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The Compelling Case for GMP Compliance Investment

"This is a unique time in our industry's history—one that compels us to select and implement tools that will lead our companies and industry forward."

GMP Compliance

Today's regulatory environment is increasing the need to invest in GMP compliance automation solutions such as Computerized Maintenance Management Systems (CMMS).

As you know, working in a world of Equipment, Instrumentation and Facilities, we have the perennial business drivers of:

- GMP compliance
- Manufacturing cost containment
- Need for greater productivity
- Increased management visibility
- Accountability

FDA Has Stepped Up Enforcement

With Congressional pressure, the FDA is stepping up the number of inspections both domestically and around the world. Not only have they added additional investigators, but they have also opened offices in China and India to further their reach into the global supply chain. In addition, they are working more closely with other International Agencies to coordinate and share enforcement activities. The FDA's new global reach was fully exercised when, in early 2012, they issued their first Consent Decree against a foreign-owned drug firm for their sites outside the USA.

With the increased activity, the Agency is finding that the GMP compliance gap has grown. The results are dramatic with an increase in both 483's and Warning Letters. They are more detailed, include more elements and the findings often span multiple sites and divisions with coordinated Warning Letters. The resulting actions have associated remediation costs. In some cases, it results in halted production, closed facilities, or in Consent Decrees – all with even *more* costly consequences.

As the Life Sciences industry has grown and diversified, the FDA has added specialists in Biotechnology, Pharmaceuticals and Medical Devices. With the Quality System Inspection Technique used in inspections, the investigators are better versed in Facilities, Equipment and Instrumentation. Also, they have seen the best practices used at other firms, leading to a heightened awareness.

The High Cost of Non-Compliance

- **Remediation Costs**
- **Recalls**
- **Plant Closing/Production Halt**
- **Negative Stock Share Price**
- **Fines**
- **Executive Liability**

The FDA Hot Buttons

In examining recent 483's and Warning Letters, a pattern emerges of what the FDA is emphasizing. These are the top compliance trends seen most frequently:

- **Quality Systems Approach** - The FDA is fully embracing the Quality System Inspection Technique and their findings reflect this shift.
- **Standardization across Departments and Organizations** - The FDA is holding organizations accountable to standardization and demanding consistency.
- **Proper Use Of Risk Based Approaches** - With the introduction of the GMP's for the 21st Century in 2002, the FDA incented the industry to use risk-based approaches that are based on sound engineering and scientific data.
- **Management of Change Control** - One of the most frequently cited GMP excursions is poor management of change.
- **Corrective Action/ Preventive Action (CAPA)** - One of the first places the FDA looks; it has become a very common GMP issue found in many Warning Letters and 483's.

While most of these GMP trends are broad and systemic in nature, their influence on the operation of facilities, the maintenance of equipment and the calibration of instrumentation is being felt. From maintaining a validated state of equipment to reporting Out Of Tolerance calibrations, these areas require new approaches to be both compliant and productive.

CMMS Technology Drivers

Tools that didn't exist just five years ago are changing companies' philosophies toward automating GMP compliance in Facilities and Equipment. Progressive manufacturers are embracing this new functionality to ensure they are meeting their business' needs as well as GMP compliance:

- Integrated Maintenance and Calibration Management
- Automated Part 11 Work Flow Tools
- Robust Measurement Data Templates
- Paperless Work Requests and Work Orders
- On-line Reporting of Non-Conformance

These tools, combined with the power of wireless infrastructure, enable true reductions in work, errors and "paperless" operations while maintaining the highest levels of accuracy, speed and consistency.

Benefits of New CMMS Technology

Major benefits of implementing a CMMS with this updated technology include:

- **Improved Quality** - Improving product quality, whether through holding tighter tolerances, reducing scrap rates, or improving process yields nearly always improves profitability and ensures greater market share. Current CMMS functionality coupled with advances in technology infrastructure can reduce lot variability and enable optimal tolerances at lower costs. By keeping production equipment in top working order, production yields increase and operating costs are reduced.

- **Increased Productivity** - There is tremendous opportunity to increase productivity both at the product and compliance record levels. By optimizing work planning and execution, improving maintenance/calibration intervals and better maintaining equipment, productivity measures, such as Overall Equipment Effectiveness, are increased. By automating GMP workflow, automatic notifications and auto-generating reports and performance metrics, the benefit of a paperless work environment offers additional productivity.
- **Higher Compliance** - With recent FDA enforcement at the forefront of the industry, the GMP compliance bar has been raised. Many companies report that this new technology provides greater consistency, enforcement of workflow and reductions in costly errors. By eliminating redundancy and conflicting data, audits are streamlined. Fully automated work rules, with built in Part 11 functionality, further improve the compliance equation.
- **Reduced Costs** - Every organization in today's environment must reduce cost wherever possible. Implementing new CMMS software offers many cost benefits including reduced calibration and maintenance costs, extended equipment life, reduced capital expenditure on new assets and large reductions in spare parts/inventory carrying costs.

Conclusion

We are working in challenging times with many new constraints. As has been the case many times, innovation, technology and new methodologies can combine to provide cost effective solutions. This is a unique time in our industry's history – one that compels us to select and implement tools that will lead our companies and industry forward. Fortunately, we have CMMS solutions that will help us achieve both high levels of compliance and productivity.

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PO Box 830, State College, PA 16804-0830