REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Remediation & Resulting Sustainable Compliance within New FDA Regulatory Framework

Client

Midsize Compounding Pharmacy

Industry

Pharmaceutical

Business Challenge

Compounding pharmacy received 2 Form 483's. FDA requested a hault on compouding and a recall.

Project Timeline

9 months

About Registered 503B Outsourcing

On January 8, 2014, FDA issued Dear Colleague and Dear Hospital/Purchaser letters informing them of the passage of new federal legislation that affects the oversight of human drug compounding and to encourage them to consider requiring compounders from which they purchase compounded sterile drugs to register with the FDA as outsourcing facilities.

Over the course of one year, FDA conducted over 70 inspections of compounding pharmacies across the country, both for cause (42), in response to serious adverse event reports and reports of quality problems, and to proactively (31) identify pharmacies with deficient sterile compounding practices. In most cases, state boards of pharmacy participated in the inspections, some of which were initiated at the request of a state.

Client Challenge

A recently registered 503B Sterile Outsourcing Facility was facing serious enforcement action from the FDA: two damaging FDA Form 483 Reports, FDA-requested cessation of compounding, and an FDA-requested recall of all sterile compounded preparations due to a lack of assurance of sterility. RCA was engaged by the compounding facility as an independent third party cGMP expert

RCA Approach

RCA experts guided client personnel to develop an effective and robust FDA Form 483 response, performed a thorough baseline cGMP audit under the draft regulations, assisted with additional FDA response communications and ultimately led a certification audit six months after the baseline audit. Although RCA found additional observations during the certification audit, it was able to certify that there remained no further sterility assurance concerns.

RCA prepared and trained facility personnel to assist in their management of the follow-on FDA inspection, and, despite the

use of three drug expert investigators by FDA, the firm received only minor, readily correctable FDA Form 483 Observations which were fully addressed by its response.

Results

After review by the FDA Dallas District Office and agency officials at the FDA's Center for Drug Evaluation and Research (CDER), the Agency stated, in writing, that it found no objection to the firm resuming sterile drug compounding operations. With that letter, Unique Pharmaceuticals became one of the first outsourcing facilities to remediate FDA's sterility assurance concerns relating to the practice of pharmaceutical compounding in general, as well as demonstrate full compliance with the new regulatory framework created by the amendments to the FD&C Act at 503B.

"Meeting the new FDA regulations is validation of our Quality Management System, our dedicated staff, and partnership with RCA. With RCA's help, we're the industry leader in our commitment to 503B quality.

The team at RCA has been a true blessing for our company and we would not have succeeded without their expertise and knowledge. We always felt that we were their top priority."

—President / CEO