SIDHDHANT SHETH
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Education

Northeastern University - College of Professional Studies Boston, Massachusetts
Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices 2018 - April 2019
Concentration in International Regulatory Affairs

Rutgers University – School of Arts & Science New Brunswick, New Jersey
Bachelor of Science in Biological Sciences, Minor: Public Health | GPA: 3.262/4.00 May 2015

Academic Experience

Northeastern University, *MS in Regulatory Affairs* | Boston, MA April 2018 – Current

- Specialized in International regulations: EU, Health Canada, ANMAT, LATAM, CDSCO, MHLW, China FDA – proficient in establishing / maintaining compliance with the EU IVD directive and other international regulations and standards as required, including registrations.
- Writing and reviewing ANDA/NDA/BLA/IND structure/510(k) applications, 513(g) Request for Medical Device Classification and Regulatory/eCopy Requirements.
- Knowledge of De Novo process, Premarket Approval (PMA), Investigational Device Exemption (IDE), Trial Master File (TMF), Humanitarian Use Device (HUD), GCP/ICH guidelines including Informed Consent for Clinical/non-Clinical trials, Protocols and development of study reports.
- Regulation of Drug and Biologic products and its special designation process, with the experience of navigating through FDA database and updating drug list.
- As a part of a project, prepared and evaluated serious adverse events (SAEs) and Safety Reports,Medical Device Report (MDR), Development Safety Update Report (DSUR), Clinical Evaluation Report (CER) Clinical Study Reports (CSR), Unanticipated Adverse Devise Effects Reports (UADEs)

Professional Experience

Roche Molecular Systems, *Quality Lab Ops Specialist* | Branchburg, NJ March 2019 – Current

- Performed all work duties via automated systems or manual operations in compliance with safe operating procedures, company and government regulations, along with cGMP guidelines.
- Participated in design and implementation of training and developmental programs as well as generated a Batch Submission Protocol and assured that the required inspection and test records are complete and accurate.
- Performed computer analysis and data entry such as SAP transactions, LIMS, MS Word, Excel and PowerPoint and analytical equipment associated software packages.
- Experienced in in-vitro diagnostics (IVD) testing such as COBAS AmpliPrep/Taqman for automated specimen processing for the quantitation of Human Immunodeficiency Virus Type 1 (HIV-A)
- Executed in-process release, stability and validation testing of diagnostic PCR/rtPCT HBV, HCV, HIV-1 bulks, filled vials and packaged kits according to the SOPs to support the production schedule, process and test method validations and the stability monitoring program.

Siemens Healthineers, *Quality Control Lab Analyst II* | Glasgow, DE May 2017 - March 2018

- Consistently obeyed Good Laboratory Practice (GLP) as well as trained in ISO 9001, CLIA, and FDA/CGMP/GMP regulations and their applications in a laboratory setting including EHS compliance.
- Performed acute care diagnostics providing precise quantifiable cardiac assays such as troponin I, CK-MB Mass, Myoglobin, NT-proBNP, D-dimer, and other assays on Stratus CS by Dade Behring.
- Analyzed patient and quality control samples on Dimension RxL Max with arrays of different methods such as TSH, MMB, TPSA, FERR, HCG conjugate reagent/concentration.
- Adopted the role of being a “floater”, engaging in and analyzing different instruments, simultaneously at times, such as Dimension RxL Max, Stratus CS and Karl Fischer.

- Responsible for obtaining samples from production daily, accurately logging in test samples daily in the log book, and accurately recording all information in testing log books, test records, and laboratory computer database system (LIMS).
- Prepared and facilitated collection of necessary information for post-market health hazard evaluations, recall evaluations, MDR evaluations.
- Compiled and reviewed medical device registration data as well as contributed and lead to preparation of 510(k) and PMA.

Sun Pharmaceuticals, *Quality Control Lab Analyst* | Cranbury, NJ March 2016 - November 2016

- Performed automated and manual assays as detailed in departmental/plant SOP's and QC Monographs, including stability, raw material, in-process and finished product.
- Interpreted test results against specifications and decides if assays pass or fail, using Microsoft Excel and Word.
- Retained live documentation of all work performed in accordance with GMP requirements as well as assisted in preparation of specification and sampling plan for release and stability samples.
- Experienced in drug testing such as Water Content, Sieve Analysis, Thin-Layer Chromatography, Loss of Drying as well as hands-on knowledge of HPLC and IR Spectroscopy as well as responsible for calibrating 7 balances, 2 pH meters and 3 Karl-Fischer (water content) equipment in the lab, daily.
- Trained new hires in drug testing as well as aid and facilitated purchase orders such as materials and lab equipment - anticipated and reported sample inventory needs of consumable supplies prior to depletion.

Skills and Interests

Computer: Expert in Microsoft Word, Excel, PowerPoint, Outlook, LIMS (Laboratory Information Management System), SAP Logon, Trackwise, Quality System management
Languages: English, Hindi, Gujarat.

References upon Request