PAT/QbD – Bringing Pharma into the 21st century

Creating Innovations for the Pharmaceutical Industry

Answers for industry.
The pharmaceutical industry is headed fundamental changes within the next decade. These changes are due to regulatory, market, scientific and technological developments, just to name a few. Manufacturing efficiency and innovation are highly welcomed by businesses that wish to secure their competitive position. The concept of Process Analytical Technology (PAT) plays a decisive role within this change.
Right-first-time quality with Process Analytical Technology

Monitoring quality in real time

The development and implementation of PAT in the pharmaceutical industry has been clearly defined in a US Food and Drug Administration (FDA) guidance. Topics embraced by the initiative “Pharmaceutical cGMPs for the 21st Century” include ongoing changes in manufacturing technology, the philosophy of product quality control, the drug approval process and the regulatory environment. PAT allows real-time monitoring of product quality and results in an improved process understanding. It also enables right-first-time manufacturing with a tightly controlled process having quality as an integrated standard in all processes. By reducing the need for trial and error, FDA regulators expect that the implementation of PAT will allow companies to more easily improve manufacturing processes and reduce product development times.
SIMATIC SIPAT software: the platform for product release in real time

The implementation of PAT in the pharmaceutical industry has started. To support this important trend, Siemens has developed the SIPAT software solution. There are a number of tools that support PAT principles in development and manufacturing plants, such as process analyzers, process control tools and reporting tools, only to name a few. But to properly implement PAT, you need more than just supporting tools. You need a solution that intelligently interprets and interconnects data generated by these quality tools. A software that installs absolute data transparency by returning correlated data back to the processes from product development onward. A solution that can make valuable predictions to continuously improve quality and efficiency from unit operation level up to ERP, MES and LIMS. This is exactly what SIMATIC SIPAT does.

Step-by-step process improvements

The common user-friendly interface is open towards third-party systems, but was developed to perfectly fit our range of SIMATIC automation products. SIPAT is scalable, modular and allows a controlled quality growth as the PAT initiative expands. With SIPAT, pharmaceutical companies may now gather in-depth process understanding, release products in real time and further develop processes based on “Quality by Design” (QbD) principles in order to manufacture “right-first-time.”
Gui permits you to record data interactively, to create new PAT procedures, or to view additional information on current or historical production batches.
Unlimited benefits – both from a business and technology perspective

The implementation of SIMATIC SIPAT offers the prospect with a risk-based regulatory framework. With SIPAT, in-process data and data analysis tools significantly improve process understanding and control. This ensures quality and reduces the risk of non-compliant products. Built-in process optimization and quality consistency thus ensure right-first-time quality. For an existing production, the benefits of SIPAT can be seen in terms of reduced cost, lower inventory levels and a move towards just-in-time production and supply. For a new production, the benefit lays in the ability to quickly develop the manufacturing process, upscale to a robust process and perform validation more easily.

Furthermore, SIPAT bears the following key technological advantages:

• One common interface platform for all PAT tools
• All analyzers and PAT tools can be linked into a single system architecture
• SIPAT offers full auditing functionality supporting compliance with legal regulations and FDA 21 CFR Part 11
• Modular structure enables a scalable PAT rollout and deployment and allows for a phased implementation and rollout
• SIMATIC SIPAT can be set up and used “out of the box” through specific configuration which strongly facilitates validation.

Reduced risk
Validation optimization
Quality consistency
Real-time product releases
Process optimization
Right-first-time quality

SIPAT business benefits

This is how SIMATIC SIPAT pays off for you
Ideas for the pharmaceutical industry

As a long-established partner to the pharmaceutical industry, we develop customized solutions together with you that will optimally prepare you to meet your market's demands today and in the future. For many years now, this is what we stand for.

Products have to be on the market fast and quality has to turn into an integrated part of production processes. This is why we not only follow the progression of PAT very closely, but also want to set the trend when it comes to this topic. Over the years, we have developed an extensive and multidisciplinary PAT know-how and have specialists in all domains that are concerned when implementing a successful PAT project.

**Acting sustainably**

We have skilled PAT experts that are able to execute successful PAT projects and can offer you profound advice on the business benefits that PAT can bring to you. Consultancy services are available in all stages and all disciplines, from preparation of the business case, over project methodology and IT, to modeling and Advanced Process Control. Siemens either uses its own experts, or involves one of the partners in the Siemens PAT network.

We are strongly committed to setting new standards in production processes in close cooperation with you as our partner. With our in-depth PAT knowledge acquired over the years and our comprehensive SIMATIC SIPAT solution, we can contribute to improve the quality in your production processes.
Discover our ideas for a strong future of the pharmaceutical industry.

The benefits of PAT/QbD at a glance

Learn more: siemens.com/pharma

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