James M. Clinton, MS, RAC

5105 Fairoaks Rd, Durham, NC 27712 (919)247-0479 e-mail: jclinton@QandRConsulting.com

SUMMARY

During a 20+ year career with pharmaceutical and medical device and companies, established a solid performance record in a series of increasingly responsible Quality Assurance and Regulatory Affairs management positions. Recognized expert in quality systems and validation; strong quality systems implementation skills; successful premarket and postmarket compliance negotiations with FDA (PMA, 510k, IDE and ANDA); FDA 483 and Warning Letter response; leadership in process validation development / implementation; aseptic processing; quality incident investigations; complaints and medical device reports; medical device labeling; microbiology laboratory management; expertise in developing; and managing cross-functional project teams.

PROFESSIONAL EXPERIENCE

Quality and Regulatory Consulting, LLC **April 2000 to Present**

Raleigh, NC *Principal Consultant. Consulting services to biological, pharmaceutical and medical device industries*

- Performed FDA compliance gap assessments of pharmaceutical and medical device manufacturing and QA organizations and developed and implemented remediation plans aimed at restoring substantial compliance.
- Developed and implemented validation projects for pharmaceutical manufacturing process and support systems (facilities, equipment, and water systems),
- Developed cleaning validation protocols for stainless steel plasma mixing vessels (100 to 10,000 liters) using total organic carbon analyzer and microbial monitoring methodologies.
- Managed validation remediation projects for pharma firms operating under consent decree with FDA,
- Prepared and executed protocols to qualify equipment and to validate sterilization, cleaning, lyophilization and production processes compliant with Good Manufacturing Practices,
- Developed sterilization validation protocols for steam, vapor phase hydrogen peroxide, dry-heat, ETO and sterile filtration processes;
- Developed master validation plans and quality assurance systems compliant with FDA regulations;
- Trained and advised client staff on investigation procedures to identify root cause and corrective actions for non-compliant events occurring in manufacturing, QA and laboratory areas,
- Developed quality systems for start-up operations compliant with FDA requirements,
- Performed FDA quality system readiness audits, gap analysis, and remediation projects for pharmaceutical firms preparing for FDA investigation,
- Prepared expert responses to FDA Form 483 Observations and Warning Letters,
- Prepared ANDA CMC sections describing facility, utility, equipment, sterilization and manufacturing processes,
- Managed software QA activities to meet requirements,
- Performed internal compliance audits of manufacturing / QA processes, external supplier sites, and clinical trial sites for compliance with manufacturer's requirements, FDA and international standards;
- Conducted internal reviews of alleged wrongful acts associated with applications submitted by client pharmaceutical firms to FDA;
- Performed risk management training for product assessment, essential user requirements and critical control point determination for medical device products;
- Audited Clinical Trial sites for biological pharmaceutical sponsor.
- Led medical device 510(k) and PMA preparation activities including labeling development and guided FDA submission activities.
- Served as US Agent liaison for non-USA based medical device companies regulated by FDA.
- Confidential client list includes numerous pharmaceutical (all dosage forms – branded, generic and API) and medical device companies in the USA, Europe, Asia, and Australia.

TriPath Imaging, Inc. (formerly AutoCyte, Inc.) **September 1998 to April 2000**

Burlington, North Carolina *Vice President / Director, Regulatory Affairs and Quality Assurance*
Medical Device and In Vitro Diagnostics.

- Prepared FDA Pre-Market Approval Applications for cervical cytology devices
- Developed clinical trial protocols and evaluated trial site compliance to GCP and approved protocols
- Successfully negotiated PMA and GMP issues with various FDA offices (ODE-CDRH and Atlanta District)
- Managed FDA inspections and prepared successful responses to FDA form 483 Observations,
- Developed Design Control and Quality Systems compliant with FDA regulations and company preferences
- Led growth of R&D Validation Group and development of Validation Master Plan for Software and Hardware
- Directed ISO 9000 / ISO 13485 registration and CE Mark certification efforts

Cardiovascular Diagnostics, Inc. and Coeur Labs **Jan 1996 to Nov 1997**
Raleigh, North Carolina *Director, Regulatory Affairs and Quality Assurance*
Medical Devices and In Vitro Diagnostics. Directed efforts of IVD Medical Device manufacturer (coagulation systems) comply with ISO 9000 standards; GMP / QSR; Medical Device Reporting regulations; Sterilization Equipment and Software Validations; Premarket Notification 510(k) Requirements; European Medical Device Directives.

- Extensive FDA interactions regarding 510(k)s; recalls, inspectional issues and medical device reports
- Administered QA and compliance programs including product testing, process / lyophilization validation, batch record review and supplier certification; FDA audit awareness and lead; international registrations; GMP training; and MedWatch response.
- Implemented and chaired Management Review Board responsible for improving quality of non-conforming materials and products. Non-conformities reduced by 50% over 6 months.
- Developed Quality Assurance Program for materials, labels and products in compliance with GMP and ISO.
- Directed company-wide program which successfully achieved ISO 9002 certification in 9 months.

Bayer Corporation **1981 to 1995**
Clayton, North Carolina *QA Manager Biology/Biochemistry* 1993 to 1995
Biological Pharmaceuticals: Managed 45 employees (exempt and non-exempt) providing various biological testing: animal; cell-culture; microbial; ELISA; coagulation; enzyme; sterility; other immunoassay.

- Responsible for product testing (biochemical / biological potency, sterility) environmental monitoring (water systems, air systems, other utilities), facilities qualification and process validation (lyophilization, sterilization and aseptic filling).
- Developed sterilization validation protocols for steam, vapor phase hydrogen peroxide, dry-heat, ETO and sterile filtration processes;
- Developed cleaning validation protocols for stainless steel plasma mixing vessels (100 to 10,000 liters) using total organic carbon analyzer and microbial monitoring methodologies.
- Coordinated FDA Establishment License Amendment allowing testing to begin off-site.
- Managed transfer of animal testing 1000 miles off-site with no loss in testing efficiency.
- Managed cross-functional project to validate construction of new animal facility and labs that completed activities on-time.

Elkhart and Mishawaka, Indiana *QA Supervisor, Chemistry Products* 1981 to 1993
Diagnostics: Supervised 8 employees providing technical support for clinical chemistry reagent and instrument products.

Boehringer Mannheim Corporation, Indianapolis, Indiana **1978 to 1981**
Supervisor, Microbiology/Immunology QA
Diagnostics: Supervised 3 personnel performing release testing of manufactured product; Radiation Safety Officer

Indiana University School of Medicine, Indianapolis, Indiana **1976 to 1978**
Department of Rheumatology Research technician 1977 to 1978
Performed cell-culture experiments to study amyloid proteins and the human immune response.
Department of Pediatrics Research assistant 1976 to 1977
Performed animal studies of intestinal transport of nutrients and its interference by anti-asthmatic drugs.

EDUCATION

M.S. Microbiology, Indiana University, Indianapolis, IN 1977
Special study of Chlamydia culture methods under the direction of E.S. Murray, M.D., Harvard School of Public Health, Boston, MA 1976
B.A. Biology, University of Massachusetts, Boston, MA 1974

CERTIFICATION/AWARD

Regulatory Affairs Professional Society Regulatory Affairs Certified (RAC) 2007
RAB Quality Systems-Provisional Auditor Certificate No. Q06821. 1998
ASQC certified quality auditor 1997
Marquis' Who's Who in Frontier Science and Technology 1984
ASQC certified quality engineer 1982

PUBLICATIONS

Clinton, JM. *Determining the key initial steps in risk management*. IVD Technology 14 (2008).

Watson, R.R., Horton, G.R. and Clinton, J.M. *Secretory IgA in tears and vaginal secretions of marginally protein malnourished guinea pigs infected with Guinea Pig Inclusion Conjunctivitis,* in The Preocular Tear Film in Health, Disease and Contact Lens Wear. Holly, F.J. ed. 826-838 (1986).

Watson, R.R., Horton, G.R. and Clinton, J.M. *Suppression of secretory IgA antibodies in protein malnourished guinea pigs following a chlamydial eye and vaginal infection*. Federation Proceedings 35: 1251 (1977).

Clinton, J.M. et al. *Concentration changes in vaginal enzymes and S-IgA following a vaginal chlamydial infection in normal and malnourished guinea pigs*. Federation Proceedings 35: 739 (1976).
Presented article to 1976 meeting of American Society for Experimental Biology.

ASSOCIATION MEMBERSHIPS

American Society for Quality, American Society for Microbiology, International Society for Pharmaceutical Engineering; Regulatory Affairs Professional Society