How Lonza Built an Automated, Digitalized End-to-end Process for Environmental Monitoring

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The Challenges and Importance of Environmental Monitoring

Rigorous and comprehensive EM is crucial for quality control in pharmaceutical manufacturing, helping to minimize the risk of microbial contamination and ensure the highest levels of product quality and safety.

However, EM can be immensely challenging. Perhaps the biggest obstacle is that sample incubation and analysis for microbiological EM are labor-intensive; sampling is performed, and EM contact plates are incubated, transferred, counted, read out, and disposed of by hand. Data capture, review, and reporting for EM are largely manual as well. As a result, microbial testing can be time-consuming, tedious, and prone to error.

While there has long been demand for proven digital solutions to alleviate these challenges, industry-wide pressure to improve operational efficiency has now created a valid business case for such solutions. This is especially the case in the cell and gene therapy (CGT) space, since processes here are long, complex, and costly, while patients have often exhausted other therapeutic options and need treatment quickly.

Moreover, the inherently unstable nature of fresh CGTs means that efficient release, shipment, and injection into the patient are paramount, necessitating a rapid TTR for EM and expedited product batch release.

Lonza's Goal: To Optimize Lengthy, Manual EM Processes with Increased Digitalization

Lonza aspired to achieve paperless quality control (QC) laboratories using automated digital systems that were easily replicable and standardized across different sites. As part of this ambition, Lonza sought an end-to-end (E2E) automated solution to optimize EM at four of its cell and gene therapy manufacturing sites across North America, Europe, and Asia. Lonza's solution was to create a unique digitalized and automated E2E EM process that integrated two systems:

Lonza's MODA-EM® Module, a leading solution for paperless data collection and management in QC microbiology, and Rapid Micro Biosystems' Growth Direct® System for automated microbial testing. Lonza realized cost savings through fewer deviations, faster product release, and streamlined compliance with reduced effort.

At a Glance: The Growth Direct® System

Rapid Micro Biosystems' Growth Direct® System provides automated microbial testing for pharmaceutical EM. The system features consumables designed to facilitate high-throughput automated handling with industry-standard growth media (instead of traditional agar contact plates), two automated incubators with a total capacity of 660 samples, advanced image analysis for colony detection and counting, and fully automated robotic sample handling.

By automating QC microbiology testing, the Growth Direct® System eliminates error-prone manual steps and significantly reduces process steps and wait times.

The Growth Direct® System is the leading platform for automated microbial testing among top global pharma, biotech, and CDMO organizations operating within cGMP environments.

At a Glance: The MODA-EM® Module

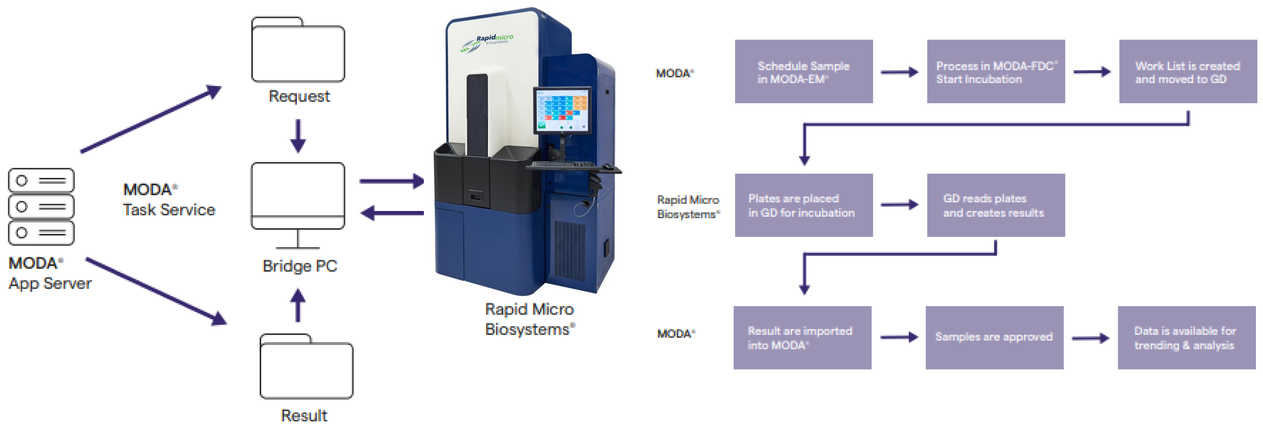
The MODA-EM® Module is a regulatory-compliant, paperless solution that automates pharmaceutical QC processes. Users can easily manage and report on the full spectrum of EM and QC information, including surface, air, personnel, compressed gas, and product testing.

The MODA-EM® Module also seamlessly integrates with commonly used instrumentation, automation technologies, and media found in manufacturing facilities, as well as with many laboratory information management systems (LIMS). With the module, organizations gain timely, accurate QC monitoring through location-based scheduling, mobile data collection, and paperless lab processing.

Today, the MODA-EM® Module remains the software of choice for EM—both at Lonza's manufacturing sites and at top 50 pharma and biotech organizations.

The integration of Lonza's MODA-EM® Module with the Growth Direct® system

Lonza installed and integrated the Growth Direct® System with existing MODA-EM® Modules at its four cell and gene manufacturing sites: Portsmouth, NH; Houston, TX; Geleen, the Netherlands; and Tuas, Singapore. Lonza's Visp site in Switzerland, which focuses on biologics and small molecules, also integrated the two systems.



Lonza's MODA-EM® Module v3.5 (and later) can now integrate with the Growth Direct® System. The v3.5 update is available to all MODA-EM® Module customers.

Lonza continually invests in the MODA-EM® Module to expand its capabilities and increase its value to QC teams, in line with the company's commitment to driving greater digitalization for its customers.

Impact:

Streamlined Testing to Get Critical Medicines to Patients Faster

An immediate benefit of the new E2E process was faster, "walkaway" testing.

As a paperless system, the MODA-EM® Module enabled Lonza's CGT laboratories to efficiently manage and report on the full spectrum of EM activity. For example, through its automation capabilities and the removal of labeling requirements, the MODA-EM® Module allowed progression from sample preparation to result approval in under two minutes—at least half, and in some cases as little as one-sixth, of the time required by manual methods. The Growth Direct® System, meanwhile, automated microbial testing workflows and could count the same number of colonies in up to half the time of traditional methods, while improving accuracy due to its greater sensitivity compared to the human eye.

By integrating the two systems, Lonza achieved additional efficiency gains. Thanks to automated two-way communication between them—without the need for operator input—time delays and data transcription errors were eliminated, and QC teams were able to auto-approve no-growth cassettes.

Reduction in Time-to-result (TTR)

The significant time savings enabled a drastic reduction in both time-to-detection and time-to-result. While TTR had previously been up to eight days, the new integrated solution could deliver results in 72 hours or less. Such substantial time savings are critical in CGT manufacturing, where it is especially important to get products to patients as quickly as possible without compromising quality.

Fewer Errors and Better Data for Smoother Compliance

Alongside the time benefits, the new E2E digital EM process also improved accuracy and eased the path to compliance.

With the integrated solution, consumables can be identified and traced via pre-printed QR codes, eliminating the need for labels, and results are automatically transferred from the Growth Direct® System to the MODA-EM® Module. Throughout the entire EM incubation and readout process, no paper is involved.

Overall, this has resulted in fewer errors due to the reduced manual workload and elimination of person-to-person variability, greater data integrity and traceability, and easier reporting. Since the entire process is compliant with 21 CFR Part 11 (the FDA's requirements for electronic records and signatures), ensuring regulatory compliance is now much smoother.

Conclusion

Lonza implemented an industry-first E2E EM process based on the integration of the MODA-EM® Module and the Growth Direct® System. As a result, Lonza has reduced costs and errors and significantly shortened EM timelines across several of its manufacturing sites.