

For the Trade Press

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Siemens launches Software Solution for Pharmaceutical Applications

With Sipat Siemens is launching a new software solution to support the application of Process Analytical Technology (PAT) in the pharmaceutical industry. Sipat is scalable and modular and allows a controlled quality growth as the PAT initiative expands. The new software solution serves as a common user-friendly interface for all PAT tools and can be fully integrated into the manufacturing and development architectures. The main feature is the ability to interface with an existing manufacturing architecture, allowing full transparency on quality aspects from unit operation level up to ERP, MES and LIMS. With Sipat pharmaceutical companies are now able to gather process understanding, strive for continuous process improvement, develop processes based on 'quality by design' principles and to manufacture 'right-first-time'.

Regulatory and financial forces are pitching pharmaceutical manufacturing towards rapid change. Process Analytical Technology (PAT) is an exceptional opportunity for pharmaceutical companies, to improve manufacturing performance, reduce manufacturing costs, reduce time to market and improves supply chains responsiveness. PAT allows to design quality into the process and move to real-time product release.

Sipat is a scalable and modular software solution which allows a controlled quality growth as the PAT initiative expands, moving from off-line to on-line process investigation, followed by controlling the process and then on towards a full real-time product release capability. Sipat serves as a common user-friendly interface for all PAT tools and can be fully integrated into the manufacturing and development architectures. Sipat integrates process analyzers, process control tools, data analysis & mining tools (multivariate data analysis), data collection, storage and retrieval tools, reporting tools and continuous improvement and knowledge management tools. One of the key features is the ability to interface with an existing manufacturing architecture, allowing full transparency on quality aspects from unit operation level up to ERP, MES and LIMS. It enables the capture of analytical and process measurements, model creation and validation, online prediction and analysis, feedback to process control and, finally, real-time product release. With Sipat pharmaceutical companies are now able to gather process un-

derstanding, strive for continuous process improvement, develop processes based on 'quality by design' principles and to manufacture 'right-first-time'.

Thanks to Siemens' wider cross-industry experience of PAT and its close interaction with the FDA, EMEA and various PAT related initiatives, like ASTM E55, Siemens has expert knowledge and offers a multidisciplinary PAT solution. Siemens possesses all the know-how, services and the right tools to guarantee a successful PAT implementation.

Further information at: www.siemens.com/sipat

This press release is supplemented by a photo which you can view on the Internet at: www.siemens.com/ad-picture/1426

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