eBook

InfinityQS®
Quality Re-imagined

Transforming the Vaccine Manufacturing Chain

How pharmaceutical companies can ensure quality and accelerate time to market

Contents

Vaccine Manufacturing in a Complex Environment

Immunization is a proven tool for controlling and eliminating life-threatening infectious diseases. According to the World Health Organization, vaccines avert between two and three million deaths each year worldwide, and most of the people saved are children. Yet even as vaccines become more readily available, manufacturers still have a long way to go to produce enough regulation-compliant vaccines in a timely manner to meet worldwide demand.

It can take nearly two years to produce a single vaccine, and 70% of that production time is dedicated to quality control[1]. Vaccine production concerns could be remedied and even avoided with faster, more efficient and precise quality procedures that improve the availability, efficacy, and safety of the vaccines. Consider some recent examples from the market.

› Worldwide deliveries of varicella (chicken pox) vaccine were suspended for months after internal production quality issues were discovered at a Belgian facility. Health officials began rationing vaccines as a result.

› A number of European countries were forced to halt the use of some flu vaccines as a precautionary measure after a suspected quality defect was discovered in components manufactured in Italy. An investigation was conducted to determine whether the affected batches should be permanently removed from the market.

› In consultation with the FDA, a major vaccine manufacturer voluntarily recalled several batches of typhoid vaccine due to potential potency issues. Although a competitor's vaccine was recommended as a substitute, the company said the recall could lead to an international shortage of the drug.

The Opportunity for Quality to Strengthen the Entire Supply Chain

Quality challenges can potentially slow patient access to vaccines and even create chronic vaccine shortages. The quality department represents the fundamental link in the vaccine manufacturing supply chain. Quality must take a more prominent enterprise role as it is the department that uniquely owns the data needed to improve the end quality of the vaccine.

[1] IPHA (Irish Pharmaceutical Healthcare Association) website www.ipha.ie

[2] Gartner Research, Hype Cycle of Consumer Goods, 24 July 2012, Analysis By: Simon F. Jacobson; Ray Barger Jr

Vaccine Intricacy Creates Data Proliferation

Rapid advances in medical science and manufacturing technologies are resulting in increasingly sophisticated vaccine formulations with a corresponding rise in complex, multifaceted supply chains. Variability of biological processes requires complicated manufacturing and testing techniques to maintain product consistency. Each process has its own specific requirements, parameters, and quality checks. As a result, the amount of data required to monitor and track production at each quality checkpoint is increasing exponentially.

In fact Gartner predicted that by 2015, "80% of life science companies will be unable to cost-effectively manage the elements of big data, exposing poor ROI for IT investments."[3] It's time life science companies take control of their data with a software platform that supports their unique data needs. With no way of controlling, understanding and using big data, life sciences companies often struggle with problems such as:

› Traditional data collection media, like pen and paper, spreadsheets — even Manufacturing Execution Systems (MES) — do not provide the continuous scrutiny required to extract immediate insights from consistent vaccine production and output.

› Even with faster data access, the plethora of data siloed in different areas can make meaningful analysis exceedingly difficult, not to mention too slow to be an effective preventive measure. Even the best procedures and systems must take variance into account, as even the slightest inconsistencies can cause serious risk.

› If quality issues occur after the fact, inventory is jeopardized as corrective actions are taken. When this happens, production must ramp up again and the bad product must be scrapped. If the product ships, it costs the vaccine maker time and money and potentially damages public health and the company's brand reputation when the unsafe vaccine is put in use.

With increased data complexity comes a greater likelihood that quality control and safety issues will develop at some point in the manufacturing process. Organizations typically have implemented good manufacturing practices (GMP), such as the ICH Q10 Pharmaceutical Quality System, and capture data about controlling the processes and facilitating continual improvement. However, the all-important difference between a good quality system versus a world-class system lies in the accessibility and value of data collected for process control and quality purposes.

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[3] **Gartner; Predicts 2014: "Life Science Manufacturers Transition to the Digitalized Era", (November 27, 2013)**

The Negative Side of Global Manufacturing

Vaccine manufacturers have responded to their markets' demands and taken advantage of strategies like multi-sourcing to maximize production capacity, drawing on a skilled global workforce and building or securing additional capacity at other locations. Global manufacturing offers clear benefits to life sciences companies and their customers. For example, global late-stage manufacturing sites located in regions with high-density populations can increase vaccine accessibility and prolong shelf life.

However, when vaccine makers utilize multiple locations for the production of a single vaccine, the are often subject to regional and country-based regulations, as well as various testing requirements for each importing country. Struggling with multiple and sometimes conflicting regulations, life sciences companies become less nimble and unable to manage vast stores of data across geographically disparate sites. If any part of the production is questioned, the procedures will be deemed as frozen by officials, causing further delays and paralysis. With no meaningful data management and analysis, these companies remain in a reactive state, unable to proactively identify and mitigate quality risks before significant problems occur.

Any delays across this far-flung supply chain could cut into distribution and vaccine administration time and negatively affect remaining product shelf life.

Breakdowns in quality adversely affect supply and profitability. To effectively mitigate risk, manufacturers need a real-time approach to quality Manufacturing Intelligence that supports their global strategies but ensures that the end product maintains its quality levels all along the production cycle.

Increasingly Complex Regulatory Requirements

As the focus on vaccine quality has escalated, the regulatory process has become more complicated, with new regulatory requirements introduced on a regular basis. To meet evolving, divergent regulatory requirements and highly demanding standards, vaccine makers must implement a multitude of manufacturing and testing processes to stay in compliance, which therefore perpetuates a cycle of regulatory and manufacturing complexity.

Quality control in vaccine production is more critical than ever and an essential aspect of quality control is quick, easy access to meaningful data. However, quality and IT departments spend an inordinate amount of time finding "the right data," porting it from place to place, and formatting it before they can even begin their analysis.

These inefficiencies are particularly jarring when reporting methods are inadequate, difficult, or time-intensive to produce. Having easily accessible and configurable reports at every stage of the manufacturing process could alleviate many delays. When data is siloed within different facilities, processes, or production lines, compiling and analyzing it in a timely fashion can be extremely difficult.

Special Considerations for 21 CFR Part 11

- Build complete traceability into your data collection plans.
- Reduce the amount of time spent on audits by using electronic records.
- Have a quickly accessible way to identify who did what when.
- Ensure regulatory compliance and client requirements by leveraging workflow rules.

"It's just so fundamentally important. If you don't have quality, all the rest of it really doesn't matter."

— FDA Commissioner Margaret Hamburg

Quality as Catalyst

Organizations in the life sciences are required to maintain quality practices throughout the entire product life cycle. This means that anyone who touches a component on the vaccine's production line plays a role. Because of this, more and more producers are looking to standardize their approach with technology. The use of a Manufacturing Intelligence system, or quality "hub," helps management transcend these challenges and leverage Manufacturing Intelligence across the supply chain. While there are many nuances particular to individual organizations, the following are a few essentials that any vaccine producer would need:

› Single, secure, easily accessible quality data repository

› Streamlined data collection and integration

› Complete system view

› Efficient workflow management

› Reporting designed for intelligence, compliance, and traceability

A single, secure, easily accessibly quality data repository

A quality hub unifies all product, process, and quality data from multiple sources into one, universally accessible data repository. Information can be shared easily across the plant, the globe, even up and down the supply chain for immediate reporting, analysis, visual summaries, and data synchronization.

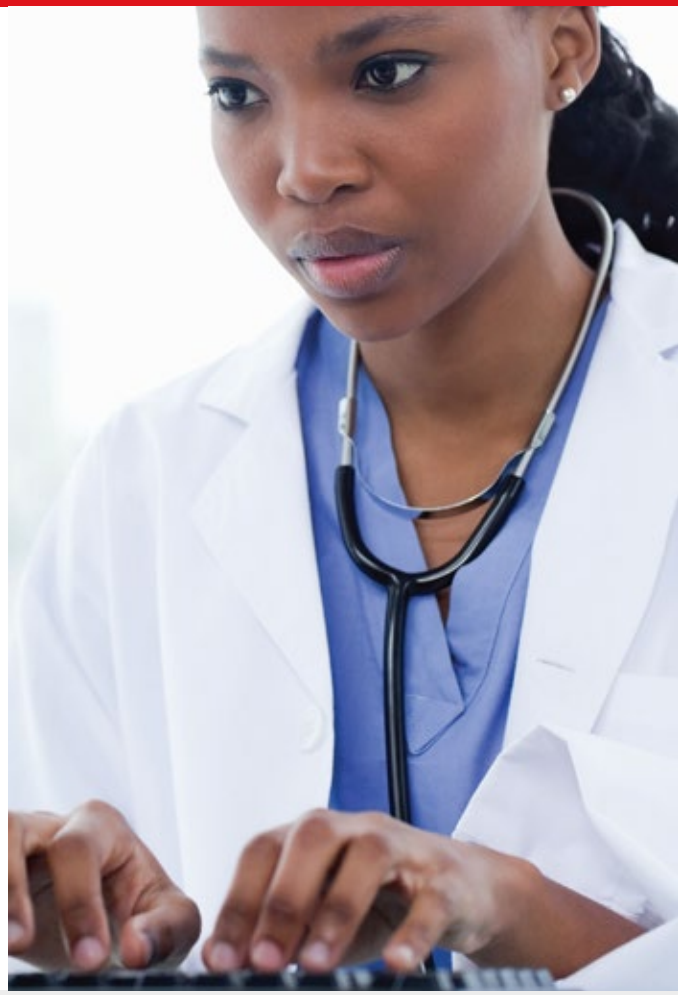
› Ability for users to select and choose data based on their needs

› Global updates for easier maintenance

› Data stored and managed to allow in-depth analysis

› Statistical analysis engine to process and manage data

› Store and manage data from sister organizations or suppliers to reduce the amount of acceptance sampling needed



A centralized database makes validation sampling easy

During the pre-production approval process, an orthopedic implant manufacturer looked for a software solution that would assist in the validation process for the machines building the parts. By collecting data from multiple sources into a centralized database, the company was able to furnish the documentation necessary to prove compliance with the FDA regulations. Using the gathered intelligence, the organization was able to identify and understand the different process personalities of the machines. Now, operators are able to adjust system processes to ensure all processes are running at optimal levels.

Quality as Catalyst (continued)

Streamlined data collection and integration

Automated data capture is more productive and less error-prone than human notations, and also greatly aids in real-time and continuous improvement decisions. Integrating data with current MES and ERP systems provides organizations a holistic global view. Additional benefits to automated data are:

› Intuitive interface for the plant floor

› Connectors to collect and integrate data from other systems or data collection points

› Flexible approach to inputting data (mobile friendly, manual, full support of automated collection)

› Ability to consolidate data from multiple databases, sites or suppliers (globally if applicable)

› Reduce the time it takes to perform acceptance sampling

A complete system view

A proactive approach to quality can eliminate problems such as wasted materials, batch recalls, and potential health concerns because issues are identified and dealt with the moment they occur. The software should notify the operator when there is an issue, rather than put the burden on the operator or engineer to discover red flags in the data reports. In addition, reports should be available remotely, so production can be monitored from the front office as well as the shop floor. Other important aspects include:

› Visuals like charts and reports update immediately when new data are entered

› Control Charts and Dashboards appropriate for all user roles

› Visual indicators of alarms

› Monitoring of data streams for violations or out-of-spec events

Improving product uniformity

A developer and producer of pharmaceuticals, vaccines, eye care products, and generics struggled to gather requested quality reports from various sources with their Manufacturing Execution System (MES) and paper-based quality system. Striving to reduce paperwork and obtain a complete picture of the operations in real time, the company made the transition to InfinityQS® ProFicient™ platform. The automatic integration of existing data from the MES to ProFicient facilitated easier operations for data analysis and collection, reducing the amount of resources typically spent on finding documentation and testing. Storing data in a centralized database provided management with the power to analyze and compile reports in real time while drastically reducing paper consumption. For operators on the shop floor, these changes have positively impacted their working culture by enabling them to focus on continuous improvement efforts rather than endless paper records.

Quality as Catalyst (continued)

Better workflow management

Workflow management can increase employee efficiency by automating workflows to create a standardized approach to data collection enterprise-wide. To ensure that the right people take proper actions in a timely manner, the quality system should include reminders and count-down timers that manage and verify data collection requirements. Also, the system should trigger automated alerts and alarms when out-of-specification issues arise, to escalate data collections and validations — even from workstations upstream or downstream of where the problem occurred.

Other types of notifications include:

› Process alarms and communications for staff members over email/SMS

› Timed prompts for scheduled quality checks

› Closed loop control for specific events

› Assignable Cause / Corrective Action codes

Reporting designed for intelligence, compliance, and traceability

It's critical for total quality control to automatically generate and distribute reports anytime, from anywhere, providing the Manufacturing Intelligence needed to ensure process control, meet Lean or Six Sigma requirements, and continually improve quality. Reporting functionality should include top-level dashboards, custom reports and visualization, and the ability to drill down to a particular supplier, plant, or single process.

Manufacturing Intelligence can help you achieve and maintain total quality control with:

› Dashboard views of KPIs such as OEE available across organization

› Easily customizable reports and visualizations

› The ability to filter the data for in-depth analysis

Consistent bag weights save money

A manufacturer of products used by critically and chronically ill patients, produces powder formulations that are blended at other facilities to create injectable liquid medications. Due to the exact nature of the production process and stringent FDA regulations, the company needed a way to ensure fill consistency and bag integrity through the supply chain. Using InfinityQS ProFicient software, the company scheduled frequent quality checks on the plastic bags that stored the product during the packaging, packing, and shipping process. The real-time visibility as well as the ability to produce on-demand records have provided management the insight needed to optimize the testing process and reduce the number of defective bags. With ProFicient, the company achieved its immediate goals of reducing defects and scrap costs while maintaining compliance. Through its commitment to superior quality, the company also achieved a critical goal of facilitating the accessibility of the much-needed injectable drugs for patients.

Why Now Is the Time for Quality to Change Its Approach

Traditionally, quality had a lagging role in vaccine production – the department that tested and confirmed finished product against specification. Quality departments often used reactive, siloed approaches, which created situations in which vaccine producers couldn't deliver to the market fast enough or in some cases didn't have the vaccine available. The traditional departmental-focused approach worked in simpler times; however, quality now must take a more prominent role and provide the Manufacturing Intelligence around the quality of the vaccine in production. With Manufacturing Intelligence, organizations can:

› Turn the abundance of data into advantage instead of burden

› Cure the local headaches brought on by global strategies

› Ensure regulatory compliance by monitoring the vaccine's entire production cycle

InfinityQS®
Quality Re-imagined

About InfinityQS International, Inc.

InfinityQS International, Inc.® is the global authority on enterprise quality. The company's Manufacturing Intelligence solution delivers unparalleled visibility across the enterprise, from the shop floor to the boardroom, enabling manufacturers to re-imagine quality and transform it from a problem into a competitive advantage. Powered by centralized analytics, InfinityQS solutions provide operational insight to enable global manufacturers to improve product quality, decrease costs and risk, maintain or improve compliance, and make strategic, data-driven business decisions. Headquartered near Washington, D.C., with offices in Seattle, London, Beijing, and Shanghai, InfinityQS was founded in 1989 and now services more than 40,000 active licenses with more than 2,500 of the world's leading manufacturers, including Kraft Foods, Ball Corporation, Boston Scientific, Graham Packaging, and Medtronic. For more information, visit infinityqs.com.

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