A RISK-BASED FRAMEWORK TO MANAGE SINGLE-USE SYSTEMS OVER LIFECYCLE: DESIGN, CLEANING, OPERATION, ONGOING PROCESS VERIFICATION

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Using a formal risk management approach, SU systems (SUSs) and classical stainless steel-based systems (CSSs) are examined in detail. The risk assessment steps include: identification, analysis, mitigation and reevaluation/verification of risks over lifecycle. Adequate risk tools are used for each step. Failure modes specific of each type of system, are considered. The scientific background described in BPOG's Guidelines on extractables (2014) and leachables (Jan.2017) for SUSs is built in, together with other authoritative sources for both types of systems.

The risk quantitation, profiling and the holistic risk visualization for both technology platforms, allows companies with stainless steel only fermentation capacity and those with a mix of both technologies, to consider how to best evolve their capacity, when potential impacts on product quality and patient safety are taken into account.

In addition to allowing the relative benchmarking of both technology platforms, comparisons over lifecycle of a specific platform are made possible by our approach, enabling companies to retain a complete picture of all their risk-based decisions and very detailed knowledge about their assets performance. The knowledge management component proposed is unique and supports several business processes and also decisions a company needs to justify before authorities.

Our talk provides an insightful discussion of SUSs, using state-of-the-art risk-based and knowledge management tools, illustrated by examples on Design, Cleaning, Operation and Ongoing Process Verification, focusing on risks to quality and safety.