

June 20, 2024

To whom it may concern,

I am a senior recruiter for TCW Global and have placed Kristin in different positions consulting for two of our life sciences clients.

The first is a medical device manufacturer who had received notice of deficiencies in their FDA inspection. Our client was looking for guidance on how to address those gaps and respond to FDA. Kristin laid out several options for remediation and our client was able to pick the one that best fit their business. She also drafted their response and FDA closed out the findings without any further questions or concerns. Kristin's guidance was key to the successful and efficient closure of this project.

The second client is a cosmetics and personal care product manufacturer. This industry has always been regulated by FDA and is becoming more heavily regulated because of the Modernization of Cosmetics Regulation Act of 2022. The industry is now expected to be cGMP compliant and Kristin was able to put together a reasonable plan for our client, draft all of the phase I procedures, and train all of the employees on the regulations, quality system, and individual procedures. Kristin will be returning early next year to help with implementation of phase II procedures and training, and later in the year to finalize the quality system with phase III.

Kristin will remain on the top of my list of consultants as I receive requests for quality and regulatory guidance from our life science clients.

All the best,

Erika Miller



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