So you’ve followed your validation plan, qualified all the appropriate equipment, and developed, challenged, and placed controls on your process. Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) is complete. Drawings, procedures have been approved. Training is complete and well-documented. The summary report indicates that all the expected activities and tests were completed successfully and any exceptions have been appropriately resolved.

You’re good to go!

Some time later, maybe years later, an auditor shows up. The questions start. All hands on deck!

Not surprisingly, by now, many of the original team members have moved on to other positions. Most of the leaders who approved the protocols and reports have transitioned to other responsibilities. The documentation must stand on its own.

Maybe there are certain links between documents (typically on change history pages), but over time they usually become difficult to follow especially if you’re not one of the document control specialists. So, if probing questions arise, wouldn’t it be great to have a way to find accurate and complete answers quickly? Not a replacement for your technical file, but one document that will bring together all the process development, specifications, testing, etc. that’s aligned with your validation report.

Here is where I see an opportunity to improve many process validation systems. Take a lesson from the
computer systems validation (CSV) group. Add a traceability matrix to your documentation.

Basically a requirement for CSV, traceability matrixes clearly indicate the relationships between user requirements, development specifications, tests, and procedures. A traceability matrix provides a means of linking relevant specifications to testing must be established and maintained. The matrix traces each requirement through design, implementation in the code, and evaluation during testing. Traceability ensures that requirements are met and can be traced to the appropriate configuration/design elements.

And that all the requirements are verified and can be traced to testing or verification activity the shows that the requirement has been met.

This concept can easily be adopted to show the relationships between production specifications, risk analysis, IQ, OQ, PQ tests, and the procedures established to maintain the validated state of your process. Best of all, it can be navigated by people not intimately familiar with the process to find all the documentation associated with any specific element of that process.

Of course, in practice, each cell in this generic example would be populated with the appropriate document identification number. Be sure to include the version number. Many of the documents will change over time, and you want to refer to the version that was in effect at the time of the validation.

<table>
<thead>
<tr>
<th>Product Specification</th>
<th>DOE</th>
<th>Critical Input</th>
<th>Controllers</th>
<th>Challenges, Checks, and Balances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seal Integrity Specification</td>
<td>Critical Inputs</td>
<td>Process Parameters</td>
<td>Heat</td>
<td>Heating Element</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Temperature Controller</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Temperature Settings</td>
</tr>
</tbody>
</table>

While you could start further back in the development process, it seems to make sense to start with your final product specifications that will be used for manufacturing. Then create a map from each specification through design of experiment (DOE), equipment qualifications, challenge testing, and run documentation.

At some point, you will be able to create a standard template for the matrix. Then you can use the matrix in two ways. The first would be to show where or how each process element was developed, tested, and controlled. Secondly, it could also be used as an audit tool to clearly show that each element was fully validated.

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