



QUALITY SYSTEM CASE STUDY

by Jesse Ahrendt

NSF recently worked with a U.S. based client’s site in India, which involved consulting in three categories:

- > Remediation of quality systems
- > Data integrity improvements
- > Training and education of subject matter experts (SMEs)

This pharmaceutical quality system (PQS) improvement project had three main objectives.

Situation	Objective	Approach/Methodology	Returns on Investment & Outcomes to the Client
Full re-deployment of the PQS which required an assessment and further enhancement of all SOPs associated with the PQS.	The PQS re-deployment project involved the assessment of approximately 550 local and corporate SOPs (as well as approximately 900 forms), which were reviewed and evaluated by NSF for compliance with corporate governing procedures and policies, as well as with cGMP regulatory expectations. The client expectations required further enhancement that resulted in a new governing body of procedures.	The PQS in place was divided into appropriate subsystems (e.g. training, management responsibility, materials control and environmental monitoring). Each subsystem was assigned to an SME consultant who assessed all related SOPs that were in place (both local and corporate). Enhancement of those existing SOPs was then completed by NSF, either through revision or complete re-creation of the procedures. The enhancement process also included discussion and agreement with the SMEs from the site group.	<p>Highlights:</p> <ul style="list-style-type: none"> > 67 percent reduction in the total number of SOPs (from about 550 down to 180) > 88 percent reduction in the total number of forms (from about 900 down to 100) > Creation of about 175 new training presentations that were given to the impacted personnel across 124 training sessions <p>The client was left with an entirely new operating system in regard to the PQS that should allow them to operate (re-start) their facility at a higher level of regulatory compliance than was previously possible. The reduced number of SOPs and forms allowed a major simplification of their previously overburdened and overly complicated systems.</p>
Re-deployment of all newly enhanced procedures requiring creation and delivery of specific training and education modules across the site.	The training and education expectation was that all newly created procedures would be deployed to site personnel with classroom instruction. This includes requirements for comprehension and associated testing with the expectation that personnel must meet the grading requirements prior to being allowed to perform the tasks. NSF developed and conducted this training to all client-identified personnel in a phased approach.	The training program was assigned to two NSF individuals who created the training materials for presentation and delivered the requisite training. Training was largely provided in the local language. These materials consisted of a PowerPoint presentation as well as a written assessment for each training module created.	<p>Because site SMEs were involved in the discussions, they will now be able to build on this new group of documents and the process overall to continue the efforts and expand into other key areas that may require this kind of enhancement exercise in the future. Our input provided the groundwork for the client to be able to re-start its manufacturing block.</p> <p>After NSF delivered training at the site, the QA group understands what a more detailed level of training looks like and will be able to continue this kind of delivery into the other areas that may be assessed in the future.</p>
Implementation of interim controls for general documentation, as well as specific data gathering activity across the site to mitigate prior data integrity issues and prevent further issues, while educating personnel and developing processes to prevent further recurrence.	NSF developed and implemented the data integrity program and the interim controls that allowed employees to be trained on the importance of data integrity, and also created strict allowances for documentation and concurrent review of those activities. This was needed to allow further work to be conducted on the site.	Data integrity was approached through the establishment of two distinct protocols. The first protocol provided very strict controls to assess personnel behavior and to assure that personnel had a comprehensive understanding of the requirements. The second protocol was initiated once confidence was gained and it was assessed that the controls from the first protocol had been engrained into the daily processing work of the site personnel. It removed some of the more strict requirements that were in place, while still leaving controls that would continue to build confidence that the personnel were adapting to the new environment for cGMP documentation requirements.	<p>The site is much more aware of what is required for data integrity, how to achieve it as a site goal and what some of the pitfalls are in relation to data and documentation management. They have also put controls in place that allow data to be trusted at a higher level than previously possible. This process created a shift in culture and exhibited behaviors throughout the entire organization.</p>

ABOUT THE AUTHOR



Jesse Ahrendt is an experienced industry consultant with over 15 years of active engagement in pharmaceuticals, biologics, medical devices and biotechnology as a certified Quality Auditor and Quality Engineer. His areas of expertise include QA compliance, third-party vendor evaluation, cGMP manufacturing, quality systems and quality auditing including validation, deviation/CAPA/EC, auditing/mock inspection, supplier qualification and QMS/risk assessment/SOPs.

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