and its documentation,” he says. “This means our customers and our employees are assured of continuing, top-level product quality – a fact that is extremely important in this business.

“And it means we can be confident about complying with regulatory audits. This is important, because if you don’t comply, the FDA or another agency can actually shut down your entire plant.”

NEXT STEP: SAP BUSINESS INTELLIGENCE

Now that about 400 laboratory professionals at Roche Diagnostics are using the quality management capabilities of mySAP PLM, the company is moving to add to its quality reporting capabilities through SAP Business Intelligence (SAP BI) – a component in the SAP NetWeaver™ platform.

SAP BI will let Roche look more deeply into inspection results and trends.

And because SAP BI is integrated with other SAP solutions, it will leverage the data already collected by the QM system. This will make it even easier for Roche to improve its quality management processes without increasing IT complexity.

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