

RESOURCES

Home Resources Resource Center

TraceLink Bahrain Community Focuses on Fast Start to Meet October Deadline



On May 6, TraceLink Community members gathered for the first Bahrain Special Group (SIG) session to help one another understand Bahrain's regulatory and legal framework for the October 1 traceability deadline. The session also covered the phased approach being taken by the Kingdom's National Health Regulatory Authority (NHRA) and the steps companies need to take now to meet the October reporting deadline.

100 days to go: A full-press team effort

Due to the compressed timeframe—fewer than 100 working days—TraceLink is supporting the effort to meet this fast-approaching deadline with experts focused on implementation and customer success: Business Management, Product Development, Solutions Consulting, and TraceLink's Center of Excellence and Client Partnership teams.

The Bahrain SIG is a forum where TraceLink customers can meet, ask questions, and get expert perspectives on the challenges they face in meeting the Bahrain track-and-trace mandate—and to stay up to date on what is expected to be an evolving regulatory landscape in the Kingdom. As the deadline draws closer, the SIG will transition to a Bahrain Product Innovation Forum to provide regular updates on TraceLink's product features and capabilities and solicit customer input



on addressing their use cases.

Understanding the requirements, roles, and responsibilities

While the timeline for design, implementation, and testing a Bahrain solution is tight, the serialization and barcoding requirements are based on proven GS1 standards and the reporting requirements are currently limited to a relatively small number of serialized events: commissioning, shipping, and receiving. Aggregation is required, but reporting requirements will not be in force until May 2022.

Nevertheless, as with every compliance mandate, companies need to do a thorough assessment of their business processes and use cases for distributing products in the Kingdom. Identifying common business practices and potential exceptions is a regular source of discussion for TraceLink SIGs—and a critical source of insight for TraceLink's product development team.

The May 6 session also discussed roles and responsibilities, and the NHRA's definition of an "Invoicing Company," which can be the manufacturer (MAH) or a separate company that handles distribution and invoicing. The Invoicing Company is responsible for:

- Submitting the required compliance reports to the NHRA-MVC Hub
- Sending the events captured on its behalf by a CMO, Repackager, or Third-Party Logistics provider
- Resolving discrepancies between the physical goods and what was reported to the NHRA-MVC Hub

A poll of attendees revealed that the majority of the companies represented at the SIG had already registered their products, as required by the NHRA, through its BrandSync portal. Some members noted difficulties in uploading data to the portal, and other members shared how they'd resolved those same issues. The group decided to continue analysis and discussion of the BrandSync requirement at the next Bahrain SIG session on May 20.



Mapping a (fast) track to success in Bahrain

The question, "What should companies be doing now?", drove a discussion on acting quickly to identify and avoid typical pitfalls. To that end, the TraceLink Customer Success team urged companies that had not already registered with the NHRA's MVC Traceability Hub to do so immediately. In light of the issues with BrandSync experienced by some attendees, companies were also advised to review and upload their company and product master data as soon as possible to ensure that their data would be synchronized with the MVC Traceability Hub for reporting.

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. Join the TraceLink Community.

Bahrain PharmaceuticalsGlobal Track & TraceManufacturingBahrain

Contact us

Learn more about Bahrain compliance solutions from TraceLink.

CONTACT US

Contact us

Learn more about Bahrain compliance solutions from TraceLink.