TraceLink Brazil Community Focuses on Updated SNCM Documentation, Customer Questions



Key Takeaways from the April 8 and April 22 Brazil Special Interest Group sessions

- As Brazil continues to focus on the Covid pandemic, ANVISA effectively suspended any discussion related to SNCM during the month of April.
- ANVISA has updated its website with a new Technical Support section that includes a guide to the SNCM reporting system and a Standards and Interfaces Manual.
- Questions persist about the reporting requirements based on percentages during the implementation phase prior to the start of the operational phase in April 2022.
- ANVISA product metadata requirements are more extensive than those of other country track and trace mandates.

ANVISA continues to postpone Normative Instruction approval

The most recent draft of the Normative Instruction for industry compliance with Brazil’s track and trace regulations was communicated by ANVISA on March 12. In early April, the major industry associations in Brazil—representing manufacturers,

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wholesalers, and dispensers— formally requested that ANVISA “suspend any discussion related to SNCM [during the Covid situation] or until normal working conditions of the industry resume.”

See the March Brazil SIG recap for an overview of the March 12 draft.

Exploring new technical documentation on the ANVISA website

ANVISA has updated its website to include an extensive standards manual for interface development and a technical guide to the government reporting system, SNCM, with a detailed breakdown of reportable events:

- Activation
- Shipping
- Receiving
- Completion
- Replacement
- Revocation

In addition, the SNCM guide confirms the 5 required elements of the *Identificador Único de Medicamento* (IUM):

- GTIN (Global Trade Item Number)
- ANVISA Registry Number
- Serial Number
- Expiry Date
- Lot Number

SIG members noted that the original 2009 requirements included reference to a Manufacturing Date on medicine packaging. However, companies that are considering whether to include Manufacturing Date should be aware that the updated guidelines do not indicate whether more than the 5 required elements are

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permitted.

Customer questions about the “Implementation Phase”

The April sessions included discussions around reporting requirements during the Implementation Phase (formerly “Assisted Implementation”), which runs from October 2021 to April 2022. Companies are expected to report 10% of their product batches from November 2021 through April 2022. However, polling indicates that SIG members have different interpretations of the requirements, with some planning to report only the 10% minimum while others would report all serialized batches. Other questions concern whether percentages are based on total batches serialized and released during the Implementation Phase, batches released monthly, or batches released during some other span of time.

A broad spectrum of product metadata

A noteworthy characteristic of the ANVISA requirements is the agency’s list of product metadata that manufacturers must submit to the SNCM portal along with their implementation and operational plans. The product metadata goes beyond standard track-and-trace applications to provide a deeper level of insight into product dosage, formulation, and other details to inform and enhance the oversight and control capabilities of the SNCM system. The SIG reviewed the product metadata fields:

- GTIN (Global Trade Item Number)
- Anatomical Therapeutic Chemical (ATC) Classification:
  - ATC/WHO (World Health Organization)
  - ATC/DDD (Defined Daily Dose)
  - ATC/EphMRA (European Pharmaceutical Market Research Association)
- Portaria 344/98 Regulatory Classification / Prescription Type
- Commercialization Start Date
- Commercialization End Date (optional)
- Commercialization End Reason (optional)

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Stay informed with TraceLink’s Brazil Special Interest Group

TraceLink's Brazil Special Interest Group will continue to be the dedicated space for TraceLink customers to share interpretations of regulatory requirements; discuss the business challenges they create and how fellow members are meeting them; and get updates on TraceLink’s track and trace solutions. TraceLink’s Brazil SIG meets every two weeks on Thursdays, with upcoming meetings on May 20, June 3, and June 17. Join the TraceLink Community.

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Brazil SIG Analyzes New Draft of ANVISA Normative Instruction, Industry Reaction

Key takeaways from TraceLink's Brazil SIG discussions regarding new provisions outlined in the March 12 draft of ANVISA's Normative Instruction.

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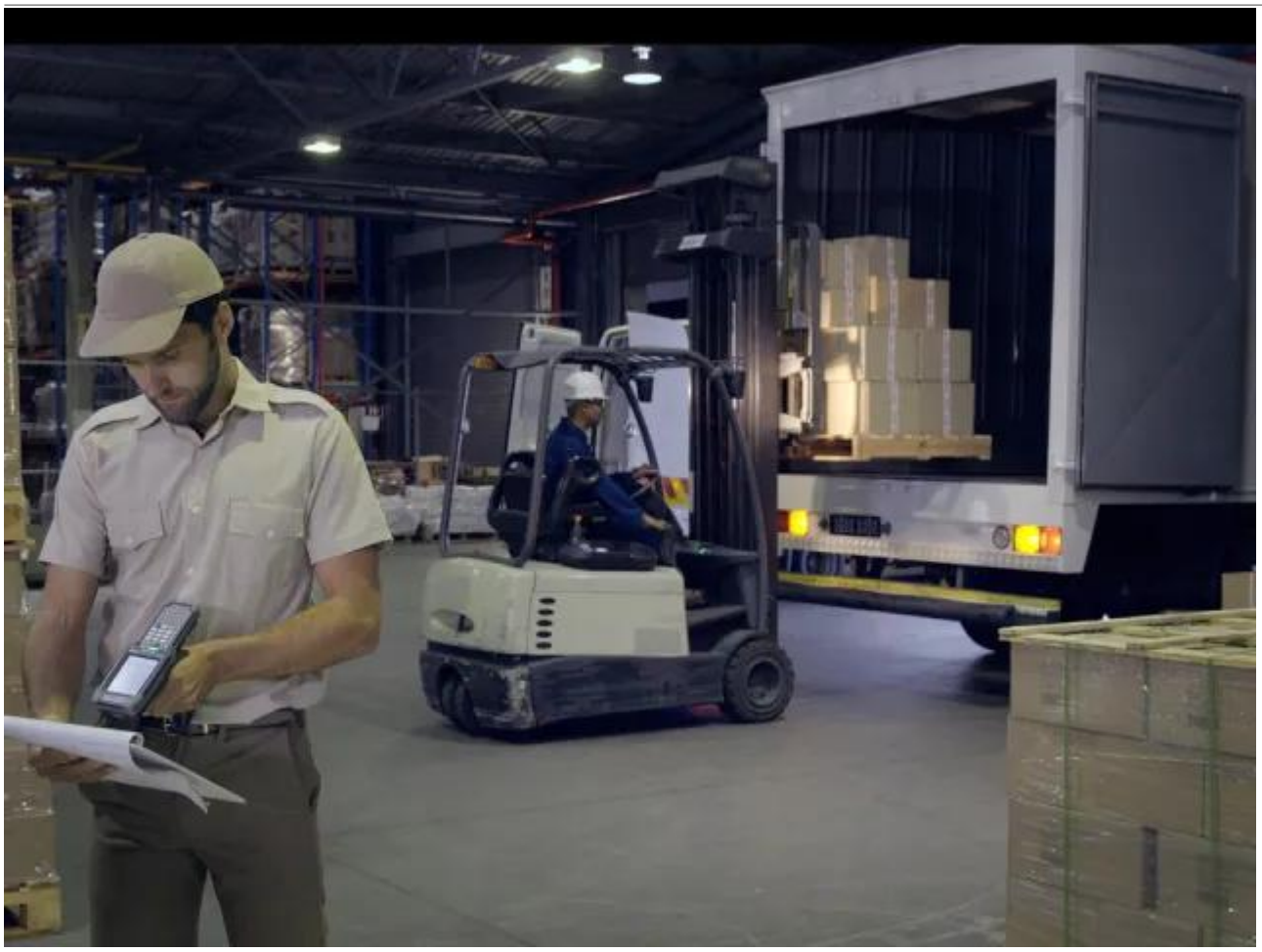
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