



## Matthew Cousens

### Consultant

With his project management skills and ability for prioritizing, Matthew is a valuable addition to the Q&C/ValidaPharm/NHP Compliance teams and an asset on any project. He is a quick learner who can efficiently integrate his knowledge and experience in validation and GMP environments into project activities. Bright and very capable, he works well as a team member or independently, and is able to establish and meet timelines for activities.

### SKILLS AND HIGHLIGHTS



#### Project Management

- Project manager for the recalls of brand name NHP/dietary supplements for both Canada and the USA:
  - Created recall response database
  - Drafted recall strategy documents
  - Provided recall response letter evaluation and guidance
  - Prepared responses to inquiries from Health Canada
  - Reviewed response to Health Canada
- Developed the quality system, including SOPs and associated documentation, for compliance to both the Canadian NHP GMP and USA dietary supplement cGMP
- Implemented a project management software, including time keeping and invoicing, for a mid-size consulting firm
- Managed qualification and validation activities, to ensure new equipment was commissioned on schedule, for large drug manufacturing company



#### Quality Assurance/Quality Control (QCO)

- Applied GMP knowledge to develop/revise SOPs and documentation for drug, natural health product, dietary supplement and medical device importers, distributors and packagers
- Developed and provided training on developed/reviewed SOPs

9-6975 Meadowvale Town Centre Circle  
Suite 410 Mississauga Ontario  
L5N 2V7 Canada

TOLL FREE: 1-877-877-5152

PHONE: 905-363-1182

FAX: 905-542-7981

info@qualityandcompliance.com

www.qualityandcompliance.com

www.validapharm.com

www.nhpcompliance.com

Matthew Cousens, Consultant – CV, page 1 of 3



- Managed environmental monitoring (EM) program for Canadian pharmaceutical manufacturer
- Implemented innovative data analysis procedure to determine root cause of EM program failures, resulting in a 70% decrease in excursions
- Initiated, determined actions and managed closure of actions for change controls related to all aspects of Quality Assurance
- Initiated, identified root causes and determined corrective and preventative actions for deviations and non-conformances
- Trained employees in use of equipment and clean room behaviour
- Addressed deviations and resulting corrective actions



## Validation

- Assessed impact of equipment modification on qualification status of equipment
- Developed and validated cold chain shipper for a Canadian drug importer
- Drafted and executed shipping validations for temperature-sensitive products
- Evaluated computer systems for validation plan requirements
- Developed computer system validation documentation (user requirements specifications and IQ/OQ/PQ scripts)
- Executed computer system validation scripts and audited computer systems against regulatory requirements
- Initiated, determined actions and closed actions for change controls and non-conformances related to computer validation
- Performed qualification (IQ, OQ, PQ) of production equipment and plant utilities, including reactors, dryers, HVAC systems, clean rooms, DI water systems, label-making and packaging for API finish drug and medical devices product manufacturer, packagers and labelers
- Initiated, determined actions and implemented actions for change controls related to Validation
- Initiated, identified root causes and determined corrective and preventative actions for deviations and non-conformances



## Technical Writing

- Drafted SOPs for Information Technology and Quality Assurance departments
- Developed and provided training on developed/reviewed SOPs

9-6975 Meadowvale Town Centre Circle  
Suite 410 Mississauga Ontario  
L5N 2V7 Canada

TOLL FREE: 1-877-877-5152

PHONE: 905-363-1182

FAX: 905-542-7981

info@qualityandcompliance.com

www.qualityandcompliance.com

www.validapharm.com

www.nhpcompliance.com

Matthew Cousens, Consultant – CV, page 2 of 3



## Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access
- SAP
- ProductVision
- Great Plains
- SQL programming (experienced)

## EDUCATION

- Bachelor of Applied Science, Engineering Science: Biomedical Engineering, University of Toronto, Toronto, Ontario

## CONTINUING EDUCATION, CAREER DEVELOPMENT

- Good Manufacturing Practices (finished products and active pharmaceutical ingredients)
- Fundamentals of Regulatory Affairs, CanReg
- Cleaning Validation and Critical Cleaning Processes - Institute of Validation Technology
- Computer Systems Validation
- Technical Writing Course, Q&C
- GMP for Importers/Distributors, Q&C
- Good Automated Manufacturing Practices (GAMP 4)
- Controlled Drug and Substance Handling, PSG
- GAMP Good Practice Guide: Calibration Management
- WHMIS certification
- Confined Space Entry
- Lock-out/tag-out procedures
- Aerial personnel lift operation