REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Strategy for Pharmaceutical Submission

Client

IV Pharmaceuticals Manufacturer

Industry

Pharmaceutical

Business Challenge

Consulting for a correct FDA submission strategy.

Background

A major manufacturer of IV pharmaceuticals was facing leakage problems with the IV bag. Their quality and engineering teams identified a solution that would eliminate the leaks by making a change to the resins in the bag. They were unclear on the submission strategy since the guidance documents were unclear, so the company was defaulting to a time-intensive Prior Approval Supplement (PAS).

Solution

The Regulatory Compliance Associates® Inc. consultant examined the corrective action, noting that the strengthening of the IV bag came from changing the ratio of the resins but not the actual resins. Because no new resins were being introduced to the pharmaceutical, RCA suggested a CBE 30 instead of the PAS.

Result

After reviewing the RCA strategy with the FDA, the company submitted the CBE 30 and was able to address product complaints and maintain product revenues.

"RCA saved about 1 ½ years from the schedule, maintaining revenues and increasing product quality."