



Whitepaper

FDA-Validated Self-Service Reporting

Author
Stephen Kern

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Over the past five years, there has been a revolution in reporting and visualization tools. Tools like Tableau, Spotfire, Qlikview, and MicroStrategy, to name a few, provide broad functionality while providing a front-end that is relatively easy for business users to generate pixel-perfect reports and dashboards. These visualization tools coupled with data bases are faster and more flexible than ever before, providing real business value and cost savings. That is except for industries that are required by federal regulation to be developed under a controlled and auditable process. This white

paper will explore the feasibility of FDA-validated business-user self-service reporting. By its very nature, validated reporting requires locking down reports to user enhancements or modifications. This approach can be discussed in terms of leveraging self-service reporting out of tool sets, such as, Tableau by non-IT business users. Moreover, this process needs to be evaluated further and the value to the organization by setting up a self-service environment in support of validated reporting.

Overview of Validation/CSV Process

First, let's understand the validation process, especially for pharmaceutical and life science industries. As the pharmaceutical and life sciences industries continue to modernize and implement more technology, there is an increasing need to be sure that these technologies are safe and accurate for patients and end users. Specific to software development, we will look at how Computer

System Validation (CSV) provides the documentation process to assure that a computer system does what it is designed to do and meets FDA GMP regulations. The Food and Drug Administration (FDA) produced guidelines for CSV practices.

There are two important reasons for performing CSV with life science technologies and software:



CSV can prevent software problems before reaching the usage environment. Specific to reporting, incorrect reporting and data can cause serious adverse consequences to the patient. This could, in turn, lead to lawsuits, fines, or eventual shutdown.



Not performing certain computer system validations in accordance with best practices could be against the law. The FDA has rules and regulations in effect for Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP). Please note that the abbreviation of GxP incorporates GMP, GLP, and GCP.

The FDA defines process validation as "establishing documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product, meeting its predetermined specifications and quality attributes." The objective of validation, therefore, is to produce documented evidence that parts of the facility will work correctly every time, when brought into use. The goal is also to make sure that quality is built in to the system at every step, and not just a factor at the 'output' end of the process chain.

Computer system validation requires, first, that you obtain or design a process that can consistently conform to requirements; and then that you run studies demonstrating that this is the case. Briefly put, the steps are:

Development of requirements

Development of a validation plan

Utilization of Standard Operating Procedures (SOPs)

Documented Training on SOPs

Development of detailed specifications

Development of a test plan and/or test scripts

Each one of these bullet points breaks down into multiple tasks with each deliverable requiring reviewers and approvers. In general, the CSV process can extend development by 10x when working with tools like Tableau. Tableau was developed from its inception specifically for end-users to generate their own dashboards using Excel spreadsheets and pre-defined databases. From practical experience, once the data model is created and the queries developed, a trained business-user can create a complex dashboard in a

day or two, while the CSV documentation can take 10 or more days. The following approach is not a validation dodge or a magic trick. It's a real process with criteria and limitations that allow business-users to develop reports and dashboards¹, in a validated environment. In addition, the techniques I describe can be used with all visualization and development tools such as, but not limited to, Tableau, BusinessObjects Webi, Cognos, MicroStrategy, and Informa, a reporting and programming toolset².

Validated Approach with Self-Service

Let's first discuss how a risk-based approach is required to use business-user self-service tools in a validated environment. In a risk-based validation model for business-user self-service tool usage, the business with the compliance team provides a standard operating procedure (SOP) that defines:

The criteria of when the SOP is applicable. Examples include when a new data model is developed and deployed v/s using a previously qualified data model, view, and query.

The degree of changes to an existing validated report or dashboard.

The approval process for moving objects into a GMP environment.

The environment to develop new and enhanced data model and reports.

Training requirements for business-users to develop in a GMP environment.

Being risk-based, the criteria defines the parameters as to how far a business-user can develop their own reports before IT professionals need to be called in to assist in the validation process. The good news is that over the last few years, compliance has taken a more proactive role in defining software development risk and as a result, business-users can now take advantage of reporting and visualization tool capabilities without having to rely on IT.

¹ We will reference reports and dashboards as reports and assume it includes all visualizations.

² The toolsets mentioned were just examples that my team and I specifically worked with.

The self-service process starts with training. Each business user who wants to develop their own reports must go through GMP software development training before they can touch a report. In most ways, the training is identical to the validation training IT takes, but at a less detailed level and specific to developing reports.

A business-user is trained on:

General validation principles

Software Development Life Cycle (SDLC) designed around self-service report development

CSV process including steps and documentation (again limited to reporting)

Development environment structure (folders, servers, GMP vs. non-GMP)

Do's and Don'ts (criteria list of what business-users can do before they need to involve IT)

Secondly, a development environment needs to be set up for the business-users as follows:

A secured folder in production or test that is non-GMP

Access to a qualified database in read-only mode

A secured non-GMP folder within the visualization tool that permits designated business-users access with full non-admin rights

Depending on compliance, business-users can have access to adding new data sources

NOTE: As discussed in Do's and Don'ts, adding new data sources, even if they are qualified, will extend the testing to ascertain that the enhanced data does not change the overall validity of the data set.

Let's make this simple. A business-user can use an existing validated report as a base to enhance or rewrite, providing the data model, views, and queries are not modified. This is very straightforward and requires only the modification of existing documentation and testing changes. The business-user can also build from scratch by using a qualified data view. This, of course will require more documentation and testing, but with today's data bases (Oracle, SQL-SERVER, HANA, Redshift, Snowflake etc.), a business-user can access thousands of attributes without having to do additional data modeling. An example that is common to most Life Science companies is reporting out of quality systems such as TrackWise. By modeling the data into a "qualified³" data warehouse, the business can access over 11,000 attributes.

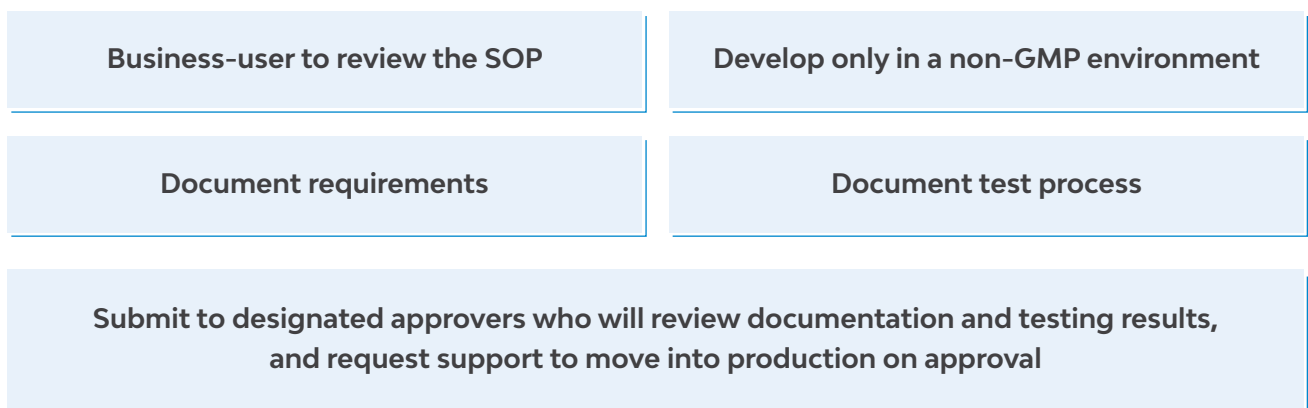
Where we start going down a different path is when a business-user makes changes to an existing data model or adds additional data (using an Excel or MS Access to enhance the data.) A business-user can still make data model changes, but this will be the time that they need to bring in IT to take their work and process it through the full CSV process in order to move the data model and report into production.

³ FDA Qualified refers to a testing and audit process that a tool or systems works as specified based on requirements.

Development

Let's get down into the weeds. Depending on IT and Compliance, a business-user can develop their work in a non-GMP production or test environment. The non-GMP object must be labeled non-GMP so that any reports or dashboards will not be confused with production. (Note: Your typical GMP environment has either three or four servers designated as "development" for IT, "test" for formal testing, "UAT" for final and pressure testing (optional-but preferred) and "production".)

The business-user should review criteria and responsibilities:



From here, the business user must copy or create the report in their non-GMP folder. As part of development, the business-user will create the following:



After the business user is satisfied with the report, they will turn over documents to designated approvers. If the business user changes the data model, documents will be turned over to IT for review and validation, consistent with the typical IT CSV process.

Testing and Deployment

It's typically required that there are two approvers, one to move object(s) into testing area and review documentation and the other to test or review test results. Depending on the degree of complexity, this can be a quick process. In any case, the business-user will turn over all documentation. The first approver will move objects as detailed in migration document to testing area.

The second approver will test/review results and on successful review:

The non-GMP display on report or dashboard will be removed

Approver will move documents into designated area (Documentum or other)

A ticket to support will be generated to move into production

Support will migrate object and create security entries (as needed)

Values of the Approach

The business user self-service process for validated reports offers many advantages:

1

Cost savings by leveraging business process understanding to directly develop reports/dashboards

2

Significant reduction in time to value from three weeks to as little as two days

3

Ability to schedule report creation and enhancements on business' timeline

4

Increases business agility and effectiveness by allowing them to experiment with their data

5

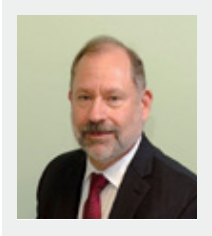
Business takes ownership over data quality by directly seeing impact on report development

Conclusion

Most Life Science companies have invested heavily in self-service visualization tools and have used them widely throughout their commercial and financial units with excellent results. There has been a hesitation and concern to allow manufacturing to use these tools in a self-service capacity where FDA validation is highly visible to outside auditors. Using the approach and criteria I've outlined, it's not only practical, but desirable that the business take advantage of self-service. In addition to the potential time and cost savings, the business can have hands-on access exploring and using their data in a production environment. Who better than the business users to know the logic and data flow through their systems.

I know of a few Life Science companies that have embarked on self-service reporting in their validated areas, and they have had tremendous success. The process is not difficult or hard to understand and simply needs IT and the business to work together.

About the Author



Stephen Kern

Senior Consultant, LTIMindtree

Stephen Kern is a Senior Consultant working for LTIMindtree InfoTech where he is a Solutions SME and Program Manager working with Life Science clients. He has over 40 years in manufacturing systems with the last 16 years at Pfizer Inc as Director of Business Intelligence and Analytics. Steve has extensive experience in validated business intelligence, data warehousing, master data management, ERP, business process design, and project management solutions. He is a frequent presenter at a number of major pharma conferences and has a passion for Artificial Intelligence and Machine Learning.



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