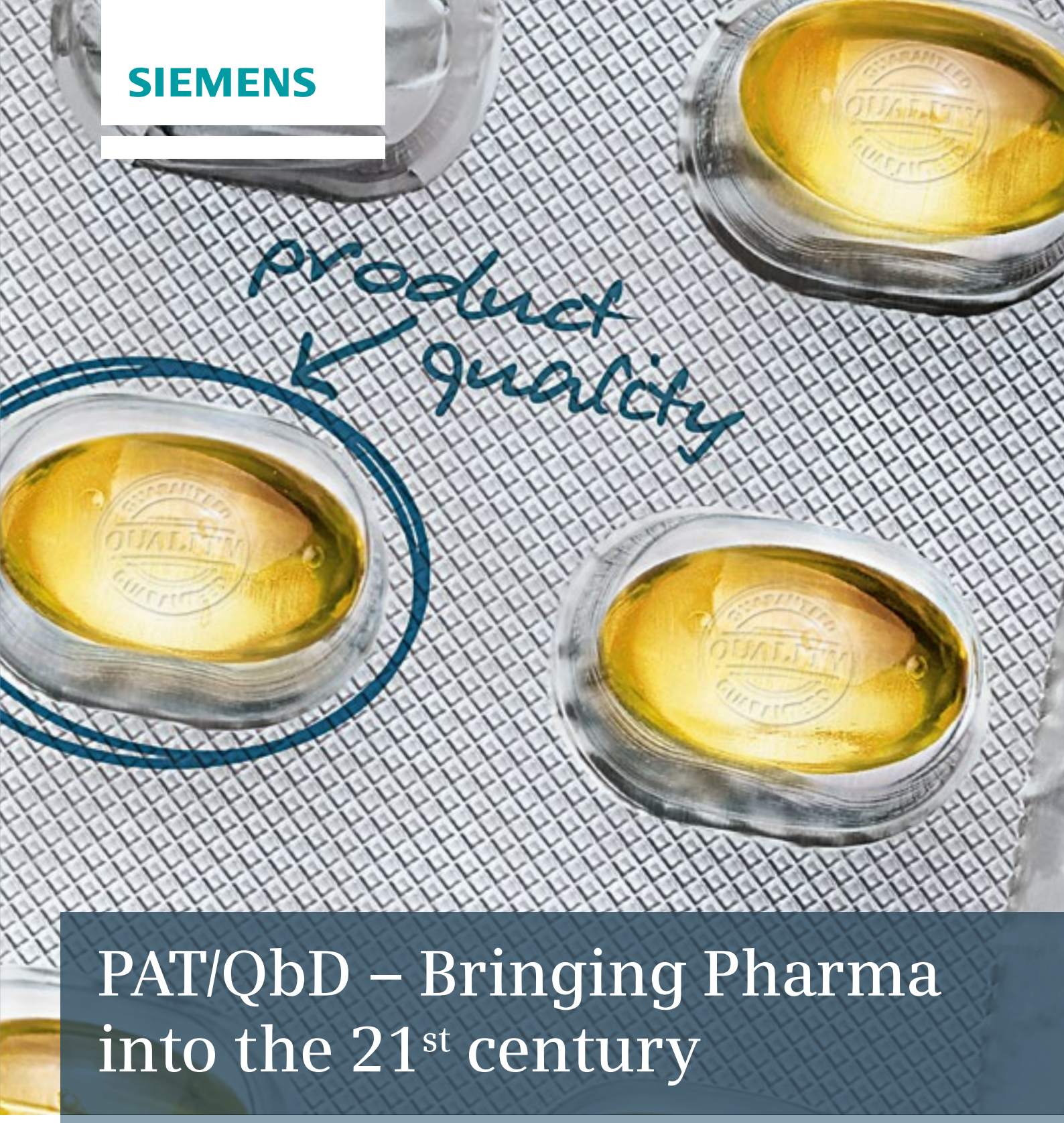
SIEMENS



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.

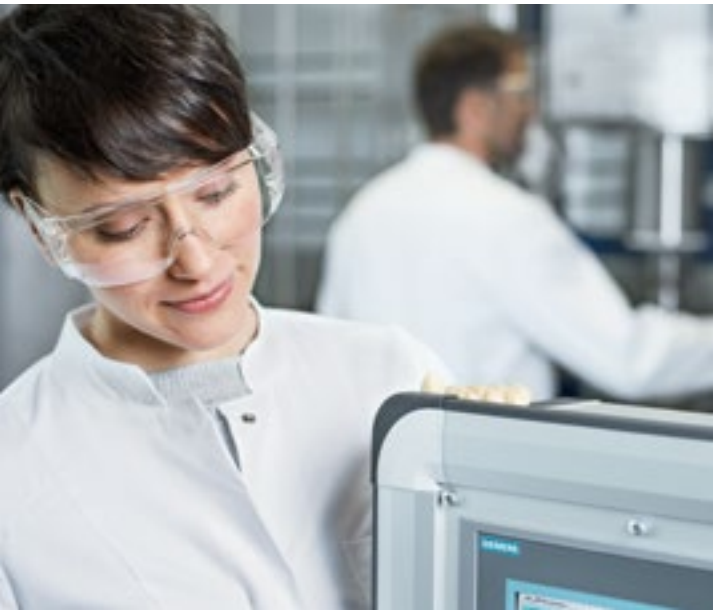
SIMATIC SIPAT software: the platform for product release in real time

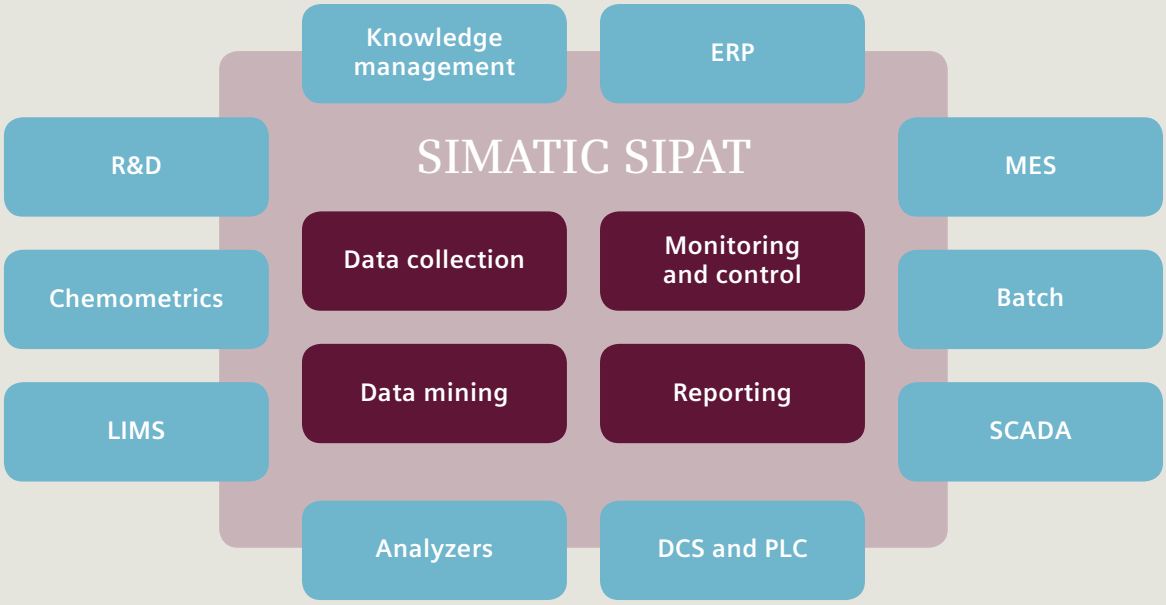
The implementation of PAT in the pharmaceutical industry has started. To support this important trend, Siemens has developed the SIPAT software solution. There are a number of tools that support PAT principles in development and manufacturing plants, such as process analyzers, process control tools and 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."

What´s new in SIMATIC SIPAT





Functional highlights

Data collection

SIMATIC SIPAT is able to connect with most worldwide used process analyzers to capture process analytical data in both manufacturing and process development. Industry standard open techniques are used to both capture these data in a reliable way as well as to feed the calculated results back into the process control system. SIPAT can include quality parameters that are measured both off-line and on-line or which are stored in a LIMS system, entered manually into SCADA or directly into SIPAT. Data from different sources – even over multiple sites – can be consolidated for better data mining.

Data mining

SIMATIC SIPAT can be used for building and applying models on various levels. This way, a specific model hierarchy can be installed to handle data efficiently. In the Data Miner, the user starts the process of preprocessing, validating and analyzing data; these data are then used to build and validate new or improved models. The models are stored in the SIPAT database with version information and status.

Reporting

SIMATIC SIPAT stores all measured and calculated data during the operational execution of a PAT method together with the available batch context information. This data is available for any standard reporting tool and can seamlessly be integrated into office applications. Both the integrated SIPAT Data Miner and the SIPAT Report Manager allow out-of-the-box browsing, filtering and querying of the measured data, its context and calibration data. This ensures that all required data can be used in the supported modeling software packages.

Monitoring and control

The SIMATIC SIPAT run-time module combines on-line data acquisition and alignment with on-line prediction of quality parameters. Within this process, SIPAT takes care of the quality aspects of the process and makes this information available to the control system. Any control system supporting OPC communication can then take care of the control and corrective actions. SIPAT predictions may be visualized in the existing SCADA system or the configurable SIPAT Graphical User Interface (GUI); all critical-to-quality attributes (CQA) can be monitored online and returned to the process control system – by comparing plotter parameters with the golden batch series. Visualization takes place either using the SCADA/process control system or the graphic user interface of SIMATIC SIPAT.

GUI permits you to record data interactively, to create new PAT procedures, or to view additional information on current or historical production batches.

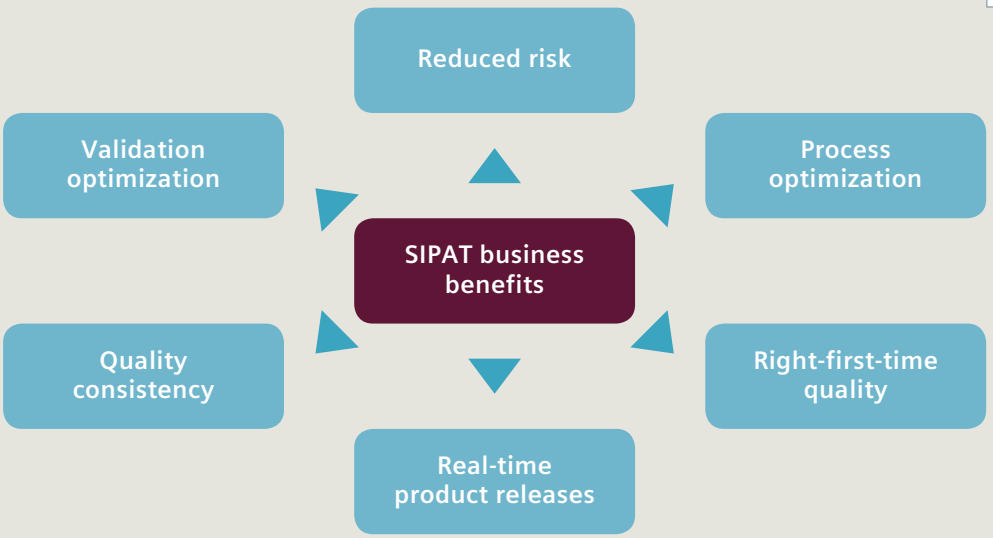
Unlimited benefits – both from a business and technology perspective

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.

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.

Learn more:

siemens.com/pharma

Discover our ideas for a strong future of the pharmaceutical industry.

The benefits of PAT/QbD at a glance

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