Validation/Qualification of Manual Serialization Process

STERLING

SITUATION

A pharmaceutical company did not have the engineering nor program management technical resources needed to have their manual serialization process validated and qualified.

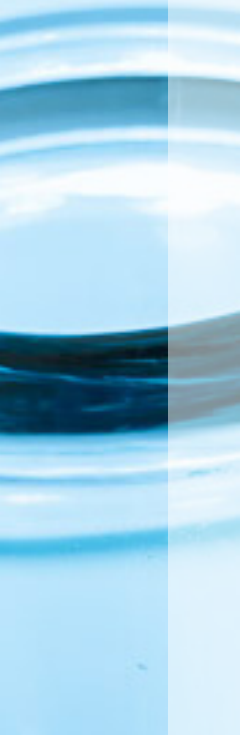
The client also needed support on preparations for performing validation/ qualification of their semi-automated system. The internal timeline was not aligned with what was needed to achieve desired results.

PROJECT SNAPSHOT

- An engineering solution was needed to ensure the manual serialization process validated and qualified.
- Established direct line of communication and programe management resources.
- Sterling fulfilled all the client's needs ahead of the dedicated deadline. Furthermore, the plan was able to acheive additional results.

STERLING SOLUTION

- Established direct line of communication with the Management team to conduct weekly updates, obtain resolution for all critical issues, and enforced timely communication protocols within the entire team.
- Evaluated internal resources and established a team, supplemented by Sterling Engineering Program Management and technical SME (Subject Matter Expertise), to redefine goals and focus on absolute priorities.
- Once all documentation requirements were identified, a proactive timeline was established to position the entire Team towards success.
- Established weekly communications with all vendor suppliers and subcontractors to identify and address any and all technical issues in a timely fashion.



Result

Once the resources were in place, priorities realigned, Management buy-in was achieved and timely communications were enforced amongst all in the team, the manual system was successfully validated/qualified per the timeline. Furthermore, the plan to achieve the same for the semi-automated system was in place.

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