



Debbie Sora

Consultant

Debbie Sora is a dedicated, flexible professional with excellent organizational and problem-solving skills supported by over 20 years of pharmaceutical experience. She is able to liaise with individuals and secure information through effective listening skills and to share information and concerns through clear communication. Debbie works successfully in a team-based environment; as well, she demonstrates the ability to work independently on large projects. Past employers include Nucro-Technics, Trillium Healthcare Manufacturing, Patheon Inc. and GenPharm Inc.

SKILLS AND HIGHLIGHTS



Quality Control Officer

- Reviewed and approved all required documentation and samples for product release
- Reviewed stability data and validation reports
- Ensured clients are in compliance with GMP and ICH guidelines, Standard Operating Procedures and testing specifications
- Prepared and edited client Standard Operating Procedures
- Performed self-inspections and warehouse audits
- Hosted Health Canada audits and prepared responses to audit comments



Quality Assurance

- Reviewed and approved batch documentation and samples for product release
- Ensured compliance with GMP guidelines, Standard Operating Procedures, testing specifications and customer requirements
- Investigated discrepancies and determined corrective and preventative action required
- Performed AQL inspections as required



Technical Writing

- Developed and updated policies and GMP SOPs to meet Health Canada requirements



Validation

- Prepared and edited analytical method development and validation reports
- Prepared and edited qualification and process validation reports
- Reviewed and analyzed all relevant physical and analytical test results
- Ensured validation batches were executed according to established procedures
- Discussed any changes/deviations to established manufacturing procedures with client groups



Laboratory

- Worked as production technician and cell culture technician for private laboratory
- Worked as research technician and microbiology technician

Computer Skills

- Microsoft Office – Microsoft Outlook, Word, Excel, PowerPoint

EDUCATION

- Bachelor of Science, Honours Biochemistry and Biology, University of Toronto

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Good Manufacturing Practices Training (for drug and natural health products)
- Document Control Training
- WHIMIS Training
- Technical Writing