Managing Regulatory Requirements / FDA / Customs Focused Assessment

A leading global medical technology company that employs approximately 7,100 people and markets its products in more than 20 countries realized there were significant issues with their trade compliance processes. When the U.S. Customs and Border Protection (CBP) agency notified the company there would be a Customs Focused Assessment (FA) forthcoming, it became clear some changes were needed.

An FA looks at a company's internal controls to measure the areas of risk with respect to their import activities. The importer is responsible for declaring the value, classification, and rate of duty applicable to entered merchandise. Many of the commodities within the healthcare industry also require information to be sent to the Food & Drug Administration (FDA). After an initial Pre-Assessment Survey (PAS), if CBP finds material risk and significant non-compliance with the importer's responsibilities, the FA will escalate to extensive review for transactions of merchandise previously imported. Needless to say, the FA can consume a lot of a company's resources and could ultimately lead to loss of revenue for the importer.

The company had previously not maintained a centralized parts database, with controlled access and an audit trail for changes to parts details. The information required for FDA purposes was not consistent from transaction to transaction. Too much of the trade compliance was reactive and being done when shipments landed, as opposed to further upstream in the supply chain.

When CBP gave the notification of the impending Focused Assessment, the importer knew they had to make changes. They looked at Tradeflow and eventually began implementing the Product Management Centre (PMC). With the PMC, they could start to build a centralized system for distributing information to their brokers. With the Harmonized Tariff Schedule (HTS) content integrated into the system, it provided a way to load parts with the HTS code and run mass validations against the HTS to confirm that classifications were valid. With a dedicated section for maintaining FDA details, the company could start building consistency with how the parts information was maintained.

After a few months of building up the parts database, the next step taken was to integrate the third-party brokers with the parts data. Several different automated data feeds were setup to distribute the HTS code, FDA information, Country of Origin, Free Trade Agreements and other important compliance attributes to these brokers. With the automated daily data feeds, the company spent less time dispatching information to third parties, leaving more time to spend on managing the compliance of their parts database.

When CBP eventually began the Focused Assessment, Tradeflow had already been implemented and had been running for several months. While the past activities and lack of compliance was still going to be reviewed, CBP made a specific note of encouragement that the importer was implementing the Tradeflow system. CBP had come across Tradeflow in the past and knew its capabilities to serve as a platform for building compliance for product information.

TRADE flow

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