

[Aptar Pharma: RFID-Enabled Rigid Needle Shields for Unit Serialization & Track and Trace](#)

Today, traceability of parenteral drug products is performed at the batch level. Health and regulatory authorities are currently looking into implementing unit serialization (Policy paper on traceability of medical products, WHO, 2021) to improve traceability from production through to patients. “Individual container traceability could dramatically improve patient safety, preventing potential mix-ups, clarifying accountability, and simplifying investigations in case of deviation during fill-finish operations,” says Audrey Chardonnet, Business Director, Aptar Pharma. “Current strategies are reaching their technical limitations and new approaches must be considered to address future requirements.”

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Easy integration into
filling lines

Enables patient
safety

Most identification strategies for injectable drugs rely on physical stickers applied onto the drug container during filling, a method that Ms. Chardonnet says is hardly applicable to unit serialization. Different technologies were considered and eventually narrowed down to two options: the engraving of a 2D-matrix on the glass container or digital chips. 2D-matrices are relatively easy to engrave on the glass, but require the installation of engraving equipment – either on the filling or glass manufacturing lines – and advanced camera systems for reading the matrix. Because it is physically engraved on the glass, the matrix cannot be read through secondary packaging and requires the container to be oriented on the filling line to allow reading. Adding a digital chip to the packaging allows individual serialization and brings further benefits. Industrial implementation requires the addition of a contactless reader to identify the dose at any point during the process – even through a secondary packaging – and the tag can be edited to attach more information on-the-go.

“The idea of unit serialization is often associated with prefilled syringes (PFS),” she says. “In addition to well-documented advantages over multi-dose or single-dose vials, including ease-of-use, safety, and reduced drug wastage, unit serialization eliminates the need for a distinct injection device, thus ensuring the patient receives the dose directly from the device that carries the tag, reducing risk of mix-ups before the injection.”

Aptar Pharma’s RFID RNS is a digitally-enabled RNS that leverages RFID technology, miniaturizing and embedding it in the RNS plastic shell. This chip acts as a tag that can be read and edited at any time from the filling process to the time of injection. “The RFID RNS enables easy implementation of unit-dose “track and trace” processes on the filling lines thanks to contactless reading/editing of the RFID chip,” Ms. Chardonnet explains. The RFID RNS allows high-throughput unit identification without impacting the filling lines beyond the addition of a reader.