DARREN L. REEVES

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EDUCATION:

Masters in Business Administration (MBA), Averett University, Richmond., VA (1996).

Bachelor of Science, Biology; Randolph-Macon College; Ashland, VA (1987).

EXPERIENCE:

President/Owner, DP Distribution & Consulting, Business, Quality and Regulatory consulting for the Medical Device Manufacturing Industry. Richmond, VA; 1997 - Present.

- Provide **Business, Operations, QA/RA advice and training** to medical device manufacturing companies.
- Specialize in regulatory and operations support for **Start Up & Existing Medical Device Companies**.
- Provide **sterilization and process validation and engineering** expertise.
- Developed a team of **expert associates** able to handle all medical device manufacturing and marketing issues.
- Expertise in acting as **Management Representative** for small, medium and very large medical device companies.
- Support companies with FDA compliance issues such as **Warning Letters and Recalls**.
- **Trainer for International and Domestic companies** on FDA compliance and QA/RA activities.
- **Sample Client List:** Cordis Company. / Ethicon, Inc. (J&J Companies); Matsushita Electric (Parent to Panasonic/Toshiba; Contract Mgr for Seimens); GAM Industries / Duromed Industries (Medical Home Healthcare Distributors); Wyeth, Inc. / Leake, Inc (Pharmacuetical Manufacturing & Distribution); Maxxim Medical, Inc / Merit Medical Systems, Inc. / MedSource Packaging Concepts / American Contract Systems (Surgical kit and tray Assemblers); Best Industries (Brachytherapy and Radiotherapy devices); Genedge; Fisher Scientific (Diagnostic Group); Welmed, Inc. (Hypodermic Syringe Marketer); Stat-A-Matrix (International Consulting & Training); American Red Cross; Benchmark Electric, Inc. (Electronic medical devices); Ajinamoto, Inc (Nutraceuticals); Coeur Medical (Disposable devices); Precept Medical Systems, Inc / Clinitech (Surgical drapes, gowns and accessories); Saudi Arabian Syringe Manufacturing company; Indian Surgical Blade Manufacturer; Altia

COVID-19 Pandemic Expertise, Supporting companies in pivot manufacturing of PPE; **Nationwide,** based in Oilville, Virginia; April 2020 – End of Pandemic.

- Contracted by US MEP program to monitor US agency activities with respect to **enforcement discretion, EUA**s and FDA & NIOSH policies, April 2020.
- Develop and present 4 US MEP Webinars on **PPE Manufacturing** during the Pandemic; beginning March 27, 2020.
- Contracted to review the Commonwealth of VA **COVID-19 PPE** Retooling Playbook in conjunction with Homeland Security Division, Virginia Dept of Health and Virginia Manufacturers Association, April 2020.
- Contracted with the State of New York to support the retooling of NY Manufacturers, April 2020.
- Contracted with the State of North Carolina to support the retooling of the NC Manufacturers, April 2020.
- Working with OEM and NIOSH on **N95 and Surgical N95 Approval** process. May 2020.
- Wrote **Quality Plan** for approval of N95 Approval process. May 2020.
- Conducted **PPE retooling Webinar** for the state of North Carolina. June 2020.
- Developed and conducted **Control of Infectious Diseases Webinar** for the VA Manufacturers Association. August 2020.
- Conducted PPE retooling Webinar for the state of Alaska, August 2020.
- Consulted with over 80 companies in retooling across the US. March through end of pandemic.
- Set up over 10 **Quality Management Systems** so that pivoting companies can continue after pandemic.

➢ DARREN L. REEVES (CONTINUED)

- Primary medical device expert for national **Manufacturer's Extension Partnership (MEP)** to support pivoting**.**
- Developed and submitted multiple **510(k)s and Q-Submission** documentation to the FDA.
- Device expertise in PPE to include ISO gowns & Masks, Surgical Gowns & Masks, N95 Respirators, other PPE.

Vice President, Quality & Regulatory, Surgical Group, Maxxim Medical; Medical Device Manufacturer (2000 Sales: $1.2 Billion); Richmond, Virginia; August 1996 – January 2000.

- Responsible for **reengineering, directing, and conforming** eight locations to **ISO 9000 & 13485 Standards.**
- Responsible for QA/RA of 9 sites, three international with 15 direct reports and ~ 170 indirect reports.
- **Project manager** for the development of **business unit goal setting** for five locations.
- Facilitator to increase throughput by 30% in Richmond location using **Theory of Constraints (TOC)** Techniques.
- Member of **Surgical Group Business Team** which developed the strategy and business plan for the group.
- Developed **Corrective and Preventive Action Systems** in an effort toward **Continuous Quality Improvement.**
- European compliance and vendor certification including **CE Marking** for five locations.
- Maintain compliance to and **develop/conduct training** for FDA's **Quality System Regulations** (QSR).
- **Due Diligence** performed on potential site acquisitions.
- **Develop budget** for a $9 million department within a $740+ million group.
- Developed a **Cost of Quality Program** for five plants in accordance with ASQ principles.

Director of Operations, Sterile Concepts, Inc.; Custom Healthcare Procedure Tray Manufacturer; Temecula, California; March 1996 - August 1996 (prior to merger of Maxxim and Sterile Concepts, spent two weeks per month for six months in Temecula, CA).

- Responsible for the **Operations** and Quality Assurance of a **$45 million** facility located in Southern California.
- Implement **TQM** and **SPC** for business units in order to track and positively impact the **bottom line**

Director, Quality Assurance and Regulatory Affairs, Sterile Concepts, Inc.; Custom Healthcare Procedure Tray Manufacturer; Richmond, VA; August 1992 - March 1996.

- Manage quality, sterilization and regulatory affairs for **$220 million**, 4 facility (one Irish) **global**, public company.
- Responsible for the **$2 million + budget** of the QA/RA department consisting of up to 80 personnel.
- Proficient in **100% and 88/12 EtO Sterilization** and Validation according to current **AAMI** guidelines.
- Submit all **510(k) premarket approvals** with the Federal Food and Drug Administration (FDA).
- Responsible party during all **FDA audits**. **Educate personnel at four locations** to appropriate regulations.
- Develop and perform **FDA GMP Audits** on company departments, raw material vendors, and offsite facilities.
- **Develop program and educate all internal company auditors** from floor to management level.
- Develop in-process and final inspection processes utilizing **statistical Process Control (SPC)**.
- Handle all **customer complaints** using statistical analysis to report findings to the Sr. Executive Staff.
- Handle **product recalls** in working with over 1200 vendors and 17,000 medical devices.

Director, Quality Assurance and Operations, CliniTech, Inc.; Surgical Drape and Gown Manufacturer; El Paso, Texas (A subsidiary of Sterile Concepts, Inc.); Dec. 1991 – Aug. 1992.

➢ DARREN L. REEVES (CONTINUED)

- Direct quality, sterilization and **Operations** of the surgical gowns and drapes produced at a **$10 million** company.
- Proficient in **Gamma Sterilization** and Validation of non-wovens and medical devices.
- Experienced in **Maquilladora Operations**, **importing and exporting** raw/finished materials through **US customs**.
- Chairman of the **Safety and Security Committee** in compliance with **OSHA** standards.
- Set up **Clean Room** meeting "Class 10,000" standards utilizing HEPA and ASHRE filter systems.

Assistant Director, Quality Assurance, Sterile Concepts, Inc.; Dec. 1988 – Dec. 1991.

- **Supervise and train** 34 office and Inspection personnel.
- **Train** new production staff and sterilizer operators to QA methods.
- Approve all documentation including **preventive maintenance** for 3 in-house EtO industrial sterilizers.
- Interpret and approve all documentation from **5 off-site sterilization facilities** for final release of product.
- Test for **EtO residual** levels and schedule annual physicals for operator protection and conformance to OSHA standards.
- **Test and approve new components** through verification of sterility and residual levels utilizing off-site laboratory.

Quality Assurance Inspector, Sterile Concepts, Inc.; March 1988 - December, 1988.

- Perform inspection on each phase of production for verification of correct medical product lines.

MEMBERSHIP

- Association for the Advancement of Medical Instrumentation (AAMI); Member since 1994.
- Medical Device Manufacturer's Association (MDMA); Member from 1998-2004.
- American Society of Quality (ASQ); Member from 1991-2005.

ISO 9001 / 13485

- Oriel, Stat-a-Matrix 2.5-day training, ***Transition to ISO 9001:2015***. Raleigh, NC, Feb 7-9, 2017.
- Oriel, Stat-a-Matrix 2-day training, *Transition to* ***ISO 13485:2016***. Orlando, FL, August 16-17, 2016.
- **ISO 19011:2011** - Guidelines for auditing management systems. Two-day BSI Webinar, Feb 10-11, 2015.
- Intertek *Mandatory Unannounced MDD audits* Webinar, March 18, 2014
- Involved in over 270+ ISO 9001 and ISO 13485 quality system audits and 135+ FDA audits since 1990. Represent companies during those audits, Continuous.
- Set up **ISO 13485:2003** compliant system for certification; Athens, TX, February 2006.
- **ISO 13485:2003** and 21 CFR Part 820–Effective Quality Management Systems; MD&M New York, June 15, 2005.
- **ISO 9001 Lead Auditor Course** by BSI Training Services in Washington, DC., October 12-16, 1998 (Cert. No. 98-260US-50757).
- Lead in 6 registration audits for **ISO 9001/9002, EN 46001** in US, Canada and Dominican Rep.; Feb.-May, 1997.
- **ISO 9001 Audit Training** given by Grant Thornton ISO Consultants, Atlanta, Ga.; November 7-8, 1996.
- One day at the British Standards Institute **(BSI)** in Milton Keynes, England; January 22, 1996.
- **Management Representative for ISO 9001 Certification**, Sterile Concepts, Inc., Richmond, Va. by the British Standards Institute (BSI). July 26-28, 1995.

- **ISO Procedures Writing Classes** given by KPMG ISO Consultants, Richmond, Va.; August 30-31, 1994.
- **ISO 9001 Audit Training** given by KPMG ISO Consultants, Richmond, Va.; October 27 and November 18, 1994.

FDA / REGULATORY

- Greenlight Guru, ICS, 2 Hr Webinar, *The Future of Quality and Regulatory for SaMD (Software as a Medical Device)*. Jul 20, 2021.
- Presafe, 4 Hr Webinar, How to prepare for the new European Med Dev Reg (**MDR**), Mar14, 2019.
- Oriel, Stat-a-Matrix 2 day training, **MDD/MDR Transition**. Boston, MA. Jan 14-15, 2019.
- *Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices*. Silver Springs, MD. October 27-28, 2016.
- FDA Medical Device Regulatory Education for Industry, Washington DC, Sep 29-30, 2015. Topics:
  - Device Classification, Clinical Trials, 510(k) program, Postmarket Surveillance, Design Control, Purchasing, Process Validation, UDI, eMDR.
- FDA **UDI** 101 Webinar, January 14, 2015.
- **510(k)** modifications and IDE approval process. MD&M, New York, Junee 2014
- Best practices in interacting, communicating and negotiating with the FDA. MD&M, New York, June 2014.
- FDA's Review & classification of medical device recalls with **FDA recall branch**. MD&M, New York, June 2014.
- Medical device registrations & approval in Japan, India and China. MD&M, New York, June 2014.
- Latest developments & practical implementation of adopting the **revised EU MDD**, MD&M, New York, June 2014.
- **Sterile Devices** in Premarket Notification [510(k)] Submissions. AAMI-FDA Mtg. March 2014.
- Life Science Training Institute, *De Novo Pathway to Medical Device Approval Webinar*. February 24, 2014
- BSI ***CMDCAS*** *for Medical Device Manufacturers Webinar*. June 24, 2013
- Facilitate and support FDA audits several times a year, continuous.
- Developed & presented 510(k) course for international training company, March 2007.
- Marketing a Medical Device in the United States; FDA. MD&M New York, June 15, 2005.
- Risk Management for Medica Devices; MD&M New York, June 13, 2005.
- Developed **CAPA** Seminar for public presentation. October 2004.
- Mastered **Risk Management** training concepts in accordance with ISO 14971. January 2004.
- Developed quality system compliant with **CMDCAS** requirements. Successful registration March 2003.
- **ISO 13485:2000** two-day training, BSI. July 7-8, 2003.
- Continuous training on **QSIT** through both industry and FDA, January-December 1999.
- CE Marking for Medical Devices, **MDD '98**, Washington, DC; Washington Laboratories: May 5, 1998.
- Product compliance to the **Medical Devices Directive (MDD)** for **CE Mark** at 3 facilities; Feb. 1997.
- Member "**INDUSTRY STANDARDS WORK GROUP**" to develop regulatory standards for FDA approval, February, 1996-7.
- One week in Europe **(London, Hamburg, Brussels)** developing regulatory protocols with suppliers; January 20-28, 1996.
- Two weeks in Ireland developing QA procedures and validation protocols for European mfg; May 15-21, 1995.

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- **AAMI 1994 International Standards Conference on Medical Devices** Co-sponsored by FDA and The National Committee for Clinical Laboratory Standards; Arlington, Va.; March 10-11, 1994.
- GMP Compliance and FDA- An Update; **MDM East, New York**, NY.; May 26, 1993.
- **Regulatory Environment for U.S. Medical Devices in Germany and Europe** (Special presentation by the German Chamber of Commerce); MDM East, New York, NY.; May 25, 1993.
- **HIMA**'s 1992 Basic Medical Device Regulation seminar; Atlanta, Ga.; October 14-15, 1992.
- Completed **Gamma Radiation** Validation of medical devices; El Paso, TX.; March-May 1992.
- Validated 100% EtO sterilization Cycle in **Europe** at the **Griffith Micro Science** facility; July 1992
- **Sterilization Workshop** sponsored by Dynatec Scientific Laboratories, Inc.; El Paso, TX.; June 8, 1992.
- **Packaging of Health-Care Devices** and Products, Atlanta, Ga.; April 8-9, 1991.
- Performed **100% EtO validations** at start up of **Sterilization Services** of Virginia, Richmond, Va.; Dec. 1990.
- Validated shortened incubation time for **biological indicators** according to the CDRH Guide For Validation of Biological Indicator Incubation Time; Richmond, Va.; June, 1990.
- FDA Medical Device Workshop, sponsored by **DSMA**, Cherry Hill, NJ.; April 3-5, 1990.

QUALITY ASSURANCE

- Building a shatterproof **CAPA system**. MD&M, New York, June 2014.
- **Risk Management** for gamma radiation. MD&M, New York, June 2014.
- Selection of **SAL for sterile products**; Evaluation of "less-than" values in **bioburden data**; Setting Alert and Action Levels. MD&M, New York, June 2014.
- Use of **Biocompatibility** Standards in FDA Submissions, AAMI-FDA Mtg. March 2014.
- **Risk Management** in Premarket, AAMI-FDA Mtg. March 2014.
- Developed & presented Medical Device **CAPA** training program for international training Co., March 2007- present.
- Package Validation; Pace Solutions, LLC. MD&M New York, June 14, 2005.
- Integrating Complaints, MDR's, CAPA, and Risk Management; MD&M New York, June 14, 2005.
- **6 Sigma Green Belt** Training; Genedge, Richmond, VA.; July 29-31, 2002.
- **Hazard Analysis & Critical Control Points (HACCP)** training, USFDA, Rockville, MD, Sep. 28-29, 1999.
- One week in Holland/Belgium working on **CE mark** requirements in compliance with MDD, Nov. 14-23, 1997.
- Implemented **Team Building** between Production and Quality eliminating QA Inspection staff, May-Nov. 1996.
- Statistics and **Quantitative Methods and Analysis**, Averett College, Richmond, Va.; May-Aug., 1994.
- **Performing GMP Audits--Internal and Vendor Issues**; MDM East, New York, NY.; May 1993.
- **Total Quality Management** seminar by National Seminars Group; Richmond, Va.; February 15, 1993.
- Weeklong **audit by 3M** led by John L. Spooner, Quality Sr. Specialist; El Paso, TX.; April 20-25, 1992.
- 3-day audit during start up of first EtO chamber at **Isomedix, Inc**. in Spartanburg, SC.; November 1-3, 1989.

➢DARREN L. REEVES (CONTINUED)

BUSINESS

- Develop systems, SOPs, sterilization and operations for **start-up device company**; Atlanta, GA, June –Dec. 2006.
- Preparing for a Winning Business in the Medical Device Industry; MD&M New York, June 13, 2005
- **Value Stream Mapping**; a NIST program; given by Genedge at J. Sargeant Reynolds Community College, Richmond, VA.; July 24, 2002.
- **Lean Manufacturing** 101; a NIST program; given by Genedge at J. Sargeant Reynolds Community College, Richmond, VA.; May 30, 2002.
- Four days of training on **Access Database Management** Systems, ExecuTrain, Richmond, Va.; May 2000.
- Three-day course: "Process Validation Requirements & Industry Practice", AAMI; Wash., DC; Oct. 20-22, 1999.
- "Jonah" training on **Theory of Constraints (TOC)** manufacturing and problem solving, Aug-Dec., 1999.
- Six-day **Theory of Constraint (TOC)** Training to analyze throughput, profit and inventory, May-June 1999.
- Developed **multiple training programs** for educating all level of personnel to **FDA GMP's, ISO 9000, TQM, SPC, Business Process Flowcharting, Goal Setting and Continuous Quality Improvement** (on-going).
- Microsoft Office Training**: Word, Excel, and Powerpoint** presentation skills, individual study and Masters Level training, Averett College, Richmond, Va.; February 1994-February 1996.
- **Business Law**, MBA Course, Averett College, Richmond, Va.; November 8-December 20, 1996.
- **Financial and Managerial Accounting**, MBA Course, Averett College, Richmond, Va.; Oct. 1994-Jan. 1995.
- Overview of **Microsoft Applications** for Windows; Microsoft Seminar Series, Richmond, Va.; July 14, 1993.

OVERSEAS EXPERIENCE

- Three-day ISO 13485:2016 supplier audit in **India**, Surgical Instruments, January 2019.
- Three-day training course on FDA QSIT in **Montego Bay, Jamaica**, August 9-11, 2016.
- Two-week supplier audits of 5 facilities in **Mexico**, March 2015.
- One week FDA compliance audit in **Saudi Arabia**, January 2011.
- Trip to **Australia** to work with the TGA on new company development; November 2010.
- Review and audit 9 **Chinese** facilities to the FDA QSR; March 2010.
- Sterilization and FDA support and contract Consultant for **Austrian** company, June 2006 to Present.
- Act as US agent for several **Chinese** and other foreign establishments.
- FDA systems development and audit, **Japan, Thailand, Vietnam**; 2006
- Support & oversee FDA activities for company in **Shin-Yokohama, Japan** (6 trips, 2003-2005).
- Support with Risk Management training in response to FDA issues in **Pattaya, Thailand** (2003).
- Over quality systems for **Mississauga, Canada** facility from 1997-1998.
- Over quality systems in **Dominican Republic** facility (approx. 10 trips between 1997-1999).
- **Germany, England, Sweden** trip to qualify vendors (1998).
- VP in charge of facility in **Netherlands**. Two trips in 1997 and 1998.
- Facility start-up and development in **Galway, Ireland** (approximately 10 trips from 1995-1996).
- Over operations for Maquiladoras in Juarez and **Aguascalientes, Mexico** (1991-1992**)**.

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