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Case Study: Validation Process Innovation in Molecular Diagnostics:

Implementing a new and innovative Computer System Validation (CSV) and Change Management program at a Molecular Diagnostics Company. Transitioning the overall validation process from paper based to an e-Val system.

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Executive Summary:

A leading and pioneering Molecular Diagnostics Company with a reputation for innovation, responded to the increasing regulatory oversight on its industry by performing a 360-degree review of all its GxP testing processes, with the goal to make them best in class. An early focus was Computer System Validation (CSV). Based on the vision, this process was re-engineered and in parallel transitioned into a fully electronic system. The result was a streamlined compliant and efficient end-to-end paperless process.

After going live with our first process in late 2014 we have seen substantial improvements in our ability to: manage their validation activities, address compliance responsibilities, cut cycle times and increase productivity. This paper looks back at the journey and the rewarding outcomes: a lean structured repeatable process delivering productivity, cycle time, compliance and data integrity benefits.

About the Company:

The Company was founded in the early 1990's and is a pioneer and leader in Molecular Diagnostics, offering innovative products that transform patients' lives. The products include leading molecular diagnostic tests for hereditary cancer, urological cancer, lung cancer, autoimmune disorders and other diseases.

These products assess an individual's risk for developing disease so that action can be taken to prevent or delay its onset.

Background:

Validation business processes and associated validation documentation prepared in compliance with regulatory requirements have been in place for BioPharma companies for some time. However, validation requirements and associated documentation have been less formally established for the emerging Molecular Diagnostic Companies and for related in house laboratory testing operations.

The Company had established a paper based validation process for most validation types (process, cleaning, equipment, facilities). However, management identified that a new structured and optimized Computer System Validation (CSV) process was needed.

Culturally, the Company is very much technology oriented and computer system focused throughout all its operations. Aligning with this strong culture the project leader saw the opportunity to not only create a better CSV process but to also make it electronic and move away from the many pitfalls associated with the traditional paper based systems.

The following key objectives were established:

- Develop and implement a new structured and lean CSV process
- Provide improvements over the existing paper based process
- Address identified GDP errors
- Eliminate potential for misplacing records
- Streamline review and approval
- Address validation records management, filing, retrieval, archival etc.
- Provide a central user-friendly system that supported processing, retrieval and viewing of records

Solution Assessment and Selection:

The project leader assembled a cross functional team and identified their alternatives:

1. Implement a new paper based Computer CSV process
2. Implement a hybrid CSV process (combination of paper and e-Document Management solution)
3. Implement a designed for purpose e-Validation system

The team settled on selecting and implementing a commercial built for purpose e-Validation solution to support their new CSV process.

Some key requirements influenced the choice of solution:

- New CSV process should align with the Company electronic systems culture and one which the employees are comfortable with
- An e-solution for CSV was the initial priority
- Select a system that is process centric not tool centric (i.e. company procedures should drive the process not the e-Validation tool)
- Select a functional, “user friendly” system that fits company culture and that supports the full process including central management, retrieval and viewing of records

- Adaptability to future business process needs (configurability)
- User feedback on system usability
- Traditional look and feel. The desire was that the system would still be document centric but with strong data management capabilities

Following the solution assessment process and subsequent evaluation of leading e-validation software, the Kneat Gx platform was selected. This decision was based on the selection criteria scoring:

- user feedback for functionality
- user feedback for ease of use
- adaptability to future business process needs (configurable)
- "traditional feel" (ease of transition and inspection presentation from old business process to new business process)

Implementation:

The following high-level implementation strategy was agreed:

- Start with the new CSV Category 3 "Off the Shelf" process
- Avoid customization - use easily configurable functionality where possible
- Move forward with the rest of the CSV categories (Infrastructure, Automation, Custom, and Scripts)
- All new QMS processes created after this point would be controlled electronically (Change Control, Complaints, etc.)
- Because of the Company elevated timeline, implementation of the new streamlined CSV process and e-Validation tool was performed simultaneously
- All procedures were written early and they were tool agnostic
- Additional existing validation processes will be implemented based on business priorities

The e-platform was installed and validated within 8 weeks. The CSV process was setup on the platform and user acceptance testing (UAT) completed within a further month. All in all, the CSV process was optimized and live on the e-platform within 3 months, complete with training and all support deliverables (validation documents, training, work instructions etc.)

The vendor support throughout was excellent and was a key factor for the project meeting its aggressive schedule.

As the CSV e-Validation process was going live, "Change Management" was identified as an urgent need. After reviewing the Kneat capabilities against the process requirements, management decided that change management would also be configured and deployed on the validated Kneat platform.

Results - Benefits Realized:

The new Company CSV process went live in September 2014. All stakeholders from users to upper management were very satisfied with the results and benefits achieved such as:

- End-to-end electronic CSV process (No more paper)
- Streamlined process with embedded lean methodologies
- A truly scalable best practice validation framework
- More effective at meeting the increasing compliance, efficiency and schedule demands on the business
- Real time visibility on the validation status (based on work completed) of any system via the management dash board
- Instant central access to all up to date information on all validation activities and deliverables, 24/7 via web browser access on any device
- External auditors have provided complimentary feedback for innovation and compliance assurance
- Overall productivity and cycle time improvements
- An e-System yet the same look and feel as traditional validation

A worthy note is that the FDA reviewed many validations (stories) that were done in our new e-Validation system and provided complimentary feedback. They commented that information was more effective and more like easy to follow "stories" rather than hard to follow disconnected information components.

The **key outcome was lean easy to use and manage CSV and Change Management processes.** The following table summarizes the key process benefits that were delivered by the project.

Process Benefits
Simplified protocol generation, review, pre-approval (including approvals while traveling)
Simplified paperless protocol execution and discrepancy management

Simplified protocol post execution review and approval
Enabled leveraging and reuse of previous validation information
No paper or document manual handling, management or storage
Reduced deviations, greater right first time, greater GDP and data integrity assurance
Improved audit preparedness
Improved metrics on all aspects of the process – e.g. dashboard on real time validation status based on deliverables complete etc.
Improved information access and visibility - Validation index, dashboards & records
Elimination of many time consuming manual steps
Provided platform to establish simple, effective and compliant Change Management

Recommendations:

The team agreed that two key factors contributed significantly to a successful outcome within an aggressive schedule. They were:

1. "Don't let perfect get in the way of good." (Make incremental/phased progress instead of waiting for the perfect solution).
2. Process driven versus e-Tool driven. Your procedures should drive the process and the tool should accommodate your process. Not the other way around where you must modify your process to fit it in to the e-tool.

User feedback:

Shane Pew: Director Quality - Project Sponsor and Champion

Shane Pew, the sponsor and champion for the project says, "implementing the e-Val system and going paperless has enabled us to streamline our work processes and provide a more efficient and effective way to meet the increasing demands of the business for compliance and productivity". He added, "we were very gratified when we reviewed the new e-Val system with the regulatory agencies and received very positive feedback on our ability to document, manage, retrieve and track validation data as well as our commitment to best in class GxP processes".

Mony Kam: Software Validation SME

“Kneat has proven to be a highly adaptable software system that can be configured for use with multiple processes. The tools that are inherent to the application also make it easy to implement/deploy updates to an existing process. The system’s ability to help configure a standard with the ease of rapidly implementing/deploying updates for multiple processes has made it a valuable tool for our business”.

Conclusion:

Our new streamlined paperless CSV and Change Management processes have made a substantial impact on the business by enabling more right first time, greater productivity, shorter cycle times and a higher compliance standard. All Company stakeholders from the line users through to senior management are very satisfied with the great success achieved. The Company intends to continue extending the e-tool to many more processes and sites. The key to this is the tools ability to model multiple processes without the need for coding or the purchase of additional modules.

About the Authors:

Shane Pew is the Quality Director for the Company with over 18 years’ experience in Life Sciences. He is also the Champion and Business Process Owner for the e-platform and the validation business process at the company. Shane can be contacted at shanep@myriad.com**.**

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