**SHRUTI S. SHAH**

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**Professional Summary**

* Strongly reliable and focused Student of Regulatory Affairs with experience in preparation of eCTD CMC Module -3 Document of ANDs and Quality Overall Summary in compliance with ICH guidelines as **Regulatory Affairs Associate**
* Skillful in ISIWriter® software for preparation of regulatory documents
* Strong interpersonal skills and ability to work with cross-functional teams to prepare documentation required for filing to meet submission timelines
* Experience in development and validation of assay and dissolution methods using spectroscopic and chromatographic method as **Analytical Chemist**
* Experience in working in accordance with GLP (Good Laboratory Practice) guidelines

**Skills**

* Technical writing skills and detail oriented
* Multitasker able to handle multiple projects, contribute effectively to project teams and achieve deadlines
* Good organization skills and communication skills
* Ability to learn and apply regulations pertinent to medical devices, biologics, drugs and combination products
* Familiar with FDA 21CFR guidelines, ISO 13485/ 14971, ICH guidelines, cGMP, GCP & GLP compliances
* Familiar with U.S. FDA regulations and Europe Medical Device Regulations (CE Marking, technical file)
* Knowledge of Medical devices regulation -510(k) procedures, PMA, IDE, CAPA system, QSR
* Proficient inMicrosoft Office Suit (Excel, Word, PowerPoint, Outlook, Publisher)
* Languages:English, Hindi, Gujarati(Native)

**Professional Experience**

**Regulatory Affairs Associate; Kashiv Pharma, LLC; New Jersey; USA Apr 2017- Dec 2017**

* Responsible for preparing, editing and formatting eCTD Document Module-3 of ANDs using ISIWriter® software to support original regulatory submissions, amendments and supplements in compliance with current FDA regulations and guidance
* Provided input in preparation of Quality Overall Summary (Module-2 QOS) of the generic product as per FDA guidance
* Provided input for collection, compilation and preparation of responses to FDA Deficiency Letters (Information Request/ Complete Response)
* Prepare and review master batch records, process study protocols and associated regulatory filing documents
* Acted as liaison between Regulatory Affairs, Quality Assurance, Research & Development, Production and analytical department in obtaining documents for ANDA compilation

**Analytical Chemist, Yash Medicare Private Limited; India Jul 2012- Oct 2015**

* Documented STPs (standard testing procedure), SOPs (standard operating procedure) and method validation protocol
* Experience of working in accordance with GLP (Good Laboratory Practice) guidelines.
* Developed assay methods and dissolution method for testing generic molecule and drug products using UV spectroscopy and HPLC chromatography
* Performed assay, impurity, residual solvents and water determination by KF
* Stability samples analysis and Particle size analysis by Malvern

**Intern, Indica Laboratories (P) LTD; Ahmedabad; India** **Apr 2011- June 2011**

* Supported sampling, testing and batch record reviews during manufacturing and packaging of generic drug products
* Assisted in managing general laboratory documents, labeling, packaging and shipping of outgoing materials and in preparation of incident reports

**Academic Projects**

* Developed mock regulatory plan [NDA (505(b)(2)/ ANDA] and studied key components like Clinical Trial Protocol, Pre- IND meetings and eCTD submissions (1 week)
* Analyzed and identified an inadequacy in Informed Consent Form as reviewer of an Institutional Review Board (IRB) (1 week)
* Drafted Pre- IND meeting request letter for FDA for a hypothetical biologic product (1 week)
* Identified and developed stepwise regulatory path for class II and class III medical devices (510(k) or PMA)
* Presentation on ‘Medtronic Minimed 670G System- Continuous Glucose Monitoring System’ as Emerging Medical Device Technology (2 weeks)
* Mock submission on minutes of meeting and risk analysis of medical device to adequately examine the severity and occurrence of hazardous events (1 week)
* Project on changes in new European Medical Device Regulation (MDR) and In-vitro Diagnostic Device Regulation (IVDR) (2 weeks)

**Education**

**Northeastern University, Boston, MA March 2018**

*Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical**Devices*

GPA: 3.667/4.0

**Dharmsinh Desai University, India May 2014**

*Master of Pharmacy in Quality Assurance*

CPI: 8.4/10

**Nirma University, Ahmedabad, India May 2012**

*Bachelor of Pharmacy*

CPI: 8.3/10