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## **Press release**

### **KMmaster® Life Science Edition with qualified electronic signature supports long-term validity at CellTrend**

**CellTrend GmbH chooses KMmaster Life Science Edition with qualified electronic signature from Pumacy Technologies AG.**

**Berlin, 21 March 2011** – Pumacy Technologies AG, a provider of web-based software solutions, today announced that KMmaster Life Science Edition (<http://www.intakt-lifesciences.de>) has been chosen by CellTrend GmbH, a contract research organisation for the pharmaceutical industry. KMmaster Life Science Edition is used as fully integrated system including qualified electronic signature. The web-based software solution ensures efficient and productive operation and helps CellTrend create, manage and train quality-related documents such as SOPs, quality forms, and templates.

Dr. Kai Schulze-Forster, co-owner and division manager quality management at CellTrend GmbH, says: "With KMmaster Life Science Edition we have found a software tool that helps manage our documentation efficiently. The system provides an effective overview of documents available within the creation, revision, training, and signed status. The Life Science Edition and the qualified electronic signature secure long-term availability of data that are relevant to our employees. Routine activities are reduced and formal errors avoided. The document creation process becomes accelerated. In addition, Pumacy provided excellent support and assistance through all stages of the software implementation."

Dr. Tobias Müller-Prothmann, division manager innovation management at Pumacy and project manager of the Life Science Edition software development, says: "Quality assurance in the

pharmaceutical industry requires documentation to a large extent, no matter the size of the organisation. With KMmaster organisations—especially small and medium-sized enterprises—benefit from a lean and web-based software solution. Our Life Science Edition can be easily integrated into existing processes—even in small biotechnology companies. The software supports an efficient management of SOPs and related processes. KMmaster helps users to manage their documentation tasks smoothly and enables them to concentrate on their core business activities.

The fully integrated software enables CellTrend to manage documents and meet all legal requirements using the qualified electronic signature. The signature process is secure and the signed documents are legally binding. In addition, the software provides provable and legally binding printouts of documents. The workflow according to GMP integrates all necessary participants giving them the opportunity to share knowledge and organisation-related information. Employees, management board, and quality management use valid documents at all times; review cycles of documents are not exceeded. The integrated trainings management, in particular, helps CellTrend streamline tasks and costs. The audit trail offers verification of the document creation process and guarantees a complete monitoring—also for external auditors and inspectors.

CellTrend (<http://www.celltrend.de>) is a biotechnology company and works as a contract research organisation for the pharmaceutical industry. CellTrend performs cell based Bioassays with the focus on oncology and immunology. Furthermore, CellTrend develops, produces, and distributes Immuno-Assays, a quick and sensitive analytical method that is characterised by specific binding of antibodies to analytes. CellTrend is certified according to ISO 9001:2008, ISO 13485:2003 (medical devices), and ISO 13485:2003 CMDR (Canada Medical Devices Regulation). Our Total Quality Management affects all processes and has been developed to fulfil our customers' needs. We strictly adhere to the rules of GMP (Good Manufacturing Practice, FDA).

### **KMmaster®**

KMmaster ([www.kmmaster.de](http://www.kmmaster.de)) is a web-based knowledge management application to manage process-based information and documents

Individually designed solution concepts promote communication and collaboration within teams working in distributed environments. The systematic management of knowledge helps businesses to improve performance and increase profitability.

The KMmaster Life Science Edition is a solution for pharmaceutical and biotechnology organisations. The current edition streamlines quality processes and GxP compliant documentation, especially for standard operating procedures

(SOPs). The Life Science Edition meets the needs of small organisations, too. It provides a set of features for managing compliance projects such as qualified electronic signatures, trainings management, integrated audit trails, and compliance with FDA 21 CFR Part 11 requirements.

### **Pumacy Technologies AG**

Pumacy Technologies AG (<http://www.pumacy.de>) is a leading knowledge management solution provider. The comprehensive portfolio of products and services is based on an interdisciplinary approach covering knowledge, process, and innovation management.

Pumacy Systems is an in-house software company of the Pumacy Group. The software KMmaster is a knowledge management application to manage process-based information and documents.

Pumacy has customers who are known as leading manufacturers from the aerospace and automotive, the plant and machinery industries as well as the life science sector. Pumacy has extensive references from significant international projects.

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