BIOMÉRIEUX

3P® ENTERPRISE
EM-POWER THE FUTURE

Fully Automated Environmental Monitoring

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

EM CHALLENGES

ENVIRONMENTAL MONITORING: A CRITICAL, CHALLENGING, & COSTLY REQUIREMENT

Traditional Environmental Monitoring (EM) in QC labs is a **complex and resource-heavy process.** This process is highly dependent on **accurate data capture, timely reporting, and stringent compliance** which ultimately impacts efficiency, product release, and patient safety.

HEAVY PROCESS & STAFF MANAGEMENT

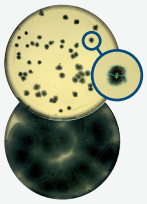
DID YOU KNOW? 40% OF MANUAL EM STEPS are superfluous and unproductive.[1]

- Paper-based EM processes are labor intensive with repetitive, tedious, time-consuming steps
- After analysis, the revision of the Annex 1 may result in increased workload and a burden on staff — while retention and recruitment of qualified candidates remains a key concern

1. Sampling Preparation and Labeling
2. Tracking Data on Paper
3. Data Transcription From Paper to Digitalized System
4. Data Verification Steps
5. Sample Inspection by Two Staff Members

ERROR PRONE PROCESSES

DID YOU KNOW? Investigation costs could add up to more than €400,000[1] WITH MORE THAN 10% linked to data integrity issues.



Manual operations can lead to errors:

- Missing samples
- Mistakes in data entry or transcription
- Operating conditions/SOPs not followed
- CFU counting errors
  - Overgrown plates
  - Merging colonies: 2 CFUs instead of 1
  - Could account for up to 30% of enumeration errors in very small events[2]

Small mistakes can lead to big problems:

- High investigation costs
- More controls needed to ensure accuracy, such as data verification at every step and multiple staff members involved in the 4-eyes reading

COMPETITIVE MARKET WITH PRODUCTIVITY DEMANDS

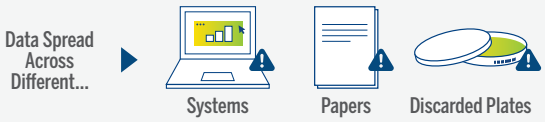
DID YOU KNOW? BETWEEN 2 - 5 PRODUCT BATCHES are scrapped each year due to OOS EM events.[1]

- Due to the increasing need to stay competitive, the pressure to reduce production costs has never been higher
- Out-of-specification results are only detected at the end of incubation, resulting in delayed decision-making and corrective actions
- Contamination could impact the product quality resulting in costly batch scrap

COMPLIANCE GAP

DID YOU KNOW? TYPICALLY, 132 DAYS are dedicated to audit preparation.[1]

- Data integrity is a key priority in ensuring a robust contamination control strategy, and is closely monitored during audits by authorities
- Data accessibility and preservation is a challenge as information is spread over different systems or folders



Address these challenges to unlock the full potential of your EM and strengthen your contamination control strategy.

EM-POWER THE FUTURE WITH 3P® ENTERPRISE

FULLY AUTOMATE YOUR ENVIRONMENTAL MONITORING

3P® ENTERPRISE is a fully integrated solution designed to streamline your environmental monitoring (EM) program and reduce your costs. This innovative system was developed and validated in collaboration with microbiologists from major pharmaceutical companies.

From sampling to trending, supervise your EM program with an end-to-end, fully digitalized and automated workflow. Increase efficiency and support the safety and compliance of your products with 3P® ENTERPRISE.

PLANNING & PREPARATION | SAMPLE COLLECTION | INCUBATION & READING | IDENTIFICATION & DATA REPORTING

3P® SMART PLATES

With irradiated **3P® SMART PLATES**, you get traditional, compliant culture media plates that have proven their high level of performance. You'll benefit from enhancements like LOCKSURE, GS1 barcode, clear design, and a double sourcing capability.

3P® CONNECT SOFTWARE

Digitalize the entire EM workflow and gain access to all data points and images anywhere at anytime. Help ensure workflow, data conformity, tracking, and supervision through our intuitive software: **3P® CONNECT**.

PHARMA INDUSTRY NETWORK

- Active Directory
- LIMS
- Back-up Servers

3P® STATION

Improve compliance and reach maximum efficiency. With **3P® STATION**, automate and standardize the incubation and reading of colony counting of Petri dishes through an advanced, continuous, and validated counting algorithm.

AT QC LAB OR DECENTRALIZED NEAR PRODUCTION AREA

END-TO-END SERVICES

Benefit from end-to-end expert **SERVICES** with rapid, accurate, and cost-effective solutions to keep operations running.

- Single Temperature Consultancy
- Implementation
- Training
- Qualification
- Support

3P® ENTERPRISE BENEFITS

OPTIMIZE PROCESS & HUMAN RESOURCE ALLOCATION

Thanks to a real-time, fully automated, and paperless process, **40% OF EM OPERATIONAL TIME CAN BE SAVED[3].**

- Optimize your process to allocate time to value-add tasks.
- We estimate that one full-time employee can be dedicated to more valuable tasks every 40,000 plates processed through 3P® ENTERPRISE.[1]

52% OF STEPS REMOVED[3]

40% OF TIME SAVING[3]

PLANNING	PREPARATION	SAMPLE COLLECTION	SAMPLE TRANSFER	INCUBATION	READING	DATA REPORTING
Assign and schedule activities	Print worklist	Open media pack	Record transport	Verify incubation conditions cycle 1	Consult SOP/ worklist	⚠ Sum up results
	Prepare and decontaminate material	Consult SOP/ worklist	Transport samples to QC lab	Place in incubation cycle 1	⚠ Read the plate	Trend result
	Prepare and decontaminate papers and labels	⚠ Reconciliate Labels/SOP tables	Acknowledge reception of samples	⚠ Complete incubation traceability sheet	⚠ Transcribe data in spreadsheet	
		Verify sample number	Open transport box	Verify incubation conditions cycle 2	Verify plate results	
		⚠ Stick label on plate	Verify number of plates relative to sampling plan	Move to incubation cycle 2	Alert and notify	
		Check label and map	Verify expiration date, plate integrity	⚠ Complete incubation traceability sheet	Sort the plate depending on action	
		Collect the samples	⚠ Complete traceability sheet		Consult documentation for approval context	
		⚠ Add information on the plate and on the work list			Approve result	
		⚠ Reconciliate samples planned and collected				
		Place the samples in transport box				

Step in a classical EM workflow

Step with risk of data integrity gap

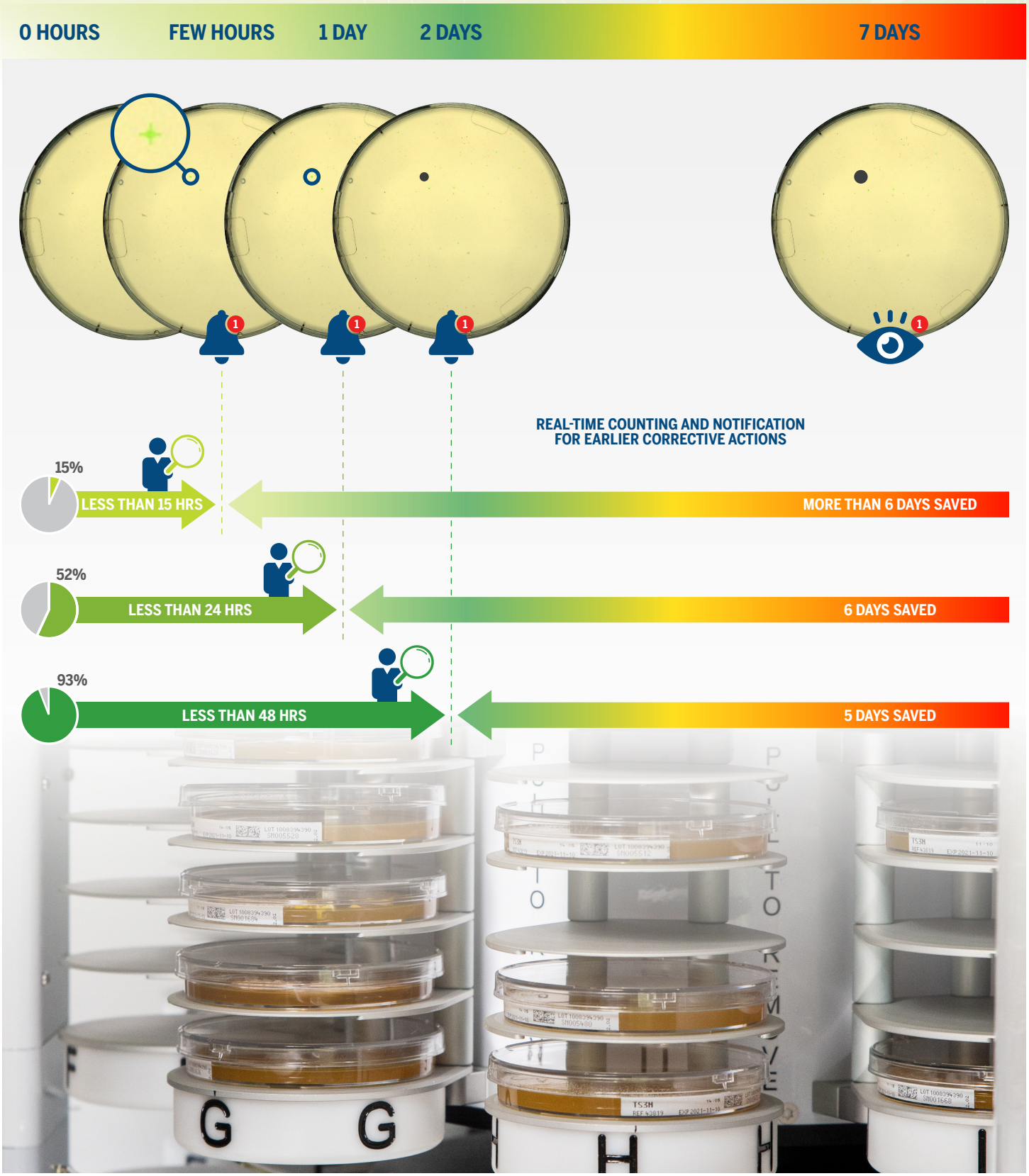
EM step that no longer exists / is automated and secured with 3P® ENTERPRISE

3P® ENTERPRISE BENEFITS

IMPROVE MANUFACTURING EFFICIENCY

With real-time counting results and notifications, you are alerted as soon as a sample is out-of-specification. Win back several days and take faster corrective actions.

- **FIVE DAYS CAN BE SAVED** for 93% of the 82 strains tested, and **UP TO 6 DAYS** for more than half of strains[4].
- This allows you to operate in the most cost-effective manner while minimizing interruptions in the supply of critical medicine and therapies.



Action level grade A reached at 25°C TTD on 82 strains (49 bacteria, 10 yeasts, and 23 molds)

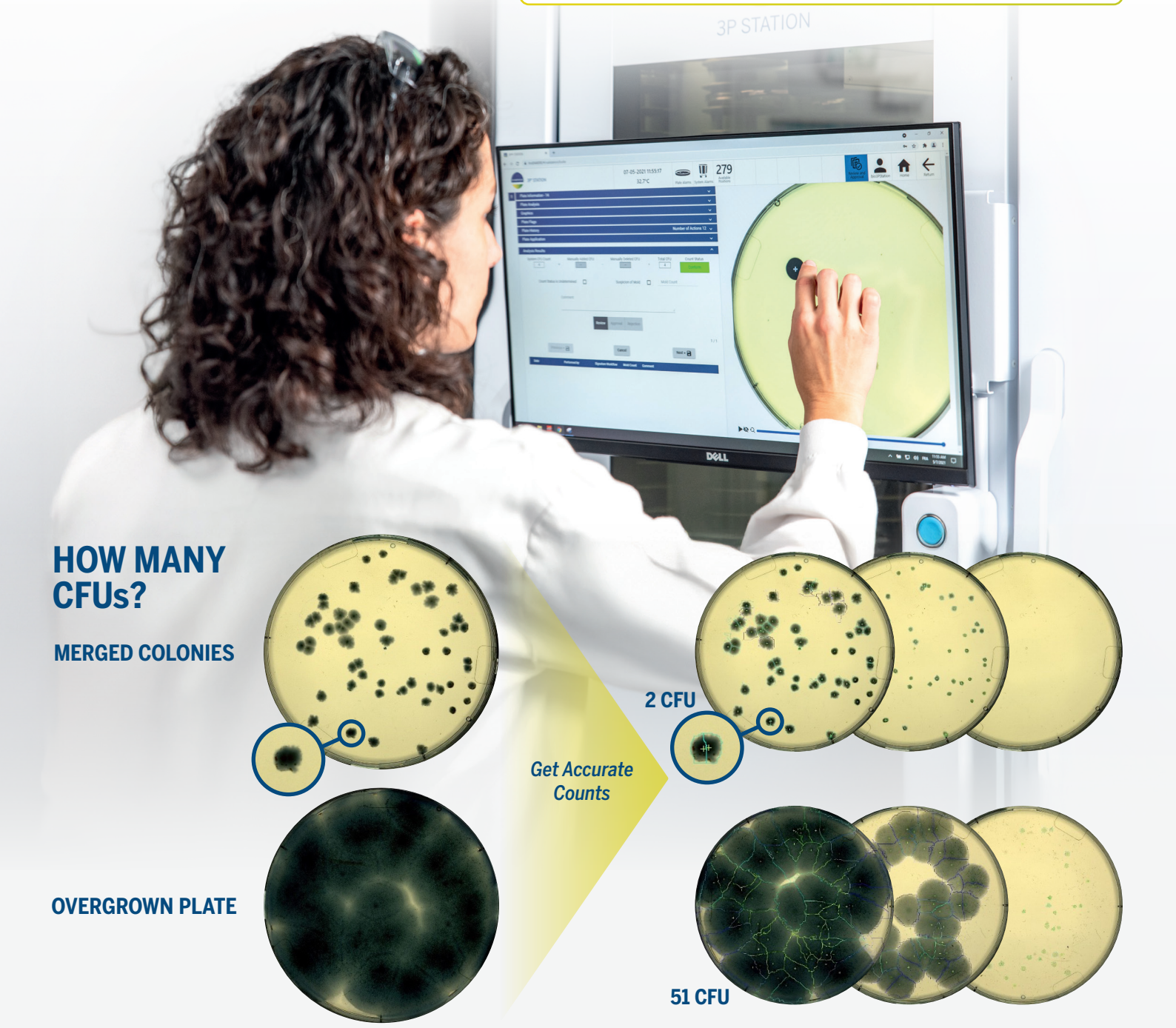
3P® ENTERPRISE BENEFITS

SAVE ON DEVIATION AND INVESTIGATION COSTS

With 3P® ENTERPRISE, decrease the number of errors and the length of investigations through digitalization and automation.

- Real-time data capture and conformity checks to secure data entry
- Compatible with traditional methods and regulatory compliant 3P® SMART culture media
- User guidance at every step
- Timelapse of colony growth on the plate to demonstrate the right count even with merged or overgrown colonies
- Validated counting performance

88% **of investigations linked to data integrity issues are removed — which will ultimately reduce the associated costs**



3P® ENTERPRISE BENEFITS

ACHIEVE COMPLIANCE AND STAY AUDIT READY

3P® ENTERPRISE helps ensure compliance of your EM data and eases audit management and CCS updates.

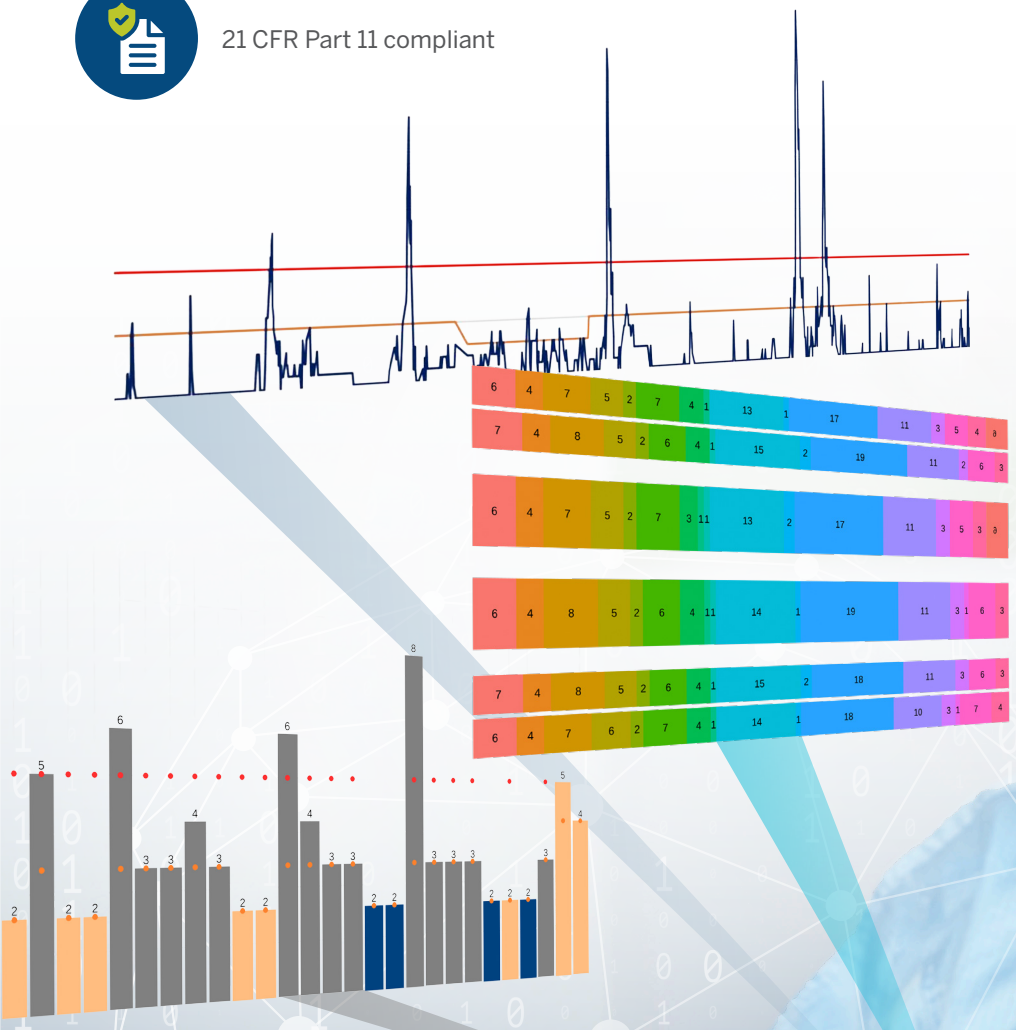
All data and images are centralized and available anytime

Complete set of trending and reporting tools

Real-time traceability of sample data, images, events, and actions

100% **of critical data integrity gaps on traditional manual workflows are corrected and secured[3]**

21 CFR Part 11 compliant



YOUR ALLY IN ADVANCING QUALITY

Thanks to our partner-first approach, our experts fully support you in transforming your EM process and decreasing your time to result for impactful operational savings.

"Ultimately, with the implementation of digitization and automation solutions such as 3P® ENTERPRISE, Selkirk strives to provide reliable delivery of quality products to the pharmaceutical market in the shortest time possible."

— The Microbiology and Environmental Monitoring team at a U.S.-based contract manufacturing organization specializing in the sterile fill and finish of injectable drugs

3P® ENTERPRISE helps maximize the efficiency and productivity of your operations. From planning to data reporting, you now have the ability to control your EM program at every stage of the process.

1. bioMérieux internal analysis based on market survey (n=40 customers; 66% traditional pharma products, 17% Cell & Gene therapy, 17% Bioproducts
2. Detection of Small events in environmental monitoring – how accurate is the visual inspection – Laurent Leblanc, Katia Imhoff, 2020
3. Efficiency gains evaluated internally and with pharmaceutical industries
4. Single Temperature For Incubation: A Real Possibility to Foster Environmental Monitoring Outcomes - Laura BAILAC, Séverine BASCOUL, Jade CISTERNINO, Lisa MALLAM, Laurent LEBLANC, 2024

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