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Optimizing Pharmaceutical Operations Through Water Purity Management and Advanced Technologies

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A transformative Approach to Pharmaceutical Manufacturing: Real-Time Monitoring, Water Management, and Operational Excellence Kok Fong Tiyo, Asia Pacific Market Manager for Pharmaceuticals and Healthcare, Water Technologies, Veolia

As pharmaceutical companies strive to remain competitive in the market, optimizing operations, productivity, efficiency, and compliance with manufacturing quality standards becomes crucial to ensure lifesaving drugs and therapeutics deliver greater results and have a longer shelf life. Regulatory and quality requirements are constantly evolving, making it essential for manufacturers to incorporate advanced analytical and monitoring procedures to ensure compliance and safety of their products.

The pharmaceutical industry relies heavily on high purity water at various stages of production, from excipients to reconstitutions, from synthesis to production of the final product, or as a cleaning agent to clean vessels, equipment, and primary packaging materials. Study findings indicate that 45% of unplanned pharmaceutical downtime is caused by water-related issues like contamination, supply failure, or non-compliance. These can lead to significant operational disruptions.

A cornerstone of modern production is mitigating contamination through cutting-edge technologies, enabling pharmaceutical processes to maintain consistent water standards. The advanced pharmaceutical production relies on Process Analytical Technology (PAT) to enhance water quality management, ensuring consistency and operational excellence. Operational excellence is achievable through PAT, an approach that has demonstrated robust scalability, sustainability, and cost-effectiveness while addressing fundamental challenges.

In an interaction with Biospectrum Asia, ***Kok Fong Tiyo, Asia Pacific Market Manager for Pharmaceuticals and Healthcare, Water Technologies, Veolia***, explores how digital solutions are transforming water systems to meet future demands, designing a roadmap for leveraging innovative water management technologies. Tiyo also elaborates on how PAT enables real-time process monitoring to minimize contamination risks, reduce wastewater load, and support sustainable pharmaceutical manufacturing. In order to achieve consistent water management and operational excellence in pharmaceuticals, he stressed the importance of addressing contamination, supply failures, and regulatory compliance from a 360° perspective and leveraging advanced technologies like PAT.

- **How have recent challenges in pharmaceutical manufacturing, such as evolving therapeutic landscapes and global pandemic uncertainty, changed the industry's approach to production and scalability?**

The industry has had to rethink resilience in the face of shifting therapeutic demands and pandemic-driven disruptions. Flexible and modular production capacity has become a priority, enabling companies to adapt quickly to new therapies. Many are also building redundancy into supply chains and utilities to safeguard continuity. Water systems play an essential role here—they must be able to scale rapidly while remaining fully compliant with global standards.

- **How do you perceive the modernization of manufacturing processes in response to the ever-evolving dynamics of the pharmaceutical industry?**

Modernization is accelerating through the adoption of digital and automated systems. But this progress is no longer judged only by productivity gains. The new benchmark is achieving sustainability without compromising productivity or contamination control — delivering performance and sustainability without compromise. Utilities such as water are expected to provide consistent, compliant quality while minimizing energy and resource consumption, reflecting the balance manufacturers must strike between efficiency and responsibility.

- **How can collaboration and technology integration in the pharmaceutical industry address manufacturing challenges to ensure regulatory compliance? Especially, how will it impact cleaning validation, contamination control, and real-time release testing?**

Addressing the complex challenges of modern pharmaceutical manufacturing requires close collaboration between industry players, technology providers, and regulators. By sharing insights, aligning standards, and jointly developing solutions, companies can anticipate regulatory expectations and implement best practices more efficiently. Technology integration further amplifies these efforts by connecting systems, enabling continuous monitoring, and facilitating data-driven decision-making.

In practice, this can be seen in how Veolia’s Sievers M9 Portable TOC Analyzer has been applied as a process analytical technology (PAT) tool for at-line cleaning validation and product changeover at a major pharmaceutical facility. The analyzer enabled real-time total organic carbon (TOC) measurements during swab and rinse sampling, allowing teams to verify cleanliness and document validation results on-site within hours. This streamlined process enhanced traceability, reduced reliance on laboratory analysis, and provided faster assurance that systems were ready for the next production batch.

By embedding such digital monitoring tools, cleaning validation becomes more efficient, contamination risks are reduced, and real-time analytics accelerate release testing—all of which reinforce compliance while improving operational reliability.

- **How can real-time process monitoring help pharmaceutical manufacturers reduce contamination risks and maintain compliance with evolving regulatory standards?**

Real-time process monitoring represents a fundamental shift in pharmaceutical contamination control—fully aligned with the intent and direction of EU GMP Annex 1 (2022). It elevates critical utilities such as Purified Water (PW), Water for Injection (WFI), and Clean Steam from passive infrastructure to actively controlled systems within a holistic, risk-based Contamination Control Strategy (CCS). This integration ensures that utility performance is continuously verified as part of the manufacturing control framework, rather than assumed based on periodic testing.

With the deployment of Process Analytical Technology (PAT), product quality assurance is no longer dependent solely on end-product testing. Instead, quality is built into the process through continuous, real-time monitoring of critical quality attributes and process parameters. This transition—from retrospective verification to proactive, data-driven assurance—enables early detection of deviations, allowing corrective actions to be implemented before risks propagate to the product level or compromise compliance.

This capability is particularly critical for high-purity utilities such as PW, WFI, and Clean Steam, where even minor microbial or chemical excursions can have cascading impacts across multiple manufacturing operations. Real-time visibility transforms these utilities into continuously validated systems, strengthening operational reliability and significantly reducing the probability of undetected contamination events.

From a regulatory perspective, real-time monitoring directly supports the core principles emphasized by global health authorities: data integrity, traceability, and scientifically justified, risk-based decision-making. It enables manufacturers to demonstrate a continuous state of control, and moving beyond static qualification toward dynamic assurance.

Ultimately, this approach reinforces manufacturing robustness, enhances regulatory confidence, and ensures sustained protection of product quality and patient safety.

- **How are next-generation water systems in pharmaceutical manufacturing leveraging Process Analytical Technology (PAT) to enhance operational excellence and sustainability?**

Next-generation water systems are embedding PAT to maintain consistent control over quality attributes such as TOC, conductivity, and microbial levels. This not only guarantees compliant compendial water and pure steam quality but also enables smarter resource use, optimizing both energy and water consumption. In doing so, PAT supports manufacturers' dual priorities: continuity of reliable operations and sustainable practices for the long term.

- **How do PAT instruments contribute to quality by design (QbD) and enable adaptable, predictive, and efficient operations in pharmaceutical manufacturing?**

Process Analytical Technology (PAT) embodies the core principle of the ISPE Baseline® Guide for Water and Steam Systems: quality must be engineered into the system, not tested into the final product. This philosophy reflects the evolution of modern GMP, where contamination control is driven by proactive system design, continuous verification, and scientific process understanding, rather than reliance on end-product testing alone.

PAT serves as the operational backbone of Quality by Design (QbD), translating its principles into real-time manufacturing control. By continuously monitoring critical quality attributes and process parameters, PAT enables immediate, data-driven insight into system performance. This shifts quality management from a reactive model—dependent on retrospective testing—to a proactive control strategy, where process robustness is designed, verified, and maintained throughout routine operation.

Beyond compliance, PAT enables a deeper and more precise understanding of process behavior and variability. Operating ranges can be established and continuously refined based on actual performance data, ensuring that system control limits are scientifically justified and operationally relevant. Over time, trend analysis provides early warning of emerging risks, enabling predictive maintenance, preventing system deterioration, and allowing timely intervention before deviations escalate into contamination events or compliance failures.

By embedding this level of continuous intelligence into water and steam systems, manufacturers achieve a sustained state of control. Operations become more predictable, more resilient to variability, and more efficient in managing resources and risk.

- **How are Veolia's technological strengths driving the evolution of pharmaceutical manufacturing practices, while maintaining operational sustainability?**

Veolia supports pharmaceutical manufacturers by ensuring reliable compendial water generation—including "Cold WFI solutions" that combine compliance with energy efficiency. On the other side of the cycle, advanced wastewater treatment technologies minimize discharge while "recovering valuable resources". These efforts align with Veolia's GreenUp strategic program, which focuses on depollution, resource regeneration, and decarbonization. Through integrated water cycle management, Veolia helps companies to streamline their operations with peace of mind, combining regulatory assurance with long-term sustainability goals.

- **How has Sievers' analytics simplified complex evaluations and supported comprehensive water quality monitoring in pharmaceutical manufacturing? How do they influence pharmaceutical production processes, especially bacterial endotoxins and bioburden monitoring?**

The Sievers "Eclipse platform" automates bacterial endotoxin testing, streamlining workflows and reducing the risk of human error, while the Sievers "Soleil system" delivers rapid bioburden testing in minutes rather than days. Alongside these, Sievers' "TOC" and "conductivity instruments" ensure water quality compliance with USP <643> and <645>. Together, these tools expand capabilities for broader microbial monitoring, strengthening control of endotoxin and bioburden risks. This suite of instruments enables more reliable contamination control, safeguarding both production processes and product integrity.