



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



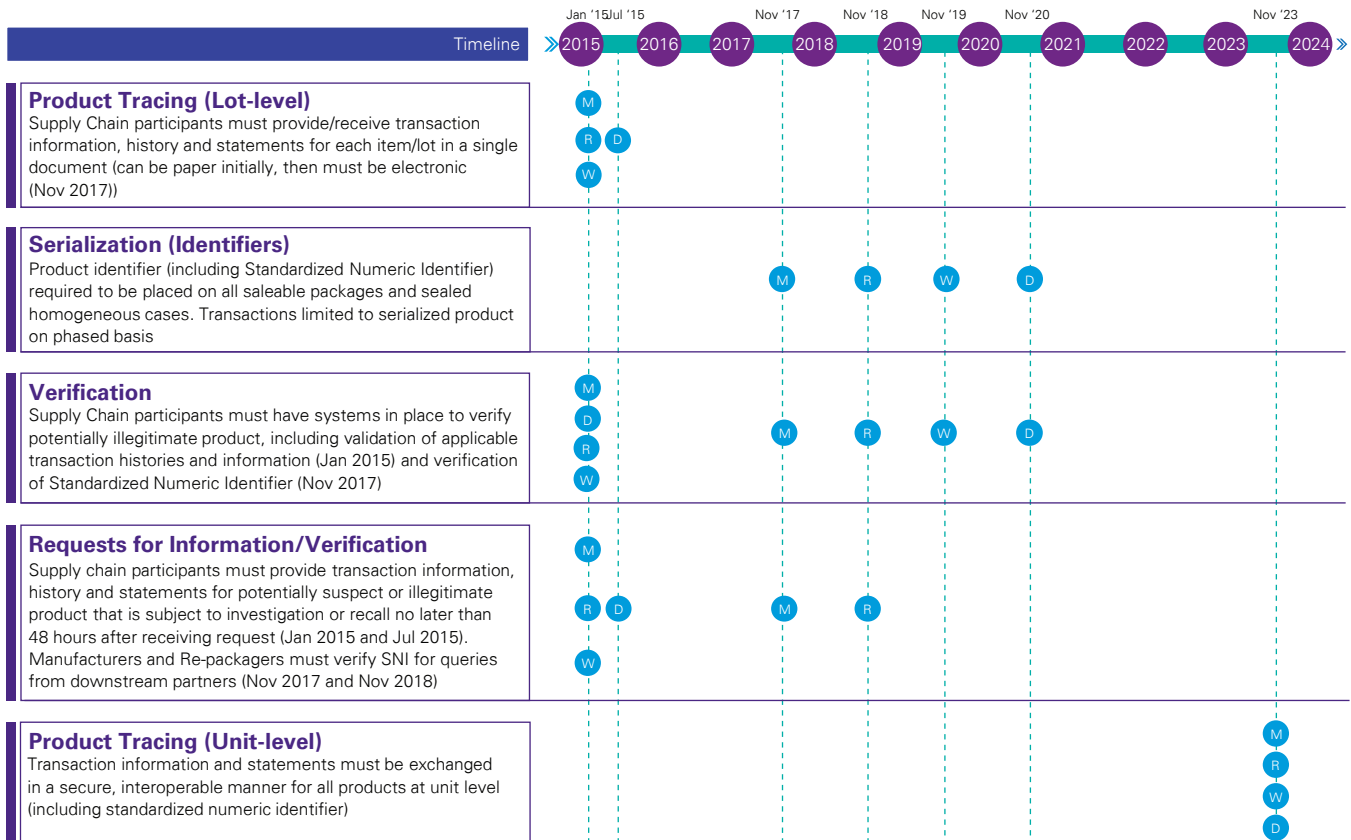
The Drug Quality and Security Act (DQSA) was signed into law on November 27, 2013. Under Title II of this Act, known as the Drug Supply Chain Security Act (DSCSA), a set of requirements and phased compliance dates have been established for prescription drug manufacturers and other participants in the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

The most recent compliance due date was November 27, 2017 when product serialization and enhanced verification processes go into effect. This is a significant compliance milestone and enabler for the next series of requirements.

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:

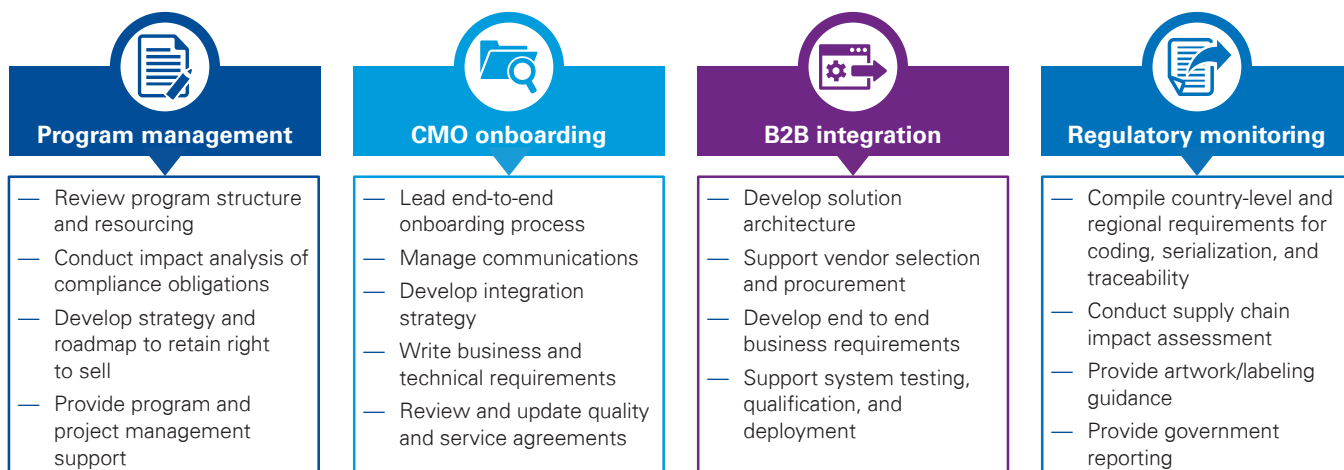
- Assessing the organization's current & future compliance status & readiness
- Identifying gaps across people/process/technology dimensions
- Providing recommendations to address gaps and to adopt leading industry practices

KPMG assessment approach



Assessment duration is typically 4–6 weeks

Our approach leverages experience gained leading and supporting serialization programs



<https://www.kpmg.com/us/traceability>

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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>

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