SHIELDWORKZ

USE CASE
PHARMACEUTICALS

Aligning OT Security with FDAand IEC 62443 Expectations Before Inspection

Three systems, three different sets of records, and an inspection date that didn't move for any of them.



A biologics manufacturer running bioreactor, purification, and fill-finish systems had grown its automation faster than its documentation. With a pre-approval inspection scheduled and a corporate mandate to show IEC 62443 alignment, the site had no single, defensible record connecting its OT controls to either expectation. Shieldworkz built one.

THE CHALLENGE

The controls mostly existed. What didn't exist was a record that showed an inspector where they were and why they were enough.

No Unified Compliance Evidence

Security controls existed ad hoc across systems, with nothing tying them to FDA expectations or IEC 62443 practice.

Inconsistent Asset Records

Bioreactor, purification, and fill-finish systems each kept different, incomplete records of what was connected and how.

No Formal Zone/ Conduit Model

Without defined zones and conduits, the site couldn't demonstrate the risk-based segmentation rationale auditors expect.

Undocumented Access Governance

Who could reach which system, and why, wasn't documented in a way that satisfied data integrity or access control expectations.

Approaching Inspection Timeline

A pre-approval inspection was scheduled, and the gap had to close without disrupting ongoing batches.

Use Case Overview
Build one body of evidence, asset inventory, zone and conduit model, and access governance, that satisfies both FDA data integrity expectations and IEC 62443 zone and conduit practice ahead of the inspection window.

SHIELDWORKZ SOLUTION HIGHLIGHTS

Passive Asset Discovery
Full inventory across bioreactor, purification, fill-finish, and packaging systems without batch disruption.

Dual-Framework Compliance Mapping
Every control mapped explicitly to both FDA data integrity expectations and IEC 62443 zone/conduit clauses.

IEC 62443 Zone & Conduit Assessment
Zones and conduits formally defined and risk-rated across every system on site.

Network Segmentation
The zone model enforced at the network layer between bioreactor, purification, and fill-finish systems.

OT Vulnerability & Risk Assessment
Findings prioritized and tied directly to the zone model rather than left as a standalone list.

OT Security Policy Documentation
A maintained policy referencing both frameworks, owned jointly by security and quality.

Access Governance Documentation
Who can reach which system, under what role, documented and enforced across the site.

Incident Response Readiness
A documented response plan meeting expectations under both the quality system and IEC 62443 practice.

OT NDR & Continuous Monitoring
Traffic monitoring deployed to provide ongoing evidence that segmentation controls are actually holding.

OT SOC & Managed Monitoring
Ongoing evidence generation handed to a team that reviews activity against the documented zone model.

HOW IT WORKED

Discover
Assets and connections mapped across bioreactor, purification, and fill-finish systems.

Assess
Risk and compliance gaps identified against both FDA and IEC 62443 expectations.

Map
Zone and conduit model built and mapped directly to both frameworks.

Segment & Govern
Zones enforced at the network layer, with access governance documented site-wide.

Monitor & Maintain
Ongoing monitoring handed to the OT SOC to keep evidence current between audits.

BUSINESS OUTCOMES

- A complete asset inventory delivered across bioreactor, purification, fill-finish, and packaging systems
- A formal, risk-rated zone and conduit model established for the entire site
- Access governance documented and enforced across every OT system on the floor
- A single compliance evidence package ready ahead of the pre-approval inspection
- Continuous monitoring providing ongoing evidence rather than a point-in-time snapshot
- Assessment and segmentation completed with no disruption to ongoing production batches

Shieldworkz Threat Research Lab Insight

Program and logic integrity is becoming a critical OT security control in automated manufacturing. Shieldworkz Threat Research shows that attackers are increasingly targeting connected industrial environments where unauthorized changes can move from network access to physical-process impact. In robotic production, continuous monitoring of controller communications and program changes is therefore essential to detect an unauthorized push before it becomes a quality, safety, or production event.

WHY SHIELDWORKZ

End-to-End OT Program
Discovery through zone modeling, segmentation, and ongoing evidence generation under one team.

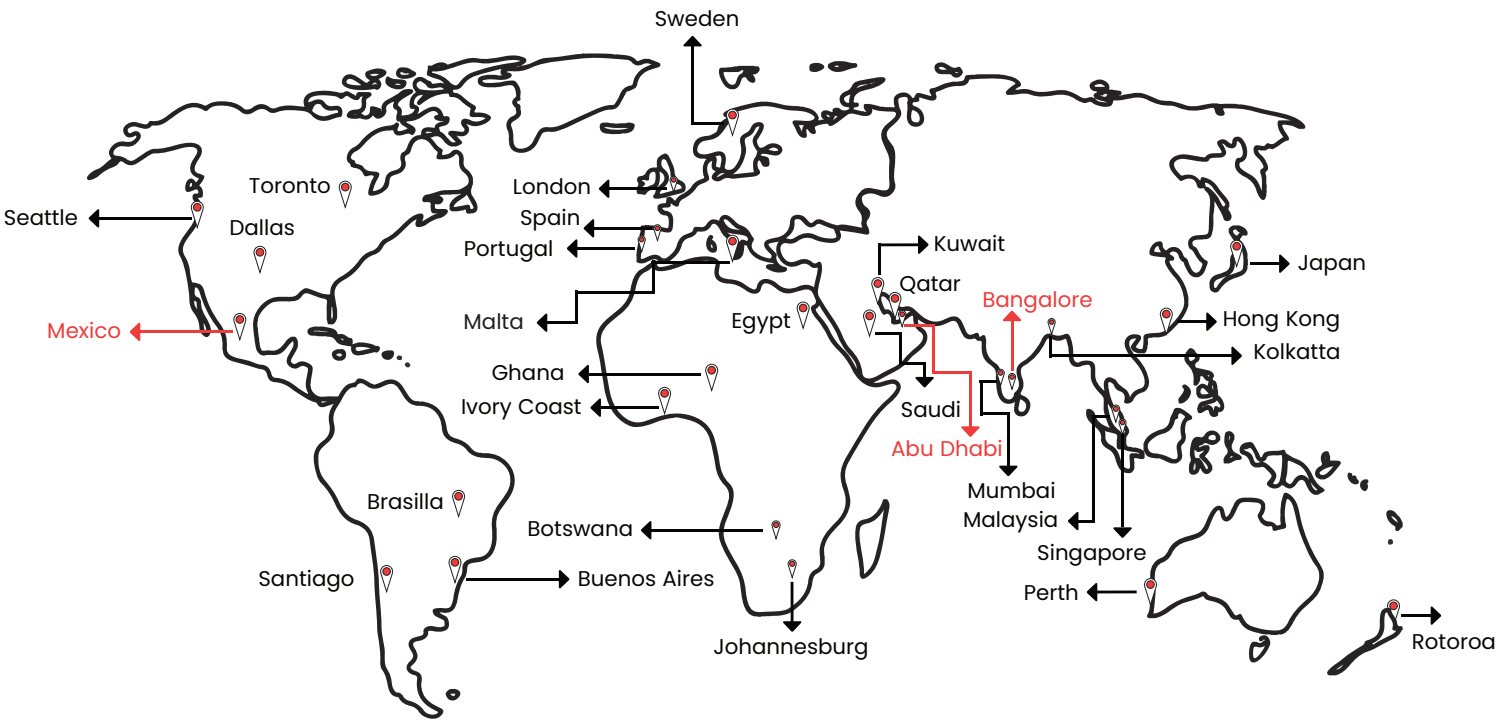
Pharma & GxP-Aware Expertise
Consultants who understand both quality systems and industrial control environments.

Dual-Framework Mapping
Controls documented once and mapped to both FDA expectations and IEC 62443 practice.

Standards-Based Approach
Zone and conduit modeling built on recognized IEC 62443 methodology, not an ad hoc checklist.

Managed OT SOC
Ongoing monitoring that keeps compliance evidence current between formal audits.

About Shieldworkz



ISOC and Honeypot Locations

Honeypot Locations

Security Operations Center

Shieldworkz is a global OT security company founded by top industry experts to protect critical infrastructure using proprietary technology and a leading consulting platform, we partner with businesses to secure assets, networks, and programs across industries. Our services are tailored to each client's cyber risks and backed by the world's largest OT and IoT threat intelligence facility and a global research team.

Secure Your Industrial Future

Talk to us today!

From OT security assessments covering NIS2, IEC 62443, NERC CIP and other regional requirements to an OT security platform, Shieldworkz covers all compliance and industrial cybersecurity enhancement needs. Talk to us to learn how you can enhance your security posture in 7 easy steps.

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