## EMA advises companies on steps to take to avoid nitrosamines in human medicines (26.9.2019)

How



Helps your company?



## **(iRISK**

has the possibility to use tools to prioritize different products

iRISK knowledge base allows an easy risk justification through the previous knowledge built in different assessments

harmonized risk communication between several approval levels through the creation of reports.

tools to compare the differences between the changes proposed and the current process.

reduces 40-50 % time spent on risk assessments



Prioritise evaluations, starting with medicines more likely to be at risk of containing a higher level of nitrosamines



Apply for necessary changes to marketing authorisations to address nitrosamine risk

Notify authorities of outcome of risk evaluations



Complete all steps within 3 years, prioritising high risk products