DSCSA Implementations

Field Learnings from a Year of Planning and Implementation Projects

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Excellis Background

- **Global Resell & Implementation Partner of TraceLink:**
  - US Core Serialization
  - US Healthcare & Dispensers
  - US VRS
  - EU Serialization
  - ROW Serialization (SA, ARG, SK, KZ, UZ, etc.)
  - MINT / SCWM

TraceLink Service Bureau sustainability package includes ongoing validation (complementary to AVM), outsourced EPCIS administration, EU Alerts, and US Exception Handling.

Global Track & Trace (GTT) Consortium Founder
- 20+ Annual Events
- 2,000+ members
- Industry Incubator for Value Pilots

Global Certifications:
- GS1 Standards Professional Designation
- GS1 Package Measurement Professional Designation
- GS1 Standards for DSCSA Certificate
- GS1 Standards for UDI Certificate
- Elected to Executive Leadership Committee – GS1 US Healthcare Initiative
- Member of Rx Secure Supply Chain workgroup
- Member of PDG – the Partnership for DSCSA Governance
- Co-led development of the November 2017 HDA Barcode Guidance
- Author of the GIRP (European HDA) EU-FMD Guidance
- International Coalition of Medicines Regulatory Authorities (ICMRA) – Industry T&T Interoperability Working Party
- EMVO/EFPIA EU-FMD project and implementation teams (2008-Present)
- GIRP representation to technical meetings (European HDA)
- GS1 Healthcare (global)
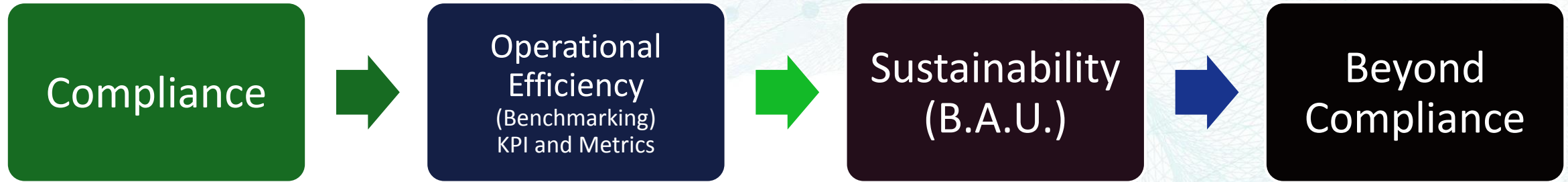- EMVO Management team (2015-2019)

Excellis Serialization Experience (w/ TraceLink)

- Formally partnered with TraceLink in 2016, and since that time:

  - 200+ Strategies

  - 230+ Technical Installations

  - 190+ Implementations

  - 4,500+ On-Boardings

  - 50+ Service Bureau customers

  - 50+ HealthChecks

- Dedicated TraceLink team/division responsible for delivery (10+ certified IPMs and TCs)

- Full SOP Library tailored to TraceLink and market specific traceability requirements

- Only TraceLink partner with automated Service Bureau (including joint offering complementary to TraceLink AVM for complete validation Services – "Full-Service Validation")

- TraceLink Service Bureau includes Release Management & Ongoing Validation, outsourced EPCIS administration, US DSCSA Exception Handling, EU-FMD Alert Management, and additional managed services to meet other country specific track & trace reporting requirements.

Serialization Maturity Stages

Compliance → **Operational Efficiency** (Benchmarking) KPI and Metrics → **Sustainability (B.A.U.)** → **Beyond Compliance**

Compliance
- **Achieve license to operate in the markets** enacting serialization/traceability requirements
- **Enterprise approach, local compliance**
- **Covers all aspects**:
  - Coding, Artwork and Labelling,
  - Manufacturing and Supply Chain
  - IT and Validation
- **Adapting Processes and Systems**

Operational Efficiency
- Complete move **from Tactical to Strategic**
- Measure and **Minimize impact on operations**
- Identify **opportunities for improvements**
- Full **review of the extended supply chain**
- **Integration of processes and systems**
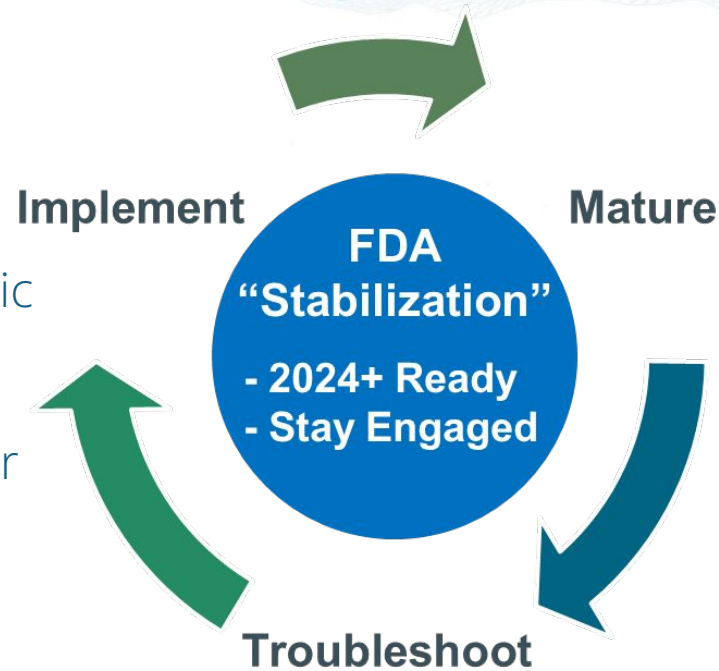- Deal with the "long tail"

Sustainability (B.A.U.)
- **Solution Maintenance:**
  - Error fix, data exchange continuity,..
  - **Alert Management** (EU-FMD)
  - New regs, SKUs, partners..
- **Solution validation**
  - Maintain state of validation
- **Processes/SOP :**
  - (re)-definition
  - Control
  - Maintenance
- **Knowledge maintenance :**
  - CoE or TSG

Beyond Compliance
- **Benefits, ROI:**
  - Short term
  - Mid term
  - Long term
- **Synergies:**
  - Supply chain digitalization
  - Healthcare Stakeholders
  - Patient access
- **2023/2024+**

Enforcement Readiness

- Monitoring & Adjust to Recent & Future FDA Guidances.

- Monitor Industry Direction, Standards, Devices and Tools (i.e. barcode fingerprints, thermochromic labels).

- FDA / Industry Processes & Tools for Prompt Tracing / Information Requests & Investigations.

- Finish Onboarding (i.e. Collaboration, Portal Usage, Outliers / Stragglers).

Implement

FDA "Stabilization"
- 2024+ Ready
- Stay Engaged

Mature

Troubleshoot

- Develop Exception Handling (Including Product Controls, Fit for Distribution, Timelines).

- Align on Exemptions (Role & Transaction Based)

- Master Data Alignment & Maintenance (i.e. GLN Cleanup).

- Sustainability: Accuracy With Master / Operational Data & Physical Product; Create / Mature Policies & Procedures.

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Lessons Learned & Common Gaps

Control Your Own Destiny:
- Internal EPCIS Repository
- Receive and Send EPCIS Downstream
- Verifications with VRS

- Serialized Operations in Warehouse/DC

- Supplier/Customer Readiness/On-Boarding

- **Exception Handling**

- GLN/SGLN Alignment

- Updated SOPs

- Program Governance & Sustainability Model post-November

DSCSA Exceptions 101

A serialization exception is generated any time 1) there is a product and serialization data misalignment in the supply chain or 2) there is a non-serialized exception that will require serialization data adjustments to correct.

Exceptions are often related to product and data movement from one point in the supply chain (internal and external) where the receiving party is unable to successfully process both the product and data.

Internal Exceptions – Everything between when a product is purchased / manufactured and before it is sold to the authorized trading partner.

External Exceptions – Prior to taking legal ownership and / or once the product changes legal ownership and is on its way downstream towards patient.

DSCSA Exception Handling Requirements

FDA Guidance:

10 days to resolve, or initiate suspect product workflow

Required processes:

- Ability to detect exception
- Exception handling playbook
- Exception triage & management P&P
- Trading Partner Alignment & Updated contracts
- Sufficient resources to support investigations & corrections
- Suspect Product P&P
- Ongoing training & education with HDA, GS1, etc.

Best Practice:

- Target 1-3 days to resolve
- Faster resolution needed to keep receiving docks clear
- Support investigations & corrective measures
- Future automation needed to expedite resolution

Each exception occurrence should be recognized, managed, analyzed, resolved, and documented in collaboration with internal & external partners

DSCSA Exception Handling: Layers of Complexity

HDA Guidance
Primarily focused on the manufacturer to wholesaler receiving events exceptions and exceptions identified in wholesaler operations originating from the manufacturer

- Data Issue
- Product, No Data
- Data, No Product
- Packaging & Labeling

GS1 Guidance
Focused on applying standardization to the exceptions. Genericized the shipping / receiving events encompassing both internal and external supply chain transactions (transfers and sales).

- Sales & Transfer Transactions
- GS1 & HDA Alignment
- All SC Trading Partners

Additional Considerations
Ensuring an ATPs internal and external SC exceptions are addressed. Focused on shipment transactions and "internal" operations (i.e. manufacturing, CMO, distribution, 3PL, etc.).

- Sales & Transfer Transactions
- "Internal" Operations
- Verifications & Investigations
- Includes Alignment to GS1 & HDA
- All SC Trading Partners

- **Operational and technical errors existed pre-serialization**

- **Pre-serialization errors and handling procedures often will need serialized correction**

- **Transaction exchange is now much more granular giving orders of magnitude more chance of exceptions**

- **Existing P&P are not set up for a serialized world**

Approach to Exceptions

Avoidance is the best way to **minimize exception handling** by ensuring **operational accuracy** and **data accuracy**. Exception handling will still significantly exist.

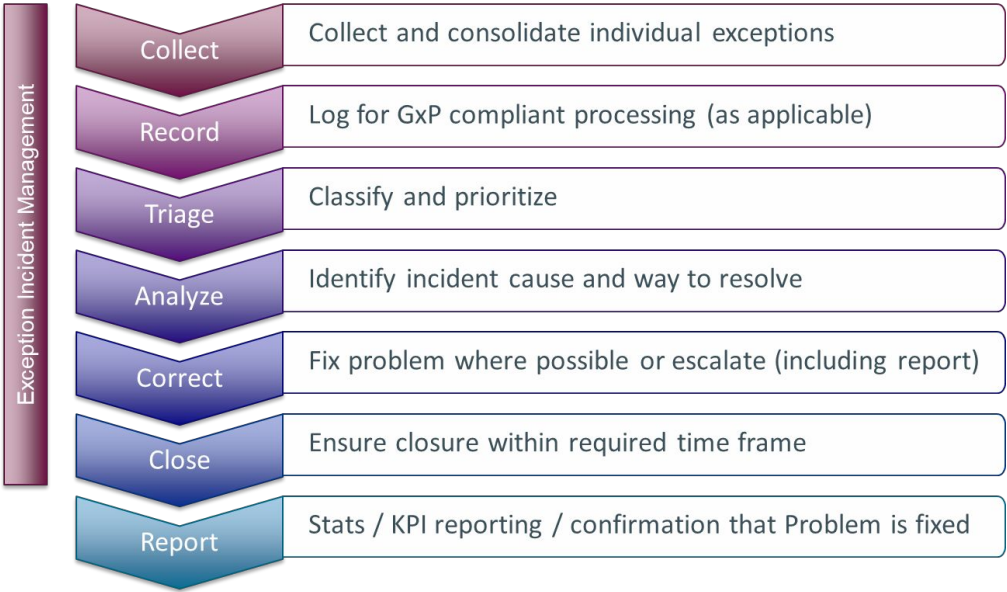**Strategy, Playbook, SOP(s), WI, & Library**

Sample MGF Playbook Metrics

- (5) Business Ares (BA)
- (25) KBEs
- (71) Exception Scenarios
- (160) Incident Causes
- (4) Corrective Types
- (393) Corrective Options
- (1704) Corrective Option Steps

Note: Varies based role & SC model

Resolution & Management Processes

Exception Incident Management

Step	Description
Collect	Collect and consolidate individual exceptions
Record	Log for GxP compliant processing (as applicable)
Triage	Classify and prioritize
Analyze	Identify incident cause and way to resolve
Correct	Fix problem where possible or escalate (including report)
Close	Ensure closure within required time frame
Report	Stats / KPI reporting / confirmation that Problem is fixed

Business Area (BA) → Key Business Event (KBE) → Exception Scenario → Incident Cause → Corrective Types & Options → Corrective Option Steps

Implementation to Sustainability

- Implementation support from strategy / plan to execution
- Partner alignments (CMOs, 3PLs, Suppliers, Customers, etc)
- Education and training
- Ongoing Service Bureau services (technical issues, issue record, issue management, etc.)