# KMmaster® Life Science Edition

Electronic SOP-Management



**LIFE SCIENCE** EDITION

Secure Processes,
Quality and Knowledge

# KMmaster® Life Science Edition

## Web-based SOP Management and Qualified Electronic Signature

KMmaster Life Science Edition combines quality, process, knowledge and innovation management aspects. The software is specifically designed for companies from the biotechnology and pharmaceutical industries.

The web-based platform can be used as hybrid system (electronic documents and processes, paper-based signature and archiving) or as fully integrated system including a qualified electronic signature (paperless solution). Additionally, the KMmaster Life Science Edition can be extended in functionality by idea and knowledge management modules such as lessons learned or best practices.

SOP Management
- ✓ web-based and GxP compliant
- ✓ FDA 21 CFR Part 11 compliant
- ✓ qualified electronic signature fully integrated & paper-based

KMmaster® Life Science Edition

**PUMACY**
TECHNOLOGIES

## Your benefits at a glance

*Electronic SOP management systems deliver multiple benefits. With an SOP management system you will:*

- reduce the cost associated with archiving and storage management,
- become familiar with new processes and procedures more easily,
- have access to valid and reliable documents,
- adhere to review cycles (punctuated by reminders and alerts),
- be able to develop quality documents using workflows based on time-related constraints,
- use an intelligent search providing fast and accurate search results,
- be able to provide customers, auditors and inspectors with documents.

*The web-based system:*

- can be implemented within available IT environments,
- offers flexible access from inside and outside the organisation,
- can be used across the whole organisation,
- requires minimal service.

*Qualified electronic signature benefits:*

- secure and legally binding signature
- storage with 2D barcode to meet legally binding requirements for printouts
- multiple signatures per document

## What will you achieve?

*Workload reduction for the SOP management:*

- hybrid system (electronic/paper-based): up to 50 per cent
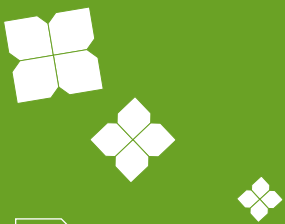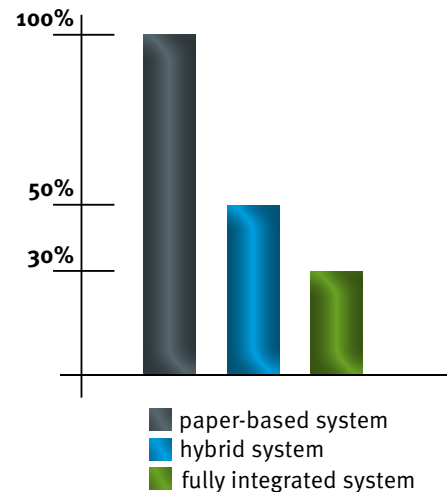- fully integrated system (paperless): up to 70 per cent

*Quality assurance for GxP audits:*

- safe and GxP compliant SOP management
- safe and GxP compliant management of quality forms and templates
- safe and GxP compliant management of trainings

*Security for third party:*

- security towards customers
- security towards investors
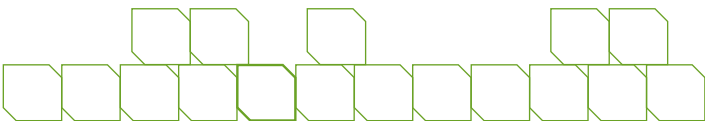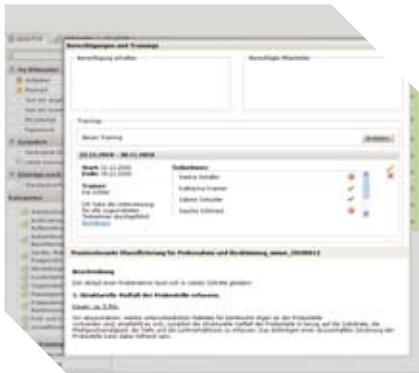- FDA 21 CFR Part 11 compliance

### Estimated Workload

- paper-based system
- hybrid system
- fully integrated system

## Features

*KMmaster Life Science Edition helps companies maintain compliance with GxP regulatory requirements for SOP management through:*

- standard operating procedure (SOP) management, quality form management, training management
- document lifecycle management covering initiation, approval, training, review, and archiving of documents
- qualified electronic signature
- advanced formatting features
- automatic version control
- integrated audit trail
- extended search options (filter, full-text including attachments)
- email notification with standard mail client
- commentary feature
- user roles and permissions (compliance with GxP requirements)
- category structure and linked to documents
- notification and reminders
- print tracking

## Customer Testimonials

*"KMmaster Life Science Edition helps us maintain focus on ensuring the electronic management of all relevant documents. We can manage our documents, past trainings, and binding signatures efficiently at any time – from production to review of a document. With the Life Science Edition and the integrated qualified electronic signature we use a secure system providing long-term access to our electronic records."*

Dr. Kai Schulze-Forster (co-owner and division manager of quality management at CellTrend GmbH)



*"The KMmaster Life Science Edition ensures secure document management and training. The integrated software solution helps us save time and money while meeting important legislative and regulatory requirements."*

Christian Buttenberg (CEO of the BlisterCentrum Berlin/Brandenburg)



## Technologies

Architecture: J2EE

Application Server: JBoss

Database: MySQL, Oracle, etc.

Users only need a web browser such as Internet Explorer or Firefox.

Certified partner product and free download of verification software for qualified electronic signature



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secrypt

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