



SMARTRISK

WHY DO ORGANIZATIONS NEED SMARTRISK?

It is an electronic tool that allows the MAH to identify the risks presented to the quality, safety and function of each excipient in a systematic and structured approach. SMARTRisk follows the same elements to be addressed as the EudraLex guideline from 2015. This ensures that when addressed correctly the company's excipient risk assessment meets the requirements of the European regulators. It gives a clear overview of what excipients are present in the various formulations and their associated risk relevant to the individual formulation.

REQUIREMENTS AND APPROACH TO USE THE TOOL?

SMARTRisk can interface with the company's ERP system to upload existing excipients and formulations, hence saving a lot of time. User-friendly, no additional knowledge about IT systems required

BENEFITS OF SMARTRISK

- ▶ Aligned with EudraLex guidelines
- ▶ Time saving as all elements are pre-empted and the risk ranking criteria are pre-defined in accordance with the EudraLex guidelines
- ▶ Various reporting formats: summary report and full detailed report
- ▶ All information about excipients and formulations captured in one data base
- ▶ Possibility to upload company specific information
- ▶ Full audit trail / revision history



SMARTRISK is a cloud based software tool that guides the user through a compliant Excipient Risk Assessment process



The software tool is designed to include all formulations relevant for each excipient



All your information brought into one easy to use and standardised Risk Assessment Tool



Fully standardized scoring definitions for an objective assessment

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

AUTHORIZATION /
APPROVAL

PRODUCT
MAINTENANCE

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