



Robert Spignesi, President & CEO, Rapid Micro Biosystems

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Robert, what made you leave Thermo Fisher and join Rapid Micro Biosystems back in 2014?

My journey from Thermo Fisher to Rapid Micro Biosystems was driven by my extensive experience in healthcare, healthcare technology, and specifically in automating critical healthcare processes. At Thermo Fisher, I led a microbiology business, which, coupled with previous leadership experience in pharmacy automation, provided me with a unique perspective on the impact of automation and technology on improving speed and efficiency and reducing errors in healthcare settings. This background made the transition to Rapid Micro Biosystems a natural step for me. I saw a significant opportunity to apply similar principles of automation, technology, and AI to pharmaceutical microbial quality control (QC) labs, which faced challenges similar to those in pharmacy environments—namely, the need for automation in repetitive, error-prone tasks to improve outcomes and efficiency.

What is the importance of contamination detection for the pharmaceutical industry?

Microbial contamination detection is critical in the pharmaceutical industry due to its potential for adverse patient outcomes and significant financial exposure for companies. Contaminated pharmaceuticals, especially injectables, can lead to serious health risks for patients. Additionally, contamination can result in costly remediations, recalls, and regulatory repercussions. The industry's reliance on outdated methods for microbial quality control, essentially unchanged since they were invented in the 19th century by Louis Pasteur, highlights a lack of innovation in this area. By addressing this stagnation and applying modern automation and analytical technologies, we aim to significantly improve the microbial QC process, enhancing both safety and efficiency within the pharmaceutical value chain.

Could you introduce us to your platform, Growth Direct®?

The Growth Direct platform leverages our fully automated system designed to revolutionize microbial detection and enumeration, which are crucial for pharmaceutical manufacturing. This platform automates the entire microbial detection process in a walk-away manner, from sample loading and processing to data reporting. It uses a combination of barcode-driven protocols, automated incubation, and proprietary vision algorithms to accurately detect and enumerate microbial growth faster and more accurately than the traditional manual method. This is designed to not only ensure data integrity and eliminate the risk of manual error and falsification but also to speed up the microbial QC process, enabling rapid and reliable decision-making.

Our system is engineered to integrate with customers' lab information management systems in order to provide a secure, seamless, paperless operation, enhancing operational efficiency and reducing the risk associated with human error in manual petri dish manipulation. By offering a robust, accurate, and efficient solution, Growth Direct supports pharmaceutical companies in maintaining high-quality control standards, promoting patient safety and achieving regulatory compliance.

What impact has Growth Direct had in the industry?

Growth Direct has made significant strides in transforming the microbial quality control process in the pharmaceutical industry, moving it away from labor-intensive and error-prone manual methods towards rapid and reliable automated testing. Our mission is to automate the majority of the market's daily routine testing volume, a goal we are steadily progressing towards. The platform's benefits—such as improved data integrity, operational efficiency, and decision-making speed—address both regulatory concerns and the practical and evolving needs of pharmaceutical manufacturing.

Our approach has been validated by our customer base, which includes 70% of the global top 20 pharmaceutical companies spread across North America, Europe, and Asia. This widespread adoption underscores the critical need for innovation in microbial QC and the tangible value that Growth Direct offers to some of the most influential players in the pharmaceutical industry.

Do you work with Contract Development and Manufacturing Organizations (CDMOs)?

Our customer base primarily consists of large, globally recognized pharmaceutical companies, particularly those involved in advanced manufacturing modalities like biologics and cell and gene therapies. Additionally, we collaborate with a number of large and mid-sized CDMOs, including notable names like Samsung Biologics. Our technology and services are designed to be agnostic to the specific segment of the pharmaceutical market, aiming to enhance microbial quality control across the board. This ambition drives our focus towards larger entities due to their significant impact and reach within the industry. Our global footprint is substantial, with about 45% of our installations in North America and Europe each, and the remaining 10% in Asia, showcasing our commitment to providing a new standard in quality control infrastructure worldwide.

What are the main challenges in changing the manual microbial quality control process to an automated one?

The transition from manual to automated microbial quality control faces a couple of hurdles, primarily related to corporate priorities and the inherent conservatism within the pharmaceutical industry. Incorporating new capital equipment like ours requires navigating extensive capital project processes, which can be slow. Additionally, the change management aspect can be significant; we are proposing a fundamental shift in a critical workflow that has not seen change in well over a century. Cultural resistance and the pharmaceutical industry's cautious approach to adopting new technologies can sometimes compound these challenges. Despite these obstacles, we focus on demonstrating clear return on investment and supporting our customers through the change management process, aiming to accelerate the adoption of automated solutions for microbial quality control.

Looking three years into the future, what progress do you hope to achieve?

In three years, we aim for much deeper market penetration and continued innovation. Our goal is to further our reach within the global pharmaceutical market, including more extensive adoption within the large companies we currently serve and expanding our presence in key manufacturing regions worldwide. Commercial execution and innovation remain at the core of our strategy.

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We have introduced and plan to continue development of new technologies that leverage our expertise in automated microbial testing, coupled with advances in AI and software to enhance microbial detection and differentiation capabilities.

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The upcoming release of Rapid Sterility testing for the Growth Direct and other pipeline technologies underscore our commitment to delivering solutions that not only improve microbial quality control but also leverage the wealth of data generated by our systems and others. This continued focus on innovation, coupled with strategic market expansion, will drive our efforts to revolutionize microbial quality control infrastructure globally.

About Rapid Micro Biosystems

Rapid Micro Biosystems is an innovative life sciences technology company providing mission critical automation solutions to facilitate the efficient manufacturing and fast, safe release of healthcare products such as biologics, vaccines, cell and gene therapies, and sterile injectables. The Company's flagship Growth Direct® system automates and modernizes the antiquated, manual microbial quality control ("MQC") testing workflows used in the largest and most complex pharmaceutical manufacturing operations across the globe. The Growth Direct® system brings the quality control lab to the manufacturing floor, unlocking the power of MQC automation to deliver the faster results, greater accuracy, increased operational efficiency, better compliance with data integrity regulations, and quicker decision making that customers rely on to ensure safe and consistent supply of important healthcare products. The Company is headquartered and has U.S. manufacturing in Lowell, Massachusetts, with global locations in Lexington, Massachusetts, Switzerland, Germany, and the Netherlands. For more information, please visit www.rapidmicrobio.com or follow the Company on X (formerly Twitter) at [@rapidmicrobio](https://twitter.com/rapidmicrobio) or on [LinkedIn](https://www.linkedin.com/company/rapidmicrobio).

Forward-Looking Statements

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