DQSA Track & Trace

Upcoming Changes to DQSA Requirements: What You Need to Know to Stay Compliant

Justin Hester| February 21 & 22, 2023

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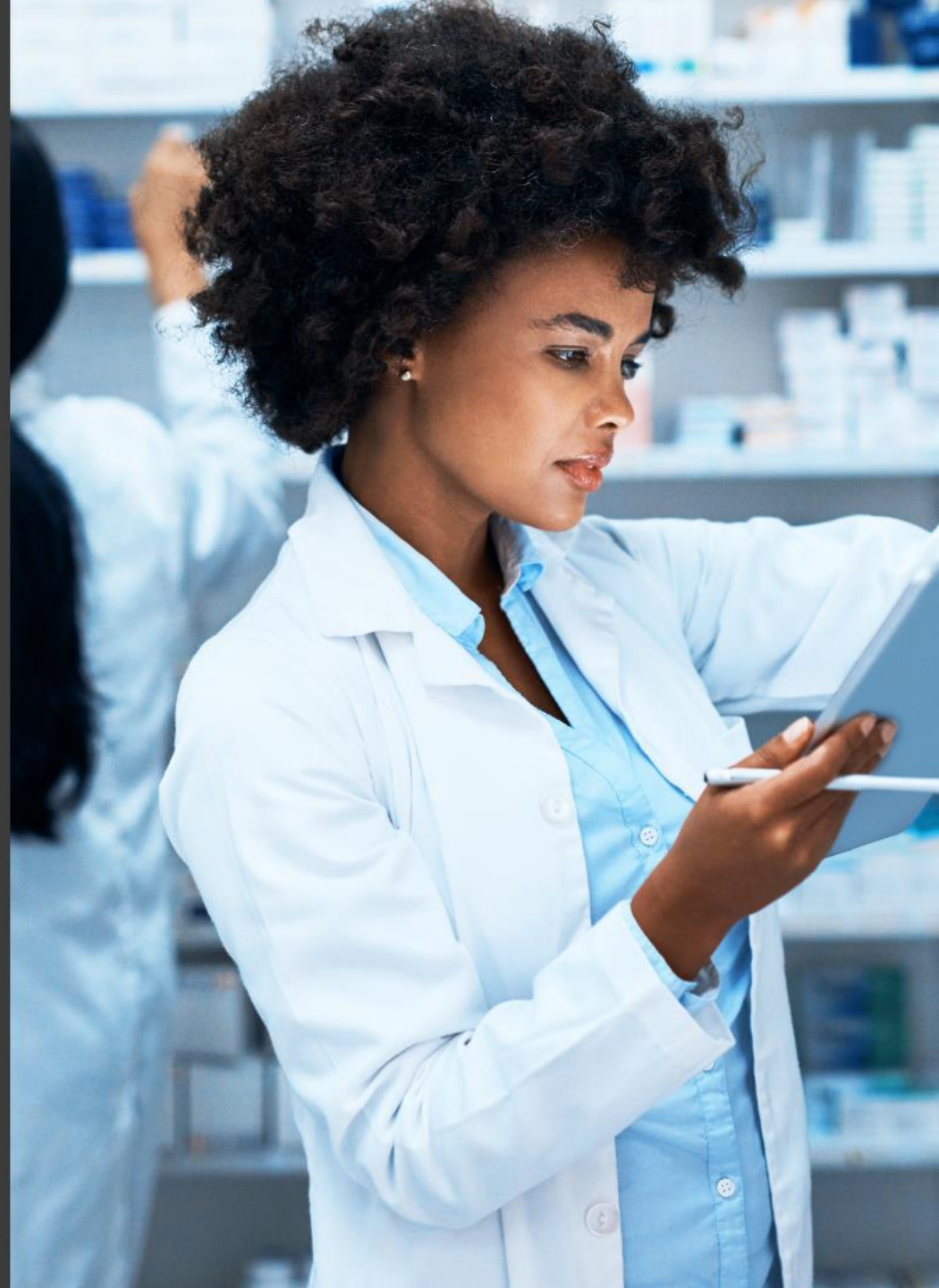
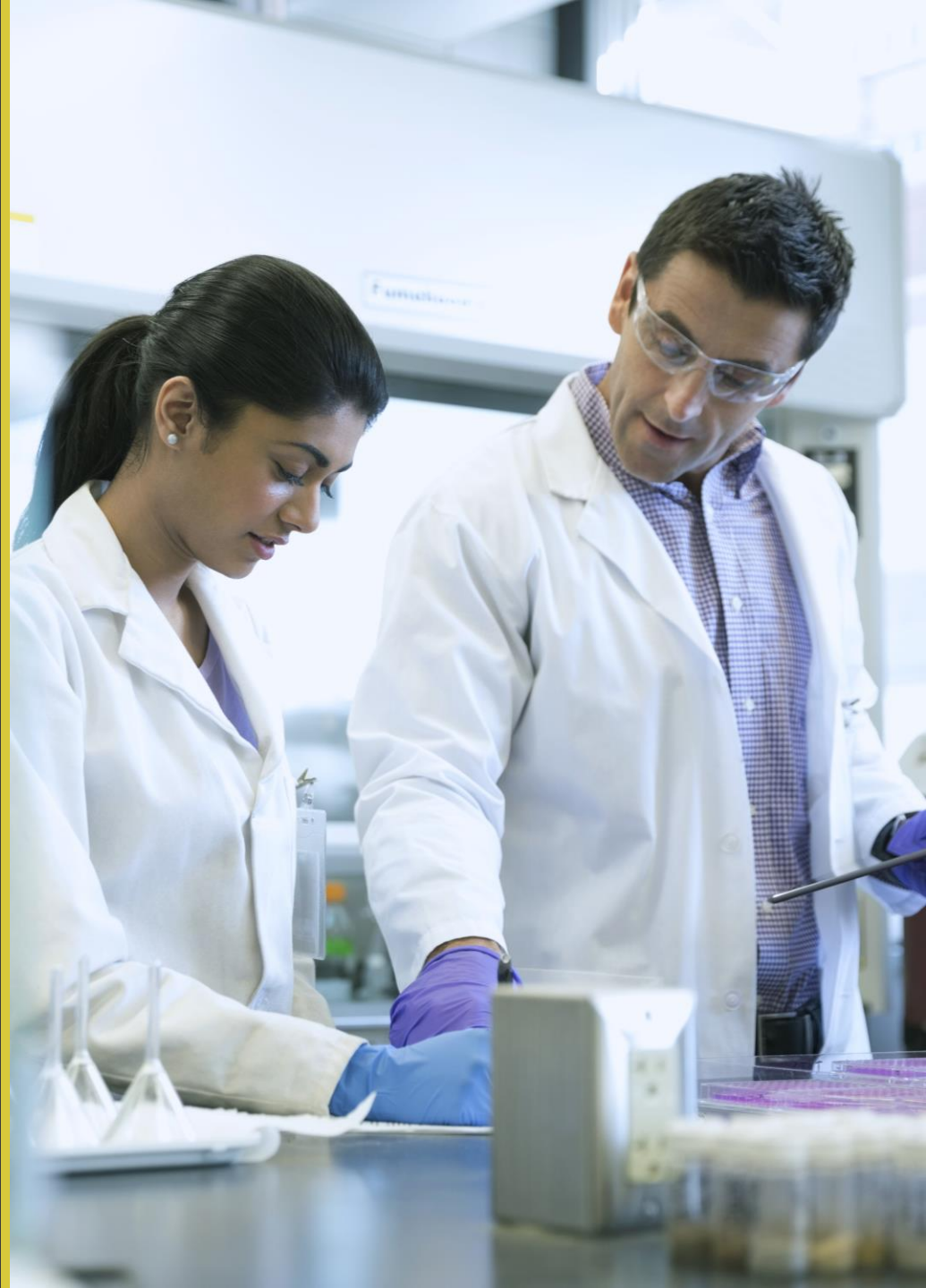
Agenda

- Enhanced Requirements starting November 27, 2023
- What this means for Pharmacies and Buyers
- EPCIS and Serialized data
- Tools used to manage the new Serialized data
- What steps hospitals should take today
- Resources Available



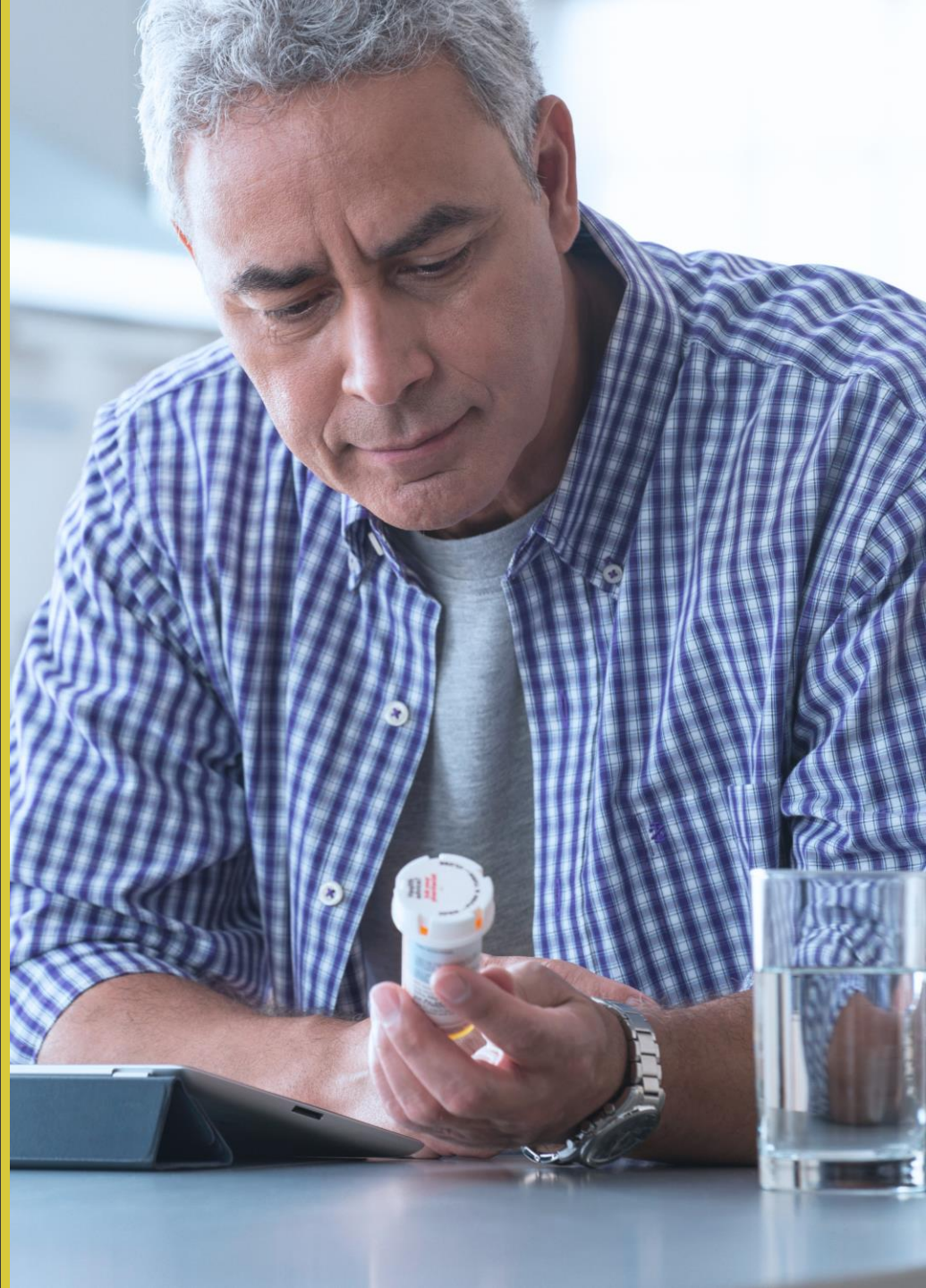
Enhanced Requirements starting November 27, 2023

- Starting November 27, 2023, the FDA will require interoperable traceability down to the Package/ Unit level.
- What this means for pharmacies is that they will need to comply with the following Enhanced Requirements:
  - **Product Exchange** - Trading partners must exchange required Transaction Information (TI) and Transaction Statements (TS) in a secure and interoperable method, and the TI must include the product identifier at the package/ unit level.
  - **Product Verification** - Trading partners must be able to verify the product identifier on a package in a secure and interoperable method - including saleable returns.
  - **Product Tracing** - Trading partners must maintain secure, interoperable systems and processes to provide TI and TS in response to a request from the FDA and be able to produce the TI for each transaction going back to the manufacturer.



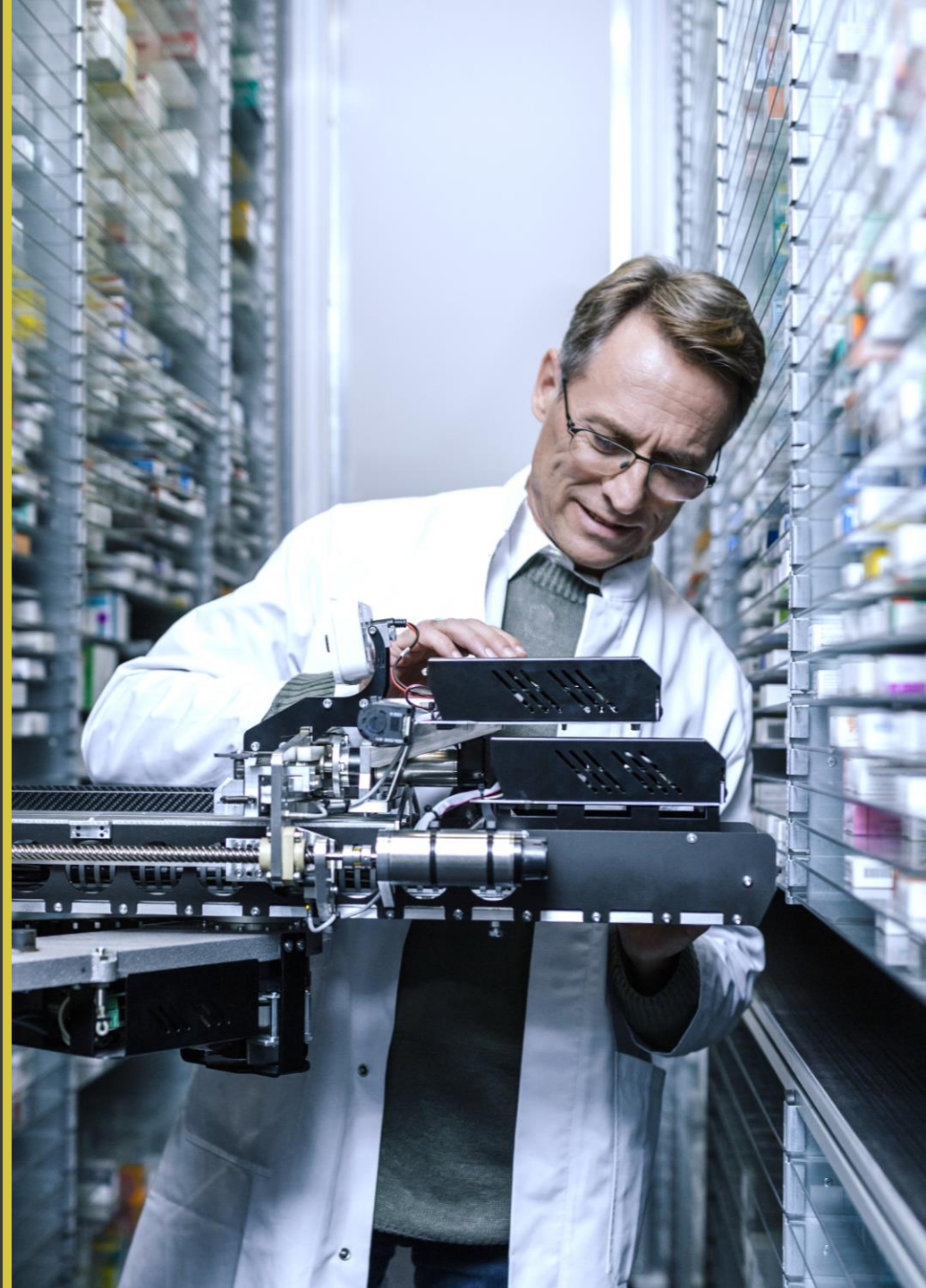
What this means for Pharmacies and Buyers

- Serialized data will need to be included in the Transaction Information that is sent with each transaction.
- Transaction data will be required for the package/ unit level (not just the lot level).
- DQSA requires electronic and automated package-level verification by dispensers. However, dispensers are not required to scan or confirm each individual package. It is anticipated that the electronic verification will be captured using aggregation.
- Dispensers will also need to provide TI and TS data for any products that are saleable returns.



EPCIS and Serialized data

- EPCIS is the data set used to send the TI in an interoperable method
- This EPCIS data will flow from supplies and wholesalers through aggregators to then be distributed to the Buyers
- These aggregators will use a Global Location Number (GLN) to identify buyers and route appropriate TI from the suppliers and wholesalers
- All products will be required to have serialized data to show TI and TS



Tools used to manage the new Serialized data

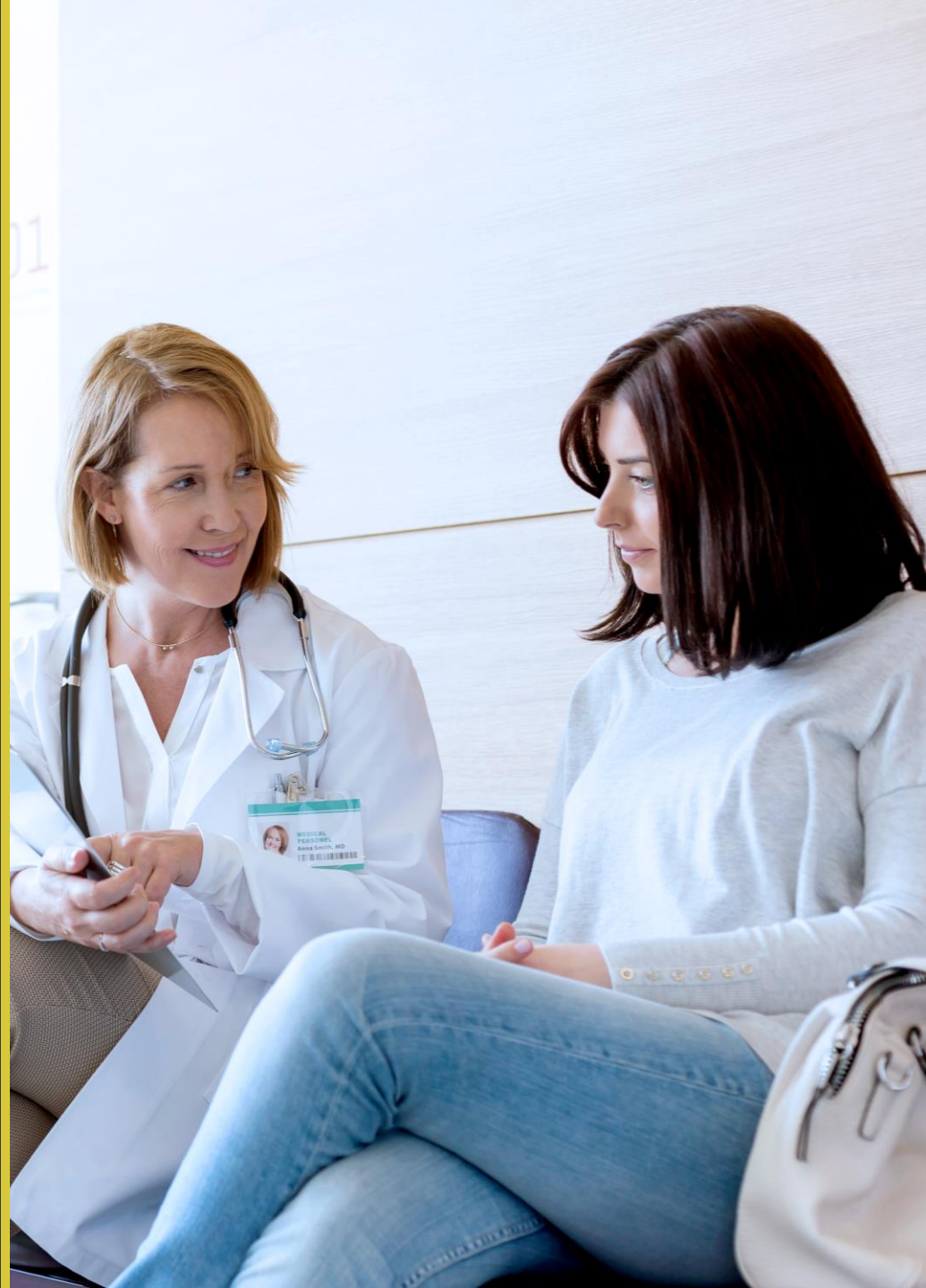
- Mobile Scanning Application
- 2D Barcode scanning capabilities
- Recall Management tools
- **

What steps hospitals should take today

- Contact your wholesaler, GPO or GS1 to obtain GLN registration information for all pharmacy locations.
- Contact your primary distributor and direct suppliers and obtain information regarding their 2023 plans to provide enhanced product tracing data (EPCIS-level data).

Available Resources

- **Title II of DQSA:** https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act
- **GS1 Website on How to Obtain GLN:** https://www.gs1us.org/industries-and-insights/standards/global-location-number/get-a-global-location-number
- **Cervey Support Email:** trackandtracesupport@cervey.com
- Download today's presentation here: https://go.cervey.com/***



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THANK YOU!