Curriculum vitae for Donald Tumminelli

Don Tumminelli

Manager, Validation & Testing Services

HIGHPOWER Validation Testing & Lab Services

125 Highpower Road · Rochester, NY 14623

Direct: 585-743-1940 Fax: (585)-697-1506

E-mail: <u>dtumminelli@highpowervtls</u>.com

RELEVENT EXPERIENCE

HIGHPOWER Validation & Testing Lab Services

2012 - Present

Manager, Validation & Testing Services

- Internal and External Lead Auditor ISO 13485 and ISO 17025 as well as FDA QSR
- Involved with all day to day Lab operations
- Project generation/study design
- Prepare Educational programs
- Trade show marketing and sales
- AAMI/ISO and ASTM committee member
- Write equipment or procedure specific LSOP's
- Develop IQ/PQ/OQ protocols
- Technical Reviewer
- Process validations
- AORN corporate member
- IASCHMM member
- ISO 18472 Co-Chair
- Audit Lead
- Medical Device Consulting
- Contract Sterilization Cycle Development for ETO/STEAM/VHP/GAMMA

SPS Medical Supply Corp

2003 - 2012

Laboratory Manager/R& D

- Research/Developed and tested new medical devices
- Chemical Indicator development
- Biological Indicator development
- Microbiology
- FDA compliance

EDUCATION

Humboldt State University – California

B.S. Environmental Science, Water Quality/Environmental Microbiology 2001

LANGUAGES- ENGLISH ONLY