What Our Remediation Projects Are Saying About the Industry

"A study on the pharma industry's GMP remediation projects reveals a lot about us and our inability to focus only on what is truly valuable," says John Johnson.

NSF International's pharma biotech team is in a unique position in that it regularly and intimately is involved in a range of GMP remediation projects across the world and across all dosage forms. When a system or process fails to provide sufficient levels of quality assurance or inadequately maintains compliance to cGMP, the best case scenario is that your quality system identifies the issue and escalates it to the right people, and those people study the problem and apply the right resources to fix it now and for the future. Often the solution can be derived in-house utilizing the available experts within the company. However very often companies like to contact us for a different perspective on current industry thinking or for us to review and verify that the proposed CAPA will be effective across the full range of key attributes. These attributes include cost, timeframe, GMP compliance, sustainability, simplicity and ease of presentation to clients and regulators.

In cases where a third party identifies a problem for you, what are they thinking:

- What else is going wrong around here?
- Why did they let this happen?
- Why did it take me to find the problem for them?
- How can I trust them to put it right?
- How does this affect my choices and judgment on next steps?

In effect, issues of this kind erode trust. I recently presented "A Question of Trust; Hard Won, Easily Lost" at the Annual PDA Europe meeting in Berlin. GMP remediation programs following "a nasty surprise" are always more expensive than doing it right the first time and are often characterized by recriminations, politics and rapid, sometimes unpredicted change. We also noted that, without a reassuring yet challenging third party who can provide expert oversight and guidance borne from multiple remediation projects, companies can languish for months while they regroup and begin the process of GMP remediation. Our services have proven to get people back on their feet sooner, helping to realign "muscle memory" and getting the organization moving forward with renewed purpose and confidence.

In almost every case we work on, the need for an expensive GMP remediation program is caused by five main drivers:

1. Inadequate foresight of what the future will demand of your business

2. Inadequate management of resources and knowledge

3. Staff turnover, lack of investment in education, coaching and development of leaders and subject matter experts

4. Inadequate identification, evaluation and mitigation of risk to ICH Q9:

- Poor Performance in
  - Quality planning
  - Management review processes
  - Internal audits
  - Preparedness for regulatory inspections

5. Inadequate Pharmaceutical Quality System (PQS), especially:

- Poor alignment of the QMS to the needs of the wider business
- Poor analysis of potential root causes leading to ineffective CAPA
- Over-complexity

Remember, simple processes always deliver predictable, measurable results.

If you recognize any of these in your organization, how are your personal or departmental objectives defined so that these are resolved before they become a crisis? What resources or budgets are assigned to these five key issues?

Let's focus on simplification, the theme of this Journal. Time and again, we note that remediation programs flounder or get mired in complexity. If your program seems to go from warp speed to snail pace and back again, if it's hard to see at a glance what is done and what is to be done and by whom, or if you can't rely on the CAPA to prevent the risk of recurrence, chances are that the program itself is over-complex. Worse still, the CAPA you are completing may be adding to complexity in the quality system. And, of course, this will store potential GMP non-conformance for the future. Complexity causes staff to struggle to follow complex SOPs, QC methods and work instructions or to complete the records as prescribed. Complexity is a hidden cost that sometimes makes us look like busy fools!

"If you can't explain it simply, you don't understand it well enough." Albert Einstein

Making a process simple is vital but not easy. It is human nature to surround oneself with equipment, tools, processes, information and co-workers; many people actually derive self-worth from the complexity of the task they are doing even though, especially when under time pressure, that task may be prone to error and variation.

So, in any project involving a paradigm shift, make sure you have someone alongside you who nudges you in the ribs and whispers…

- *How can we make this less prone to error?*
- *How can we reduce the number of steps in this process?*
- *How can we make the key steps more apparent, their standards better defined and the checks more explicit?*
- *How can we reduce the risk of omission, overlap and human error?*
- *What can we eliminate from this process to make what is critical more apparent?*
- *And especially in a GMP remediation program, how can we make sure that each of the following are considered when deriving each CAPA:*

Visit our resources library (**www.nsf.org/info/pblibrary**) and view the below video and webinars for more information on our simplification projects and personal and organizational well-being:

- *Video:* How to Jumpstart Your Pharma Business by Simplifying Processes
- *Webinar:* Firefighting to Fire Prevention – How to Reduce the Risk of GMP Deviation and Crisis in the Pharma Industry
- *Webinar:* The Art and Science of Simplification – How to Win Your War on Complexity

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