

The market-leading, validated approval accelerator  
for convenient generation of flawless technical  
documentation for medical devices



# RISK MANAGER

**EUROIMMUN**  
a PerkinElmer company



**SUCCESS STORY**

**Comprehensible, clear and easy-to-use Risk Management, even  
for broad product ranges**

**„I can recommend the RISK MANAGER to anyone who needs  
to prepare comprehensive risk management files.“**

Dr. Jan Ole Jungmann  
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**BAYOOSOFT**  
MANAGEMENT SOFTWARE

EUROIMMUN is one of the leading manufacturers of test systems, devices and software for human and veterinary laboratory diagnostics. More than 3000 employees worldwide work together in development, production and distribution of reagents and automated systems. The products of EUROIMMUN are used in more than 150 countries to diagnose autoimmune and infectious diseases as well as allergies and to perform genetic analyses. The company has extensive expertise in the areas of immunology, cell biology, histology, biochemistry and molecular biology.

**EUROIMMUN Medizinische Labordiagnostika AG**

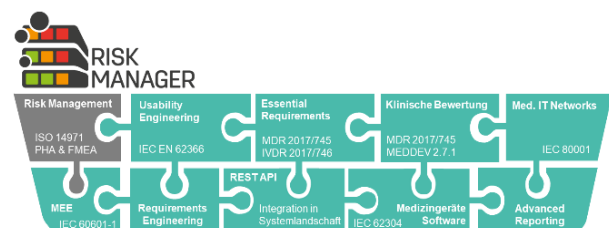
## Challenge: Find a perfectly matched system

As a manufacturer of IVDs, EUROIMMUN has a very broad range of products and therefore has to maintain an individual risk management file for each of them. Unfortunately, this has led to many uncertainties among the employees regarding the risk files. Methodological and formal inconsistencies have also repeatedly arisen. "With over 200 employees working on risk management in our company, a common understanding and a uniform approach is absolutely essential.", explains Dr. Jungmann during the interview.

In order to handle this work and to meet the regulatory requirements (e.g. **FDA - CFR 21 Part 11 Compliance**), EUROIMMUN started looking for an appropriate software in 2017 and found the BAYOOSOFT Risk Manager.

## Choosing the Market Leader

After attending a webinar and having a free test evaluation, EUROIMMUN decided within the same year to use the BAYOOSOFT Risk Manager from now on to create their risk management files. Further support in the technical documentation of in-vitro-diagnostics is provided by the modules Essential Requirements, Requirements Engineering and Usability Engineering. The supplementary Prevalidation Package was also chosen in order to fulfil a comprehensive software validation according to ISO 13486. Thus, all requirements and standards relevant for EUROIMMUN are covered within one system in a clear, structured and time-saving manner.



The validated approval accelerator  
for a perfect technical documentation

## Achieving Cost Savings

After a quick and smooth implementation of the software and the training of the employees, the processing of the documentation could be started immediately within the BAYOOSOFT Risk Manager. “The existing input masks, which fulfil the requirements of the given standards, facilitate the activities of the risk management very much.”, describes Mrs. Gehring, Quality Management at EUROIMMUN. “The Risk Manager is also taken on positively during audits and makes them easier due to the clearly structured documents and the graphic presentation with filter options.”

Especially in the area of Usability Engineering, which is closely linked to risk management in several points, EUROIMMUN has seen many improvements. The template, which is now available through the Risk Manager, enables the usability file to be maintained in compliance with the required standards.

„Previously we worked with Excel-Sheets and therefore some things could easily get lost in the process. Our alternative ALM software solutions were very generic and not much better than the Excel-Sheets. With the BAYOOSOFT Risk Manager we do not have to worry anymore, because a well-maintained documentation is generated by clicking just one button. All in all, the Risk Manager allows us to focus on the content of the risk analyses and guides us through the process.”, concludes Dr. Jungmann.



*With the expansion module Usability Engineering the Risk Manager integrates the process completely into the risk management according to ISO 14971 and leads step by step to the usability engineering file according to DIN EN 62366 and IEC EN 60601-1-6 by using a field-tested macro structure.*



# RISK MANAGER

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BAYOONET AG is a German software company established on the market since 2001 and the manufacturer of the Risk Manager within BAYOOSOFT, our business unit for Management Software. Our solutions are aimed at heavily regulated sectors and critical infrastructures in enterprise environments. Our quality management processes – certified in accordance with ISO 9001 and ISO 13485 by TÜV-Hessen – reflect our passion for sustainable enterprise solutions and distinct customer focus.

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