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“AI, Automation & Analytics: A new era of modern microbiology testing!”

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Pharmaceutical manufacturing is undergoing a paradigm shift. As the industry moves towards complex biologics, personalised therapies, and stringent global compliance, the role of microbiological quality control (QC) is being redefined. Once seen as a back-end process, microbial QC has now become a strategic function, balancing speed, safety, and sustainability. Diwakar Sharma, Country Head, Industrial Applications, India & Neighbouring Markets, bioMérieux shares how QC labs are evolving into digital, data-driven command centres that power business success.

What has changed in pharma manufacturing that makes microbial QC more business-critical than ever?

The entire landscape of pharma manufacturing has transformed. We’ve shifted from traditional formulations to complex biologics, biosimilars and sterile injectables—all of which are far more sensitive to contamination. With these modalities, the margin for error is extremely small. A single contamination event can affect patient safety and result in significant financial losses.

Speed to market has also become a key differentiator. Any delay in QC—especially in sterility or release testing—directly impacts batch release and revenue. At the same time, regulators are insisting on faster, more transparent, and data-integrity–driven QC workflows. So, QC today isn’t just about compliance. It’s a **business-critical function** that ensures operational continuity, regulatory trust, and market competitiveness.

Where do most QC workflows break down today—time, traceability, or team coordination?

It's usually a combination of all three. **Time** is an obvious challenge—traditional sterility testing can take up to 14 days, keeping inventory on hold. **Traceability** suffers when teams rely on manual logbooks or partially digitised systems, which are prone to transcription errors. And **team coordination** becomes difficult when QC, QA and manufacturing operate in silos.

Take a simple deviation: if your data is scattered across spreadsheets and paper logs, root cause analysis can take days. The real issue isn't lack of capability—it's lack of connectivity. A truly modern QC workflow must bring time, traceability and teamwork together through digital integration.

How have rapid microbial tools like SCANRDI®, BIOFIRE®, and ENDONEXT™ helped real pharma customers cut risk and time?

Rapid microbial methods are transforming QC by combining **speed, precision, and reliability**. For example, **SCANRDI®** enables sterility testing results in under four hours—ideal for sterile injectables and high-value biologics. **BIOFIRE® Mycoplasma** provides species-level results in about an hour, replacing workflows that traditionally spanned several days. **ENDONEXT™**, on the other hand, offers an animal-free, cartridge-based endotoxin testing approach that's faster, sustainable, and highly consistent.

Collectively, these tools are helping manufacturers **reduce batch release time, improve predictability, and minimize risk exposure**, without compromising on data integrity or compliance.

Data integrity is a hot-button issue—how do digital tools reshape audit readiness and documentation workflows?

Data integrity is now the backbone of regulatory trust. Modern digital QC platforms are built for **21 CFR Part 11 and EU Annex 1 compliance**, featuring audit trails, role-based access, and secure electronic signatures. Automated reporting and real-time data capture drastically reduce human error.

When every test, trend, and deviation is traceable at the click of a button, **audit readiness becomes a continuous state** , not a last-minute scramble. This not only saves time but builds credibility with inspectors who value transparency and consistency.

If you had to build a QC Microbiology lab for a sterile facility from scratch, what would it look like?

It would be a **smart, connected, and paperless lab**. Rapid tools for sterility, Mycoplasma, and endotoxins would be seamlessly integrated with a **central LIMS**. Environmental data would be monitored through real-time dashboards. **AI-driven analytics** would identify trends, trigger CAPAs, and even predict potential risks.

Sustainability would also be at the core—using **animal-free reagents**, minimising plastic usage, and enabling **remote audits** . The idea is not just to test faster, but to test smarter—with science, sustainability, and digitalization working together.

How do you see the role of automation and AI evolving in pharmaceutical QC over the next 3–5 years?

We're entering the era of **predictive quality control**. Automation will handle repetitive tasks like sampling, testing, and documentation, freeing teams to focus on analysis and decision-making. **AI will bring intelligence to QC**—identifying early warning signals, spotting recurring deviations, and even suggesting preventive actions. The goal isn't to replace humans, but to empower them with insights that drive faster, more informed decisions.

Sustainability is now a boardroom priority. How can QC labs contribute to greener pharma operations?

QC labs have a direct role to play. Shifting to **animal-free reagents**, **cartridge-based rapid tests**, and **digital documentation** reduces waste and resource consumption. Remote audits and virtual validations further cut travel and carbon footprint. A green QC lab isn't just eco-friendly—it's **cost-efficient, compliant and future-ready**.

How has bioMérieux been supporting the food industry with their Innovative & rapid Microbiology testing solutions?

At bioMérieux, we offer pathogen detection and quality testing systems for the food industry that are faster, more efficient, and cost-effective than traditional methods. Our technology streamlines lab work and helps you deliver quality products to your customers.

Our Augmented Diagnostics approach helps customers optimize their food safety and quality workflow by leveraging the power of data and genomics, custom molecular diagnostics, and our proven microbiology testing solutions to deliver actionable insights to their operation.

Food products highly sensitive to microbial contaminations. Therefore, receiving the pathogen test results on time can be almost as important as receiving accurate results. The testing delays can lead to spoilage and product losses, making reliable and timely microbiological testing methods of the highest importance in brand reputation and maintaining their bottom line.

How is Food Safety evolving in India?

We have observed numerous changes in recent years, with regulatory bodies increasingly focusing on establishing a robust infrastructure for food safety. Key initiatives include the development of state food laboratories, the introduction of Food Safety on Wheels, and the launch of a Microbiology Testing Manual by FSSAI, to name a few. Concurrently, consumer awareness has significantly risen over this period. Consumers are now more concerned about the nutritional value of the food they consume.

How can the rapid microbiology testing solutions offered by bioMérieux assist the food industry?

To support the food processing industry in adapting to the rapidly evolving environment, we are making substantial investments in disruptive science and technology. This empowers our customers to anticipate emerging risks and maintain full control over their operations.

Our technologies, such as VIDAS®, TEMPO®, and GENE-UP®, are well accepted by regulatory bodies globally, allowing food processors to export their products with confidence. In fact, at several ports, our technologies like VIDAS® are utilized to test consignments. In India, numerous regulatory laboratories are employing our technologies.