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How to Implement a Risk-Based Requalification Program

By Ivan Soto Dec 17, 2018 1:48 pm PST

INTRODUCTION

Requalification is a critical regulatory function in the pharmaceutical and biotech industry. The intent of a requalification program is to periodically requalify GMP systems to ensure that they remain in a validated state.

Historically, the industry struggled with the implementation of requalification programs that are risk-based, compliant, efficient, and meet the intent of the process and regulatory expectations.

These challenges are mostly driven by the lack of a risk-based approach in some companies and the fact that there is still some level of reluctance to implement an approach that is based on the system risk and the impact to product quality and patient safety.

Instead, companies tend to implement overly conservative requalification programs that have inadequate frequencies, and which are not based on a system level risk assessment.

These challenges create a significant amount of inefficiencies that have a negative impact to the business and increase a compliance risk.

This article will discuss the challenges with traditional requalification programs and how to implement a risk-based approach that is compliant, efficient and meets the intent of the process and regulatory requirements.

CHALLENGES WITH TRADITIONAL REQUALIFICATION PROGRAMS

The largest challenge with traditional requalification programs is that they are not based on the risk impact of the system to product quality and the patient.

This challenge typically yields requalification programs that are overly conservative where the frequencies are inadequate and not risk-based.

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