About Sharlene Lucio career:

Five plus years working with regulatory affairs activities and writing submissions to solve problems and communicate regulatory requirements. I am certified GxP and have been committed to quality for more than 25 years.

While working at Boston Scientific I wrote global submissions for IVD/IVDR – Invitro diagnostics and FDA 510K for global use.

Working at Oraya Therapeutics as the document manager, I wrote dossiers and applications for MDR, FDA 510K and global registrations for filing of the license for AMD – age-related macular degeneration medical device. I assisted in the international regulatory operations of the global MDR 510K device license. I wrote the global regulatory submissions at Oraya Therapeutics and Integra Life Sciences for medical devices. Serving as a regulatory representative/liaison ensuring all government reporting agencies notified.

Working at Endo Pharmaceuticals I gained a full CMC expertise in supporting Investigational Medicinal Product Dossier (IMPD) is a central piece of Investigational Medicinal Product (IMPD) and IVD – Invitro Diagnostic testing and the related documents required for clinical and non-clinical approval of clinical trials by Regulatory authorities in the US and the EU. Writing, compiling and submitting the documents for Investigational New Drug (IND) and M3 non-clinical safety applications with the ADME - drug absorption, distribution, metabolism and excretion.

To ensure all government reporting agencies have been notified with complete documentation packages to comply with regulatory standards and requirements for OTC drug products internal and external. I was tasked with the framework of cGMP, labeling, issues and audits. While documenting compliance conflicts and applying risk management principles.

Working at Integra Life Sciences I was committed to the core values and guiding ethical principles and for strict compliance with numerous regulatory applications to ensure the documentation complied with eCTD for the medical device that was designed and submitted for global regulatory submissions.