



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



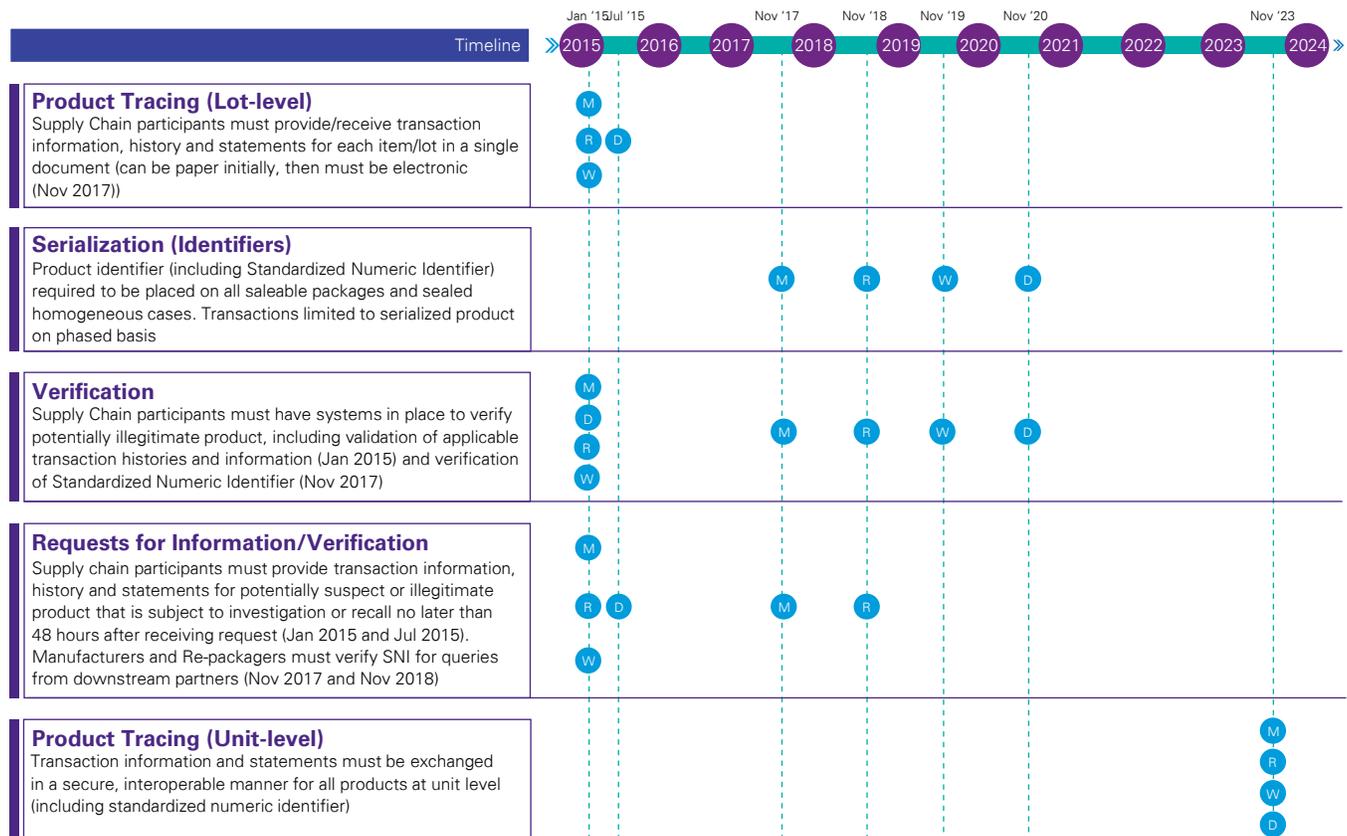
The Drug Quality and Security Act (DQSA) was signed into law on November 27, 2013. Under Title II of this Act, known as the Drug Supply Chain Security Act (DSCSA), a set of requirements and phased compliance dates have been established for prescription drug manufacturers and other participants in the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

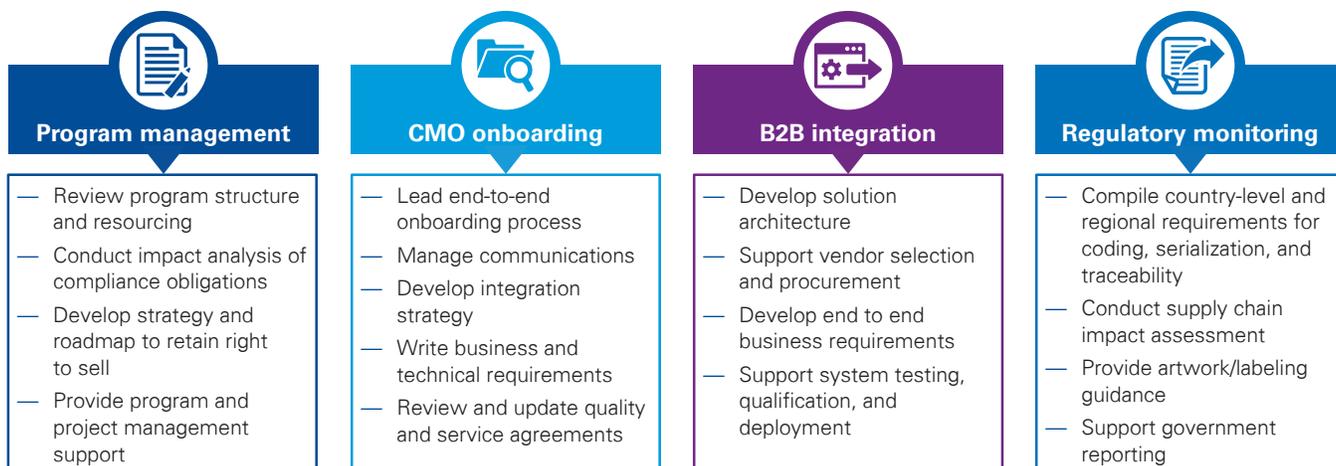
- Assessing the organization's current & future compliance status & readiness
- Identifying gaps across people/process/technology dimensions
- Providing recommendations to address gaps and to adopt leading industry practices in addition to offering other strategic considerations that leverage serialization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

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