The Drug Supply Chain Security Act Explained: Second Edition, Plus Explanations Of Key FDA DSCSA Guidances

Dirk Rodgers
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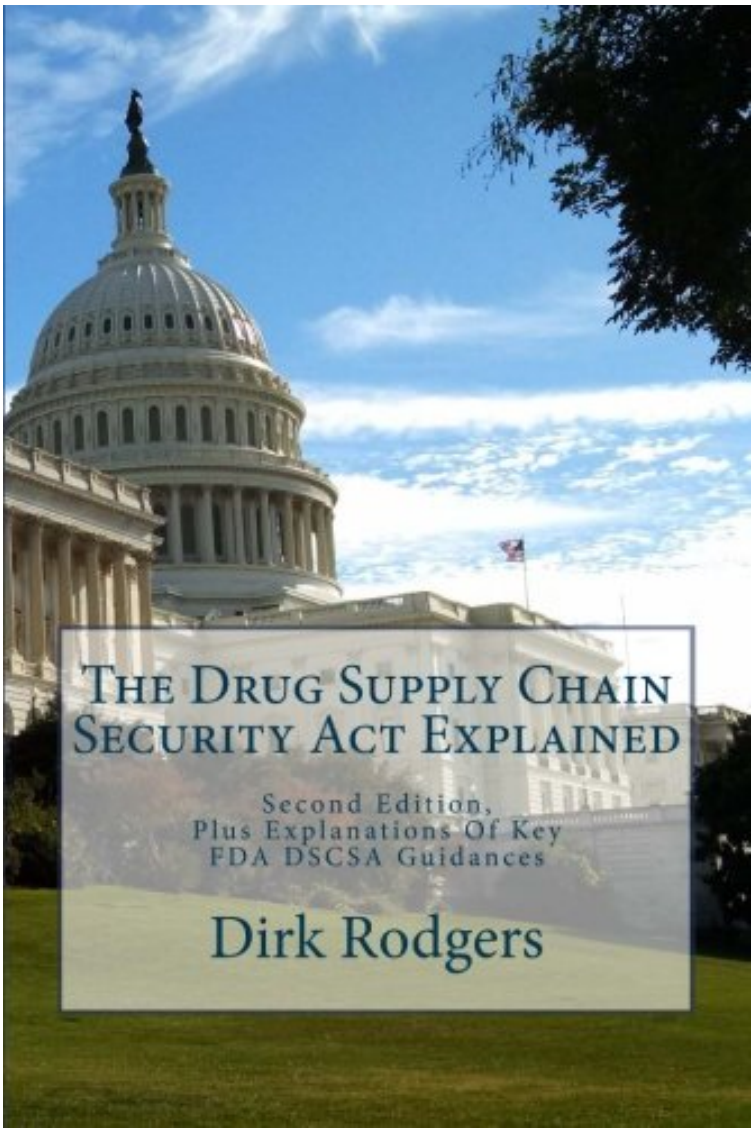

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Dirk Rodgers : The Drug Supply Chain Security Act Explained: Second Edition, Plus Explanations Of Key FDA DSCSA Guidances before purchasing it in order to gage whether or not it would be worth my time, and all praised The Drug Supply Chain Security Act Explained: Second Edition, Plus Explanations Of Key FDA DSCSA

Guidances:

The Drug Supply Chain Security Act (DSCSA) was passed by Congress in the fall of 2013 and signed into law by President Barack Obama on November 27, 2013. The DSCSA was Title II of the Drug Quality and Security Act (DQSA). The law establishes new requirements that must be administered by the Food and Drug Administration (FDA). These requirements escalate over time from 2015 through 2023 in a series of stages. They include lot-based tracing of prescription pharmaceuticals from the manufacturer to the dispenser from 2015 through 2023 and serialization-based tracing after 2023. Drug manufacturers must apply unique identifiers on all prescription drug packages by November 2017 and repackagers, wholesale distributors and dispensers must begin to buy and sell products marked with those identifiers by November of 2018, 2019 and 2020 respectively. This book explains the DSCSA, section by section, so that drug manufacturers, repackagers, wholesale distributors, dispensers, contract partners (CMOs, CPOs, 3PLs), solution providers, consultants, law firms, regulators and students can understand the text, the meaning and the significance of the law. The book also includes more than two dozen of the most informative RxTrace essays about various aspects of the DSCSA. These essays, by Dirk Rodgers, help to expose the implications of the law and provide the context necessary to understand its full impact on companies in the supply chain. In these essays, the latest FDA guidance related to the DSCSA, as of book publication, are explained. Praise for The Drug Supply Chain Security Act Explained, Second Edition: "Dirk Rodgers has an unparalleled knowledge of federal track and trace legislation. This book is essential reading for anyone who wants to understand and benefit from coming changes to the pharmaceutical supply chain." -- Adam J. Fein, Ph.D., president, Pembroke Consulting, Inc., and CEO, Drug Channels Institute Through RxTrace, Dirk Rodgers has provided stakeholders valuable insights on DSCSA. As DSCSA has evolved, his questions and opinions have helped all the stakeholders understand compliance. Dirks new book brings years of wisdom from RxTrace and more together in one volume." -- Napoleon Monroe, Managing Director, New Directions Technology Consulting, LLC As dispensers entrusted with the last encounter for patient safety, it is important to have a venue for discussion on DSCSA implementation challenges amongst trading partners. In this book, Dirk provides his experience as a resource for companies to use to create solutions. -- Chris Chandler, PharmD, VP of USDM Healthcare

About the AuthorDirk Rodgers is an regulatory strategist and founder of RxTrace.com where he writes regularly in an exploration of the intersection between the pharmaceutical supply chain, track and trace technology, standards and regulatory compliance. He has posted over 350 essays on these specific topics. A logical thinker, Dirk is skilled at making complex technical topics understandable to non-technical readers and listeners. An Electrical and Computer Engineer by education, Dirk has worked as a consultant, software architect and automation engineer during a career spanning 30 years. In 2002 he became employed by Cardinal Health, one of the big 3 U.S. drug distributors, where he studied many approaches to applying serialization and track trace technology to solve supply chain integrity problems and improve supply chain efficiencies at the same time. In 2003 he represented Cardinal Health on Accenture's seminal Jumpstart project, an early pharmaceutical supply chain RFID pilot. Dirk has served on HDMA, NCPDP, EPCglobal, GS1 and GS1 US technical and standards work groups. He served as co-chair of the GS1 EPCglobal Drug Pedigree Messaging (DPMS) work group and the GS1 Network Centric ePedigree (NCeP) work group, among others. Overall, Dirk's thought leadership has helped to expose hidden complexities and reveal surprising consequences and implications of drug serialization and pedigree laws.