



# Traceability Interoperability Summit

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*Making the pieces fit...*

# What does government want?

## ❑ Electronic Records

- Information available via database
- Ease in searching
  - Implies use of standards vs cross-referencing

## ❑ 24-48 hour response to inquiry

- Near to impossible without computers
- Consistency in format of response

# What does industry want?

- No added costs
- One standard
  - Number
  - Case label
  - Pallet label
- One process (not system) that everyone can use
- Interoperability between vendors/systems

# What is feasible?

- One process using:
  - Existing technologies
  - Existing information
  - Existing standard
  - Existing systems
- Immediate access to information
- Consistent reporting format
- Interoperability between vendors

# Logical Questions

❑ If FDA wants Electronic Records and 24-48 hour response time on inquiries:

1. Is needed information available on ITEM or on **CASE?**
2. How does the needed information get off of the case and into a database? **MANUALLY** or **AUTOMATICALLY?**
3. Should the industry use **BARCODES** or RFID?
4. What barcode standard should be used? **GS1**
5. What information should reside in the barcode?  
**CASE identifier + Lot/Batch #**
6. What number should be used for the CASE?  
**PROPRIETARY** or **STANDARD**