



# U.S. Drug Supply Chain Security Act (DSCSA) compliance assessment



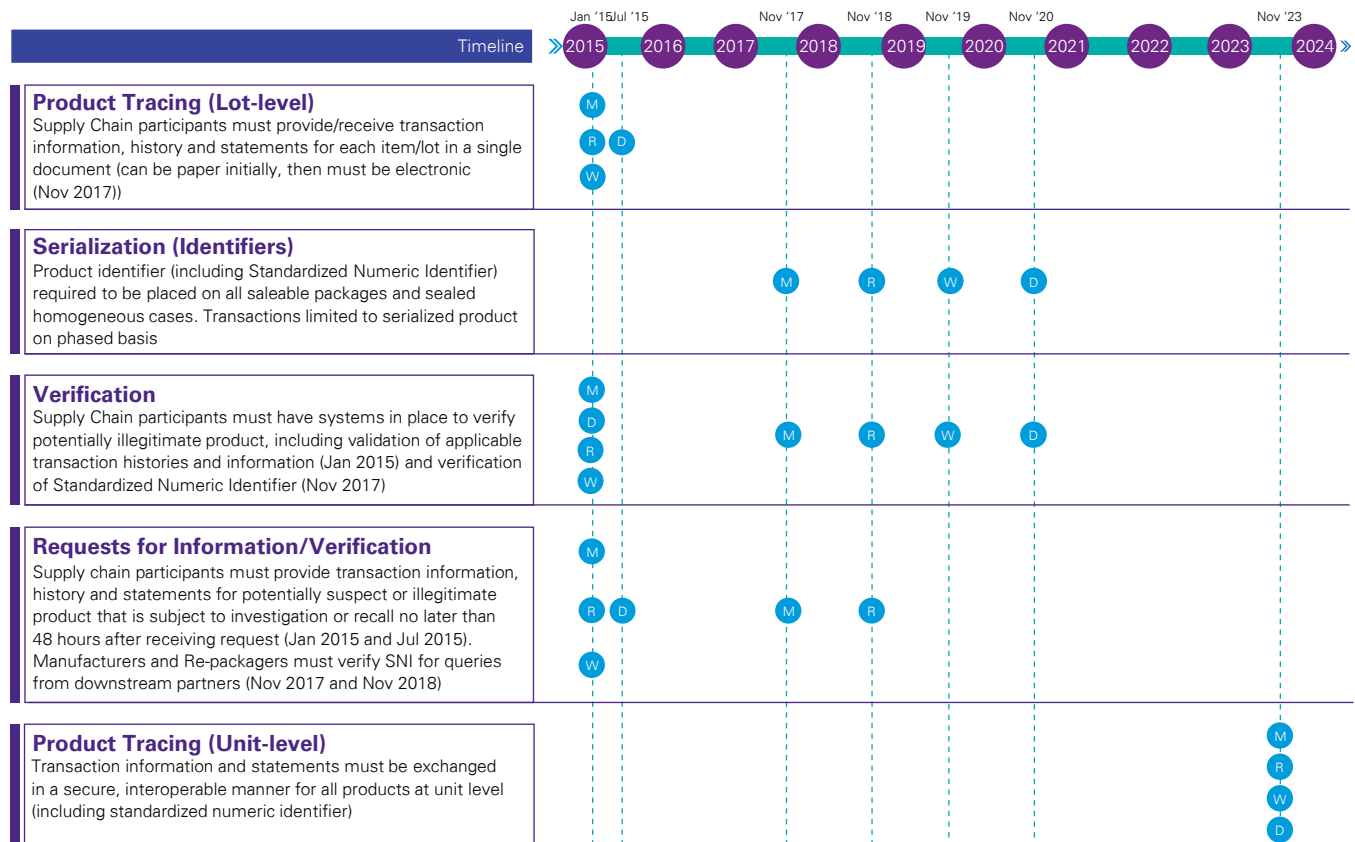
The Drug Quality and Security Act (DQSA) was signed into law on November 27, 2013. Under Title II of this Act, known as the Drug Supply Chain Security Act (DSCSA), a set of requirements and phased compliance dates have been established for prescription drug manufacturers and other participants in the distribution chain. The first major compliance milestone was January 1, 2015.

Upcoming compliance due dates (with deferred enforcement) are in play for saleable returns verification and ultimately for inter-operable exchange of serialization data when product ownership changes.

## Can you confidently answer “Yes” to the following questions?

1. Are all of the applicable requirements of the DSCSA understood within your organization?
2. Have impacted roles and processes been assessed and supporting policies & procedures updated?
3. Have impacted resources been identified and trained on changes to processes and systems?
4. Has appropriate technology been deployed and qualified to support on-going execution activities?
5. Is your organization adopting leading industry practices to meet both regulatory and trading partner requirements?

## DSCSA Timeline of summarized requirements



Legend: M Manufacturer R Re-packagers W Wholesalers (Distributors) D Dispensers

KPMG has developed a compliance assessment toolkit and methodology for pharmaceutical manufacturers tailored to the U.S. DSCSA requirements.

Our approach helps life science companies by:

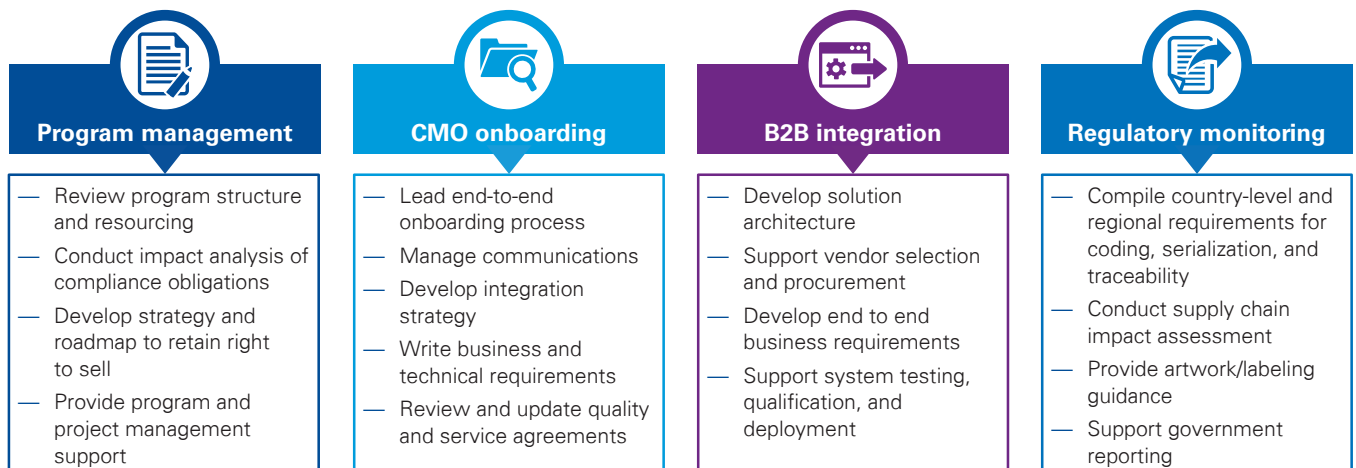
- Assessing the organization's current & future compliance status & readiness
- Identifying gaps across people/process/technology dimensions
- Providing recommendations to address gaps and to adopt leading industry practices in addition to offering other strategic considerations that leverage serialization data

## KPMG assessment approach



Assessment durations vary. Typical length ranges from 8-12 weeks and can be conducted virtually

## Our approach leverages experience gained leading and supporting serialization programs



## Contact us

### David Colombo

Advisory Director, KPMG LLP T:

317-650-0800

E: davidcolombo@kpmg.com

### Sarath Ramakrishnan

Advisory Director, KPMG LLP

T: 217-721-5371

E: sramakrishnan@kpmg.com

### Rajesh Misra

Advisory Principal, KPMG LLP

T: 781-856-8176

E: rkmisra@kpmg.com

### KPMG insight

The KPMG knowledge base of articles and publications demonstrates our understanding of the complex business challenges faced by companies around the world.

Check out our thought leadership at <https://institutes.kpmg.us>

\*Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates.

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

© 2020 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. Printed in the U.S.A. The KPMG name and logo are registered trademarks or trademarks of KPMG International. NDPPS 705476

[kpmg.com/socialmedia](https://kpmg.com/socialmedia)

