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Automation in validated environments

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Abstract

Challenge: A complicated system with a number of monolithic pieces, compliant with PDMA and 21 CFR Part 11 regulations had to be developed in a short time with a small team was just the beginning of the challenges. Missing the date would have put the entire business at risk owing to resource constraints; also the system in use was not able to support the demand coming in from the clients. Additionally, the nature of the business requires all validation documentation to meet the expectations of every client, which includes many of the top 10 pharmaceuticals. Any high impact failure in Operational Qualification stage would have potentially reset the progress of the project.

Approach: In order to mitigate the issues and bugs that will arise and also to meet the schedule, two steps were taken. One, regulations team was brought to work very closely with the developers to avoid high risk bugs. Second, many test scripts that were to be executed manually by the validation team were automated.

Results: Following the approach stated above, Operational Qualification of the system was completed in 10 days as compared to the initial estimate of 25 days. The approach not only proved fruitful to meet the deadline but also made work more fun and eliminated a lot of manual work.

Conclusion: Manual execution of protocols is not only time consuming but also lead to human errors which could be very expensive depending on its implications. To use automation in the regulated environments needs money and time to be invested in the beginning, however, if the result is a robust execution process with reduced delivery time then it is worth it.