EMERGO GROUP

Gus Bock

Senior Consultant, Quality Assurance and Regulatory Affairs

EXPERIENCE:

- Vice President RA/QA: Salter Labs
- Vice President RA/QA: Biolase Technology
- Vice President RA/QA: Advanced Sterilization Products, a J&J Company
- Vice President RA/QA: Sorenson Medical
- Director QA: Hudson RCI
- Vice President RA/QA: Birtcher Medical Systems
- Director RA/QA: Innovision
- Director QA: IOLAB, a J&J Company
- Director RA/QA: Cardiovascular Devices
- Director RA/QA: CILCO
- Manager QA: Edwards Laboratory, American Hospital Supply

AREAS OF EXPERTISE:

Including, but not limited to

Products:

- Respiratory Devices and Sterile Water and Saline for Respiration
- Ophthalmic, including Intraocular Lenses and Surgical Lasers
- Surgical Lasers and Medical Electronics
- Cardiovascular, including catheter systems and heart valves
- Electrosurgical and Laparoscopic
- Dental and Orthodontics
- Orthopedic

Disciplines:

- FDA Quality System Regulation – 21 CFR Part 820
- ISO 13485:2003 – Medical Devices – Quality Management Systems
- ISO 14971:2007 – Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993 – series: Biological Evaluation of Medical Devices
- ISO 14969:2004 – Medical Devices – Quality Management Systems –Application of ISO 13485:2003
- CE marking – Technical Files and Design Dossiers
- Material Biocompatibility, Controlled Environments and Sterilization
- Canadian Medical Device Regulations and Product Licensing

EDUCATION:

- M. Management, Claremont Graduate School
- B.Sc. Biology, California Western University

PROFESSIONAL AFFILIATIONS:

- American Society for Quality (ASQ)

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TRAINING AND CERTIFICATIONS:

- RAB/QSA QSM Auditor