

JOHN DOE

3455 Lebon Drive, Unit 1618, San Diego, California, 92122 ▪ 123.456.7890

johndoe@gmail.com ▪ www.linkedin.com/in/john

REGULATORY AFFAIRS AND QUALITY ASSURANCE ASSOCIATE

QUALIFICATIONS PROFILE

Astute, performance-focused and analytical professional with hands-on experience in conducting critical phase inspections related to good manufacturing practice, good laboratory practice and reviewing documents for pre-approval by US Food and Drug Administration, Health Canada, EMA and other regulatory agencies.

- Equipped with project management and research and development expertise; keynoted for completing scientific projects and writing and publishing numerous articles, grants and quality documents.
- Effective at training for graduate students and lab personnel regarding biosafety and laboratory procedures. Armed with in-depth knowledge of cGMPs and ICH guidelines, Clinical Trial Applications (CTA) notifications, Annual Product Quality Review (APQR), corrective and preventive action (CAPA) and Food and Drugs Act.
- Proficient with Microsoft Office, Adobe Creative Suite, EndNote, Mendeley and SAP.

AREAS OF EXPERTISE

- cGMPs, GxPs, ICH Guidelines
- Regulatory Submissions and Label Reviews
- Quality Management
- Quality Documentation Review for Product Release
- Manufacturing Process
- Drafting and Revising SOPs
- Raw Materials and Finished Products Inspection and Sampling
- Laboratory Aseptic Techniques
- Biosafety Procedures
- Data Gathering and Validation
- Biochemical Assays
- Large Scale Genomics
- Protein and Nucleic Acid Biology

PROFESSIONAL EXPERIENCE

MINT PHARMACEUTICALS INC. • MISSISSAUGA, ON

Quality Assurance and Compliance Associate

Sep 2019–May 2020

- Guaranteed adherence to Mint's procedures through in-depth review of quality assurance documentation
- Observed compliance of all good manufacturing practice documentation and performed comprehensive cross-verification of documents for accuracy
- Served as liaison between Health Canada representatives and Mint
- Held responsibility in managing and updating current revisions of Master Batch documents for auditing
- Supported the Regulatory Affairs Team and assisted with label reviews and post-Notice of Compliance (NOC) changes; as well as with the compilation, writing and publishing of regulatory submissions to Health Canada
- Thoroughly reviewed submission documentation for Health Canada requirements compliance
- Contributed to the development of a clinical database; compilation and preparation of responses to deficiency letters from regulatory authorities; and coordination and project management of biostudies

UNIVERSITY OF TORONTO • TORONTO, ON

BOONE AND ANDREWS LAB–DONNELLY CENTRE | MENEGHINI LAB -MARS CENTER

Laboratory Technician (Acting Manager) | Synthetic Genetic Array (SGA) Technician

Apr 2016– Jun 2018

- Managed daily laboratory operations such as preparing microbiological media, monitoring stocks of chemicals, solutions and disposables, sterilizing glassware and cleaning and checking laboratory equipment for functionality
- Ensured adherence of lab operations to set regulations by monitoring bio-safety practices
- Established and updated the standard operating procedures in accordance with the needs of personnel

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- Completed yeast strain construction and characterization which involved high-throughput genetic interaction screens and data analysis through specialized BioMatrix and Singer robotics; genetic interactions mapping between pairs of yeast gene mutants in various environmental conditions; and large number of yeast trains maintenance
- Conducted cloning, PCRs, microscopy, cell biology assays, microscopic tetrad dissections, DNA and RNA purification, protein purifications and qPCR and biochemical and cellular assay when required
- Demonstrated knowledge of using colony arraying robots, autoclaves, centrifuges, multi-pipettes, PCR machines, and Opera high-content microscope

EDUCATION

PHARMACEUTICAL REGULATORY AFFAIRS AND QUALITY OPERATIONS (RAQC): 2020

Seneca College of Applied Arts and Technology

Coursework: Biotech and Biopharmaceuticals | Pharmacoeconomics | Product Formulation & Manufacturing | Technical Writing | Quality Assurance | Principles and Ethics of Clinical Research | Regulatory Affairs (Canada, USA and Europe)

MASTER OF SCIENCE IN CELL AND DEVELOPMENTAL BIOLOGY: 2015

The University of British Columbia ▪ Vancouver, BC

International Partial Tuition Scholarship, 2013–2015 | College of Interdisciplinary Studies Graduate Scholarship, 2013

BACHELOR OF SCIENCE (HONOURS) IN BIOLOGICAL SCIENCES: 2012

The University of Windsor ▪ Windsor, ON

Graduated with Distinction | Dean's List

AFFILIATION

Member, Rotary Club–South Indian Chapter

COMMUNITY INVOLVEMENT

HIV/AIDS Awareness Outreach Programs | Basic Sanitation and Personal Hygiene Seminar/Presentation

Teaching Programs for Underprivileged Kids

PUBLICATIONS

Dharwada, S. T., (2015). *Intracellular trafficking of a polytopic membrane protein*. (Master's Thesis). The University of British Columbia. Vancouver, BC.

Dharwada, S. T., Dalton, L. E., Dean, B. M., Padmanabhan, N., Choi, K., Schluter, C., ... Conibear, E. (2018). The chaperone Chs7 forms a stable complex with Chs3 and promotes its activity at the cell surface. *Traffic*, (19)4, 285-295. <https://doi.org/10.1111/tra.12553>.