TraceLink Bahrain Community: Clarifying Scope, Responsibilities, and Plan of Attack



On May 20, the TraceLink Bahrain Community continued its discussions with a focus on planning and implementation over the final 4 months until the October 1 deadline.

Due to the compressed timeframe and limited number of remaining meetings, these sessions are joined by TraceLink experts focused on implementation and customer success: Business Management, Product Development, Solutions Consulting, and TraceLink's Center of Excellence and Client Partnership teams. The May 20 session addressed questions raised in the May 6 session and solicited additional member questions for follow-up in upcoming community meetings.

The majority of companies are targeting October 1. Or sooner.

When asked, "What is your company's deadline for meeting Bahrain's traceability requirements?" more than 80% cited on or before October as their target to begin reporting to the Kingdom's National Health Regulatory Authority's MVC (Medical Value Chain) Hub. In fact, the NHRA has been emphasizing the need for all companies doing business in Bahrain to connect to the MVC Hub by October 1 to avoid interruptions to their product flows.

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Invoicing Companies: Registration and reporting requirements

The NHRA has defined the “Invoicing Company” as the designated reporting entity for Bahrain compliance. In many cases, the Invoicing Company may also be the MAH, but could also be a distributor/importer. It is critical for an MAH to understand who is identified as the Invoicing Company for the purpose of serialized event reporting:

- Commissioning (Product)
- Commissioning (Logistics Unit)
- Packing
- Shipping

Attendees reviewed the scope of the regulations and the technical guidelines for manufacturers importing medicines into Bahrain, beginning with the requirements for reporting EPCIS (Electronic Product Code Information Services) events:

- EPCIS events are specified in Bahrain’s Onboarding Technical Guide and generally conform to GS1’s EPCIS R1.2 and CBV (Core Business Vocabulary) R1.2
- The shipment of imported products to Bahrain triggers reporting of commission, aggregation, and shipping events in a single EPCIS document.
- The commission and aggregation events in the EPCIS traceability document should only pertain to the serialized products included in the shipment.

The TraceLink team reminded members that *Business Entities* and *Locations* associated with a product must be registered with the GS1/United Arab Emirates BrandSync portal before traceability reports can be submitted—and that they test their BrandSync connections early to avoid the initial master data upload issues experienced by some members.

Plan of attack: Critical steps to final go-live

TraceLink’s Director of Client Partnership and Customer Success, April Fitzgerald,

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provided an overview of the “solutioning phase” in the journey to Bahrain compliance. This phase precedes final deployment of the country compliance module and comprises several critical steps that must be completed in the next 4 months:

- Engineering specification review and acceptance
- Solution development
- Customer review of solution design
- Qualification testing
- Government system connectivity testing

Representing the TraceLink Center of Excellence, Caitlin Czulada emphasized the importance of ongoing trade partner engagement during the solutioning phase, including new partner onboarding, partner system integration, and testing end-to-end reporting flows with the Bahrain test system.

Stay informed with TraceLink’s Bahrain Special Interest Group

TraceLink's Bahrain 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. To join the TraceLink Community, visit the TraceLink communication preference center:

- Select “Join the TraceLink Community” checkbox
- Once the new options appear, select the “Bahrain” check box
- Scroll to the bottom of the page and select the “Update Communication Preference” box to submit your request

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