



RISK MANAGEMENT

The Smarteeva Risk Management Solution embeds a state of the art approach to managing risk in general and FMEA in particular as they pertain to various internal and external product related events. The Smarteeva Risk Management solution provides a deeper take on risk management, embedded in all post-market surveillance activities.



Artificial Intelligence

With a state of the art Artificial Intelligence engine and machine learning algorithms, the Smarteeva Risk Management solution utilizes AI driven risk assessments, machine learning decision trees and Intelligent Risk Scoring.



Seamless Integration

The Smarteeva Risk Management solution is seamlessly integrated with all applications including the Intake and Complaints solutions enabling real-time risk assessments and subsequent risk mitigation activities.

While Risk Management has always been a key element of any quality program, the 2017 EU MDR regulation places a major emphasis in this area since some highly publicized safety events occurred in recent years.

Smarteeva Risk Management

A closer look at features and benefits

Smarteeva's Risk management solution addresses the latest increased focus of the EU MDR initiative to ensure product safety. In the new European regulatory context, post-market surveillance (PMS) requires device companies to conduct risk assessments and reassessments.

Features

- Risk assessment forms
- Built-in risk evaluation for each product issue, complaint or adverse event
- FMEA/pFMEA/dFMEA
- Real Time Device risk analysis
- Dashboards
- Artificial intelligence driven risk assessments
- Risk analytics and risk scores

Benefits

- Smarteeva's Risk Management solution includes Embedded risk management data capture and analysis
- The solution supports root cause analysis and any follow-up actions required
- Smarteeva users can access Smarteeva anywhere on any device
- Detailed Risk analytics via interactive dashboards and Reports
- Cross-application risk management integration
- Detecting emerging risks on the basis of factual evidence with AI driven risk analysis, decision trees and risk scoring
- Built completely on the Force.com the most modern cloud architecture available today
- Seamless integration with our simple to use API's connecting all your data
- Maximize adherence to company processes and reduce costly lag in data collection
- Smarteeva offers lower up-front implementation costs and more predictable spending
- Eliminates the need for costly upgrades and maintenance with no new hardware
- This lightweight, web-accessed solution accelerates deployment, with minimal burden on your IT department
- Smarteeva is built on a user-friendly platform and it takes less time to train your staff
- Each release includes a Validation Package with all of the supporting documentation

