IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM A division of UBM Americas

Published on IVT Network (htt://www.ivtnetwork.com)

Case Study: Implementation of an Electronic Life Cycle Management System for Validation ….and Beyond

By Adam Tessneer, Lou Killian, and Rick Mineo
Published on February 21, 2017

A Case Study on Implementation of an electronic Solution for Validation Life Cycle Management resulting in Productivity improvements greater than 100%, Cycle Time improvements greater than 50% and Equipment Change Over resource cycle time efficiency improvements of 85%.

Contents

EXECUTIVE SUMMARY - COMPLIANT BUT NOT SATISFIED:

Increasing competition, aggressive time to market and pricing pressures are driving companies to look for innovative ways to maximize their resources and manage data. Validation Life Cycle Management is a business process that that can be optimized to meet the increasing demands placed on the Pharmaceutical, Biotechnology and Medical device industry. This case study will outline the journey of converting from a paper based system to an E-Validation Solution system. It will cover the problem statement, selection, implementation and outcome of this process. The implementation section identifies challenges and opportunities encountered during the process. The results section details the rewarding outcomes - Establishing a lean, multi-site harmonized validation process with Productivity improvements of more than 100% and Cycle Time improvements of more than 50%.

BACKGROUND:

This case study describes the experience of one of the global biotech companies within the biotechnology industry with multiple sites, many validations and expanding products and facilities.

The Company facility, utility, and equipment validation system historically has created effective, efficient, and compliant means to perform equipment qualification through a paper based system. With the growth and increase in the number of therapies we support, the global validation team over the past two years have been working to modernize and innovate how we execute, track, data mine, and archive facility, utility, and equipment validation documents and protocols. The modernization is comprised of two key components with a focus to create a streamlined and world-class business process:

- First, the transformation of the validation document format to a “batch record” style document to improve the end user experience and make it more suitable for electronic execution.
- Second, the introduction of a Global Electronic Validation Life Cycle Management Software (Kneat). The Kneat solution provides a platform for electronic generation, execution, and approval of documents while delivering real-time validation metrics and dynamic data searching capabilities.

On average, globally, the validation department creates approximately 700 protocols annually. The number of protocols is forecasted to increase over the next few years, resulting from the addition of new therapies to our manufacturing facilities. Implementation of these optimized process components is expected to reduce the total number of steps to generate, execute and archive protocols by over 50%. In conjunction with these savings electronic protocols and documents are expected to greatly reduce the overall protocol approval routing time by over 50% with parallel approval work streams. Additionally, as a centralized repository for validation

documents and parameters, Kneat will significantly reduce the time it takes to track and report on protocol status as well as data mine for legacy validation information which is currently a manual process.

The global validation organization is confident these initiatives will have a profound impact on the process of protocols from generation through archival as well as improving and enhancing the execution, review and approval processes. This new way of working will enhance our facility, utility, and equipment validation activities with a focus on maximizing compliance and value by eliminating non-value added steps in our processes. In addition to facility, utility, and equipment validation the team is working with owners of other business processes to identify and develop the business case for other applications of Kneat throughout the Company.

BUSINESS NEED/DRIVERS:

Much like most Pharmaceutical and Biotechnology companies, management is challenging business process owners to find efficiencies in their work processes. With increasing levels of Commissioning and Validation activities across the business, coupled with increasing regulatory expectations and the growth of the Company, the demand for compliant and timely Validation services was increasing rapidly. The Validation team evaluated their current Validation processes and mapped their challenges and the opportunities for validation process improvements. These historic areas identified for improvement included:

- Management of Validation records such as Requirements, Protocols, Test Scripts, Risk Assessments, Trace Matrices etc.
- Review and Approval cycles
- Test execution and summary reporting
- Leveraging best practice across projects and sites
- Real-time (automated) Metrics
- Record storage and retrieval
- Search and retrieval of Validation Information
- Management visibility into their process at both site and global level
- Capturing of third party (CMO/Vendors) information
- Data integrity (i.e. ALCOA principles)
- Meeting critical path project activities

SOLUTION:

A cross-site “Validation Process Improvement Team” considered three potential options: streamline and lean out the current paper systems, develop an in-house Electronic Lifecycle Management System (ELMS) or acquire a leading e-Validation solution. They decided an e-Validation solution enabling flexible configuration for Company processes provided the greatest return on investment for their current and future needs. They assessed several vendor

solutions, which were then reduced to two for further detailed evaluation against the following key criteria:

- User Requirements – Company current and future vision
- Configurability of the tool to the various Company processes
- Usability - would users find it easy to learn and use
- Capability to scale globally across multiple sites
- Capability to improve productivity and cycle times
- Capability to make the process fully paperless, end-to-end

The Kneat e-Validation tool scored highest and the team proceeded to a proof-of-concept (POC) to determine if it could deliver the predicted benefits. Upon conclusion of the POC the Kneat software platform was selected for global deployment.

BUSINESS CASE:

The team compiled the business case justification using data collected from the POC.
The business case identified significant payback, primarily based on the following:

- Enabled cross site Validation process alignment
- Global real time Validation status information
- Instant access to all global Validation records and data
- Ease of extendibility to many processes and new sites
- Easy to use, easy to train users
- Eliminated more than 50% of the manual paper process steps
- Productivity and compliance improvements
  - ✓ Productivity improvements of 100%
  - ✓ Work effort reduction of 50%
  - ✓ Compliance assurance for data integrity and record accuracy

IMPLEMENTATION:

The Company cross-site team understood the challenges with adopting a new business process/system, not least the cultural change when moving from paper based to electronic and the need to map the paper base process to an electronic validation process. They started by developing and communicating widely the new harmonized business process. After gaining the support of all stakeholders they proceeded on an incremental implementation approach, starting with Equipment, Utilities and facilities Validation across all sites. The Kneat Validation Lifecycle Management System (VLMS) was installed, configured, validated and deployed during a four-month period. As the software is all server side and fully accessible via a browser it was hosted on servers at a Company facility. No custom coding was required and all global sites accessed the application via their own dedicated workspaces which can seamlessly share the

centrally configured processes and templates. User access is based on authorized User Roles and Permissions and training was conducted using vendor provided role based training materials, including test driven interactive video training.

As the Equipment Validation process was going live, production requested to have their equipment changeover paper based process configured on the platform. This was configured within weeks on the Validated Kneat platform, a PQ was performed and the changeover team went live with a fully electronic, automated process achieving an 85% resource and cycle time improvement.

Further subsequent processes that were configured on the tool include the Company Cleaning Validation/Monitoring, the ASTM E2500 Commissioning and Qualification (C&Q) process and QC Laboratory Validation. At present, there are 1000 global Company users on the platform and C&Q for a new state of the art facility is being managed in Kneat, providing a new innovative capability to leverage information through the full facility lifecycle. More processes are earmarked for automation on the platform in the coming year.

RESULTS:

The Company VLMS solution went live globally in September 2015. The Validation process owner, says, "going Paperless has enabled us to streamline our work processes across our global locations and provide a more efficient and effective way to meet the increasing demands of the business". He adds, "by going fully electronic, we reduced the number of manual and paper based Validation process steps by 60% and the results are impressive; productivity improvements of more than 100%, cycle time reductions of more than 60%, cross site alignment, Validation quality and Compliance assurance improvements".

In addition to the productivity increases, the Company saw significant improvements (reduction in the number of days) in the cycle times for test protocols across all sites:

- *Test Protocol Cycle time was **reduced by 60%** on average across all sites*
- *Test Protocol pre-execution approval time was **reduced by 48%** on average across all sites*
- *Test Protocol post-execution approval time was **reduced by 58%** on average across all sites*

This demonstrates excellent productivity improvements related to a more efficient process and productive resource usage.

50% SAVINGS IN MAN HOURS:

The consultant who supported the process owner throughout says "The Kneat software allows staff to apply their skills by eliminating frustrating clerical type paper based activities. It removes

the chain that is the paper system". This is seen when analyzing the time savings in the usage of the new VLMS compared to the Company's previous paper process:

Description of Savings Using New VLMS	Average Savings Per Protocol (Hours)
Reduced time to route protocol (protocol approval pre-testing)	2
Reduced time to route executed protocol (protocol approval post-test)	2
Office supplies no longer needed	0.06
Logistics (Status, Tracking, Reporting, Organizing, Questions)	2
Reduced time to mine data from database	2
Reduced time to generate a protocol	2
Reduced time routing protocol deviations (per deviation)	1
Scanning and archival of approved protocols no longer needed	2
Protocol number request no longer needed	1
Reduced time to write Validation summary report	3
Reduced time to write deviations	1
Reduce time to create/maintain/approve VMP annual report	1
Reduce time execute testing	2
Records storage management time	2
Total average Savings Per Protocol	23 hours

Table 1: Time Savings Using VLMS for Equipment, Utilities & Facilities Validation

Note: Average total protocol processing time before implementation of the Kneat VLMS was calculated at 40 hours/protocol (number protocols created per year divided by hours worked) .

These savings represent a more than 50% reduction in man hours for Equipment, Utilities and Facilities Validations, representing an increase in productivity of more than 100%. This resulted in the Company Validation team being able to take on additional responsibilities contributing to greater output for Company.

SUMMARY OF TESTING PROCESS IMPROVEMENTS:

The business owners gathered feedback from all the users to identify the benefits that were underpinning the productivity, cycle time and compliance improvements. The benefits identified by the team which underpin the productivity gains of more than 100% and cycle time reductions of more than 50% are shown in the table below:

Company Validation Team Confirmed Process Improvements	
1.	Simplified protocol generation
2.	Simplified protocol pre-approval
3.	Simplified protocol execution
4.	Simplified protocol post-approval
5.	Improve review collaboration
6.	No document manual handling
7.	Reduced inventory
8.	Reduced deviations/defects
9.	Improved audit preparedness/response
10.	Improved feedback
11.	Improved metrics
12.	Dynamic data (central data management and auto population of documents)
13.	Improved status communication
14.	Improved data mining
15.	Reduced total cycle time
16.	Enabled cross site process alignment

Table 2: Benefits Underpinning Productivity and Compliance Improvements

USER FEEDBACK – INTUITIVE AND USER FRIENDLY:

The Company users were immediately impressed with the new VLMS; "Kneat is very user friendly and intuitive. I have found that protocols are easier to review both on initial review and final." Company QA Engineer.

"I really like the convenience of not having to locate and manage multiple binders during review. I like the templates which are easy to follow and the color coding for the sections that are non-editable, editable and required" – Company QA Engineer.
The business owner explained how he can get valuable real-time metrics on all systems, i.e. instant visibility into the overall Validation/In progress status of any system globally in real time from anywhere via the Validation operations dashboard.

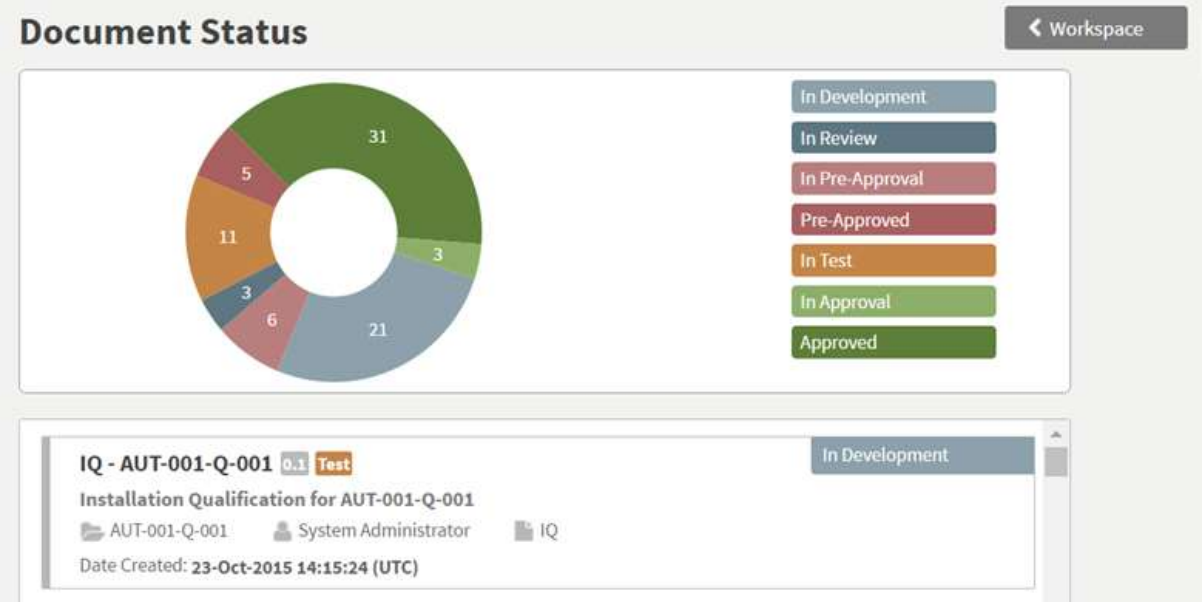

Figure 1: Kneat Reporting showing full visibility of all Validation Documents

He further explained how the Validation process, templates, information can be accessed and leveraged by all authorized users across all sites. GDP issues can be corrected in real-time, protocols are easy to track and review as they are being executed. For management, the Kneat VLMS reporting allows transparent and 100% visibility of all Validation processes and data.

"A real testament to the success of the Kneat software is when other units, after seeing its capability request to have their key processes configured on the application. Expansion to other departments and processes is ongoing".

CONCLUSION:

All Company stakeholders from the production operators through to senior management are very satisfied with the great success achieved. The process optimization project facilitated by the Kneat GxP testing system has added significant value by:

- Enabling users to be more productive and compliant as they do their work.
- Providing management unprecedented visibility and control of all areas of the process.
- Providing a real tool for senior management to drive down capital and operational costs, minimize compliance risk and ensure audit readiness.

The Kneat platform is a genuine breakthrough, which allows technology to serve as a true enabler of business innovation, leading to very significant productivity and cycle time improvements. The cycle time and productivity improvements demonstrate and confirm the value of applying the Kneat tool to automate and simplify the Validation business process.

Kneat software has enabled the Company to create best practice processes that can be leveraged over and over globally across the company. The Company intends to continue extending the tool for many more business processes. The key to this is the tools ability to model multiple processes without the need for coding. For example, the Engineering team have configured their work process for their new multi-billion-dollar facility All system deliverables from factory acceptance testing (FAT) and turn-over packages through to Qualification and Validation are being captured directly into the Kneat tool.

ABOUT THE AUTHORS:

Adam Tessneer is the Sr. Manager Quality Engineering at Biogen. He is also the Champion and Business Process Owner for the e-validation VLMS Solution and validation business process. He can be contacted at Adam.Tessneer@biogen.com

Rick Mineo is the founder and president of Encova Consulting. He has provided extensive technical and validation consulting support to the Company. He can be contacted at mineor@encovaconsulting.com

Lou Killian is the Customer Success Director at Kneat Software. He has over 35 years of Life Science Industry experience at Abbott, Genentech and BioMarin. Lou can be contacted at lou.killian@kneat.com

---

Source URL: http://www.ivtnetwork.com/article/case-study-implementation-electronic-life-cycle-management-system-validationand-beyond