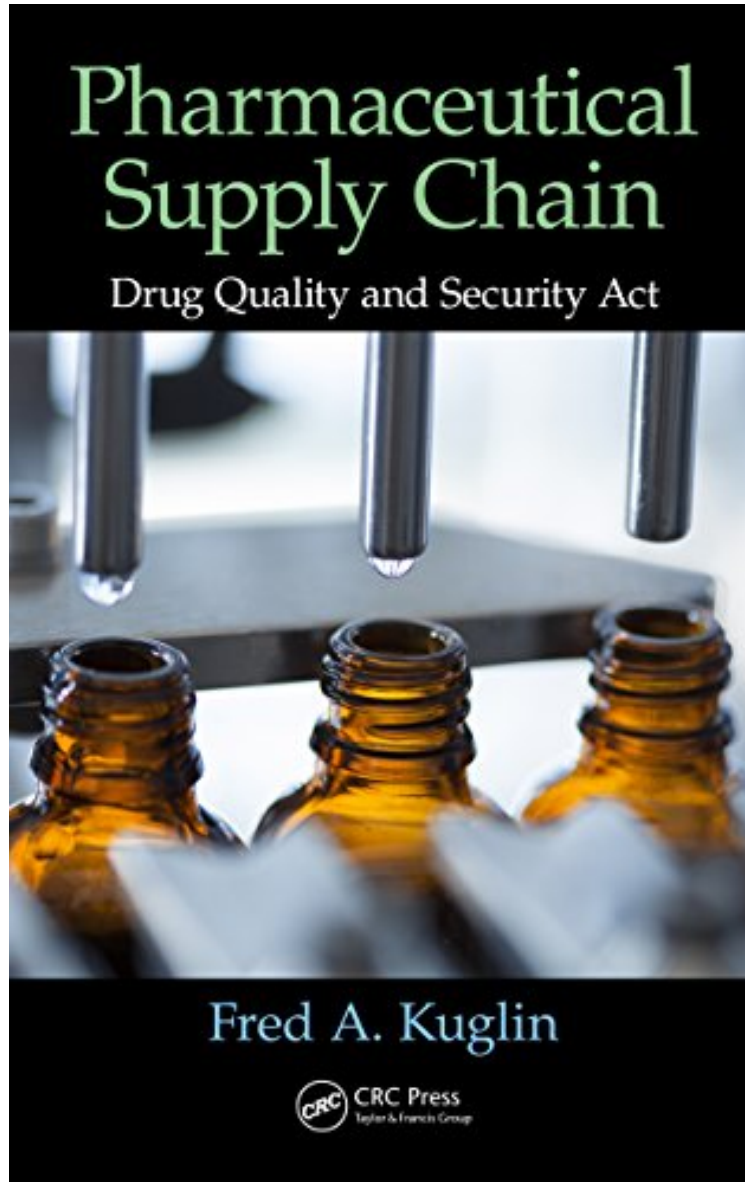


Pharmaceutical Supply Chain: Drug Quality and Security Act

Fred A. Kuglin

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Fred A. Kuglin : Pharmaceutical Supply Chain: Drug Quality and Security Act before purchasing it in order to gauge whether or not it would be worth my time, and all praised Pharmaceutical Supply Chain: Drug Quality and Security Act:

Error-proofing in the production process of pharmaceuticals isn't just a matter of good business, it has life-and-

death implications for consumers. To that end, the 2013 Drug Quality and Security Act in large part requires new mandates on tracking and tracing chain of custody in the supply chain. *Pharmaceutical Supply Chain: Drug Quality and Security Act* overviews the new mandate and its implications, including implementation strategies for track-and-trace programs along with presenting a fuller understanding of the mechanics of intergovernmental policies and oversights. The book focuses on the delicate balance between protecting the public through legislation against negligent compounding pharmacies and protecting patients by assuring a supply of needed compounded drugs by not over-regulating the industry. The author discusses lessons learned from the earlier e-pedigree initiatives, the technology advances that enable supply chain security, and how the industry will need to respond to the myriad of threats facing the pharmaceutical drug supply chain and comply with this act. He goes in depth into each segment of the pharmaceutical drug supply chain, describing the industry segment and how it will need to adapt to the new act. By incorporating real-world examples of industry leaders, the book underlines the contributions of individuals who have made a difference through innovations and execution. It also addresses how laws are made, and specifically how the Drug Quality and Security Act was passed by Congress and signed into law. In an industry that is so big, you may feel that you cannot make a difference. This book provides you with key insights on how the forward supply chain process should work and how anyone can make a difference at all levels.

About the Author Karl F. Kuglin is a professional services consultant with Ernst Young LLP in the EY Life Sciences industry group. He helps pharmaceutical companies to adapt and lead change to the industry, including emerging science, new products and services, shifting demographics, evolving regulations (such as the Drug Quality and Security Act), transforming business models, and increased stakeholder expectations. Kuglin has operational leadership experience with one of the leading return logistics companies in the pharmaceutical industry. This experience includes an in-depth knowledge of the regulations governing pharmaceutical drugs (including controlled substances). He led a team responsible for the receipt, processing, return to manufacturer, and destruction of returned pharmaceutical drugs, and the accuracy of the application for credit allowances to pharmaceutical manufacturers. His contribution to Chapter 7, "When Things Go Bump in the Night: Reverse Logistics," was invaluable. Kuglin is a graduate of Indiana University with a major in business administration.