

Some potential questions an inspector (e.g., FDA, state board, PBM) might ask You.

- Show me your DSCSA SOPs.

- How do you check that your suppliers are licensed?

- How often do you check that your suppliers are licensed?

- Tell me / show me how you know you received all of the product identifier information (NDC, lot #, exp. date, serial #) for a specific order.

- Tell me / show me how you check that the lot #, exp. date, serial # on a drug matches the data the supplier provided (this is often referred to as Reconciliation).

- Tell me / show me what you do when some part of the lot #, exp. date, serial # information the supplier provided doesn't match the physical products you received.

- Tell me / show me your process for deciding if you can give a patient a drug that you do not have the product identifier information (NDC, lot #, exp. date, serial #) for.

- Tell me what is a Product Identifier (PI) Verification?

- Tell me / show me how you do a Product Identifier (PI) Verification.

- Tell me where you got a specific NDC / serial # from (they'll point to a drug on the shelf and ask: "where did you get it").

- Show me from where you obtained a drug.

- Tell me / show me how you will provide ownership information about a specific NDC / serial # (Tracing).

- Tell me / show me how you determine if a drug is suspect or illegitimate.

- Tell me / show me how you document an investigation of a suspect drug.

- Tell me / show me how you can identify if a drug has been recalled.

- Tell me / show me how you document where a drug has been returned to (for saleable returns and recalls).

- Tell me / show me your documentation that a supplier is licensed

- Tell me / show me how you document the wasting of a drug (by serial #)

- Tell me / show me how you document a drug provided to another pharmacy that is not part of your organization (T2 transfer)

- If you transfer a drug to another pharmacy for a specific patient, how do you document this?

- If a transfer is not for a specific patient, how do you send the pharmacy the T2 information?

- How do you identify a suspect product?

- What is your documentation process for a suspect product investigation?

- Tell me what an FDA Form 3911 is used for?