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seceon

Securing Pharmaceutical Innovation From Research to Production

This whitepaper explains how pharmaceutical organizations can secure intellectual property, GMP manufacturing, and clinical environments against modern cyber threats.

Executive Summary

Pharmaceutical organizations are increasingly targeted by ransomware groups, nation-state actors, and insider threats seeking to compromise drug research, clinical systems, manufacturing operations, and sensitive intellectual property. At the same time, growing regulatory requirements and expanding IT, OT, cloud, and third-party ecosystems have made cybersecurity operations significantly more complex.

Traditional security tools often lack the visibility and automation needed to detect and contain modern threats across pharmaceutical environments before operational or financial impact occurs.

This whitepaper explores how a unified AI-native cybersecurity platform helps pharmaceutical organizations improve threat detection, automate response, strengthen compliance, and protect R&D, GMP manufacturing, clinical systems, and global operations through a single platform approach.

Securing Pharma Innovation From Lab to Market

Unified AI-native cybersecurity for global pharmaceutical organizations protecting R&D intellectual property, GxP-compliant manufacturing OT environments, clinical trial data, and worldwide commercial operations under a single platform with a single data model.

<5 min	95%	70%	1,100+	9,800+
Mean Time to Detect	False Positive Reduction	Incidents Auto-Contained	Native Integrations	Global Customers

The Pharmaceutical Cybersecurity Challenge

Why Traditional Security Fails Global Pharma

- **8-12 point tools required:** to cover research, manufacturing OT, clinical systems, and global commercial operations
- **Dangerous visibility gaps:** between IT, OT, cloud, and identity silos exploited by APT groups for lateral movement
- **Weeks of rule-writing:** before traditional SIEM delivers value in new pharma environments
- **No unified compliance:** across 21 CFR Part 11, EU GMP Annex 11, HIPAA, GDPR simultaneously
- **No OT/ICS awareness:** legacy SIEM cannot monitor SCADA, DCS, or batch automation systems
- **Signature-based detection:** fails against the custom malware nation-state actors use against pharma targets

Pharma Threat Reality - 2025/2026

Key Statistics

- 82% of pharma organizations suffered a significant cyberattack in the past 12 months AI-powered intrusions targeting R&D and clinical trial IP up sharply year-over-year
- 256 days average APT dwell time in pharma networks AI-assisted living-off-the-land tradecraft now evades 70%+ of legacy SIEM rule sets
- $750B+ annual pharma IP lost to theft globally single oncology, GLP-1, or mRNA drug formulas now valued at $3 -10B to competitors and nation-state programs

Financial Impact

- $5.9M average pharma ransomware demand in 2025, manufacturing OT and cold-chain environments remain the highest-leverage targets
- 96% of pharma manufacturing facilities have unpatched OT/ICS vulnerabilities legacy Windows endpoints and PLCs continue to dominate the attack surface
- 71% of pharma breaches now originate via third-party CRO, CMO, or SaaS supply-chain compromise identity-driven attacks against vendor accounts are the dominant 2026 entry vector

Seceon OTM Platform - Core Modules for Pharma

aiSIEM™ AI-Native SIEM	**aiSecOT360™** GMP OT Security	**UEBA** Insider & IP Theft	**SOAR 4.0™** 500+ Playbooks
aiNDR™ Network Detection	**aiITDR™** Identity Protection	**Compliance** GxP / HIPAA / GDPR	**Threat Intel** 100+ Feeds

Adversaries Targeting the Pharmaceutical Industry

Nation-State APT Groups

APT10, APT41, Lazarus Group, Cozy Bear, and the Volt/Salt Typhoon clusters specifically target pharmaceutical R&D — vaccine research, oncology pipelines, GLP-1 and mRNA platforms, and Phase II/III clinical data. 2026 campaigns now combine GenAI-generated spear-phishing, AI-assisted lateral movement, and 256-day average dwell using LOTL techniques invisible to signature tools.

410% increase in pharma-targeted APT activity since 2020, nation-state focus on biotech IP intensifying

Ransomware & Double Extortion

Manufacturing OT environments are prime ransomware targets. A single sterile fill-finish line halt costs $1M+ per hour. Double extortion combines encryption with clinical data theft, triggering simultaneous HIPAA/GDPR regulatory exposure.

Average pharma ransom demand: $5.9M (2025) - up 28% YoY

IP Theft & Industrial Espionage

State-sponsored actors and competitors systematically steal pre-approval drug formulations, synthesis processes, and Phase III clinical trial results. A single stolen oncology formula can represent $2-8B in lost competitive and regulatory advantage.

Target: Pre-NDA compounds & biosimilar formulations

OT/ICS Manufacturing Attacks

Legacy SCADA systems controlling batch processes, clean room environments, cold chain integrity, and sterile fill-finish lines are targeted. Attacks can alter drug formulations, contaminate batches, or trigger costly FDA/EMA recalls.

76% of pharma OT systems still run unsupported or end-of-life OS versions

Supply Chain & Third-Party Risk

CROs, CMOs, SaaS clinical platforms, and logistics providers are major entry vectors. A CRO compromise or stolen federated identity provides access to Phase II drug candidate IP without directly attacking the pharma perimeter - 71% of pharma breaches start via third-party or non-human identity abuse.

71% of pharma breaches originate via third-party / SaaS-identity compromise

Insider Threats & Exfiltration

Scientists, clinical researchers, and commercial staff with legitimate access to high-value data present significant insider risk from departing employees taking drug candidates to nation-state recruited insiders with deep access to research repositories.

Insider IP theft: avg. detected 11 months after departure (legacy tools)

Pharma Attack Surface — Four Critical Domains

R&D Infrastructure

Lab instruments, LIMS, genomics platforms, ELN, HPC clusters, cloud research environments, CRO connections

GMP Manufacturing

SCADA, DCS, batch automation, clean room HVAC, cold chain monitoring, PAT systems, OT historian

Regulatory & Clinical

eTMF, CTMS, EDC, electronic batch records, regulatory submissions, patient data repositories

Global Commercial

CRM, SAP/ERP, distributor portals, medical affairs platforms, multi-country cloud estates

Seceon Platform — Pharmaceutical Use Cases

R&D IP Protection & Exfiltration Detection

<5 min detect

AI-powered UEBA baselines every scientist's normal data access patterns. Detects anomalous bulk downloads of compound libraries, unusual access to pre-NDA formulation databases, or large transfers to unrecognized destinations even through encrypted channels vs. industry average of 11-month insider detection. aiITDR adds cross-platform identity correlation across AD, Azure AD, Okta, AWS, GCP, and SaaS to surface federated-identity abuse used in 2026 pharma IP-theft campaigns.

UEBA Behavioral Baselining | Data Exfiltration Detection | Encrypted Traffic Analysis | CRO/Third-Party Monitoring

GMP Manufacturing OT Security — Production Integrity

100% OT Visibility

Passive, agentless monitoring of batch processing systems, DCS, SCADA, and clean room automation, zero GMP validation impact, zero production disruption. Detects unauthorized parameter changes, recipe tampering, unauthorized remote access, and IT-to-OT lateral movement used by ransomware groups to reach production assets.

Passive OT/ICS Monitoring | aiSecOT360™ | IT/OT Lateral Movement Detection | IEC 62443 Compliance

Clinical Trial Data Protection & Patient Privacy

Automated Compliance

Automated monitoring of eClinical systems (EDC, CTMS, eTMF) with automated HIPAA, GDPR, and ICH E6 GCP compliance workflows. Instant breach detection and automated 72-hour regulatory notification — critical for multi-country trials under FDA, EMA, and PMDA oversight simultaneously.

HIPAA/GDPR Automation | PHI Access Monitoring | 72-Hr Breach Notification | Multi-Jurisdiction Compliance

Supply Chain & Third-Party Risk Management

65% Risk Reduction

Comprehensive monitoring of all CRO, CMO, and vendor remote access sessions. Each third-party connection is baselined access outside authorized scope, unusual data volumes, or off-hours activity triggers immediate investigation. Detects persistent access through vendor credentials (Salt Typhoon-style TTPs).

Third-Party UEBA | Vendor Access Analytics | Supply Chain TI Feeds | Zero Trust Enforcement

Nation-State APT Detection — Long-Dwell Threat Hunting

256→4 day dwell

4,000+ pre-trained ML models detect APT10, APT41, Lazarus Group TTPs including living-off-the-land techniques, custom malware with no known signatures, and multi-stage infiltration patterns invisible to signature tools. Cross-domain correlation surfaces APT campaigns weeks earlier than traditional detection.

MITRE ATT&CK (85%+) | APT Behavioral Detection | 100+ Threat Intel Feeds | LOTL Detection

Global Multi-Site SOC Operations & Regulatory Compliance

70% Analyst Savings

Single-pane visibility across all global sites US, EU, APAC research and manufacturing. Automated pre-built compliance reports for 21 CFR Part 11, EU GMP Annex 11, FDA CDER guidance, and EMA guidelines. SOAR 4.0 with 500+ playbooks reduces analyst workload 70%, enabling lean global SOC teams to cover complex multi-site environments.

Multi-Site Multi-Tenancy | SOAR 4.0 Automation | 21 CFR Part 11 | EU GMP Annex 11 | 500+ Playbooks

Seceon OTM Platform Modules for Pharmaceutical Industry

aiSIEM™ — AI-Native SIEM

- **Dynamic threat models:** self-tune from Day 1, no weeks of rule-writing in new pharma environments
- **1.5M+ EPS capacity:** ingests lab systems, ERP, clinical platforms, and manufacturing historians simultaneously
- **21 CFR Part 11 audit trail:** WORM-compliant, 7-year forensic log retention with chain of custody
- **Real-time compliance scoring:** continuous monitoring against GxP, HIPAA, GDPR frameworks
- **95% false positive reduction:** AI correlation eliminates analyst noise in high-volume pharma environments

aiSecOT360™ — GMP Manufacturing Security

- **100% passive, agentless:** zero GMP validation impact, zero production disruption on manufacturing lines
- **70+ industrial protocols:** Modbus, DNP3, OPC-UA, EtherNet/IP, Siemens S7 full pharma DCS/SCADA coverage
- **Purdue Model auto-zoning:** automatic Level 0-5 zone classification from passive network traffic analysis
- **IEC 62443 compliance:** automated security level assessment and compliance reporting
- **IT/OT correlation:** detects ransomware lateral movement from corporate IT toward production systems

UEBA — Insider & IP Theft Detection

- **Per-scientist behavioral baselines:** calibrated within 7 days to normal research workflows and access patterns
- **Research-specific anomalies:** bulk compound database downloads, unusual pre-NDA data access, after-hours queries

- **Departing employee risk scoring:** elevated monitoring automatically triggered on resignation or termination
- **CRO/CMO third-party analytics:** each vendor session baselined and monitored for scope creep or data staging

SOAR 4.0™ — Automated Response

- **500+ pre-built playbooks:** including GxP-safe OT isolation, HIPAA breach notification, clinical data lockdown
- **<60 second containment:** automatic isolation of compromised research workstations, OT segment quarantine
- **Multi-jurisdiction notifications:** automated simultaneous HIPAA, GDPR, and PMDA breach reporting workflows
- **ServiceNow/JIRA integration:** automated incident ticketing aligned to pharma SOC workflows and escalation

aiNDR™ — Network Detection & Response

- **Full Layer 7 DPI:** detects APT C2 beaconing, covert channels, and data exfiltration in encrypted traffic
- **East-west monitoring:** catches lateral movement from compromised endpoints toward R&D repositories
- **SSL/TLS analysis:** JA3/JA3S fingerprinting identifies malicious patterns without requiring full decryption
- **Auto network topology:** discovers and maps all pharma network assets including shadow IT and rogue devices

aiITDR™ — Identity Threat Detection

- **Impossible travel detection:** <60 second cross-platform correlation of AD, cloud IdP, ERP, clinical systems

- **Privileged access monitoring:** enhanced surveillance for researchers with access to compound databases
- **Golden/Silver Ticket detection:** AD attack technique coverage critical for pharma enterprise environments
- **MFA bypass attack detection:** catches nation-state credential harvesting campaigns targeting pharma leadership

Seceon Platform — Healthcare & Hospital Use Cases

USA / FDA	Europe / EMA	APAC / Japan	Industry Standards
21 CFR Part 11	EU GMP Annex 11	PMDA ER/ES Guidelines	ICH E6 GCP (Clinical)
FDA CDER Cyber Guidance	GDPR (72-hour automated reporting)	MAS TRM (Singapore)	IEC 62443 (OT Security)
HIPAA / HITECH	NIS 2 Directive	APRA CPS 234 (Australia)	GAMP 5 Alignment
NIST CSF 2.0	EMA Cyber Resilience	PDPA (Thailand/Singapore)	PIC/S Guidance
SOC 2 Type II	ISO 27001:2022	China MLPS 2.0	MITRE ATT&CK (85%+)
CMMC (Defense Pharma)	DORA (Financial Operations)	India DPDPA 2023	PCI-DSS (Commercial)

Automated Evidence Collection - FDA Inspection Ready

Seceon continuously collects compliance evidence across all monitored systems eliminating 200+ hours typically spent on manual audit preparation. Pre-built report templates for each framework generate on-demand or on schedule, with complete chain-of-custody preservation and electronic signature support for 21 CFR Part 11 compliance.

Seceon OTM vs. Traditional Approaches — Pharmaceutical Requirements

Pharma Requirement	Seceon OTM	Traditional SIEM + Point Tools	Legacy SIEM Alone
Day-1 detection (no tuning)	Dynamic AI models with immediate value	6–12 weeks of integration work required	3–6 months of rule development
Passive OT/ICS monitoring (GMP-safe)	aiSecOT360™ native support with 70+ protocols	Requires a separate OT security tool	No OT/ICS capability
R&D IP exfiltration detection	UEBA with per-scientist behavioral baselines	Requires separate DLP and UEBA tools	Signature-only detection misses novel exfiltration
APT long-dwell detection	4,000+ ML models with cross-domain analytics	Partial visibility requiring dedicated threat hunters	Limited visibility into LOTL and evasive TTPs
Automated GDPR/HIPAA/21 CFR notifications	Automated multi-jurisdiction compliance workflows	Manual GRC processes required	No compliance automation
Multi-site global deployment (data residency)	Supports on-prem, cloud, hybrid, and air-gapped environments	Complex multi-tool global deployment	Cloud-first limitations with data residency concerns
Automated incident response (<60 sec)	SOAR 4.0 with 500+ automated playbooks	Requires a separate SOAR platform	Manual response workflows only
eClinical system monitoring (EDC/CTMS)	1,100+ connectors including eClinical systems	Custom integrations needed for each tool	Limited healthcare-focused integrations
Asset-based predictable licensing	No EPS or data-volume pricing surprises	Volume-based costs increase at scale	EPS-based pricing penalizes growth
Unified platform with no tool sprawl	One platform, one data model, one UI	Requires 8–12 separate tools	Missing OT, UEBA, SOAR, and NDR capabilities

Proven Outcomes — Seceon OTM Platform

<5 min	95%	70%	47-58%	3-5x
Mean Time to Detect across all pharma environments	False positive reduction - analyst focus on real threats	Incidents auto-contained via SOAR 4.0 playbooks	Total Cost of Ownership savings vs. multi-vendor stack	Security analyst productivity improvement

Flexible Deployment — Built for Global Pharma Data Residency

On-Premises	Cloud / SaaS	Hybrid (On-Prem + Cloud)
Complete data sovereignty for R&D facilities and GMP manufacturing	Rapid deployment for new site acquisitions and post-M&A environments	R&D and manufacturing OT on-premises; commercial and sales operations in the cloud
Full AI/ML analytics without internet dependency	AWS, Azure, and GCP support with regional data residency for GDPR, U.S. sovereignty, and APAC requirements	Single-pane visibility and unified analytics across all global locations
Air-gap support for classified research programs and defense pharma	Instantly scales with business growth without upfront infrastructure investment	Supports mixed regulatory environments simultaneously, including FDA, GDPR, and PMDA
Best for: R&D labs, government-partnered clinical programs, and strict data residency mandates	Best for: Commercial teams, SaaS-first environments, and post-M&A integration	Best for: Global pharmaceutical enterprises, multi-country M&A, and mixed environments

Platform Scale - Enterprise Ready

1.5M+ EPS sustained throughput |50TB/day indexing | 7-year WORM log retention | 1,100+ native connectors including eClinical, ERP, OT systems | 4,000+ pre-trained ML models Day-1 effectiveness | 99.9% uptime SLA with active-active HA and geo-distributed DR |10,000+ global customers including 70+ Fortune 500

Securing Pharmaceutical Innovation From Research to Production

82%	256d	$750B	71%
Hit by a significant cyberattack in the past 12 months	Avg. APT dwell time before detection	Annual pharma IP lost to theft globally	Of breaches via third-party CRO/CMO compromise

Active Threat Landscape

Nation-State APT Groups
APT10, APT41, Lazarus Group target oncology & mRNA pipelines with 256-day average dwell.
410% increase since 2020

Ransomware & Double Extortion
GMP fill-finish lines cost $1M+/hr when halted. Avg. ransom demand $5.9M — up 28% YoY.
Avg. demand: $5.9M (2025)

Insider IP Theft
Departing scientists exfiltrating compound libraries detected on average 11 months after departure with legacy tools.
11-month avg. detection lag

GMP OT / Manufacturing Attacks
Recipe tampering, batch contamination, and clean-room HVAC compromise 96% of pharma OT systems unpatched.
96% OT systems unpatched

Active Threat Landscape

256→4
Days APT Dwell Reduced
From industry average to near-real-time detection

95%
False Positive Reduction
Analysts focus on real threats, not noise

<60s
GxP-Safe Containment
Automated response with no production disruption

58%
TCO Savings
Replace 8–12 point tools with one platform

200hrs
Audit Prep Eliminated
Compliance reports generated on demand

5×
Analyst Productivity
From alert triage to proactive threat hunting

Global Regulatory Compliance — Automated

USA / FDA	Europe / EMA	APAC / Japan	Industry
21 CFR Pt 11	GMP Annex 11	PMDA ER/ES	IEC 62443
HIPAA	GDPR	MAS TRM	GAMP 5
NIST CSF	NIS 2	MLPS 2.0	ICH E6 GCP
SOC 2	ISO 27001	DPDPA	PIC/S

About Seceon

Seceon enables MSPs, MSSPs, and Enterprises to reduce cyber threat risks and their security stack complexity while greatly improving their ability to detect and block threats, and breaches at scale. Seceon's Open Threat Management (OTM) platform augments and automates MSP and MSSP security services with our AI and ML-powered aiSIEM, and aiXDR platforms. The platform delivers gapless coverage by collecting telemetry from logs, identity management, network logs and flows, endpoints, clouds, and applications. It's all enriched and analyzed in real-time by applying threat intelligence, AI and ML models built on behavioral analysis, and correlation engines to create reliable, transparent detections and alerts. Over 850 partners are reselling and/or running the industry's lowest TCO, efficient security services with automated cyber threat remediation and continuous compliance for over 9,800 clients.

References and Citations:

This whitepaper is based on research and data from:

- Seceon Open Threat Management (OTM) Platform
- CISA Cybersecurity Guidance for Critical Manufacturing & Healthcare
- IBM X-Force Threat Intelligence Index
- Verizon Data Breach Investigations Report (DBIR)
- NIST Cybersecurity Framework (CSF) 2.0
- FDA Guidance on Cybersecurity in Medical Devices and Pharmaceutical Manufacturing Systems
- ENISA Threat Landscape Reports
- HIPAA Journal Cybersecurity & Data Breach Statistics
- IEC 62443 Industrial Security Standards
- MITRE ATT&CK Framework
- Gartner Research on SIEM, XDR, and Threat Detection Platforms
- EMA and EU GMP Annex 11 Compliance Guidance
- 21 CFR Part 11 Electronic Records & Electronic Signatures Guidance

About the Author

Seshi Sompuram

Director of Cybersecurity BD & Partnerships (Life Sciences & Healthcare), Seceon Inc.

With a distinguished career in biotechnology, he has led the development and commercialization of innovative cancer diagnostic solutions as Co-Founder, Co-Inventor, and VP of R&D, with expertise spanning translational research, clinical validation, and FDA approvals, while also serving as an Adjunct Assistant Professor of Pathology at Boston University School of Medicine. At Seceon, Dr. Sompuram bridges life sciences and cybersecurity, helping organizations protect sensitive data, intellectual property, and clinical systems through AI-driven, unified security platforms.