



## Richard A. Vincins

*Vice President, Quality Assurance*

### EXPERIENCE:

- Director, Regulatory Affairs and Quality Assurance, HemaCare BioScience
- Director, Quality Assurance and Regulatory Affairs, StatSpin, Inc. (Iris Diagnostics)
- Manager, Regulatory Affairs, Cytosol Laboratories, Inc.
- Manager, Quality Assurance Compliance, Lumenis (ESC Sharplan)
- Manager, Quality Assurance reporting to VP of Quality and Regulatory, bioMérieux, Inc.
- Manager, Quality Assurance and Regulatory Affairs, Medtronic Gastroenterology Group (Zinetics Medical)
- Manager, Quality Assurance Specialist reporting to Quality Assurance, Bard Access Systems (Division of C.R. Bard)

### AREA OF EXPERTISE:

Including, but not limited to

#### *Products:*

- Biological Cell Therapy
- Biotech
- Combination
- Dental Equipment
- Diagnostics
- Disposable
- Ear, nose, and throat
- Electrosurgical
- Gastroenterology/urology
- Hospital hardware
- Imaging equipment
- Implants, active/non-active
- Irradiated cancer therapeutics (for liver cancer)
- *In Vitro* Diagnostics
- Material Suppliers
- Mobility aids/equipment
- Neurological
- Ob/Gyn
- Ophthalmic/optical
- Orthopedic
- Patient monitoring
- Pharmaceuticals
- Reusable Instruments
- Sleep Apnea



- Software
- Surgical Instruments
- Therapeutic
- Apps/smart phone application

*Disciplines:*

- Regulatory Affairs Certified (RAC) in both United States and European Union regulatory affairs
- Pre-IDE, PMA, and 510(k) submissions
- Preparation of technical files and design dossiers for medical devices and *in vitro* diagnostics
- Regulatory strategies for new product development
- Multiple medical device license applications, TPD, Health Canada
- Development, implementation and maintenance of quality management systems for compliance with 21 CFR Part 820 quality system regulation, ISO 13485:2003, and ISO 9001:2008
- Internal quality system and supplier quality audits for medical devices and *in vitro* diagnostics
- Conformity assessments for CE Marking to 93/42/EEC, Medical Devices Directive and 98/79/EC, In Vitro Diagnostic Devices Directive
- Conformity assessments for Canadian Medical Devices Conformity Assessment System (CMDCAS) to CAN/CSA ISO 13485:2003 for quality management systems
- Conformity assessments for Japan Pharmaceutical Affairs Law (JPAL) to Ordinance #169 for quality management systems
- Compliance audits for Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP)
- Validation support for various processes; sterilization, cleaning, software, equipment
- Clinical affairs including site qualification, site monitoring, and protocol development

**EDUCATION:**

- Biomedical Biology Bachelor of Science Degree, Bridgewater State College, Bridgewater, MA USA
- Chemical Engineering Associate of Science Degree, Salt Lake Community College, UT USA

**PROFESSIONAL AFFILIATIONS:**

- Senior Member of American Society of Quality (ASQ)
- Member of Regulatory Affairs Professional Society (RAPS)
- Member of the US Technical Advisory Group (TAG) 176 for Quality Management Systems (ISO 9001)
- Active Committee member of the Biomedical Division for ASQ

**TRAINING and CERTIFICATIONS:**

- Certified Quality Auditor – CQA through American Society of Quality
- Certified Quality Technician – CQT through American Society of Quality



- Regulatory Affairs Certified (US) – RAC(US) through Regulatory Affairs Professional Society
- Regulatory Affairs Certified (EU) – RAC(EU) through Regulatory Affairs Professional Society
- Accreditations and certifications for Medical Device applications (clean room, sterilization, DOE)