

WHITE PAPER

EVALUATING THE CASE FOR ENTERPRISE HYGIENE REPORTING

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Introduction

Enterprise Hygiene reporting systems offer new levels of practical and affordable solutions for Food/Beverage and Pharma producers. These systems fulfill regulatory requirements, while delivering a mix of strategic and operational benefits, including Compliance and Quality, Engineering, Operational efficiency, and operating cost reduction. While paper-based systems are still commonplace, they are no longer a best practice for quality and safety minded organizations. This article surveys a few of the strategies and benefits pursued by leading producers through advanced CIP, COP and MCP Reporting.

Sanitization, Food Safety and Quality

Experts estimate that 30 to 70% of Food Safety events are associated with inadequate or poor quality CIP processes,¹ with similar issues among Pharma producers. While Paper CIP charts and MCP/COP checklists can adequately document compliance, they are time consuming to manage, fail to provide transparency into the cleaning process, and woefully inadequate as a foundation for scientific hazard analysis. For example, CIP program exceptions such as operator “skips”, “aborts” and manual steps are not exposed on paper charts in a meaningful way. They are cumbersome to retrieve and cannot be readily accessed outside the plant. They cannot be integrated with other quality and process information such as lab test results, and they are a dead end for companies pursuing advanced CIP scheduling or traceability strategies, with critical time saving business process integration. That is why companies seeking “best in class” performance require electronic reporting systems.

Electronic CIP reporting systems not only document wash compliance, but they also provide a foundation for building on the Quality ethic and culture of a processing company. Transparency means wash status can be monitored at any time, and records are available when and where they are

needed. Business rules can be integrated with electronic reporting data to enhance productivity, safety and quality, cultivating higher levels of corporate goal awareness and accountability. Test results, exception management, trend information are stored and can be accessed with the wash record or unit being washed.

Better wash quality management means better product quality, less manufacturing cost, and lower compliance risk. For highly regulated products with short shelf lives (e.g., Fluid Dairy), attention to detail can improve retail shelf-life, enhance brand value, and reduce the cost of retrieving and scraping finished product. Regulated consumables with longer shelf lives can realize yield improvements, while significantly reducing recall risk associated with inventory. Expected benefits vary with prior historical performance (poor historical performance suggests greater potential gains), but a broad survey suggests that a typical Grade A dairy producer can project tens of thousands of dollars in annual cost savings associated with reduced Food Safety and Quality events (see Appendix). The corresponding benefits among Nutritional Supplements and Pharmaceutical producers tend to be more strategic, and scale into millions per year as the costs of a single averted FDA event are considered.

Consistency, Standardization and Sustainability

Surveys show that CIP Washes on the same equipment vary plant-to-plant by up to 100%, and vary within a plant by as much as 50%² These variances can be measured and systematically improved. The lack of effective standardization is due a range of factors, including:

- Operators bypass CIP Process Control to manually add chemical or water
- Differences in vintage, and physical differences in plant and processes
- Heterogeneous automation control environments

with different integration teams

- Inadequately documented CIP programs, with limited change-control in PLC logic
- Operator intervention (such as to put the Wash on Hold, or Skip or Step the program)
- Varying performance of Plant System maintenance

In addition, the costs of stocking supplies for paper chart recorders, ordering those supplies, retrieving and filing CIP/SIP records easily total over \$10,000/year for a typical plant, and they continue to increase annually. By contrast, these costs are avoided altogether with paperless reporting systems, and Moore's Law³ predicts further real cost reductions in software, memory and CPU (excluding the PLC) going forward.

Expanded Capacity and Extending the Life of Existing Process Control Systems

Electronic CIP Reporting Solutions can seamlessly integrate with existing PLC and Process Control, to breathe new life and enhanced functionality into an older process control system. This can avoid having to re-validate the manufacturing process (the incremental validation of the BI layer is de-coupled from the process layer, and is straightforward when the product is already validated by the FDA). The alternative is a complete upgrade of the plant floor control system, and/or an expensive process re-validation effort.

In addition to extending the useful life of existing infrastructure, enhanced reporting systems also materially improve productive capacity of existing plants, by highlighting areas for operator training and effectiveness. Time spent in cleaning processes is, after-all, time taken away from plant production capacity.

Avoiding a \$200,000 to \$500,000 investment in new PLCs, process engineering services, and plant down-time is a reality for organizations that take advantage of these reporting solutions.

Analytics: a win for Engineering, Finance, Quality, and Operations

"The gains that you get by statistical methods are gains that you get without new machinery, without new people." W. Edwards Deming⁴

In large manufacturing corporations, various plants often have their own methods for performing statistical process control (SPC). It is challenging to coordinate and transform data into actionable information using manual SPC (statistical process control) methods. The resulting ad hoc analysis is rarely effective, and companies fail to pinpoint root cause, or move to correct systemic issues.

An enterprise management system based on formulating performance indicators for CIP operations starts with a set of standardized definitions and indicators needed for assessing CIP performance. Enterprise reporting takes summarized results from plants and provides a consolidated view of CIP operations across the enterprise, using key performance indicators, exposing systemic issues and successes. This drives consistency across the enterprise, encourages collaboration and success sharing, and allows enterprises to achieve best in class performance.

This brief survey summarizes some of the strategies and benefits being sought and realized by Food and Beverage producers throughout the United States. These systems improve regulatory compliance, dramatically improve accountability, result in significant reductions in Food Safety and Brand risk, and provide a foundation for significant operating cost reductions, as well as extending the useful life and capacity of existing plants.

Notes

1 Martin Weidman, Cornell University

2 Vigilistics Survey of CIP Operations, 2011

3 Moore's law is a rule of thumb in the history of electronics whereby the period for doubling semiconductor performance

is roughly 18 months; capabilities of business intelligence software in manufacturing is strongly linked to Moore's law, when the business intelligence functions are moved to a standard computing environment, such as SQL server, as it benefits from increased processing speed, memory capacity, and sensors. These same improvements are not possible within PLCs or "proprietary" architectures.

4 If Japan can, why can't we?, a white paper, broadcast by NBC in 1980

About Vigilistics

Vigilistics, Inc. is transforming the way food and beverage operations use manufacturing data. Our software solutions monitor, record, analyze and optimize production and cleaning processes used in manufacturing operations, to deliver actionable real-time intelligence to managers and executives.

Our software is now in use by some of the largest food manufacturers in the world, and validated by the FDA for paperless compliance reporting. Our secret is a novel and patented data model that unlocks an ability to configure data collection to the nuances of each plant, and monitor every process step and parameter the same way, without using highly technical engineering resources. We offer solutions for receiving, pre-op inspections, CIP management, traceability, yield, and more.