



Case Study: Using TPSoP® to Develop Process-Centric Procedures / Standard Operating Procedures for a Leading Biotechnology Company

www.torquemanagement.com

The Brief

The quality management system is critical to the biotechnology company in question, but it creates a huge burden for employees. New hires need to read hundreds of procedures, employees find it difficult to understand the bigger picture, it is impossible to remember all the content and it takes a long time until employees can effectively perform their job.

The organisation engaged Torque Management to implement a pilot project for a business process centric approach to SOPs.

By modeling procedures as process flows and mapping them to business processes, lengthy text documents were replaced by visually represented pieces of controlled information. Employees can navigate the process landscape to understand the big picture and learn procedures through intuitive visual models.

In the longer term this approach will also enable further automation, e.g. a Business Process Management System (BPMS) system may guide the employee through the procedure step-by-step at the time of execution.

Benefits include shorter time to train with better recall of learned content, improved understanding of the bigger picture, which will lead to better collaboration, and higher quality of procedures as inconsistencies and redundancies show up when mapping them to processes.

The scope of this pilot project was to test this approach using ten procedures. Success was measured as reduction in training time, increase in recall of content and general employee feedback. Torque Management utilised its TPSoP® solution to carry out the project.

Scope, Approach & Method

Torque Management deployed its TPSoP® solution to deliver this pilot project. The scope of this project was to test this approach using ten procedures. Success was to be measured as reduction in training time, increase in recall of content and general employee feedback. As part of this effort, the procedures were to be mapped as process flows, within a BPMS which also supports navigation through the process hierarchy and training on the procedures in their new form. The project included learning from best practice, selecting vendors, implementing a working pilot and measuring success. The methodology comprised of three elements:

- TPSoP®
- BPMS – Tibco / Nimbus Control www.tibco.com
- Torque Management Business Process Engineers

TPSoP®

Developed with businesses of all types in mind, the TPSoP® methodology supports the development of process-centric procedures and Standard Operating Procedures. TPSoP® can be deployed as part of a wider quality or compliance programme or simply as a means of delivering instructions in a consistent and repeatable manner to employees and third parties e.g. contractors, suppliers and the public. This solution is particularly effective in delivering procedures and instructions to groups of persons for whom traditional instruction-based training is impractical or inappropriate, for example:

- A geographically dispersed audience where parties cannot travel to training
- Multi-lingual delivery is required
- Acknowledgment of receipt of instruction or training is required by regulation such as Life Sciences organisations; safety instructions on construction sites; hospital environments etc.

The TPSoP® methodology is a rigorous, collaborative process. As a methodology, TPSoP® is consistent with formal quality management and improvement methodologies such as six sigma (DMAIC) and Deming's (PDCA) and therefore also consistent with ISO methodologies and regulatory systems e.g. International Conference for Harmonisation (ICH). The timeline to deploy the methodology was determined by:

- The quantity of process-centric procedures / SOPs to be developed
- The quality of the current (text based) procedures / SOPs
- The availability and knowledge level of client Subject Matter Experts

TPSoP® consists of five distinct phases, as follows:

- Discover
- Build and Test
- Convert
- Implement (and control)
- Report (and improve)

Torque Management combined its unique capability in developing process-centric SOPs with our TPSoP® methodology and BPMS tools to ensure that process-centric procedures and SOPs were:

- Fit for purpose
- Easy to use and follow
- Fast to develop
- Easy to deploy, change and re-deploy new versions
- Meet regulatory requirements for traceability and auditability
- Supplement and integrate easily with formal quality and compliance management systems and business process management architectures.
- Provide a lower cost of ownership than paper-based or other e-instruction tools

BPMS

Due to the fact that this is a pilot project, Torque Management provided the company with the tools necessary for the pilot, removing the additional expense and additional activities associated with the procurement, evaluation, installation and management of software and hardware associated with a BPMS.

Our experience of similar pilot projects indicates that the focus of the pilot should be primarily on the methodology to develop and deliver process-centric procedures and their effectiveness, and less on the back-end of the BPMS.

Torque Management is a partner of Tibco (www.tibco.com) for its Nimbus Control BPMS product and provided User access to the tool for a small number of staff during the pilot phase of the project.

Torque Management Business Process Engineers (BPEs)

Torque Management's Business Process Engineers undertook

- The development of a Process-based Environmental Health Safety and Sustainability Management System (EHSMS) based on the ISO14001/OHSAS/180001 standards. The EHSMS provides a reference for all EHS&S procedures.
- The authoring of the in-scope procedures.
- The creation of dynamic links between the Management Framework, the processes and other systems (e.g. IT systems, forms etc.)

The reason for retaining authorship of the processes during the pilot is that the development of process author competency requires a combination of specialist, post-graduate level knowledge of business process management, business analysis or Lean Sigma, in addition to acquiring competence in the chosen BPMS. Therefore, the timeline of the pilot indicated that the development of these skills and competencies was a topic for the future strategy rather than the initial project.

Torque Management BPEs provided the necessary qualifications; process and technical, to undertake the tasks required by the pilot project. Also, whilst the initial procedures to be converted to processes were environmental (non GxP), our BPEs are cognisant of the general and specific requirements of a GxP environment and therefore ensured that the format and content of procedures were designed to meet both pilot and future requirements. This approach ensures no redundancy or re-work in the event that the pilot is extended to other areas.

Outcome

All pilot deliverables were tested as part of the pilot project, including the conversion of 90 pages of text based procedures to processes. The results of the study are positive. Clear benefits are indicated from the conversion of text-based procedures to process-based procedures.

Benefits were identified in a range of up to 87%, based on the criteria defined in the independent tests designed and implemented as part of the pilot.

Benefits that were not evaluated as part of the pilot e.g. removal of redundancy, reduction in maintenance and management of the system offer additional improvement opportunities.

Conclusions

The project met or exceeded all of its goals. Findings in the final report concluded:

- There is evidence that there are many benefits to be gained from taking an innovative, process-based approach to the development, management and maintenance of procedures. The independent comparative and general tests performed by the organisation's personnel confirm the rewards from process-based procedures with test results indicating that improvements are available in a range of up to 87%. Furthermore, this result is considered conservative.
- There was evidence to show that Torque Management's TPSoP® methodology is efficient and effective in the conversion of text-based procedures to process-based procedures.
- Torque Management provided evidence of the capability of the Nimbus / TIBCO BPMS software, within the defined scope of the pilot project.
- Torque Management delivered an EHS Management System and Process Architecture, providing evidence of integrity checking and traceability from compliance requirement to individual procedures. A modest additional investment, together with the necessary internal resources, could convert the pilot deliverables to a valuable asset for the organisation.

Conclusions are based on actual test results, commentary and feedback provided with the test results, and discussion with the pilot project team members.

1. The results of testing would clearly indicate a difference between Procedure and Process scores that favour process-based procedures, with results indicating improvements are available in a range of up to 87%.
2. Due to an absence of system orientation and an explanation of process-based concepts, it took testers longer to find and use processes. Therefore results for the time taken to locate and read processes are understated.

Future opportunities

Longer term, the approach piloted can be expanded to other areas of the business. Furthermore, a process-centric approach to procedures will allow further automation in the future. A Business Process Management System (BPMS) can guide users through a procedure step by step, providing instructions and policy information when needed. Process steps can be automated or handovers can be actively managed and monitored by a BPMS. Ultimately, the BPMS could entirely eliminate the need to maintain procedures in document form.

For more information on TPSoP® or how we can help your organisation, please visit

www.torquemangement.com