

CASE STUDY

How NovaStar Solutions Automated Environmental Compliance at Scale

A2LA-Accredited Calibration · 21 CFR Part 11 · 60,000+ Calibrations/Year

THE OUTCOME

- Manual monitoring eliminated across all lab zones · 21 CFR Part 11 audit trail — fully automated
- Staff time recovered from data entry & reconciliation · Zero undetected excursions since deployment

THE PROBLEM

Calibration labs are uniquely sensitive to environmental variation. Temperature and humidity are not background conditions — they are active variables that directly affect measurement accuracy.

Why Environment = Measurement Accuracy

- Metal expands under heat, skewing dimensional calibration
- Low humidity generates static that damages electronics
- High humidity accelerates corrosion on precision instruments
- Any deviation can invalidate results — triggering re-calibration

Before MySirius, NovaStar faced three compounding failures:

Manual data collection

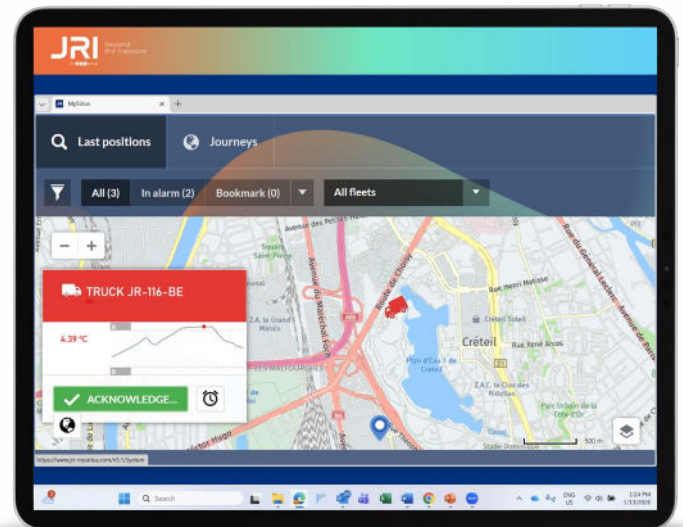
Staff rounds, handwritten logs, and spreadsheet entry consumed measurable hours — adding administrative burden without improving measurement outcomes.

Compliance exposure at scale

With 60,000+ calibrations per year, any gap in continuous environmental documentation created audit liability under 21 CFR Part 11 — a framework that demands timestamped, tamper-evident records with no manual reconstruction.

Reactive incident response

Condition drifts were discovered during post-hoc review rather than at the moment of occurrence — meaning excursions could span entire calibration batches before corrective action was taken.



MySirius EMS — Live Lab Environment · All Zones In Specification



Configurable Alert Thresholds by Zone — Real-Time Notification

60,000+

Calibrations Per Year

72

Calibration Professionals

1 Week

Standard Turnaround

99.98%

Environmental Uptime

0

Undetected Excursions

THE SOLUTION: JRI MySirius

Automated. Validated. Integrated. Built for regulated operations.

Automated Monitoring

Continuous Environmental Tracking

JRI MySirius replaced manual rounds with continuous, automated temperature and humidity tracking across all calibration zones. Configurable thresholds tied to HVAC performance trigger instant alerts — surfacing excursions the moment they occur, not hours later.

- Real-time temp & humidity per zone
- Threshold-based HVAC-linked alerts
- Timestamped variance data for RCA
- LoRa-connected sensor network
- No manual logging or spreadsheets

Compliance Infrastructure

21 CFR Part 11 Audit Trail

Every environmental event is automatically recorded with a tamper-evident timestamp, user attribution, and electronic signature capability — producing a defensible, reviewable data chain that survives auditor scrutiny without manual reconstruction.

- FDA 21 CFR Part 11 full compliance
- Tamper-evident electronic records
- Role-based access controls
- Electronic signature workflows
- Instant audit report generation

System Integration

On-Premises + LIMS Connection

NovaStar chose local server deployment for data sovereignty and operational continuity — the monitoring system runs independently of third-party infrastructure. Direct integration with NovaStar's LIMS means technicians never toggle between systems or perform manual data transfers.

- Local server (no cloud dependency)
- Redundant backup architecture
- LIMS / LIS direct integration
- Staff focus shifts to calibration
- Scales with operational throughput

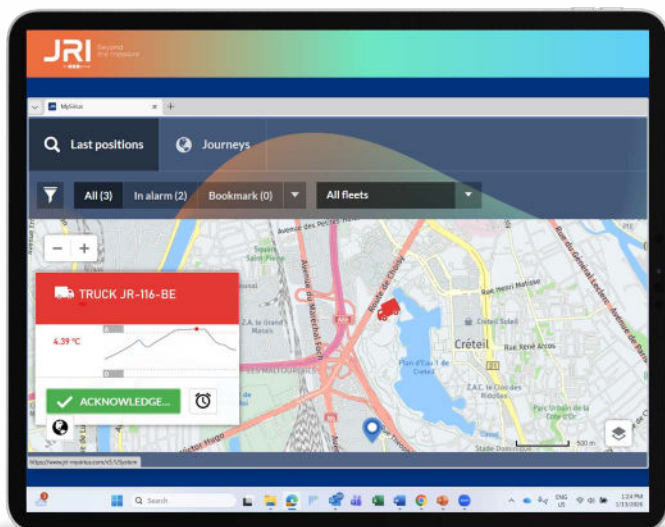
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Manual processes for humidity control create challenges in data compilation and trend analysis.

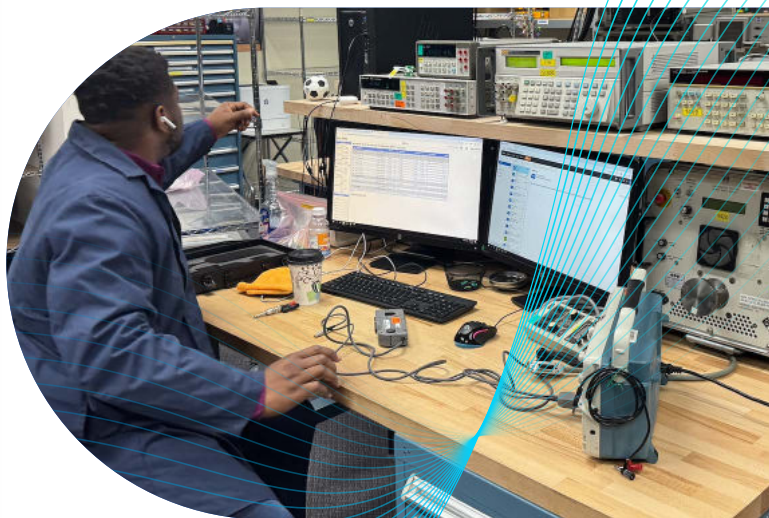
— **Candace Bryant**

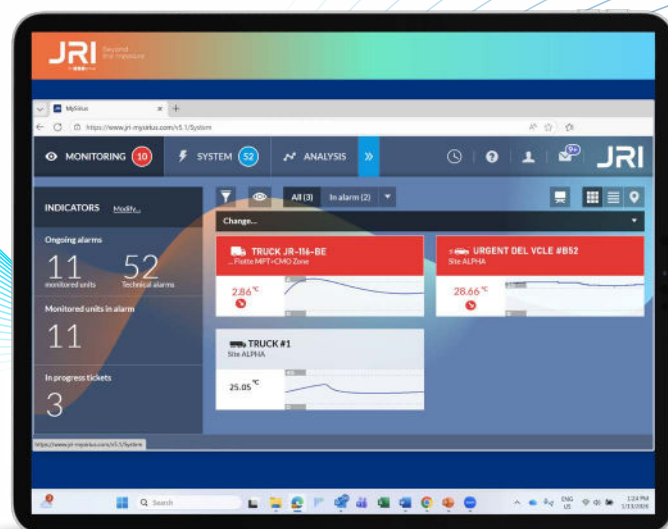
Quality Manager, NovaStar

NovaStar
SOLUTIONS

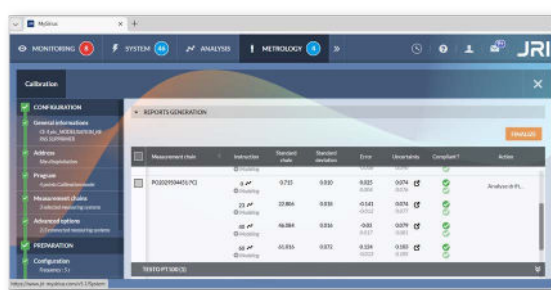


MySirius EMS — Live Lab Environment · All Zones In Specification





MySirius EMS – Main Dashboard



Calibration Process



21 CFR Part 11 Audit Trail – Automated & Tamper-Evident

“JRI's equipment allows NovaStar to automate processes, reducing manual data entry and minimizing human error during calibrations.

— Guy Howe
Director of Calibration Services

“The JRI system reduces administrative burden on staff, enabling them to focus on other critical areas of the business.

— Candace Bryant
Quality Manager

RESULTS ACROSS THREE DIMENSIONS

Compliance Integrity

Automated 21 CFR Part 11 trail — zero manual reconstruction.
Auditor-ready at any moment.

Staff Efficiency

Hours recovered from manual rounds and data entry — redirected to calibration throughput.

Client Trust

One-week turnaround protected. Excursions caught in real time before batches are compromised.

REGULATORY COVERAGE

FDA 21 CFR Part 11

21 CFR Parts 210/211

EU GMP Annex 11

ICH Q7-Q10

USP 797 / USP 800

CLIA / CAP

ISO 17025-aligned

NF EN 12830

PIC/S PI 011-3

Built for calibration labs. Proven in regulated environments.

For A2LA, ISO 17025, or FDA-regulated calibration operations managing environmental compliance manually, JRI MySirius elvers the automated monitoring, integrated audit trail, and validated platform documentation to replace fragmented processes with a single source of compliance truth.

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