

REXS

Risk Expert System

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REXS – by experts for experts

REXS is based on the extensive experience of VTU experts in the GMP and safety sector. The system is specifically designed to support experts engaged in the pharmaceutical, medical and engineering sector during the implementation of risk management that is FDA and EU GMP-compliant.

- Development and validation in accordance with Annex 11 of the EU GMP Guideline, 21CFR11 and GAMP 5.0
- GMP-compliant risk analysis documents can be version-managed, created and released by authorized persons and are unchangeable when archived.
- Lifecycle-oriented risk management e.g. in accordance with ICH Q9 and EN ISO 14971

We provide you with support during introduction of the software in your company. Together with you, we define your risk management process and help you to implement it in the software system.



Company profile

VTU Engineering is both planner and consultant for the pharmaceutical, life science and medical technology industries. One focus of our activities is on GMP services within the scope of qualifying and validating equipment, processes, computer systems and medical devices.

We also provide consulting for the introduction of GMP-compliant processes in engineering, production, laboratory and quality assurance through to collaboration during audits and inspections.

The experts at VTU Engineering have experience in a variety of different projects and are very familiar with industry requirements as a result of their work and continuing professional development in the GMP and pharmaceutical sectors. You can benefit similarly from the high standard of our technical and organizational skills.

VTU has been conducting risk assessments in-house and in customer projects for many years, both in the GMP sector and in safety engineering. Our risk analysis experts often take over moderation of the risk analyses in the process.

VTU, in cooperation with gempex, developed the model of object-oriented risk management for the implementation of a lifecycle-orientated quality risk management. It aims to assist companies to implement and optimize their risk processes.

The REXS software was developed based on our many years of experience in the safety, GMP, risk and quality management sectors.

Software for efficient risk management

It has been a legal requirement for years for companies to implement a risk management process throughout the entire product life cycle. REXS was developed specifically for the pharmaceutical, medical and engineering sector. The software system is based on the extensive experience of VTU experts in the GMP and safety sector in addition to the FDA and EU GMP-compliant risk management process of our development partners.

- Risk analyses for GxP, QM, safety & technology
- No loss of knowledge, expert know-how at your fingertips
- Effective action management
- Cross-site consistency
- Centralized data management
- Import/export of risk analysis
- Risk management across the entire lifecycle

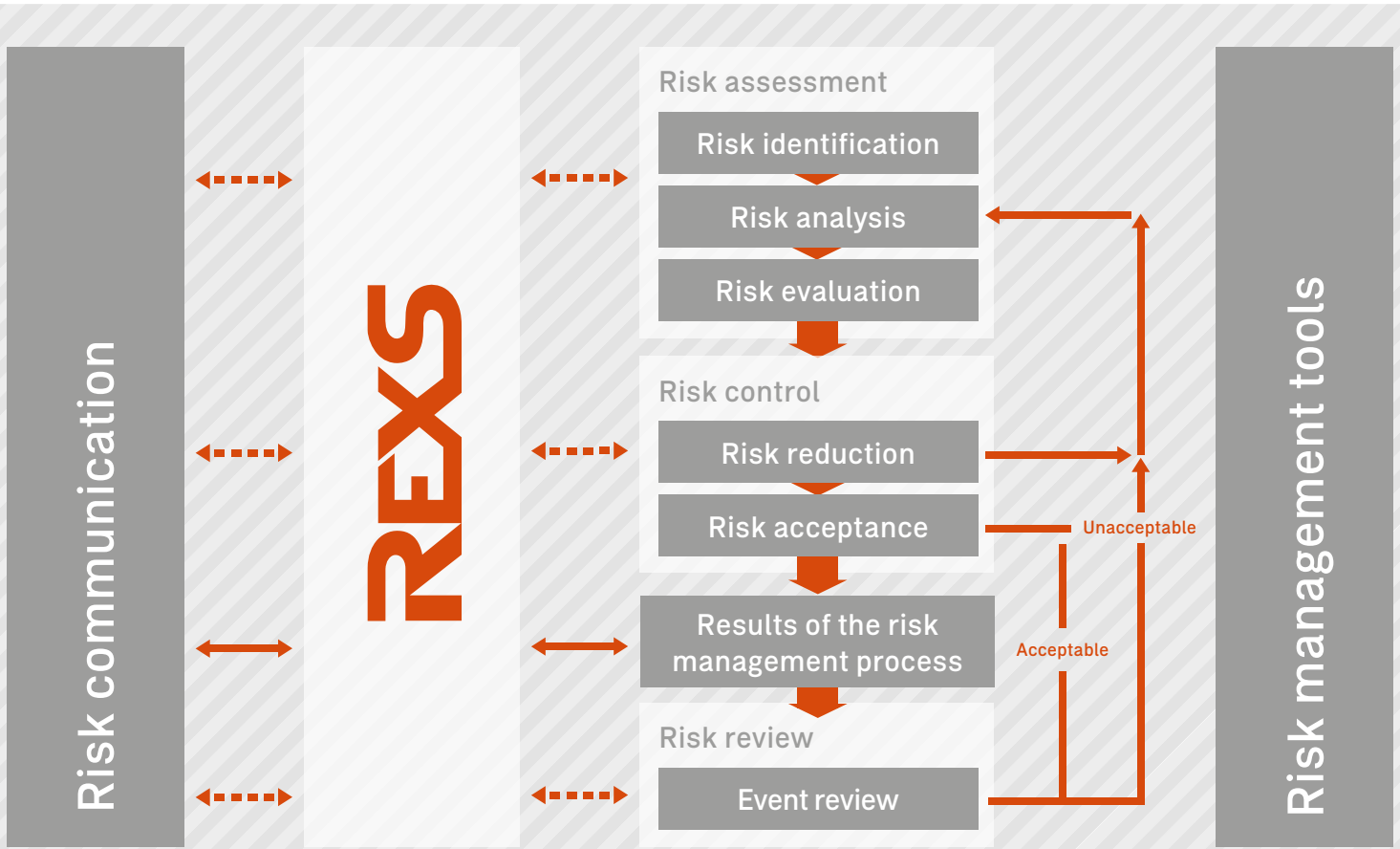
Easy and GMP-compliant risk management

REXS is an innovative software system for efficiently creating risk analyses and managing actions centrally.

The software enables the use of various methods such as FMEA, HAZOP, Ishikawa diagrams or user-defined methods and is the perfect moderation and documentation tool for performing risk analyzes.

The regulatory requirements on lifecycle-oriented risk management (e.g. in accordance with ICH Q9 or EN ISO 14971) are put into practice in REXS. It is easy to implement risk communication in REXS – by reusing knowledge at the touch of a button.

- Customer-specific configuration (e.g. of forms, evaluation catalogues and risk matrices)
- Combination of tabular/graphical methods
- Automatically generated action catalogues for tracking status and deadlines for each defined measure
- GMP-compliant document creation
- Document release by authorized individuals via the integrated comment process
- Data output in common formats such as PDF, RTF (Word) and Excel
- Creation of standardised risk analyses in your company-specific document layouts



Lifecycle-oriented risk management

Risk analyses are always performed for defined objects – equipments, products, processes and their combinations throughout the entire product life cycle.

When creating new risk analyses – starting from product development to routine production – REXS shows you at the touch of a button the risks specifically relevant for these objects and actions to reduce their risks. In this case, the system makes use of all the data from old risk analyses which already exists in the system. So experts have access to the extensive risk knowledge at any time - from product development to application.

- Intelligent object-oriented suggestion system
- Suggestions for risks including their evaluation and actions for reducing them
- Central management of all site-related objects
- Hierarchical structuring enables mapping at different system levels

Effective knowledge management

Your company's pool of knowledge expands constantly due to the self-learning database. The risk knowledge of every analysis is available company-wide and independent of time. Even risks only considered once are not forgotten. Suggestions for evaluations of the same risks from previous analyses create consistent data.

- Your risk knowledge grows with each analysis
- Consistency with and across risk documents
- Efficient knowledge transfer: Knowledge already acquired can be reused easily and extensively
- Location- and time-independent knowledge transfer enables risk management over the entire lifecycle
- Support during the risk review or change control due to comprehensive risk requests





From document overload to information network

On the one hand, risk analyses are created by different people and, on the other hand, over a very long time period. With REXS resulting gaps in knowledge and information exchange can be easily minimized.

REXS is a client-server application and can be used across departments and locations to optimize the risk management process company-wide. The data entered when creating a risk analysis in the REXS database are linked via a logical network and made available to users for all other risk analyses and evaluations. Actions can be managed simply and centrally in the system. Thus knowledge already acquired is not lost but continues to be available companywide, is well-structured and can be called up at any time.

- Site-independent management and reuse of risk knowledge
- Central management of risk analyses and all related documents in the integrated Explorer
- Actions module for centralized management and follow-up of all actions to be executed
- Take the right information to the right people, anytime
- Import/export functions for risk analyses
- Extensive search functions – find even those risks that you have only considered once
- Fast system installation and user acceptance due to intuitive user interfaces



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