

# Managing the Drug Supply Chain

## Best Practices

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<b>Appendices (can be found on the CD in the back of this report)</b>	
A. 21 CFR Part 210	
B. 21 CFR Part 211	
C. Contract Manufacturing Arrangements for Drugs: Quality Agreements (FDA draft guidance)	
D. ICH Q7: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients	
E. ICH Q9: Quality Risk Management	
F. ICH Q10: Pharmaceutical Quality Systems	
G. EU GMP Guide, Volume 4, Chapter 7: Outsourced Activities	
H. Drug Supply Chain Security Act	
I. DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information (FDA draft guidance)	
J. DSCSA Implementation: Product Tracing Requirements – Compliance Policy (FDA guidance)	
K. DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy (FDA guidance)	
L. Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages (FDA guidance)	
M. Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification	