Pengcheng Wang

Greater Boston Area, MA • C: 617-4498254 • E: wang.pengch@husky.neu.edu

EXPERIENCE

JangSu HengRui Medical Co,. Ltd Nanjing, China
Regulatory Affairs Specialist Intern July 2018-Sep 2018

- Maintained daily research document and supervised laboratory quality assurance process
- Associated in developing strategies and timelines for generic drugs to market, including collecting information of 3 reference listed drugs and patents; Prepared documents for importing the RLDs
- Negotiated with CFDA in supplements of marketed drugs; Handled documents of changing manufacturing address
- Handling materials about exporting 3 starting materials both to US and EU.

Innovative Regulatory Science Group Boston, MA
SOP Specialist Intern (virtual) Apr 2018-July 2018

- Designed SOP and timelines for a new medical device; Involved in finding predict device
- Implemented and managed FDA compliant Quality Systems, mainly focusing on verification and validation process
- Ensured records are sustained, secure and retrievable throughout defined record retention periods

Food and Drug Administration of Jiangsu Province Taizhou, China
Research Assistant Jun 2015-Aug 2015

- Advised pharmaceutical company how to better comply with CFDA in food and drug supervision
- Performed pharmaceutical enterprise research and wrote research report

EDUCATION

Northeastern University Boston, MA
Master of Science in Regulatory Affairs for Drugs, Biologics and Medical Devices Sept 2017-present

China Pharmaceutical University Nanjing, China
Bachelor of Science in Pharmaceutics June 2013-June 2017

SKILLS

- Familiar at laboratory equipment's operation, such as HPLC, tablet machine, scale, UV detector
- Good command of MS office; Problem-solving skills; Detail-oriented
- Strong written and verbal communication and presentation abilities

ASSIGNMENTS COMPLETED

CMC: 21 CFR 820-compliant method validation document of pesticide
SOP: Procedures for transporting time-sensitive clinical products to recipient patients
INFORMED CONSENTED FORM: 21 CFR 50-compliant ICF of phase II Alzheimer's clinical trial
END OF PHASE II MEETING REQUEST: 505(b)(1)-compliant EOP II request of EXONDYS 51
DUE DILIGENCE: Requesting necessary data and documents from big company to move to Phase II trial
PRE-IND MEETING REQUEST: Section 505(b)-compliant pre-IND meeting request about Duchenne muscular dystrophy
ECTD DOCUMENT: Provide information of what would likely to be involved in an approved pharmaceutical product's eCT
MEDICAL DEVICE STRATEGY: Creating strategies and timelines for a specific medical device to launch in the market glo
INVESTIGATIONAL PLAN: Phase II and 21 CFR 312.23(a)(3)-compliant investigational plan of validating the ESP1 device as a treatment for dysphagia after brain injury