ARTICLE – Q&A

Your Journey to Digital Transformation

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SUMMARY

In July 2022 the BioPhorum Operations Group (BPOG), a collaborative body of biopharmaceutical manufacturers and suppliers, published Part 1 of its Digital Technology Roadmap (DTR) surveying digital technologies in the industry. To share the roadmap's findings and suggest new opportunities for organizations considering digital transformation, Rapid Micro Biosystems turned to three of its experts for their insights.

INTRODUCTION

Published in July 2022, Part 1 of the Digital Technology Roadmap (DTR) from the BioPhorum Operations Group (BPOG) surveys the pharmaceutical industry and outlines a vision of the next 10 years. To discuss its findings on the state of the industry, as well as challenges and opportunities that widespread digitalization might offer to patients and organizations, we interviewed Rapid Micro Biosystems experts:

- **David Jones**, Ph.D., Director of Industry Affairs
- **Kham Nguyen**, Director of Validations
- **Shahab Siddique**, Product Manager

INDUSTRY 4.0 AND DIGITAL TECHNOLOGIES

Shahab, you represented Rapid Micro Biosystems at BPOG during development of the roadmap. Why are digital technologies so critical to the future?

Shahab Siddique: As we reviewed survey results with other industry professionals, quality was the most important driver for the adoption of digitalization. Cost of quality in pharmaceutical R&D is high due to the need to maintain the safety and efficacy of medicines. Respondents believed that digital transformation would reduce human error, yield better insights and decisions through better data, reduce quality notifications, and drive real-time problem solving – all while enabling greater agility and speed to market.

THE DRIVE TO 2030

Charting a course for digital transformation of the pharma industry by 2030, BPOG's Digital Technology Roadmap (DTR) predicts a steep learning curve for many organizations. But that road is easier with experienced partners.

At Rapid Micro Biosystems, our Growth Direct® System was the first technology to qualify as an automated system for the incubation and reading of the traditional plate count, validated at multiple customer sites since 2015; in addition, our track record includes cGMP processes for environmental monitoring and water testing through internal change control procedures – plus successful implementation of in-process bioburden testing following successful license review by EMA and FDA.

Experienced support can help shorten your journey to Industry 4.0. For more, visit us online at **rapidmicrobio.com**.

Those beliefs ring true, in our experience. At Rapid Micro Biosystems we have seen the benefits of digitalization already realized in automated quality control, serving the early adopters – companies that were quick to recognize traditional compendial methods as a barrier to digitalization. Now our challenge in the decade ahead is to see that kind of thinking become the rule rather than the exception.

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How would you characterize industry attitudes toward digitalization?

Kham Nguyen: Historically, the industry has been very slow to adopt new approaches. Many manufacturers understand the opportunities and aspire to reach complete digitalization of their operations. But, to cite the example we're most familiar with, microbial enumeration in QC workflows remains a manual process in most labs. Larger organizations are the ones pushing the boundaries.

Shahab Siddique: Bioprocessing companies benchmark against competitors. They ask, "Where do we see ourselves on the change curve – as early adopters, the majority, or laggards?" Not everyone wants to be an early adopter.

What about the costs involved?

Shahab Siddique: Digitalization obviously requires upfront investment in information technology and expertise. Respondents clearly viewed this as a long-term investment which should ultimately decrease costs. They also said it was important to make a strong business case for transformation, while shifting the focus to value rather than cost. Bottom line, the industry is looking at significant investments in both time and money, They are a necessary next step to keep the development process fast and accurate.

Let's talk more about regulations, which are a key driver in BPOG's roadmap.

David Jones: Among biopharmaceutical end-users surveyed, two big hurdles to adopting new and rapid detection methods were regulatory acceptance, and validation of a non-compendial method. However, mature technology partners such as Rapid Micro Biosystems are in the market today, offering the strong support and knowledge needed to fill the gap for smaller organizations and startups that lack in-house expertise.

Shahab Siddique: We believe more organizations will gain confidence in new technologies and electronic data as digital transformation of facilities and laboratories becomes common. Ultimately that confidence will help change their view of regulatory bodies. They should be seen as partners in the quality process and included in early development and testing to assure the applicability of new technology.

Kham Nguyen: As it becomes clearer that auditors and inspectors don't have issues with these technological changes, it drives the next-level organizations to take the risk. Regulatory bodies such as the FDA are encouraging technology investments in an effort to automate and streamline how organizations manage their data. So, regulatory attitudes are very influential on industry attitudes.

TOPLINE SUMMARY: BPOG'S DIGITAL TECHNOLOGY ROADMAP

In August 2021 the BioPhorum (BPOG) Digital Technology Roadmap team began surveying the current state of digital transformation in the industry, identifying six key drivers impacted by digital technology: Quality/Regulatory, Workforce/People & Processes, Supply Chain, Processing, Facility/Autonomous Plant, and Data Needs. Here are key takeaways from Part 1 of the roadmap, published in July 2022.

QUALITY: All respondents felt that digitalization had the potential to increase quality, identifying this as the most important driver for digitalization. Specific ways that it would drive quality improvements included reduced human error, improved data conversion to better insights and decisions, reducing quality notifications, and driving real-time problem-solving speed.

SPEED: Respondents agreed that digitalization could decrease lead time and enhance speed to market through a variety of mechanisms including reduced manual work, increased speed of investigations, and enabling RTR. Digitalization was seen as an enabler of agility, driving faster discovery and development, automating processes, and providing better analytics to enable quick decision making.

COST: Digitalization requires upfront investment (for example, in IT systems and experts) and so costs could go up. However, respondents were clear that it should be viewed as a long-term investment which should ultimately decrease costs. The need for business cases and a shift to focus on value, and not just cost, were also seen as important.

TESTING: Recent BPOG publications reflect the industry's movement away from offline testing in the quality control laboratory to in-line, on-line or at-line testing on the manufacturing floor.

VALIDATION: Consensus is that detection technologies were continuing to evolve and a guidance document that enabled sharing of best validation practices in the industry (multi-site and multi-company) and including regulatory involvement, would have the greatest impact on widespread industry adoption of new methods.

OBSTACLES: A BioPhorum survey completed by biopharmaceutical end-users revealed that the biggest hurdles to adopting new and rapid alternative adventitious agent detection methods are:

- Regulatory acceptance of these alternative methods
- Filing a regulatory change control and the time taken to validate a non-compendial method

THE FUTURE: BPOG's vision for the future indicates order of magnitude changes in cost of quality and process performance, faster speed to patient with more agile facilities, and overall value and sustainability. The opportunities provided by Industry 4.0, as a toolset toward digital transformation, are only bounded by the barriers we place on ourselves.

SOURCE: Problem Statement,
BioPhorum Operations Group (BPOG)
Digital Technology Roadmap

A VISION OF 2030

The destination of BPOG's roadmap is adaptive manufacturing. How would you define that?

Shahab Siddique: BPOG describes its model digital plant, the kind we'd hope to see in 2030, as an adaptive facility featuring "In-line, real-time, continuous, closed-loop, process verification and control with automated real-time quality release." This is the pinnacle of Industry 4.0, a term coined to outline the advantages that a wide array of digital technologies running in concert can bring to manufacturing and critical facilities.

David Jones: In contrast, today there are digital technologies in place delivering some value for most manufacturers. But they are not enterprise wide, not fully integrated, don't leverage the full extent of the available infrastructure, and are not working together.

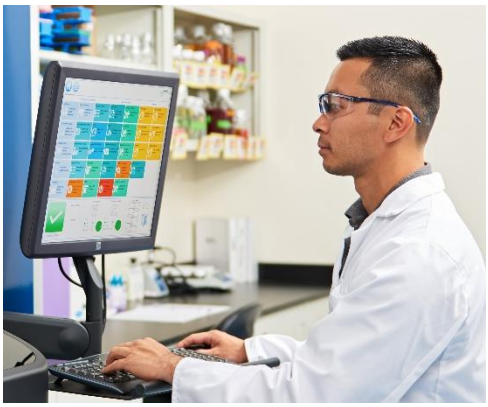
Shahab Siddique: Everyone knows that cost, speed, and safety pressures are only going to increase. That's why we expect to see greater emphasis on defining, managing, and monitoring critical attributes for every link of the value chain – tech transfer, R&D, production, IT, and more.

Let's underscore an important point: BPOG's Digital Technology Roadmap might seem like a futurist's speculation, but it's already happening. Here at Rapid Micro Biosystems we work with a majority of the Top 20 global pharma companies, plus many cell and gene therapy manufacturers on the cutting edge. They're not only automating manual batch review processes, but networking automated Growth Direct® System instruments at multiple sites. Sample analyses that once took five to seven days are being turned around in half that time. Digitalized labs are eliminating deviations, reducing cost, and improving quality.

How about QC testing moving to the manufacturing floor?

Kham Nguyen: We've already seen customers bridge laboratory and manufacturing operations after implementing the Growth Direct® System. Manufacturing execution systems (MES) have long been used to track and document the production of goods from starting materials, but customers are taking advantage of our universal communication features to interface automated test instruments and laboratory information management systems (LIMS) with their MES. That level of connectivity and integration helps satisfy stringent data integrity standards, which should be the number-one priority for QC micro labs that want to remain effective.

Shahab Siddique: Agreed. With increased use and reliance on digital solutions, there will be increased regulatory oversight of data and its use. Quality assurance activities will be driven by exception management, placing automated accuracy at a premium.



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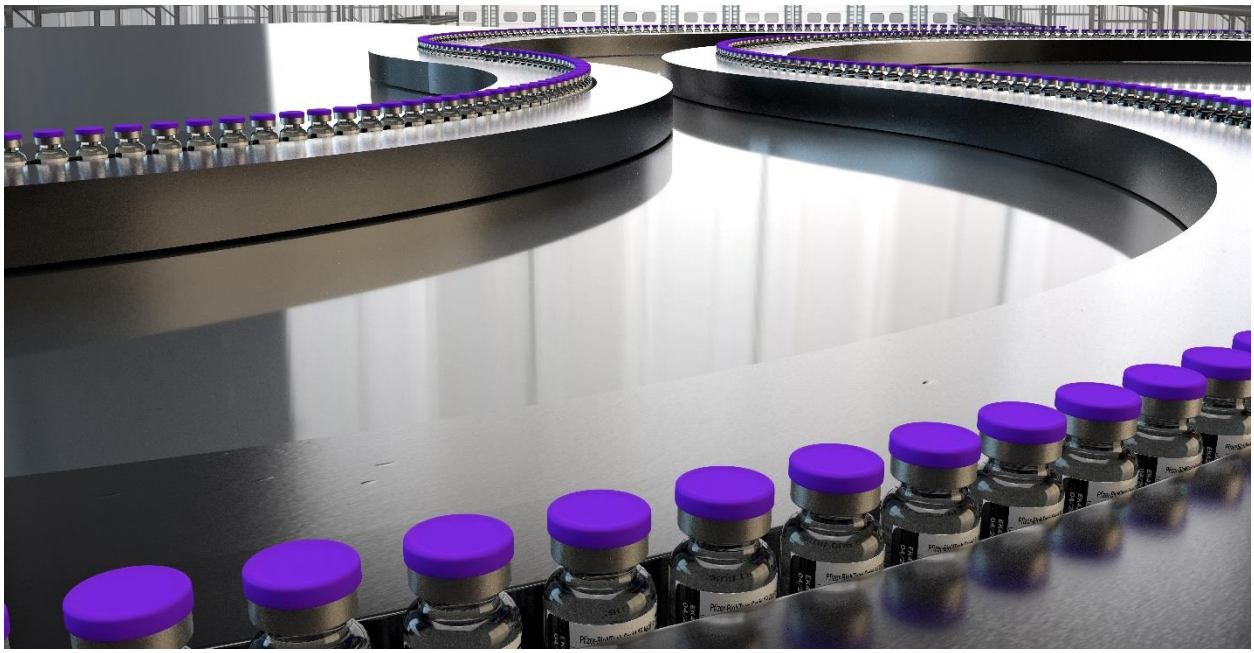
David Jones: If the adaptive plant of 2030 fully implements automated, real-time quality release, then bioprocessing and manufacturing will operate at significantly different performance levels from today. There could be an order-of-magnitude change in the cost of quality. Picture an industry with quality assurance set rules for predictive controls

and automated decision-making, working closely with digitally connected regulators who are free to access curated quality data as quickly or as deeply as needed.

Kham Nguen: Organizational IT departments will play a key role in ensuring access and integrity of data. Technologies, skills, and procedures all must combine to fulfill quality requirements with a high degree of confidence, yet it doesn't have to be burdensome. QA activities will be driven by exception management.



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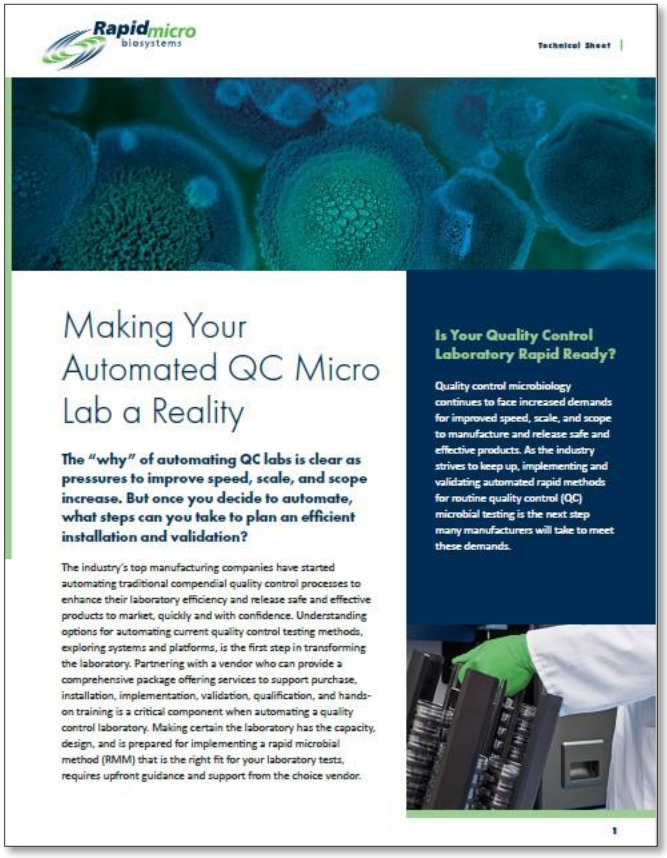
THE NEXT STEP ON THE JOURNEY

There's a great deal to consider when pursuing such a high degree of digitalization. What's the next step?

Shahab Siddique: I'd suggest that interested professionals should register with BioPhorum and get a free copy of BPOG's Digital Technology Roadmap. Becoming involved is a great opportunity to share your perspective and learn from some of the industry's leading manufacturers and suppliers. Work is already underway on Part 2 of the roadmap, outlining practical guidance, tools, and evidence for digital transformation, so why not get an advance preview of the future?

Like any journey, digital transformation carries potential for false steps and uncertainty. Yet we believe it is a necessary journey, not only for competitiveness but for the wellbeing of patients worldwide. And Rapid Micro Biosystems is committed to helping our customers get there as quickly as possible.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Technical Sheet

Making Your Automated QC Micro Lab a Reality

The "why" of automating QC labs is clear as pressures to improve speed, scale, and scope increase. But once you decide to automate, what steps can you take to plan an efficient installation and validation?

The industry's top manufacturing companies have started automating traditional compendial quality control processes to enhance their laboratory efficiency and release safe and effective products to market, quickly and with confidence. Understanding options for automating current quality control testing methods, exploring systems and platforms, is the first step in transforming the laboratory. Partnering with a vendor who can provide a comprehensive package offering services to support purchase, installation, implementation, validation, qualification, and hands-on training is a critical component when automating a quality control laboratory. Making certain the laboratory has the capacity, design, and is prepared for implementing a rapid microbial method (RMM) that is the right fit for your laboratory tests, requires upfront guidance and support from the choice vendor.

Is Your Quality Control Laboratory Rapid Ready?

Quality control microbiology continues to face increased demands for improved speed, scale, and scope to manufacture and release safe and effective products. As the industry strives to keep up, implementing and validating automated rapid methods for routine quality control (QC) microbial testing is the next step many manufacturers will take to meet these demands.

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Are You Ready?

As you map your digital future, automating your QC microbiology lab is an important step. Download our free planning guide to learn more or contact Rapid Micro Biosystems.

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