James M. Clinton, MS

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SUMMARY

During a 20+ year career with medical device, plasma fractionation, and pharmaceutical 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 manufacturing quality systems implementation and auditing skills; successful premarket and postmarket compliance negotiations with FDA (PMA, 510k, IDE and ANDA); FDA 483 and Warning Letter response; leadership in validation development and implementation (Process, Cleaning, Software validation / Part 11, IQ/OQ/PQ); aseptic processing including batch record design / compliance review; quality incident investigations; complaints and medical device reports; medical device labeling; microbiology laboratory management; expertise in developing; and managing cross-functional project teams. Extensive auditing pharmaceutical and medical device Quality Management Systems for compliance with requirements and standards

- Pharma: 21 CFR Parts 210 &211, ICH Q7 GMP Guide for APIs, ICH Q10 Pharmaceutical Quality Systems
- Medical Device: ISO 13485:2016, US FDA 21 CFR Part 820, EU Medical Device Regulation 2017/745, ISO 14971 Risk Management

PROFESSIONAL EXPERIENCE

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

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

- Audited quality systems for compliance with regulatory requirements and international standards. Auditees included medical device, pharmaceutical companies and combination device-drug companies. Systems audited include complete quality systems, supplier site audits, and clinical trial sites. Assessed EU MDD Technical File documentation for compliance with 2017 EU MDR Annex I Technical Documentation Requirements.
- Consulted on numerous pharmaceutical and medical device consent decree projects as an independent cGMP expert to identify compliance gaps, remediate discrepancies and restore compliance with FDA and international regulations with efficient systems geared to specific client needs. Worked as a subject matter expert and team leader in the following areas:
  - Corrective and Preventive Action (CAPA) systems: remediated non-compliant systems focus on root-cause investigations, identification of corrections and corrective actions to prevent recurrence and implementation of plans for CAPA effectiveness verification.
  - Design Controls: remediated deficient systems bringing all required elements of 21 CFR 820.30 into compliance (Design Planning, Design Input, Design Output, Design Review, Design Verification, Risk Management, Design Validation, Design Transfer, Design History File, Device History Record, Design Change).
  - Product Surveillance: remediated ineffective complaint investigation procedures and medical device reporting practices.
  - Manufacturing / Quality Engineering: remediated systems for Manufacturing Quality, Calibration/Test Equipment; device labelling, batch records, and process validation (facility / equipment qualification, process, cleaning and software validation activities).
  - Sterilization: Remediated systems for controlling microbial contamination of products and environments: sterilization validation (steam, ETO, gamma), aseptic processing / media fills (clean rooms and isolators), environmental monitoring / bioburden analysis and control.
  - performing independent verification activities of various quality system elements and preparing final certification reports as defined by consent decrees that supported substantial compliance.
  - Aseptic process assessments including batch record re-design and review.
- Developed and implemented validation projects for pharmaceutical manufacturing process and support systems (facilities, equipment, water systems, laboratory systems, software validation and 21 CFR Part 11 compliance),
- Developed risk-based cleaning validation protocols for stainless steel plasma mixing vessels (100 to 10,000 liters) and processing equipment using total organic carbon analyzer and microbial monitoring methodologies.
- 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 Chemistry, Manufacturing and Controls 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;
- 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), medical device and combination device-drug product companies in the USA, Europe, Asia, and Australia.

TriPath Imaging, Inc. (formerly AutoCyte, Inc., now BD Diagnostics TriPath) **Sep 1998 to Apr 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 Quality Systems compliant with FDA regulations and company preferences, including Design Controls, Complaint investigations and medical device reporting,
- 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, complaint investigations 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 (now Grifols) *QA Manager Biology/Biochemistry* 1993 to 1995
Biological Pharmaceuticals - Plasma Fractionation: 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 (now Roche Diagnostics), 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

Medical Device Lead Auditor (ISO 13485:2016) with Scope of Certification: EU Medical Device Regulation (EU) 2017/745, Exemplar Global Certificate No. 206209 Oct 2019
Regulatory Affairs Professional Society Regulatory Affairs Certified (RAC) 2007, 2013
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

TRAINING / PRESENTATIONS / PUBLICATIONS

Clinton, JM. *Medical Device Compliance and Postmarketing Activities,* 2-hour training presentation at North Carolina Regulatory Affairs Forum (NCRAF) for professionals preparing for US Regulatory Affairs Certification (RAC), 2008-2019.

Clinton, JM. *IVD 510(k) Workshop,* Educational presentation at Medical Devices and IVD meeting of RegAffairsNC , 31 October 2014.

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