insights clearBLUE

Leveraging Technology for Maintenance and Calibration: Going Paperless

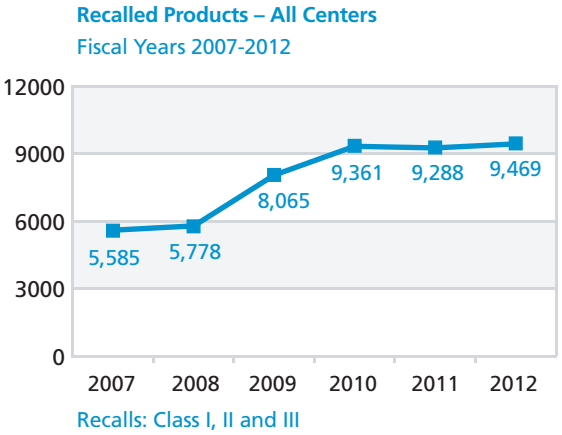
Going Paperless

Going paperless in Life Sciences manufacturing has been a persistent trend for many years. Recently, the industry experienced an increasing demand to go paperless as a result of several significant industry-wide drivers of adoption as well as the growing availability of technological components. Both of these trends increase the lasting success of paperless environments. This white paper will explore the drivers of adoption and the technology needed to achieve a modern paperless environment.

Paperless Drivers of Adoption

There are four significant paperless drivers of adoptions. Many of these drivers are a result of an adapting business landscape in regards to health trends, regulations, new laws and a growing global economy. These four drivers include:

1. Demand for Improved Product Quality and Higher Levels of Patient Safety

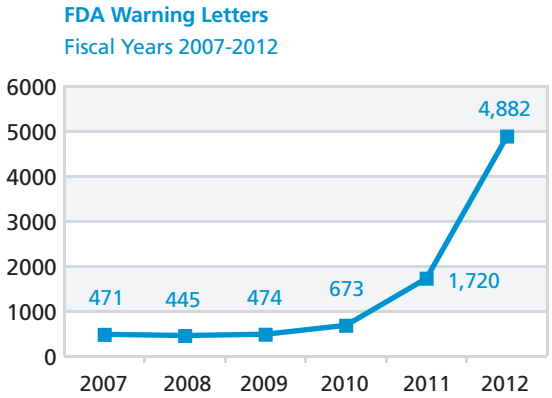


*Source: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.pdf

By looking at the number of recalls made by the FDA between the years of 2007 and 2012, it is evident that the FDA has focused on product quality. The significant increase in the number of recalls made by companies is an indicator of a growing number of products made with poor manufacturing practices. The FDA's drive to improve product quality is further cemented by Deputy Assistant Attorney General Dr. Frimpong:

"We will also be taking an especially hard look whenever patients are placed at an unacceptably high risk of harm by those violations of current good manufacturing practices."

2. Increase in FDA Warning Letters and cGMP Violations



*Source: http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.pdf

There is a significant increase in the number of FDA Warning Letters given in both pre-approval and on-going inspections between the years 2007 and 2012. The FDA is more aggressive than ever before. This makes it important for Life Sciences companies to stay up-to-date with new technologies in order to maximize the level of compliance in a facility.

3. Patient Protection and the Affordable Care Act (PPACA)

"After a century of striving, after a year of debate, after a historic vote, health care reform is no longer an unmet promise. It is the law of the land." – *President Barack Obama*

Healthcare reform, while serving to meet a long term goal of improving healthcare coverage within the United States, provides a number of short term effects for Life Sciences companies. While the law provides a larger marketplace for the future, it also places demands on Life Sciences companies to meet pricing constraints (e.g. Medicare pricing constraints and Medical Device Excise Tax, new tax treatments and fees).

4. Competition drives cost cutting and improved productivity

Foreign imports of FDA regulated products have tripled between the years of 2000 and 2010. With an increase in globalization, there is significant growth in competition among Life Sciences companies. The number of drug-related and medical device products imported into the United States is on the rise as well as generic drugs that will spike following a swell of now off-patent drugs.

All of these trends are direct drivers towards creating a paperless environment in your manufacturing facility. Paperless environments allow for decreased costs and enhanced manufacturing performance which will ease the pressures of the above drivers.

Paperless Requirements

The following requirements directly impact the overall success of a paperless implementation:

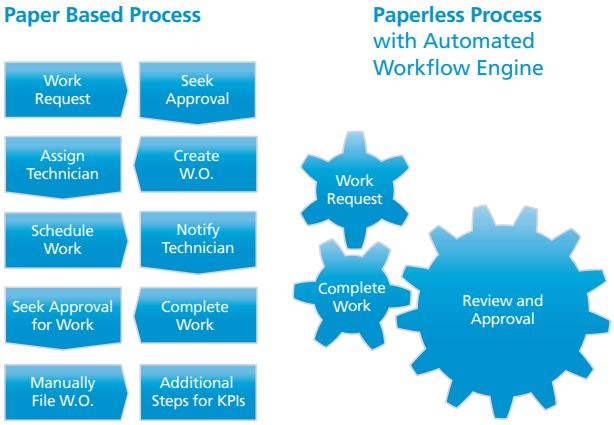
- Established Corporate Need
- General Acceptance of Management
- IT Acceptance
- Funding / Justification

Four Vital Paperless Components

Four major components that aid in the on-going support of a successful paperless implementation include:

1. Workflow Automation

Workflow Automation creates a process driven, automated work environment that consistently executes and manages the paperless system by maneuvering records throughout their lifecycle.



Record lifecycles include asset induction, work management, work execution for both calibration and maintenance work and record keeping (documented evidence that all of the necessary actions and sign-offs were completed and that errors were reduced with simplified data entry and reviewed work). Some examples of workflow automation include the processes for

1. Corrective and Preventive Maintenance
2. Calibration Work Orders
3. Maintenance Work Orders
4. Calibration Out of Tolerance

Benefits of Workflow Automation include the controlling of records on a time, sequence or event basis, generating accurate metrics from state based statuses (open, closed, review and other definable states) and automating notifications sent to necessary individuals.

Paperless Evolution

21 CFR Part 11 (1997)

- Specific FDA regulations regarding electronic signatures
- Landmark regulation for industry
- Creates a pathway to paperless

Y2K Upgrade Cycle (2000)

- Year 2000 issues in software leads to upgrade cycle

Web Based Systems (2004)

- Prior to, most were clunky client-server applications with high bandwidth and difficult to be used broadly
- Now, web-based applications offer low-bandwidth, broad use and are paperless friendly

Software Functionality (2007)

- New and on-going upgrades and updates to software
- Specific focus on workflow functionality

Ubiquitous Wireless (2010)

- Today, wireless is available in almost all reaches of facilities

Tablets (2014)

- Tablet use becomes widespread

2. Work Execution

Paperless Work Execution streamlines and controls processes for technicians. Both maintenance and calibration technicians rely on a digital set of tools to:

1. Show steps needed to complete work (specific to each asset)
2. Automatically request e-signatures
3. Immediately trigger notifications for completed, failed or in progress work

Paperless systems enable technicians in the field to focus on performing work rather than processing paperwork.

A. Maintenance in a Paperless Environment

Paperless work execution allows maintenance technicians to record work *as it is being completed* by utilizing work plan templates. Work plan templates automatically display the necessary steps (SOPs) to completing that particular maintenance activity. Using work plan templates in paperless systems, maintenance technicians can create a log of activity automatically and can also record measurements, readings and comments.

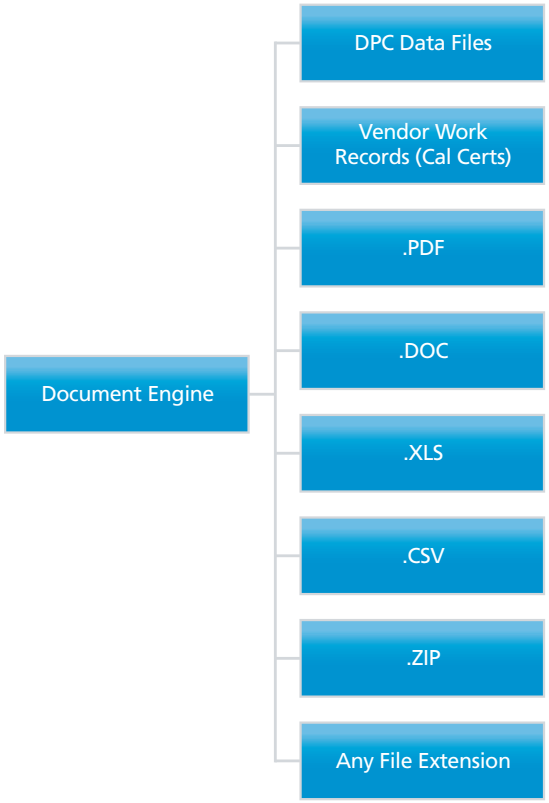
B. Calibration in a Paperless Environment

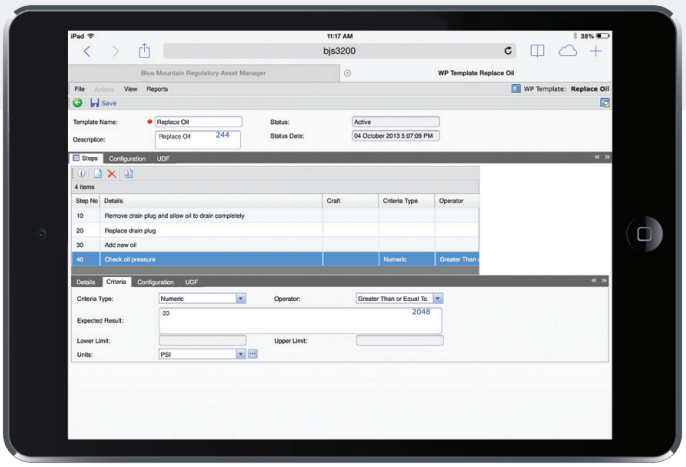
Utilizing paperless work execution, calibration technicians are able to record measurement data on the shop floor. Measurement data comes in numerous formats, and very little of it is automated from the instrument level – so it must be manually entered. Being able to enter it right at the time of calibration provides the following benefits:

1. Reduces redundant work
2. Improves quality of work
3. Aids in error reduction
4. Triggers automatic notifications
5. Calculates measurement uncertainty and accuracy ratios automatically confirming that adequate tolerance accuracies were used
6. Provides measurement data analysis for selecting the right tolerances, calibration intervals and performance metrics

3. External Documentation

One of the largest barriers of reaching a successful paperless environment is the management of paper documents and external files. Document storage engines provide a simple solution to storing paper records and records from external systems. It will store files in a database rather than relying on links and external file systems. By storing files in a database, they are embedded with assets, work and other records and stored in a version by version manner in the audit trail without the risk of lost files.





4. Mobile

As we have seen in many facilities, the use of wireless network access (or even cellular access) has become ubiquitous. Wireless network access within a facility can drastically improve the success of your paperless environment by allowing maintenance and calibration technicians to utilize work execution tools out on the floor. Mobile coverage used in paperless environments directly refers to the usage of different mobile form factors. These form factors typically include laptops, mobile phones and tablets.

The use of mobile devices allow maintenance technicians to:

1. View SOPs and work instructions on a mobile device, mark the steps as complete and/or sign off on steps
2. Review and evaluate work requests on the floor, approve or disapprove the request and schedule a follow up activity remotely
3. Evaluate, update and complete work through the use of a mobile device
4. Locate equipment and spare parts remotely
5. View a schedule of upcoming work

The use of mobile devices allows calibration technicians to:

1. Record measurement data while it is being measured
2. Validate measurements as they are being completed and entered
3. View a schedule of upcoming work
4. Sign off on completed and reviewed work

Benefits of Paperless Environments

1. Improve compliance by using Work Execution tools such as work plan templates and measurement data templates. These tools improve the consistency and accountability of completed work by requiring specific, controllable steps and sign offs.
2. Increase productivity by providing mobile access to all the necessary procedures and tools for technicians to complete their work. This includes the ability to initiate automatic workflows for e-signatures and review processes.
3. Limit paper using a powerful document storage engine that stores all of your documents in a single location. No more filing paper, lost documents or missing versions.
4. Gain site wide metrics and KPIs by storing all technician data for calibration and maintenance work done in the field. Managers can create unique, real-time reports across multiple sites.

Conclusion

Companies have been able to go paperless over time with varying degrees of success. Now with the alignment of industry drivers, the layout of paperless requirements and the four key technological components, the success rate of achieving a paperless environment that provides high levels of return on investment has significantly increased. Now is the time to invest in a paperless environment that will enhance productivity and provide continued ROI.

About Blue Mountain Quality Resources

Blue Mountain Quality Resources is the leading developer of industry standard asset management products and services—designed exclusively for the Life Sciences industry since 1989.

The company's Blue Mountain Regulatory Asset Manager® was the first regulatory asset management system, designed specifically as a harmonization of calibration, maintenance and validations systems into a single comprehensive solution for Life Sciences companies.

For more on products and services available from Blue Mountain Quality Resources call us at 800-982-2388, email us at bluemountain@coolblue.com, or visit www.coolblue.com.

BLUEmountain
QUALITY RESOURCES

PO Box 830, State College, PA 16804-0830