

Interoperable Tracing

PDG Blueprint

Key Terminology

Interoperable Tracing is the DSCSA 2023 requirement that trading partners maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a valid request and promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

TI Request Messages provide interoperable information about the requester, the products being traced, the circumstance of the trace, and the kind of information requested to be returned.

TI Response Messages provide interoperable information about the responder, the products traced, and trace endpoints associated with known buyers and sellers for the requester to use in the trace.

Trace Endpoints are the endpoint where TI request and response messages can be submitted, such as an email address or an OpenAPI or DIDComm endpoint.

To support a sequential request-and-response tracing model, the *Blueprint* defines a standardized protocol for requesting TI information and responding to such requests.

Why It Matters: The standardized protocol provides predictability to authorized trading partners (ATPs) and supports interoperability *between* ATPs while permitting each ATP to define its own *internal* processes.

Five Things to Know

- 1** Interoperable tracing is achieved when the ATP or regulatory authority executing the trace sequentially requests and receives relevant TI data from each of the owners of the product.
- 2** ATPs may only trace product as part of a suspect or illegitimate product investigation; regulators may trace on account of a suspect/illegitimate product investigation *or a recall*.
- 3** The *Blueprint* defines a standardized protocol (i.e., message format) for requesting TI and responding with TI to support a trace.
- 4** Each ATP will define their own internal process for evaluating requests, determining whether to respond, and collecting the data to respond.
- 5** Each ATP must determine how they will be able to provide the trace endpoint/contact for each ATP they bought from/sold to.