

Microbiology and more – Unleashing the power of the MODA-EM[®] Solution

How utilizing its full functionality can eliminate the need for a separate LIMS

Executive summary

- Nikon CeLL innovation Co (NCLi) needed an IT solution for environmental monitoring in their new cell and gene therapy facility
- They installed the MODA-EM[®] Solution and used its expanded functionality to eliminate the need for a separate Laboratory Information Management System (LIMS)
- With a single IT system, they could minimize investment and maximize efficiency, quality and safety
- By not being reliant on paper-based systems, they have improved data integrity, reduced errors and boosted efficiency.

Impact

Lonza's MODA-EM[®] Platform enabled NCLi to:

- Improve both quality and efficiency
- Reduce investment and duplication by removing the need for a LIMS
- Reduce process time, workload and stress

Challenge: Capturing QC data electronically in a single system

When setting up their facility in Tokyo, Japan, NCLi wanted to maximize the efficiency of their quality control (QC) laboratories by digitalizing their workflows and data capture and leveraging an informatics platform to achieve this. By implementing the MODA-EM® Solution they were able to realize this vision and achieve these efficiencies in a single system.

NCLi was formed through a strategic partnership between NCLi and Lonza in 2015, with NCLi given full access to Lonza's quality and operating systems, facility design, and extensive cell and gene therapy manufacturing expertise. Through the partnership, NCLi offers a broad selection of contract development, manufacturing and testing services for early-to-late-phase clinical and commercial cell and gene therapy products. NCLi explained, "Built in 2017, the NCLi facility is one of the largest contract development and manufacturing organization (CDMO) facilities in Japan, with more than 6,000 m² of floor space over two levels, including more than 1,000 m² of cleanroom space. The facility is highly flexible and includes process development laboratories, Good Manufacturing Practice (cGMP) manufacturing suites, QC labs, support areas, and space for future expansion. The facility's QC laboratory performs material and product analysis, environmental monitoring, and detection of bacterial endotoxins. Today, all QC samples are controlled and managed by the MODA-EM® Solution."

NCLi added, "When sourcing an IT solution for the QC laboratory, we were looking for a system that would be efficient, reduce reliance on paper, and provide confidence that QC data would be stored and managed safely and accurately."

Solution: Implement MODA-EM® System for all test methods

In 2017, NCLi installed the MODA-EM® Solution – a comprehensive informatics platform that automates QC processes for all regulated manufacturing in the life sciences industry. It offers improved decision making, regulatory compliance, and productivity.

NCLi uses the system to not only manage their environmental monitoring but to also provide the functionality that might traditionally be provided by a LIMS. "When we discovered the MODA-EM® Solution could offer this additional functionality and we wouldn't need an additional LIMS, we were impressed and it seemed like an obvious choice," said NCLi.

NCLi uses the MODA-EM® Solution for tracking and recording (with the option to add more assays as needed):

- Environmental monitoring: air viable, surface viable, settle plate, total particulate
- Personnel monitoring – grade A and B
- Water testing: bioburden, total organic carbon (TOC), conductivity, endotoxin, nitrate
- Aseptic process simulation (APS) samples
- Gowning qualification
- Gas monitoring: air viable, total particulate
- Incoming gas testing: gas chromatography
- Bacterial endotoxin analysis of raw materials and products
- Product assays: flow cytometry, cell count

CA strategized implementation

Implementation of the MODA-EM® Solution at NCLi took 6 months. "The implementation was complex," explained NCLi. "However, with the excellent support of the Lonza team, it was completed in a very short timeframe and we were very happy with the process." During this period, a number of Lonza personnel worked onsite while others provided remote support.

Speaking on the tailored support Lonza commented, "To ensure the implementation was as smooth as possible and delivered to NCLi's specific requirements, several Lonza experts gave detailed one-to-one training for key processes like sampling operations, and provided customized settings for each user."

NCLi added, "The high-quality training from Lonza ensured that we were confident in using the system effectively. This was our first time using this kind of system, but by following the Lonza training and thanks to the simplicity of MODA-EM® Solution, we have found it very easy to use."

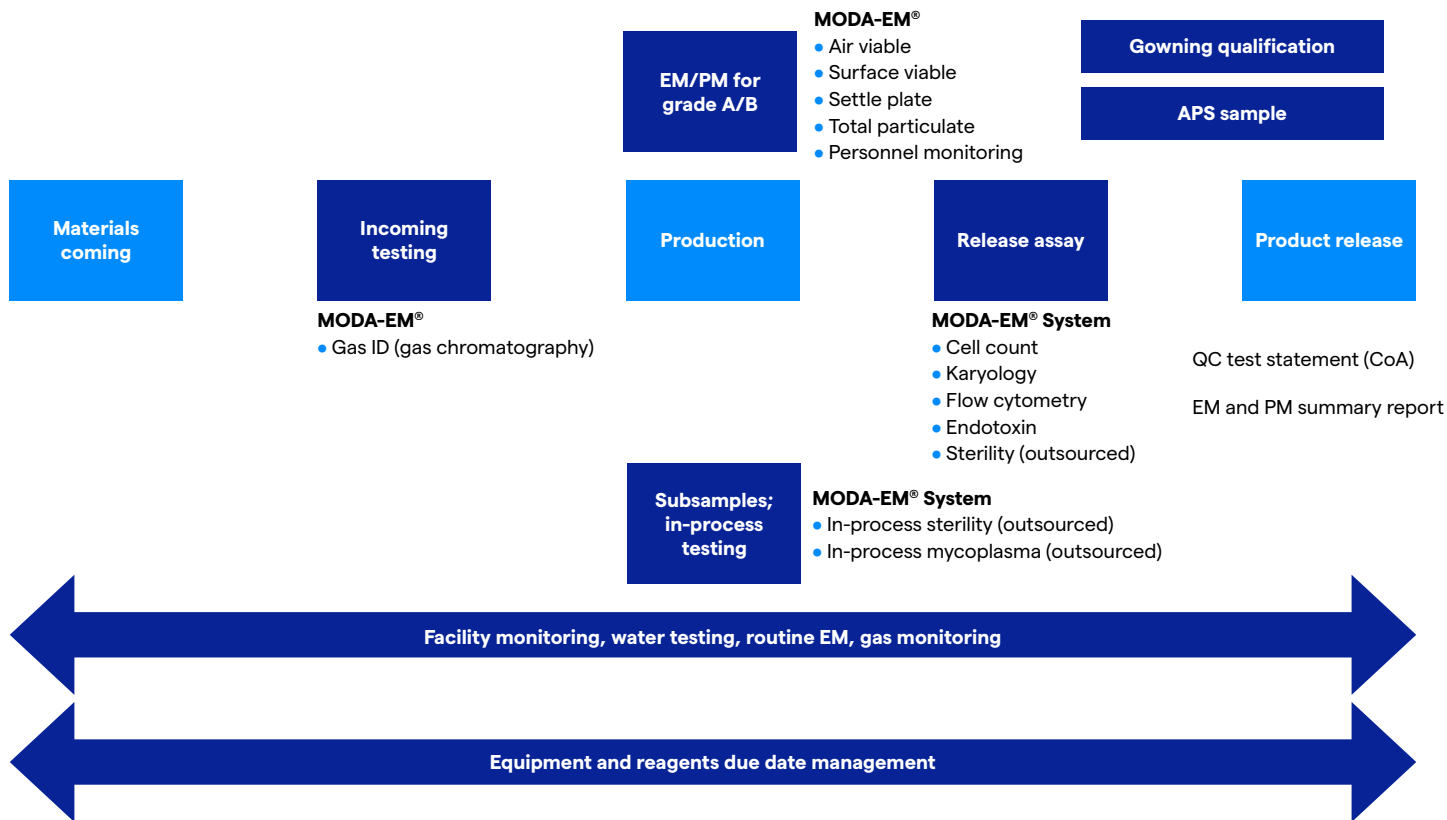


Figure 13. Overview of how the MODA-EM® Solution is used by NCLi

1. Identify method to be implemented
2. Raise change control
3. Generate workflow in MODA-EM® Solution validation environment
4. Verify the method workflow and its limit with virtual sampling and testing by using MODA-EM® Solution validation environment
5. Revise assay SOP(s) and related SOP(s) if needed
6. Implementation to MODA-EM® Solution production environment and close change control
7. Proceeds with routine use stage.

A single system: No need for a separate LIMS

Many laboratories around the world rely on the MODA-EM® Solution for environmental monitoring. However, it is also capable of offering functionality usually provided by a LIMS. This opens the door to laboratories installing a single system rather than both an EM system and a LIMS. At NCLi, the MODA-EM® Solution is also used to manage functions such as aseptic process simulation (APS), cell counts and flow cytometry.

NCLi explained, “Rather than also installing a LIMS, we made the decision to install the MODA-EM® Solution only. This approach was recommended by Lonza and we have found it to be successful. Not only did it mean not hav-

ing to invest in a second system, we also don’t have the duplication of tasks and effort that might otherwise have been required. We don’t need a separate LIMS because the MODA-EM® Solution can issue unique IDs for all samples and enables us to manage those samples easily and efficiently. Using one system is better for controlling and managing all of the samples and offers a major benefit.”

Improving the process: Efficiency built in

NCLi reports the MODA-EM® Solution has improved their testing process. In particular, they have interfaced the system with their endotoxin detection systems and non-viable particle counters. “The MODA-EM® Solution is very useful for data integrity and we have seen excellent results. For example, in particle counting, we would have a lot of paper forms every day but with the MODA-EM® Solution we are more successful as a paperless environment,” said NCLi. Handling data electronically is also faster for processing testing results. For environmental monitoring, each sample is tested and approved in a shorter time and the overall processing time is much shorter.

The QC team processes a lot of EM and APS samples and recognizes that, using a paper system, there would be a significant risk of mistakes when entering results. By providing a unique ID and registration of predetermined results via barcode, the MODA-EM® Solution helps eliminate such errors.

With all the data stored in one place, the MODA-EM® Solution is particularly powerful for observing trends.

“We use the standard report generation function with the trend analysis function to quickly and easily generate graphs,” explained NCLi. “We find this very useful. It allows us to monitor operators in a grade B cleanroom area, for example, to give us better visibility and allow us to see trends.”

In addition, the MODA-EM® Solution alerts the team via email to upcoming equipment calibration and maintenance due dates to ensure everything is kept up to date. If they were to let a due date pass, expired equipment would not display on the system meaning it couldn't be selected by operators with the risk of invalidating tests.

A shared experience

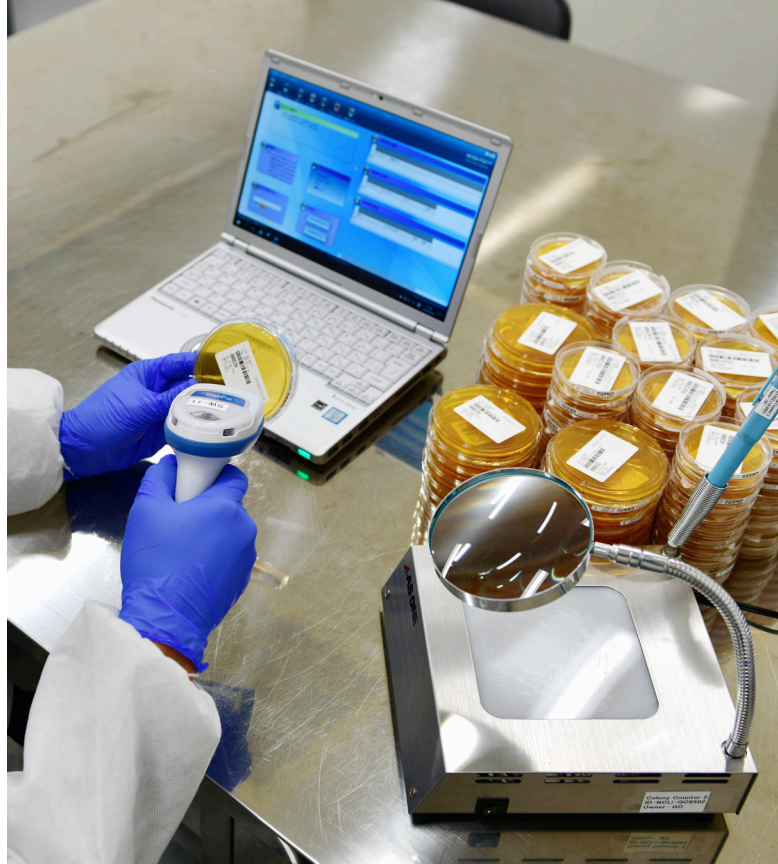
At NCLi, the IT team are responsible for account and system management, while the QC team are responsible for creating and implementing test plans and test details. “We have received very positive feedback from both our IT and QC teams,” said NCLi. “In fact, one of our IT specialists, who used to be involved in the development of LIMS systems, says that the MODA-EM® Solution is very simple, can register various kinds of information and can easily be customized for very different purposes. This makes it very unique and interesting from an IT perspective. Likewise, our QC team also report finding the MODA-EM® Solution easy to use and very useful.”

Seeing the benefits

Having installed the MODA-EM® Solution from the outset, NCLi is confident that they have successfully avoided many errors that are more common with paper-based laboratories, such as manual inputting errors and missed dates. This is important from a safety perspective but also for optimizing efficiency and cost. NCLi concluded, “With the MODA-EM® Solution, we can manage the sample life cycle, including sampling, sample submission, testing and result entry. Lonza’s MODA-EM® Solution is very useful and user-friendly, and it is successfully reducing process time, workload and stress.”

Conclusion

With QC laboratories always striving for increased levels of throughput and efficiency, having the right IT system in place is essential. NCLi have demonstrated that not only can the MODA-EM® Solution help labs achieve this, but also that its expanded functionality can eliminate the need for a separate LIMS, offering further efficiency and cost-savings.



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