



Verna Rathore

Consultant

Verna Rathore is a resourceful professional with top Quality Assurance training and over 20 years experience in the pharmaceutical industry. Verna's dedication to detail, organizational, communication and problem-solving skills were recognized in her many previous management roles. In addition to quality assurance, Verna also brings considerable experience in the medical device, biologics, NHP and dietary supplement industries. Her ability to persist in probing and evaluating information has enabled Verna to find smooth transitions in complex group and individual project work.

SKILLS AND HIGHLIGHTS



Quality Assurance/Quality Control (QCO)

- Management of Change Control, Product Complaint and Nonconformances
- Coordinated and performed inspection, inventory control and release of finished product
- Prepared and hosted Health Canada audit
- Work as site Quality Assurance releasing pharmaceuticals, NHPs and dietary supplements
- Prepared report summaries of Quality Assurance systems for referencing and evaluation
- Assisted with internal audit for conformity to ISO 9001 element 4.15 Handling, storage, packaging preservation and delivery
- Facilitated development of Design Control element ISO 9001 quality system for process qualification for medical device company
- Performed ELISA, stability, and inspection testing of reagents for medical device establishment



Large Compliance Project Management

- Introduced a more efficient ELISA procedure in order to reduce testing time by 50 per cent
- Extended shelf life and approval of 60 antibodies eliminating backlog of ELISA testing
- Redesigned, developed and resolved problems of oncology diagnostic kit
- Handled 4 individual and 3 group projects to redevelop/optimize, qualify and produce diagnostic products
- Successfully evaluated and transferred an immunoaffinity purification procedure reducing labour time and production costs
- Assisted in product launch by coordinating the method transfer from US and Canadian laboratories



Regulatory

- With Regulatory Affairs and Research Development designed a label for a new clinical product



GMP Training

- Provided SOP training



Technical Writing

- Coordinated the development, writing, review, and approval of SOPs, ensuring that all complied with GMP and cGMP requirements
- Developed Quality Plan
- Developed, revised and updated product specifications for complex pharmaceutical products
- Developed Lot Release Protocol templates for biological products to support release to various agencies



Computer Skills

- Microsoft Office – Microsoft Word, Excel, Visio
- Documentum
- PeopleSoft
- Kintana

EDUCATION

- Bachelor of Science, Chemistry-Biochemistry Specialist, Mathematics Minor, University of Toronto
- American Society for Quality Control (ASQC) Certificate, Quality Assurance

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Annual Product Review, PSG
- Fundamentals of Regulatory Affairs, CanReg
- Good Manufacturing Practices
- Industrial Drug Legislation, Seneca College
- ISO 9001
- Quality Auditing, Sheridan College
- Radiation Protection
- Technical Writing Course, Q&C
- WHMIS certification