Effective Standard Operating Procedures (SOPs) are key not only for establishing and maintaining ongoing compliance, but also for meeting your business goals in terms of operational performance, enhanced quality, and efficiency improvements. SOPs describe and regulate your processes throughout the different levels of the enterprise, and the individual stages of the drug life cycle.

FDA’s current initiatives propose a risk-based approach for applying resources (time, personnel, and assets) against highest risks to support compliance to regulatory requirements. Regulations like revised GMPs, Sarbanes-Oxley, or upcoming standards like IT Infrastructure library (ITIL), force regulated users to revise their SOPs and make them more efficient and more comprehensive than ever before. Moreover, regulatory inspections reveal a constantly high number of findings related to the management of and compliance to written procedures.

This implies three basic challenges for today’s QA and IT managers:

1. To make sure that the benefits of a risk-based approach is consistently used on the different levels of the company and in the appropriate phases of computerized system development, operation, and maintenance, it must be clearly reflected in your processes and procedures. The strategies, methods, and practices for assessing the risk and deploying the results to control the activities should be supported by the Standard Operating Procedures for your system development life cycle (SDLC), as well as for use and maintenance of the systems.
2. To make sure that the quality of processes and procedures is high, because they dominate the effectivity and costs of your operations.
3. To make sure that procedures and processes can be easily applied, efficiently enforced, and their efficiency can be measured during operation, by the use of adopted software technology.

Rockwell Automation’s Compliance Services support and lead initiatives to help optimize, enhance, or substitute your SOPs to optimally use risk-based concepts and to streamline your SOP system for efficiency. We can assist you by providing sound compliance and technical expertise, as well as proven practices and tools.

Rockwell Automation integrates risk-based techniques as appropriate and required into the different phases of the SDLC. Particularly the SOPs for system operation and maintenance can be optimized using a holistic view on your system infrastructure. Thereby, synergies between different systems, respectively system categories, can be identified and used to simplify your SOP system. The results are fewer SOPs that can be easier used and maintained.

Partnering with Rockwell Automation, a recognized Automation and Compliance Services industry leader with quality, manufacturing and compliance expertise provides you with step-by-step guidance on how to assess, plan, design implement or test GxP related automation and computerized systems and associated Standard Operating Procedures tailored to your organization’s size, needs, and culture.
This is how we support you:

- Conduct a workshop to assess your SOP system and derive an action plan
- Develop a risk management plan and associated procedures covering your IT-related operations
- Implement risk-based methods in key processes and procedures, like validation planning, testing, change control
- Streamline your SOP-system by applying standard SOPs to reduce the variety of system-specific procedures, whilst still reflecting necessary variations
- Optimize selected processes using proven methods and techniques, and deploying fully developed templates, e.g. for testing or change control

- Identify processes where automated tool support is highly beneficial and define user requirements for software tools
- Support tool vendor evaluation based on your user requirements
- Manage the implementation and validation of selected software tools
- Train your employees in applying the revised SOP system

For more information, go to www.rockwellautomation.com/regulatorycompliance

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