# Scott Sardeson, RAC US/EU

## EXTERNAL PROFESSIONAL ACTIVITIES

- ISO Convener for Technical Committee 210 Working Group 1 (TC210 /WG1) -Application of quality systems to medical devices
    - *ISO 13485:2016 Medical Devices – Quality Management Systems -Requirements for regulatory purposes*
    - *ISO 13485:2016 – A Practical Guide – Advice from ISO/TC210*
- Asia Harmonization Working Party (AHWP) Industry Advisor
    - *Playbook for Implementation of a Medical Device Regulatory Framework (AHWPTC/OB/R001:2014)*
- St. Cloud State University Adjunct Faculty –
    - *Adjunct Professor in Master of Science in Regulatory Affairs and Services Program*
- Former Global Harmonization Task Force (GHTF) Study Group 3 US Industry Representative
    - *GHTF N18 - Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes*
    - *GHTF N19 Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange*
- Medical Device Single Audit Program (MDSAP) Pilot Program participant
- Member of various AdvaMed International working groups
- Regulatory Affairs Professional Society certification US and EU regulations

## WORK HISTORY

**9/2002-Present 3M Health Care Business, Minnesota**
***International Regulatory Affairs and Quality Compliance Director***

- Responsible for international compliance of health care products (medical devices, drugs, and cosmetics) globally marketed to support 3M's Health Care Business
- Assure Regulatory filing and quality system applications are compliant to support marketed sales in > 60 countries
- Support global harmonization and convergence of regulation to assure all class of products are represented

**9/2000- 9/2002 Baxter (formerly Synovis Life Technologies), Minnesota**
***Quality System/Regulatory Affairs Director***

- Responsible for the regulatory and quality requirements for new product development and joint business ventures
- Manage regulatory compliance for bovine tissue based medical devices globally

**3/1996- 9/2000 Ethicon (CLOSURE Medical Corporation acquisition), North Carolina**
***Regulatory Affairs Specialist and R&D Chemist***

- Prepare, review, and maintain US, European, and international regulatory submissions
- Assure company compliance to US FDA QSR, ISO standards, EU Medical Device Directive, and US FDA Medical Device Reporting
- R&D internal auditor, supplier controls for surgical adhesives platforms

**Pre - 1996 – Various R&D positions (In-vitro Diagnostics, pharmaceutical research, and clinical laboratories**

**EDUCATION: Bachelor of Science in Chemistry, University of Minnesota**