

Press Release

Metastorm Meets GAMP 4.0 Guidelines

Metastorm BPM® Completes Successful Audit by Top Pharmaceutical Company

BALTIMORE, MD – June 23, 2008 – Metastorm, a leading provider of Business Process Management (BPM), Business Process Analysis (BPA), and Enterprise Architecture (EA) software for aligning strategy with execution, today announced that it adheres to the version 4.0 guidelines set forth by the Good Automated Manufacturing Practice Forum (GAMP). GAMP is part of the International Society for Pharmaceutical Engineering, which promotes the understanding of the regulation and use of automated systems within the pharmaceutical industry.

One of Metastorm's customers – a top global pharmaceutical manufacturer that is subject to the compliance requirements of the U.S. Food and Drug Administration (FDA) – requested to audit the Metastorm BPM suite so that the company could use the software more widely within the organization. The audit, which followed GAMP 4.0 methodology, validated that Metastorm BPM provides this customer with the functionality, process, and technical controls it needs to help comply with regulatory standards including FDA Title 21 CFR Part 11, which governs the use of electronic records and signatures to maintain the security and integrity of certain types of information.

The audit encompassed a review of Metastorm BPM and related aspects including:

- The software development life-cycle (SDLC)
- Full traceability of business requirements, design, development, testing and release
- Metastorm's HR & personnel qualifications
- Standard operating procedure (SOP) adherence

- IT & infrastructure best practices

As part of the audit and in an effort to ensure ongoing compliance, Metastorm implemented a formal Quality Management System (QMS) using the good practice guidelines identified by GAMP.

“Metastorm is proud to have successfully completed this rigorous evaluation which confirmed that Metastorm BPM as used by this pharmaceutical customer adheres to the GAMP 4.0 guidelines,” said Greg Carter, Metastorm CTO and Vice President of Development. “BPM is a logical choice for organizations seeking to achieve compliance and governance objectives because it can enforce and manage compliance at the business process level – most often the level at which an organization’s compliance objectives are either met or missed. This latest achievement is evidence of Metastorm’s dedication to being a leader in this industry and should help to make Metastorm an important enterprise platform for other life sciences and pharmaceutical customers.”

Metastorm continues to gain momentum as an EA, BPA and BPM vendor of choice for some of the world’s largest and most successful life sciences and pharmaceutical organizations. For example, Wyeth uses Metastorm to help define business processes and unify its information systems to break down barriers between organizational and geographic divisions and to improve collaboration and innovation. “Wyeth’s Prescription for Business Process Management Success” was featured in the May 30, 2008 issue of CIO Magazine. The story can be viewed online at http://www.cio.com/article/375067/Wyeth_s_Prescription_for_Business_Process_Management_Success

About Metastorm Inc.

With a focus on enterprise visibility, optimization, and agility, Metastorm offers market-leading software for Enterprise Architecture (EA), Business Process Analysis (BPA) and Business Process Management (BPM). As an integrated product portfolio, Metastorm Enterprise™ allows organizations to improve business results by unifying strategy, analysis and execution. Metastorm is bringing together these critical disciplines to enable an understanding of enterprise architecture and strategy, accurate impact and opportunity assessment, effective process execution, and accelerated value realization for organizations worldwide. For more information on powering strategic advantage with Metastorm Enterprise, visit www.metastorm.com.

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