RESOURCES

Can My CMO Upload Product Data to the European Hub?



Many pharma companies in Europe rely on contract manufacturing or packaging organizations (CMOs/CPOs). As those pharma companies prepare for EU FMD, they are asking if their CMOs or CPOs can manage the requirement to upload their product data to the European Hub. For pharma companies that also act as CMOs to other pharma companies, the question takes on deeper meaning.

The short answer to the question is a resounding no.

Only the Marketing Authorization Holder (MAH) of a product can register with the EMVO as an Onboarding Partner (OBP) to upload product data to the European Hub. A CMO is not permitted to be an OBP nor to connect directly to the European Hub. The MAH is only authorized to upload the data for the products it manufactures under its own brand names.

Once the MAH has connected to the European Hub, it may create a gateway account within its portal for a CMO to upload product data on its behalf. In this case, the data is still being uploaded under the MAH authorization, after the MAH has initially developed the connection to the European Hub.

The MAH also has the regulatory obligation to report product updates to the European Hub, such as decommissioning and removal from the market. At this stage, the product would already be in the supply chain and not in the CMO’s

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possession—a key reason why CMOs are not authorized to report on the MAH's behalf.

What if my CMO is also an MAH?

When a pharmaceutical company also operates as a CMO or CPO to manufacture or package products for another MAH (its "customer"), it is still not eligible to upload that customer's product data to the European Hub. Once it has applied the safety features to the customer's products, it must send the product data back to that customer (an MAH) who must connect to the Hub as an authorized OBP.

In this instance, the company would need to maintain separate connections: a direct connection to the European Hub for its own products, and one to the customer or the customer's gateway account for the products it manufactures as a CMO.

How TraceLink Helps

For pharmaceutical companies, establishing and maintaining multiple connections—to the European Hub and to your supply chain partners—can be a significant technical and administrative challenge. With our network approach, you only have one connection: to TraceLink. You then use our certified connection to the European Hub to upload data, and connect to your supply chain partners via our digital network.

The TraceLink Life Sciences Cloud is the only purpose-built solution that digitizes the entire pharmaceutical supply chain to help pharma companies and CMOs meet existing and emerging regulations. With nearly 400 pharmaceutical and contract manufacturing customers on our network—including more than 140 that are exchanging live serialization data with their partners today—TraceLink offers the only proven playbook for serialization-readiness.

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