

Curriculum Vitae for Walt Brittle, MBA

Summary of Achievements

- Thirty-five years of experience in marketing, manufacturing, regulatory compliance, research and development, and clinical practice. Competency in contract sterilization, single-use device reprocessing, sterility assurance products, endoscopes, surgical drapes, medical textiles, biological products, hospital supplies, specialized medical electronic devices, complex diagnostic systems, optics, laser systems, surgical instruments, microsurgery, and fiber optics.
- Written or reviewed more than 100 510(k) applications over a 30-year period.
- Led 15 regulatory inspections, reviewed 483 responses, and installed six complete quality management systems in the past 10 years.
- Extensive knowledge of medical devices and device sterilization gained while working at V. Mueller-AHSC, Narco/Pilling, Synthes, Meadox Medicals, Surgicot, and Steris.
- More than 20 years of experience in medical device general management, with hands-on leadership of product development (design controls), marketing, regulatory affairs, and manufacturing operations in seven different companies.
- Several surgical product marketing campaigns developed that resulted product market leadership.
- Performed internal and external GMP audits, both domestic and international, over 10 years.
- Six years' experience troubleshooting sterilization cycle failures in hospitals, including one extensive ethylene oxide sterilization cycle failure investigation covering three years of device history sterilization records to identify and recommend corrective and preventive actions.
- Fourteen-month warning letter remediation for a prescription drug packaging firm supervising a team of three consultants.

Professional Experience

FDA Compliance Help Desk, Inc. (Chapel Hill, NC)

(2004 - Present)

Managing Partner

Regulatory compliance consulting services to medical device and pharmaceutical firms

- Performed ethylene oxide sterilization cycle failure investigation covering three years of device history sterilization records to identify and recommend corrective and preventive actions to conform with the following standards: ANSI-AAMI-ISO 11135, TIR 14, TIR 15, TIR 16, and the United States Pharmacopeia (USP).
- Performed retrospective review of biological indicator CAPA investigations.
- Reviewed and corrected report files used to qualify two interim contract sterilization suppliers.
- Performed complaint file documentation review and correction project covering more than 300 files.
- Collaborated with an associate consultant to develop a complaint-handling/MDR training program for RA/QA management and complaint investigators.
- Coached staff managers in post-market risk assessment and failure modes, effects, and criticality analysis (FMECA).
- Performed pharmaceutical firm non-beta lactam facility decontamination and requalification.
- Performed pharmaceutical firm sampling and laboratory testing to develop objective data to demonstrate a product recall is not necessary.
- Designed and qualified a new beta lactam packaging facility.
- Performed pharmaceutical firm employee training and validation, Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records.

- Responsible for pharmaceutical firm environmental qualification.
- Responsible for pharmaceutical firm component and labeling records compliance to CFR 211.184 Component, drug product container, closure, and labeling records.
- Acted as U.S. registered agent for overseas manufacturer, complaint and MDR handling, pre-market notifications, quality system installation, and auditing.

Rx Textiles, Inc. (Monroe, NC)

(2003 - 2005)

VP Marketing, CFO, administrative services, consultant

Quality and regulatory compliance and other activities

- Market Research— New Product Line.
- Developed Marketing Strategy.
- Performed compliance audits.
- Completed a recall in accordance with FDA regulations.
- Installed a fully compliant quality system.
- Established an appropriate quality control and regulatory compliance department.
- Performed warning letter remediation triggered by the recall.
- Hired and trained a regulatory compliance staff.

Brittle and Company (Chapel Hill, NC)

(1999 - Present)

Managing Partner

Business improvement engineering and pre-acquisition due diligence, including FDA compliance

- Design and facilitation of Strategic Plan Development Retreats.
- Performed FDA readiness and QSIT audits.
- Performed MDR assessment and corrective actions.
- Customer site investigations to solve sterilization process failure complaints.
- Installed an FDA-compliant quality system.
- Audited medical products firms as part of pre-acquisition due diligence.

Steris Corporation (Mentor, OH)

(1992 - 1999)

CEO of Surgicot, Inc. subsidiary (business sold to Steris in October 1996)

Sterility assurance products

- Led the acquisition of the business from Bristol-Myers Squibb.
- Recruited the management team and consolidated three facilities into one within six months after buying the business, as required by the seller.
- Completed regulatory compliant facility qualification in 24 months.
- Brought biological indicator spore manufacturing in house in 1995, improving product quality, reliability, and cost.
- Defended intellectual property of the company as the only witness for the company in a lawsuit resulting in a \$1.4 million settlement paid to Surgicot, Inc.
- Defended Class II biological indicator claims for reduced readout time to a team of consultants conducting due diligence and to the FDA, which was conducting inspections to ensure that all sterility assurance biological indicator readout claims were still valid. Surgicot was the only firm in the industry not required to change its 24-hour readout claims.
- Led the integration of Surgicot and AMSCO into a combined biological products subsidiary.

Synthes USA (Paoli, PA) (1990 - 1991)

Vice President and General Manager

Maxillofacial Orthopedic Products Division

- Established a new product development team of product directors and engineers to develop maxillofacial implants.
- Coordinated clinical investigations with leading maxillofacial surgeons at UCLA Medical Center, Johns Hopkins University, the University of Connecticut, and universities in Switzerland and Germany.
- Served as a key member of the regulatory compliance team for maxillofacial products concerning cGMPs and regulatory submission and strategies.
- Performed new product joint venture development work with 3M.

Flow Laboratories/ICN Biomedical (Costa Mesa, CA) (1988 - 1990)

Managing director, Asia-Pacific Region

Medical Research Products Division

- Increased financial results from Asia-Pacific operations by more than 25 percent.
- Led a project team including a leading microbiologist to develop a patented replacement for fetal blood serum. Completed the due diligence and terminated the project for failure of the inventor to prove product effectiveness based on good scientific laboratory practices.
- Assessed the Australian fetal blood serum manufacturing plant's ability to comply with cGMPs, international regulatory standards, and its ability to effectively produce a high-quality product.
- Led the Asia-Pacific region subsidiary CEOs to develop regulatory compliant transfer strategies that substantially reduced local taxes and increased corporate parent profits.

Meadox Medicals, Inc. (Oakland, NJ) (1986 - 1988)

President of Surgimed A/S and Surgimed, Inc.

Interventional radiology, cardiology and urology catheters

- Restored the companies to profitability by implementing a cost-effective strategy for regulatory compliance, effective expense controls, growth, and strategic pricing.
- Installed an FDA-compliant quality system in Denmark.
- Led the largest new-product development program in the history of the company to develop patented heart angioplasty products, including a balloon catheter, a coronary artery stent, and accessories.
- Performed clinical investigations in Sweden, Germany, and France.
- Reengineered manufacturing processes to ensure EC, ISO, and FDA compliance.
- Completed and qualified a state-of-the-art clean-room manufacturing facility in Denmark in accordance with FDA and international regulations.

Healthdyne, Inc./Narco Scientific (Marietta, GA) (1980 - 1986)

Vice President Marketing, President of the Pilling Company, CEO of two ventures

Cardiovascular, surgical lighting, fiber optics

- Planned and implemented a multiyear production process improvement and modernization program to be compliant with cGMPs.
- Established an aggressive new product development program in compliance with cGMPs. More than 100 new products developed with proper premarket regulatory documentation.
- Defended several medical device lawsuits using good instructions for use, contraindication documentation, and other cGMP documentation.

- Developed a corporate acquisition strategy for the surgical products division and implemented the strategy by negotiating three primary acquisitions and completing due diligence to ensure strategic fit, value, and regulatory compliance.
- Established and led two research and development corporations: International Endoscope Manufacturers and Infrared Fiber Industries.

American Hospital Supply Corporation (Niles, IL)

(1973 - 1980)

Successive positions to Director of Sales and Marketing

Surgical instruments and equipment

- Conducted marketing research by surveying more than 5,000 hospital operating room supervisors. Received a letter of commendation from AHSC's Vice President of the Medical Specialties Group for this work.
- Led the new-product development team working with leading surgeons, including Denton Cooley and medical researchers at Indiana University, on a plasma-cutting device.
- Developed the product labeling and all documentation to support market introduction in 1976.
- Developed a quality improvement plan that resulted in annual general surgical product sales growth greater than 20 percent.
- Led a team of eight and submitted 510(k) premarket notification data on hundreds of product lines to the quality department for submission to the FDA.
- Developed and introduced a new microsurgical product line to address the emerging needs in the markets of eye, ear, nose, throat, and neurosurgery in compliance with FDA regulations.
- Negotiated the acquisition of a line of IOL products and a major line of specialty microscopes.
- Increased business center revenue more than 20 percent per year.
- Designed, developed, and implemented an innovative business model making it possible to effectively market multiple lines of specialty products through a single sales force of 210 people supported by six product line specialists.

Education and Training:

Rx Textiles, Laragh course, (quality management, ISO 9001:2000, certification, and auditing)	2004
Steris Corporation, CAPA, design control, and MDR training	1998
Surgicot, cGMP and Quality System Regulation training	1997
Narco Scientific, regulatory compliance and cGMP training	1982
Clinical and surgical care training (OJT), U.S. Naval Hospital	1980
American Hospital Supply Corporation, cGMP training	1978
New Product Development and Engineering course, New York University	1977
Executive Technique, communication workshop	1977
Columbia University Executive Program	1976
University of Miami, MBA in Finance and Marketing	1973
University of Miami, BBA in General Management	1971
U.S. Coast Guard Reserve Officer Training	1971
Post-graduate study in systems and inventory and process controls	1970
Florida Community College, AA, course work in biology and physiology	1969
Hospital Corpsman Training, Great Lakes U.S. Naval Hospital	1968

Publication:

Regulatory guidance article: "Consider more than 510(k) class for sterilization trays," *Healthcare Purchasing News*

August 2001

Affiliations:

Three-time recipient of V. Mueller AHSC Management Excellence Award	1975, 1976, 1978
Recipient of Rudy Garfield Award, Narco Scientific, presented for superior growth, general management capability and practice (the only time the award was presented).	1982
Guest speaker at the Biomedical International Conference on Minimally Invasive Surgery to address trends in laser surgery.	1984
Member of the Association for the Advancement of Medical Instrumentation	Present
Member of AAMI working groups tasked with drafting national and ISO standards for biological and chemical sterilization assurance products	1993 - 1998
Operations chairman and business counselor for SCORE small-business consultants, Chapel Hill-Carrboro, NC	2005 - Present
Webmaster for www.SCOREchapelhill.org	2005 - Present
Organize and facilitate planning workshops for nonprofit firms	1981 – Present

Contact Information:

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