VistaLifeSciences
Better Information. Better Health.

October 14, 2021

Lori A. Carr, RAC (US), CQA (ASQ), RABQSA
Regulatory Consultant

Dear Ms. Carr:

Vista LifeSciences, Inc. is very appreciative of the work that you continue to do in support of our FDA regulatory efforts. Our company has been working on our regulated product listings and 510(k) applications for medical devices since 2010. We have engaged other consultants, some from large companies. It was not until your engagement in the past two years that we have the appropriate advice, guidance, and counsel during reviews and internal audits that we have what we need.

We have specifically benefited from your guidance on FDA required documents, in particular SOPs. Your ability to suggest "how" the FDA might review and question our procedures gives us better insight into how and why something should be written in a specific way. Your guidance regarding “best practices” has been invaluable as we implement improvements. You have been able to attend calls with FDA reviewers and help us understand their guidance and questions during the interactive review of our most recent 510(k) application. And lastly, you help balance us between writing too much vs. too little, enabling an efficient but effective set of documentation required for approval and appropriate for our next inevitable compliance inspection.

With your support, we now have more confidence in our Quality System processes and documentation. Most importantly, your guidance allowed us to successfully navigate our most recent pre-market notification and subsequent interactive review that resulted in being awarded 510(k) Clearance of our Class II Software as a Medical Device product.

Feel free to have prospective customers contact us if you want a recommendation. We have enjoyed the engagements so far and will continue to use your services when needed.

Sincerely,

S. Michael Lutz
COO and CTO, Vista LifeSciences, Inc.