



Richard Parcels

EVP Regulatory & Compliance

A proven team leader and team player, Richard Parcels has a wide range of experience from scientific/technical analysis and validation to consolidating two microbiology laboratories into one. Richard is versatile and thorough in working with the "big picture" to competently covering the smallest detail in GMP documentation. Richard has been involved with Natural Health Product (NHP) regulation since their inception. Well regarded in the NHP and drug industries, Richard builds on his expertise earned from Estee Lauder, Astra Pharma Inc., Warner-Lambert Parke-Davis, and Agriculture & Agri-Food Canada.

SKILLS AND HIGHLIGHTS



Regulatory

- Completed and submitted:
 - Drug Establishment Licence applications
 - Medical Device Establishment Licence applications
 - Category IV Drug Applications
 - Labelling Standard Drug Applications
 - Division I Drug Applications (old drugs)
 - Notifiable Changes
 - New Drug Submission in CTD format
 - Precursor Licensing
 - Drug, NHP, Medical Device and Cosmetic Label Reviews
 - Annual Drug Notifications
 - Site Licence Applications, amendments and notifications

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Regulatory (cont.)

- Completed and submitted:
 - Quality Assurance Reports (QARs) for:
 - Domestic and foreign manufacturing facilities
 - Importers and warehousing facilities
 - Quality Assurance Person forms
 - Product licence applications, amendments and notifications (compendia, transitional and non-traditional)
 - Class II Medical Device Licence Applications



Quality Control Officer (QCO)

- Managed QCO Setup for importers, distributors, and wholesalers
- Hosted and conducted Health Canada (HPFBI) regulatory inspections
- Acted as Quality Assurance Person for natural health product importers
- Performed The GMP Gap Analysis™ to evaluate compliance to Health Canada natural health product GMPs as part of a self-inspection program to meet importing and distribution requirements



Quality Assurance

- Reviewed and managed detailed QA batch record review for release to market for sterile parenteral products
- Conducted biological indicator studies such as D-values and resistance verification according to USP
- Administered routine environmental monitoring in Classes 100, 1000 and 10, 000 using standard microbiological techniques and laser particle counters

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Quality Assurance (cont.)

- Completed routine water analysis and initiated investigation reports on products involved with the water samples when out-of-specification results were obtained
- Routine and non-routine microbial analysis and investigation reports for finished products, bulk and raw materials
- Performed routine and investigational microbiological analysis of raw and ready-to-eat domestic and imported meat samples submitted by government meat inspectors
- Conducted PCR analysis on samples for detection of Verocytotoxin-producing E. coli (VTEC). Maintained cell lines for use in Vero Cell assays for detecting VTEC
- Carried out species verification of raw meat samples using agarose gel immunodiffusion (Ouchterlony Method)
- Determined microbial identifications using Vitek Jr. API 20E and API NFT



Training

- Delivered numerous Drug and NHP GMP training programs for manufacturers, importers, distributors and wholesalers according to Canadian and US GMPs. These sessions ranged from 3 to 50 individuals per session and included practical exercises to ensure understanding of the material



Technical Writing

- Devised, wrote and updated standard operating procedures
- Wrote methods of analysis as well as method revisions and adaptation
- Developed and maintained a raw material supplier quality metrics database

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Validation

- Performed validation studies for Getinge-Castle Autoclave, Bactometer, Laboratory Instruments, Microbiological Test Methods, Cleaning Validation, Process Validation and Water System Validation
- Implemented a reduced powder product testing program based on formula type and validated manufacturing processes
- Performed USP XXIII Sterility testing, bacteriostasis/fungistasis testing, LAL and Liquid Particulate testing on finished product samples
- Performed microbial limits preparatory testing (validation of microbial methods) on raw materials and finished product formulations
- Validated the use of slit-to-agar samplers for the monitoring of filling zones of aseptic filling processes on Rommelag and Automatic Liquid Packaging machines
- Served on committee for the implementation of a system for the validation of test methods in a technical operations department



Medical Devices

- Importer/Distributor Quality Systems
- Classification of medical devices
- Completed and submitted MD Establishment Licence applications



Consulting

- Practical experience in a range of situations, including the following:
 - Development of cosmetic products at the lab batch and pilot batch level with respect to preservative systems and processing steps
 - Implementation of a novel procedure for the growth promotion testing of culture media
 - Supervision of team of microbiologists, performing budgeting and annual performance reviews

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Large Compliance Project Management

- Managed the implementation of a quality control/assurance system for large disinfectant manufacturing company which included implementation of numerous procedures, training programs, test method validation, water system validation and equipment validation. The implementation included a re-inspection by the HPFBI regulatory authority, resulting in a compliant rating.

Computer Skills

- Proficient in use of MS Office -- Word, Excel, PowerPoint
- Experienced with Documentum

EDUCATION

- Bachelor of Science (Honours Microbiology), University of Guelph

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Advanced GMP Auditing
- Audit Report Review
- Auditing Skills
- Auditing, PSG
- cGMP Overview, Aventis Pasteur
- Clinical Trial Overview/Introduction to Clinical Quality Assurance
- Color & Make-Up, Society of Cosmetic Chemists
- Delegation Workshop/Thinc Strategies, THINC Ideal Inc.
- Design of Experiments, G.R. Technologies

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CONTINUING EDUCATION, CAREER DEVELOPMENT (cont.)

- Deviations and Change Control
- Drug DIN Applications
- Fundamentals of Regulatory Affairs, CanReg
- GMP for Wholesalers, Q&C
- GMP Training, Aventis Pasteur
- HPFBI Audit Management
- ICH Stability Guidelines
- Industrial Drug Legislation, Seneca College
- Internal Auditor for Manufacturing, QMI
- Introduction to Clinical Quality Assurance, PSG
- Introduction to GMP Training for Importers/Distributors, Q&C
- Introduction to Regulatory Affairs, PSG
- NHPD workshop - Guidance workshops for Product Licences and Site Licences (Dec 2004)
- NHPD workshop - Introduction to NHPD (Nov 2003)
- Product Disposition, Q&C
- Project Management, Kepner-Tregoe
- Review of Changes to Risk Classifications of GMP Observations, Q&C
- Supervisory Training
- Technical Writing Course, Q&C
- Validation and Qualification of Pharmaceutical Processes and Equipment, Seneca College (12-week course)
- Validation for the 21st Century, PSG

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