

?Lessons Learned in a Non-Regulated Software Validation Project

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Though this statement is obvious to any team leader or consultant who has executed software validation in an FDA-regulated company, it can be difficult to grasp for managers more concerned with production schedules and challenges than with validation, and especially for managers in companies not directly regulated by the FDA. Risk can be higher or lower; team understanding of the need to validate can be greater or less, and technical specifics of the software in question may present a variety of challenges. Because of these differences, every validation project presents a unique set of lessons....

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