Managing Filtration Integrity With Collaborative Technology

Millipore's Bioprocess Division uses the right technology in a team environment

By Rich Bianchi

In the pharmaceutical and bioprocess environments, strict quality control standards ensure that production meets specification.

Pharmaceutical companies use filters in their production process to filter out impurities. These filters require testing to determine whether they are functioning properly, allowing manufacturers to make certain that contaminants are not inadvertently passed into the drugs by faulty filters. This is a highly regulated process that must be validated every step of the way to ensure that it meets the high standards set by the FDA.

Filtration manufacturers are attentive to the integrity of a filter because it greatly affects the quality of the product produced. The integrity of a filter refers to its ability to stay intact without the filter media breaking off or migrating downstream into the process fluid. This is a very important quality control measure and needs to be monitored through periodic testing.

In addition to filter integrity, the downstream process fluid needs to be closely monitored to ensure that no impurities are passing through the filter and contaminating the fluid used for the bioprocess. This is also critical to the operation and needs to be controlled through careful testing and monitoring.

Case in Point: Millipore

Tom Hirsch is a senior consulting engineer for the R&D Group in the Bioprocess Division of Massachusetts-based Millipore Corp. His group is responsible for building testing software used to monitor and check the integrity of filters used in the production of pharmaceuticals. Hirsch and his group use Alexsys Team 2 Pro software to track all events in the testing process. The management of such testing involves a team of scientists and engineers in remote locations. Because facilities are large and dispersed, filtration integrity is often monitored from central locations.

During any given project, this team consists not only of people in Hirsch's office but also people in different time zones around the world. These scientists and engineers are part of a team environment and have actions and tasks that need to be

captured, tracked, and facilitated among team members. With the click of a mouse, members of the project team can easily record tasks in Team 2 Pro, allowing them to be prioritized, assigned, and completed with detailed documentation of pertinent discussions, notes, attachments, and a record of the time spent on each task.

Using Team 2 Pro, members of the R&D staff can instantly view and organize their assignments, create and update tasks, and collaborate with other team members. Reports and live views are easily generated for a variety of organizational needs.

Millipore's customers are concerned about internal records and mandate that their R&D team provide a "big trail of evidence" to allow an easy audit of the testing software, any problems discovered in the testing, what problems where fixed, how they were fixed, and by whom they were fixed.

Their effort to monitor filtration integrity and their use of collaborative software to document their actions are right in line with the software best practices. According to research conducted by the Connecticut-based Gartner Group in 2002, titled "Software Best Practices Start at the Top," software applications need to use good common sense. The research advises: "Think before doing. Understand your objectives and your realities. Keep things simple. Plan for intermediate manageable results. Establish a feedback loop. Reuse the reusable. Track and evaluate the modern technology trends, then apply only those that fit. In most projects, however, most of these common sense guidelines are compromised &#151 or worse, avoided."

In Millipore's case, its filter integrity testing utilizes state of the art technology, common sense guidelines, and a steady stream of feedback information. This approach has helped the company's Bioprocess Division become one of the largest and most successful components of its overall business.

Competitive Edge

In order to gain a competitive edge in the market, organizations must capture, track, and facilitate the human processes of their groups. No matter how big or small a company might be, the right project management process tools bring better productivity and more effective leveraging of limited resources. They give management and employees the ability to automate people-centric processes to stay ahead of the competition.

With the right collaborative software, teams are more productive by working with their existing processes &#151 instead of forcing new or additional processes on them. Good collaborative project management software offers groups a more effective means of sharing data and enhancing individual effectiveness.

Team 2 Pro software, engineered to be easy to install and use, is easier to implement and use than traditional project management software packages. It works in Microsoft Windows and uses standard web browsers. Administrators can use the product out-of-the-box or customize it with a proprietary Adaptive Rules

Engine to create specific fields, forms, tables, escalations, and notifications, which become immediately available to members without the need for rebuilding, rebooting, or restarting. Users can instantly view and organize their assignments, create and update tasks, and collaborate with other team members.

Reports and live views are easily generated for a variety of organizational needs. Managers can quickly get a snapshot view of both individual user and project workloads to identify bottlenecks, balance workloads, streamline group communications, and better leverage human resources.

Traditional Approaches

Project management software and traditional tools lack certain key elements for today's environment. Traditional project software often omits the role of the knowledge worker. While they do offer thorough scheduling features, they lack a focus on information, tools, and work allocation for the many individuals dispersed throughout a corporation. Also missing are enabling tools that allow the team to prioritize and focus their efforts. The right things at the right time by the right people can run amuck with traditional project management software.

Truth in Details

With the right technology, potential problems can be avoided. How? Ask the question: "What do I need to do today to have the greatest impact on the bigger picture while keeping the project on track and on schedule?" This focus needs to be melded into project management technology. In other words, collaboration technology should be designed to be the "on ramp" to dispersed task management. The truth is in the details. By allowing knowledge workers common access to key documentation, communication can be greatly improved. Information is available to all, and an audit trail is automatically in place for regulatory authority.

How can that be done? The following six concepts are key when creating dispersed project team management technology.

&#149 Classify: Define and categorize task items.

&#149 Targets: Parlay action items into specific tasks on a milestone schedule.

&#149 Prioritize: Rank and order task action items for the common good of all team members.

&#149 Collaborate: Select and direct the right tasks for and to the right people. The "it's not my job" syndrome is out. The division of labor responsibility is clear.

&#149 Monitor: Track and monitor tasks with regard to schedule and milestone adherence and completed task actions. This is an excellent way to keep all task members informed of what has been completed and what has not.

&#149 Track: If history repeats itself, there is valuable information in project history files. Such information may help predict the future and provide lessons learned for concurrent and future projects. Historical data gives way to continuous improvement. It also documents your actions and automatically provides a trail for auditors. Government regulators have increased their pressure on required documentation in many industries, and such technology available in task management history files allows for an organized and complete compliance with their requirements.

Automated and Expedited

Projects can be intimidating. Today's project managers need drill-down tools and tactics that can transform an obese project scope into very specific bite-sized tasks. This requires smart technology. Such technology must respect workloads, milestones, and task priority. Simply stated: Knowledge workers need to know who is doing what, when, where, and how. Once a task is completed, a record of the completed task should become available and accessible by all.

Managing a process operation with a dispersed team of players is greatly facilitated when all the legwork is automated and expedited. For Millipore's Bioprocess Division, the task of monitoring filter integrity exemplifies the right technology in a team environment.

Rich Bianchi is the president of Alexsys Corp. based in Stoneham, MA. Alexsys provides software solutions designed to automate the management of tasks and business processes. Its software has been deployed by hundreds of organizations of all sizes around the world including Fortune 50 companies. Information: www.alexcorp.com.