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PharmaLex

SMARTRISK

A next generation risk assessment tool developed to assist companies with the correct implementation of formalized risk assessment.

What is SMARTRISK?

As of March 2016, all Marketing Authorisation Holders (MAHs) must ensure that the excipients used in authorised medicinal products for human are suitable by completing a formalised risk assessment.

SMARTRISK 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

Delivering success with confidence

PharmaLex is now part of Cencora, a leading global pharmaceutical solutions organization centered on improving lives around the world.

PharmaLex adds to Cencora's expanding suite of pharma solutions and serves the pharma, biotech, and medtech industries. We guide clients from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities. Our experts use technology-elevated solutions to support clients through the entire product lifecycle.

25+
years of industry experience

1000+
subject matter experts worldwide

50+%
of our projects are global

9/10
of the top pharmaceutical companies are our clients

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