KVALITO

DSCSA Training Curriculum

Our DSCSA Training Curriculum enables global pharmaceutical manufacturers to meet U.S. compliance requirements for serialization, traceability, and secure supply chain operations.
With a focus on cross-functional readiness and real-world implementation, it equips teams to navigate FDA expectations and enforcement deadlines with confidence

The program includes 10 targeted modules, each addressing a critical area of DSCSA compliance.

Module 1: DSCSA Overview and Legal Obligations

- Purpose and scope of the Drug Supply Chain Security Act (DSCSA)
- Definitions: Product, Suspect Product, Authorized Trading Partner (ATP), Standardized Numeric Identifier (SNI)
- Legal responsibilities across the supply chain (manufacturer to dispenser)
- Enforcement dates and timeline milestones
- Applicability to Aurobindo's U.S. export operations

Module 2: Serialization and Product Identification (SNI)

- Components of a SNI: GTIN, serial number, lot, expiry
- Site-level serialization protocols and packaging line readiness
- Integration with ERP/Track&Trace systems (SAP ATTP, rfxcel, etc.)
- Validation of 2D barcode printers and scanners
- Case studies: Serialization infrastructure from large multinational pharmaceutical companies

Module 3: EPCIS and Interoperable Data Exchange

- Overview of EPCIS (Electronic Product Code Information Services) – Version 1.2 vs. 1.3
- Event data types: Commission, Aggregation, Shipping, Receiving
- Data transmission protocols and secure partner onboarding
- Exception handling and real-time alert systems
- Cross-functional integration: IT, Regulatory, Packaging, Quality

Module 4: Product Tracing and Verification Requirements

- Transaction Information (TI), Transaction History (TH), Transaction Statement (TS)
- Building traceability workflows with trading partners
- Verification Router Service (VRS): Architecture and use cases
- Verifying product at saleable return or suspect product identification
- Batch-level vs. unit-level verification readiness

Module 5: Managing Suspect and Illegitimate Products

- Identifying red flags in packaging or shipment data
- Quarantine protocols and internal investigation workflows
- FDA Form 3911 notification process
- Partner communication protocol during incident management
- Case studies adapted from large-scale pharmaceutical environments

Module 6: Authorized Trading Partners (ATP) and Licensure

- Who qualifies as an ATP (Wholesale Drug Distributors, Third-Party logistics providers)
- Ensuring distributor licensure: NABP and state-by-state variations
- Establishing procedures for ATP verification (pre-trade checks)
- Due diligence checklists and periodic reassessment

Module 7: SOP, Documentation and Audit Readiness

- Developing DSCSA-specific Standard Operating Procedures (SOPs) and work instructions
- Internal DSCSA audit checklist templates
- Data retention policies (6-year archival requirement)
- Inspection preparation: Evidence collection and deviation logs
- Audit documentation practices, modeled on global pharmaceutical operations

Module 8: Role-Based Training Programs

- QA/QC: Audit response, investigation reports, root cause analysis
- Regulatory Affairs: Partner communication, FDA submission alignment
- Packaging: Aggregation protocols, barcode standards, packing slips
- IT & Digital: EPCIS architecture, VRS endpoints, system maintenance
- Warehouse/Logistics: Receiving, scanning, exception handling at point-of-distribution

Module 9: Reporting Mechanisms and Continuous Monitoring

- Establishing centralized dashboards for DSCSA traceability tracking
- Key reporting indicators:Exceptions, transaction failures, verification lag
- Integration with internal QMS and regulatory review processes
- Monthly and quarterly compliance reporting formats
- Real-time escalation paths and audit trail generation

Module 10: Post-Training Certification and Readiness Validation

- Knowledge assessments per department
- Real-world scenario walkthroughs
- DSCSA certificate of participation
- Continuous learning plan (e.g., semi-annual refreshers)

Questions or walkthrough requests? Connect with your Strategic Client Advisor, Swathi Priyadarsini Kota.

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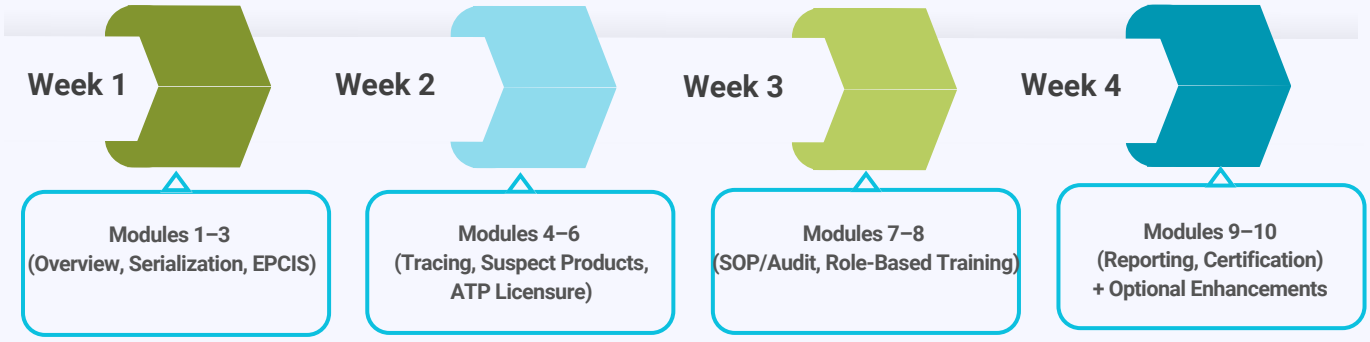
DSCSA Training Curriculum

Training Delivery Timeline

This DSCSA training curriculum is tailored to align with Aurobindo's regulatory goals, compliance needs, and operational realities, while benchmarking against industry leaders and U.S. FDA expectations.

Proposed schedule (3–4 weeks):



Beyond the Core Curriculum: Optional Enhancements

Upon successful completion of the core 10-module DSCSA training, participants can engage in optional enhancement sessions. These are designed to deepen expertise, improve audit preparedness, and support continuous compliance and capability building.

Optional Enhancements

- Mock audit facilitation
- DSCSA readiness maturity assessment
- Custom SOP and work instruction authoring support
- **Extensive, comprehensive role-play exercises**
- **Guest lecture on *How AI Can Help in DSCSA Compliance***
- Video-based learning series (DSCSA trends, challenges, and FDA expectations)
- Content enrichment from peer-reviewed publications and compliance reports highlighting evolving FDA interpretations, serialization trends, and cross-functional supply chain execution challenges

Alternative Format: DSCSA Boot Camp (5-Day Intensive)

For accelerated delivery, a condensed 5-day DSCSA Boot Camp is available, covering all modules through workshops, practical exercises, and live case discussions:

- **Day 1:** Introduction, Regulatory Overview, Serialization Fundamentals
- **Day 2:** EPCIS Interoperability, ATP Verification
- **Day 3:** Product Tracing, Suspect Product Management, VRS
- **Day 4:** SOP/Audit Simulation, Role-Based Interactive sessions
- **Day 5:** Reporting, Certification Assessments, and Capstone Case Role-Play

Empower your teams to achieve DSCSA compliance with training tailored to your operational needs.
Customized modules, real-world scenario walkthroughs, and role-based enhancements are available upon request to ensure alignment with your systems, teams, and regulatory priorities.

For more information or to schedule a walkthrough, reach out to your Strategic Client Advisor, Swathi Priyadarsini Kota.

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