

Press Release

Lisbon - August 24th, 2018

Striving for excellence in Quality Risk Management



Merck implements 4Tune Engineering's QRM platform - iRISK™

With the aim of improving its Quality Risk Management (QRM) activities, Merck has chosen 4Tune Engineering's solution. iRISK™ will be the integrative QRM platform for Merck's products and processes entire lifecycle. iRISK™ proprietary features, user-friendliness, versatility and efficiency was praised by Merck's users as the best fit for their worldwide needs.

"The seamless fit with Merck's own QRM practices, agility to achieve the Go-Live and very good users' acceptance, all gave us full confidence that iRISK™ is the right choice. Key innovative aspects and the agility to incorporate new requests in future releases were decisive factors." – said Sven Streit, Director eQA Systems at Merck. With this choice, Merck is enhancing its leading position in Quality Risk Management in line with recent and forthcoming global regulatory requirements, such as ICH Q12 for example.

"The selection process was very demanding and we are pleased to have found the ideal answer to all the requirements. Incorporating our QRM platform iRISK™ into Merck is for us at 4 Tune Engineering, a key landmark in our twelve-year long partnership with Merck", emphasizes José Menezes, CEO of 4Tune Engineering, adding: "iRISK™ is the result of our profound knowledge and patent protected innovation in this area. Our corporate QRM platform has four decisive advantages: First, it integrates all necessary tools for risk management throughout the whole lifecycle. Second, it is easy to fit with other systems. Third, it enables true comparisons over the lifecycle. And fourth, it is the perfect solution for global companies such as Merck, with multiple sites, business units and user levels and roles, because it really drives the consistency of the entire Quality & Knowledge Management Culture on a global level. So, it permits benchmarking, for example, of sites, processes, products and suppliers."

On June 2018, Merck started taking advantage of its new global platform for Quality Risk Management.



About Merck

Merck is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions.

About 4Tune Engineering & iRISK™

4Tune Engineering is a leading company in Manufacturing-Sciences & Technologies (MSAT). Providing advanced, intelligent and industry-proven 4.0 solutions over entire process and product lifecycles, it has been a partner to top pharmaceutical companies in Europe, North America and Latin America for over a decade.

iRISK™ is the next generation of Quality Risk Management Platforms as it enables risks to be identified, quantified and prioritized through the platform and can create risk mitigation strategies over the lifecycle for new or existing products and processes. It was fully developed by 4Tune Engineering to ensure that risk activities are aligned with Business Processes while meeting all regulations (e.g. ICH, WHO, FDA, EMA).