

# RCA Designs a Shipping Validation Study for a Pharmaceutical

## Client

Medical Device Manufacturer

## Industry

Medical Device

## Business Challenge

Implement a new product and logo change across 60 countries.

## Background

A medical device manufacturer was consolidating its product portfolio, leading to a product and logo change in 15 products distributed across 60 countries. Since the company name and the manufacturing address remained unchanged, the manufacturer was unclear on the registration requirements.

## Solution

On a country-by country basis, Regulatory Compliance Associates® Inc. developed the registration and customs requirements and executed the go-forward plan. In some countries, re-registration was required and RCA handled the submission. In many countries, the bigger hurdle was ensuring the newly labeled product would pass customs requirements, so RCA communicated the new label to the local Ministries of Health and the distributors in each country.

## Results

The manufacturer was able to change the product label and not interrupt any product sales.

*“We were in jeopardy of losing confidence from our export partners; this remedy saved our reputation and prevented product backorders.”*

