To Whom it may concern: April 3, 2024

* I have 25 years of experience in Regulatory technical writing exp along with End-User manuals and IFUs. Most recently I worked with Peraton Pharmaceuticals from 2022-2023 and their software team. I wrote about:
* 1) Planning 2) Analysis 3) Design 4) Requirements 5) Traceability Matrix 6) Implementation 7) Testing (types of test documentation, test execution, testing strategy, testing scenario and test process, etc.) 8) Compliance 9) Revision 10) Date of Implementation (release date) 11) Maintenance
* For more in-depth documentation about my SDLC experience, go to my website: https://[sharlenelucio.godaddysites.com](http://sharlenelucio.godaddysites.com/)
* Again in 2017 I wrote for Integra Life Sciences, regulatory submissions and all global documentation. FDA 510K memos, BLAs, MAAs and INDA and risk/issue management reports, and IT reports and IFUs.
* 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. I guided all clinical trials through all aspects of the patients and confidentiality of controlled personal information, supplies, location reservations, medical doctors in clinical trials and all information submitted (CFR) to applicable government agencies for submission and approvals. This information is specific and precise, submitted per the federal regulations.
* Working at Endo Pharmaceuticals 2015 – 2016 I gained my CMC expertise in supporting Investigational Medicinal Product Dossier (IMPD) a central piece of Investigational Medicinal Product 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 FDA BLAs under process (21 CFR 600 – 680) and revisioning BLAs and MAA 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.
* Again in 2008 I worked for Oraya Therapeutics where I wrote and released all of the specifics of the Form 356h requirements for a BLAs. In 2008 the BLA had not been introduced, it was better known as Regulatory Affairs 101.
* The documentation for clinical and portions of non-clinical toxicology thorough pivotal studies and the final step prior to regulatory approval is the Health Authority review to evaluate whether the data supports a positive benefit/risk profile. This can take several months before the patients may access the therapy. The documentation at this point is strategic in all areas, just to name a few and what I was in charge of: regulatory, design and risk analysis, software and hardware documentation for a medical device system related to AMD (age related macular degeneration). I was tasked with creating an online ANSI standards library of ISO, IEC Consensus Bodies (ANS Voting Groups – the work of 240 voluntary consensus standards bodies accredited by ANSI). I was Instrumental in all aspects of writing and organizing the clinical trials, organized user/patient manuals and IFUs into 7 different languages.

Thank you,

Sharlene Lucio