



UNIFYING SUPPLY CHAINS IN LIFE SCIENCES COMPLIANCE & BEYOND

Our executive team is comprised of experts with over 25 years experience implementing project management and business minded solutions for the pharmaceutical, financial, supply chain management and health sciences industries.

FOR MORE INFORMATION. CONTACT US

 1 W. Monroe, 4th Flr
Chicago, IL 60603

 312.880.9815

 info@tencountconsulting.com
www.tencountconsulting.com

ABOUT US

Ten Counts Consulting was Founded in Chicago in 2013 for the supply chain and life sciences industry. We focus on serialization compliance readiness and traceability systems. Our expertise in project management, supply chains and innovations helps push our clients ahead of the compliance curve. We believe strongly in community engagement and social responsibility - a bedrock of our founding principles.

Ten Count Consulting is a trusted partner of the Fortune 500 in health and pharmaceutical supply chain technologies and socially responsible project management. We have helped some of the most innovative companies in the world solve their most pressing Rx and serialization supply chain needs. We partner with clients to architect compliant DSCSA product traceability systems with the power to innovate and increase return on investment. We help turn track and trace compliant data into "smart data" to inform future decision making.

CAN YOU ANSWER "YES" TO THE FOLLOWING?

- 1 Are you confident your organization is fully ready and aware of all FDA/ DSCSA guidelines?
- 2 Do you have processes and tools in place to support planned and unplanned federal or state audits?
- 3 Is your equipment integrated to accept or ship DSCSA compliant 2D barcodes and data?
- 4 Do you need to select and implement a product traceability system?
- 5 Are you ready to meet or support trading partners in 2019 DSCSA saleable returns verification?

• LEADERSHIP LEVEL SERVICES

Gain an interim or full time leader to manage packaging line conversions, integration downstream to 3PL, optimal serialization systems, and compliance oversight.

• DSCSA TRAINING

Arm your employees with training on applicable FDA, GS1, HDA guidance, data retention, saleable returns, and unplanned audits.

• BARCODE IMPLEMENTATION

Stay compliant with 2D barcodes that meet FDA/GS1 guidelines while maintaining proper 4 AI's and T3 practices.

• DISPENSER READINESS

We prepare hospital and dispensers for their upcoming 2020 DSCSA roles and responsibilities and help put in place processes to efficiently manage their serialization systems.

THE TEN COUNT WAY

APPROACH & INSIGHTS

We use holistic systems and risk management thinking to orchestrate track and trace solutions across the Rx serialization supply chain ecosystem.



PROJECT MANAGEMENT

PMO development, conduct analysis, review tools, structure & methods, develop strategy, workshop & meeting facilitation, risk management, status reporting



ONBOARDING

Internal education and establishment of cross functional serialization team, create integration strategy



B2B INTEGRATION

Configuration and trading partner testing for interoperability of systems (Including ASN & EPCIS Data), support vendor selection, procurement, and deployment implementation



REGULATORY MONITORING

Monitoring of physical and virtual systems to ensure continuity and compliance of environments, data, and audit readiness.

WHY CHOOSE TEN COUNT

We know this is a challenging time for many life science companies in feeling confident they are fully ready and aware of all guidance and standards, but it doesn't have to be. Our DSCSA readiness assessment evaluates supply chain and track trace programs to identify any gaps in order to ensure readiness for FDA DSCSA deadlines. We help:

- Organizational understanding of DSCSA roles and responsibilities
- Alignment with FDA, GS1 and HDA guidances and specifications
- Processes required to support planned or unplanned FDA or OIG audits
- Barcode serialization and artwork grading
- Data retention and quarantine policies
- Barcode scanning and data compliance
- Serialization systems and equipment benchmarking
- Identification of future value beyond compliance (ROI Opportunities)

”

“Today, generics account for 90 percent. Supply chains have also expanded globally. This has created new complexities, and new opportunities for novel risks. Our program has evolved to meet these new challenges, and we continue to implement policy measures to address emerging threats.”

FDA Commissioner Scott Gottlieb¹

¹ Source: FiercePharma: [Hyperlink](#)

INDUSTRY FEEDBACK

Jeff Uligan, Site Head Distribution, Genentech:

"We've had the opportunity for Mark to contribute to our serialization journey for a number of years. Three words describe working with Mark: Professional, Collaborative and Delivers."

Jeff Denton Sr. Director Global Supply Chain, Amerisource Bergen:

"Mark is a true professional with a strong ability to work through difficult issues on the table and especially between different parties. Couple this with his broad knowledge of the pharma industry, this makes him a real valued partner"

Josh Clark, Sr. Program Manager Logistics, Genentech:

"Mark and Ten Count Consulting support your company's DSCSA needs. It's never too early to start thinking about 2023 interoperability!"

WORLD DRUG SUPPLY

↑ **75%** 
Governed by Track n Trace in 2019
R&D Mag

Countries adopting

40

TRACK N TRACE
LAWS

Sign up for updates
www.tencountsconsulting.com

© Copyright 2019 Ten Counts Consulting. The information contained herein is subject to change without notice.