

Press Release

eQCM[®] Compliance Process Control Solution Is Designed to Fulfill the Recently Finalized “Guidance for Industry – Quality Systems Approach to Pharmaceutical CGMP Regulations” from the US FDA

Karlsruhe, 2 November 2006 – The US Food & Drug Administration released its finalized “Guidance for Industry – Quality Systems Approach to Pharmaceutical CGMP Regulations” at the end of September 2006 (<http://www.fda.gov/cder/guidance/7260fnl.htm>). By explaining the FDA’s thinking on current good manufacturing practices (CGMP), this Guidance for Industry is designed to help FDA-regulated companies in implementing quality systems and risk management approaches to meet the requirements of the FDA’s CGMP regulations, namely 21 CFR Parts 210 and 211.

Systec & Services GmbH is pleased to announce the availability in Western Europe of the software solution eQCM[®] (Enterprise Quality and Compliance Management) from our partner Amadeus International. eQCM[®] is a set of compliance process control modules that are fully integrated to deliver the most comprehensive compliance process control system on the market. The eQCM[®] solution offers a document management system, full support for internal and external audit management, corrective and preventive actions, nonconformances, customer satisfaction, and employee competency management. eQCM[®] additionally incorporates a scorecard of compliance issues to provide companies with actionable intelligence on areas that need attention.

According to Pierre-François Isabel, Vice President of Sales & Marketing at Amadeus International, “Amadeus tailored eQCM[®] to the specific needs of FDA-regulated companies, providing a balanced approach to quality, compliance and risk management.”

Fred Schiffmacher, Managing Director of Systec & Services GmbH, stated: “We are excited to be able to offer our customers eQCM[®]. This comprehensive compliance control suite provides an ideal tool for our customers in the life sciences industries to meet the requirements of the FDA’s CGMP regulations in a user-friendly, flexible and easily configured solution.”

About Systemic & Services GmbH

With its headquarters in Karlsruhe, Systemic & Services GmbH is a system house that offers comprehensive IT integration to customers in the pharmaceutical, food and cosmetics industries. We are specialized in integrated production management. Our international customers profit from our many years' experience in the optimization of their business processes in production-related environments and they value our full-service offering. Systemic & Services is an IT system integrator of MES systems in SAP environments, as well as of specialized GMP IT platforms and compliance process control solutions for the regulated industries.

About Amadeus International Inc.

Amadeus International is a pioneer and leader in compliance process control solutions. Its flagship product, eQCM[®], is a flexible, Web-based integrated suite of applications that allow organizations to map regulated business processes such as CAPA, non-conformances, customer satisfaction, audits, and other related quality and business processes. The application suite is coupled with powerful business intelligence capabilities, enterprise content management, and related technologies that help organizations achieve sustained compliance. Amadeus International's global headquarters are located in Quebec City. Amadeus solutions are distributed across four continents.

For Additional Information:

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