

Client Needs

A pharmaceutical manufacturer requested support for a qualification upgrade for a design/process change from a preprinted to an automatically labeled ampule.




Challenges

- A controlled process must be established for the label print/apply equipment before starting qualification of the label material and print.
- An understanding of product manufacturing, distribution and storage conditions is needed to establish label qualification testing requirements.
- The project required an aggressive timetable that was tied to the implementation of the product serialization process.



*Preliminary testing revealed that the addition of the applied label increased the size of the ampule, which interfered with loading into the secondary packaging. This issue was identified early in the process, allowing a solution to be implemented and qualified prior to release of the new label.

Results

-  The qualification was successful
-  Addressed a package design issue* found during initial testing
-  On-time completion



STEPS TAKEN BY ADEPT

- Evaluated the process and distribution risks affecting label application and print legibility
- Ensured that a controlled process for the print/apply equipment was developed and qualified
- Created qualification testing based on an understanding of manufacturing, distribution and storage requirements
- Executed a successful qualification

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