EMVO Approval: Certification vs. Conformance Tests

The European Medicines Verification Organization (EMVO) has recently stated that there is no longer a formal certification to connect to the EU Hub. Instead, Marketing Authorization Holders (MAHs) are required to complete conformance testing before receiving approval from EMVO to submit data to the EU Hub. To achieve EMVO approval, all MAHs must now submit a series of test transactions for review. Once the tests are approved by EMVO, the MAH will receive access to the certificates required for production and data submission to the EU Hub.

The approval process for connecting to the EU Hub

Under EU FMD, the MAH must upload its product data to a central router known as the European Hub, so that their products can be verified before being dispensed to patients. With patient safety at stake, EMVO requires that the data upload meets strict security and technical requirements. The MAH must:

- Execute an Onboarding Partner (OBP) agreement with EMVO.
- Establish the technical connection to the hub.
- Test and troubleshoot the integrated connection.
- Execute the required product master and product pack data transactions for all products that have been serialized for the market

To meet these requirements, most OBPs work with solution providers—known as

Onboarding Partner Connection Providers, or OBP-CPs—to establish the technical connection to the EU Hub. The connection must then be approved through a testing process:

1. The OPB submits a series of 3 transactions to EMVO via its connection.
2. EMVO reviews those transactions.
3. If approved, EMVO supplies the certificate that allows the MAH to move into the EU Hub production environment.

In its clarification, EMVO clearly states that this conformance test is not designed to certify an OBP-CP's EU compliance solution; rather, the test indicates that the EU Hub integration APIs are correct. According to EMVO, passing the conformance test "…does not mean or imply that the OBP system has been certified, validated or otherwise checked by EMVO.

How TraceLink helps

As part of its EU compliance module, TraceLink has developed product functionality for its customers to execute the EMVO conformance testing. In addition, TraceLink's Services team will guide customers through the EMVO approval process for connection to the EU Hub. After executing a conformance test, any TraceLink customer using the EU compliance module will receive automatically generated files that are ready to be submitted to the EU Hub for approval.

TraceLink's investment in customer service and support—and guiding our customers through the conformance testing process—ensures that the transition to production is a smooth one. Find out more about our EU FMD solution.

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