PALADIN MEDICAL®

Your Champion for Product Success

Elaine Duncan, President

Elaine Duncan, MS.ME., RAC, FAIMBE, FBSE, is the founder and president of Paladin Medical, Inc. Elaine is a certified regulatory affairs professional with a master's degree in engineering (mechanical/biomedical). Elaine holds an appointment as an Adjunct Professor of Biomedical Engineering in the F. Joseph Halcomb III, M.D. Department of Biomedical Engineering at the University of Kentucky.

Brief Resume

Elaine Duncan is a recognized leader in regulatory/clinical strategies for new medical technology development. Prior to forming Paladin Medical in 1987, Elaine held key executive positions in start-up medical companies, including vice-president of new ventures, vice-president of research and development and vice-president/director of regulatory affairs/ quality assurance. Her Fortune 500 company experience in acquisition and technology assessment gives Elaine a unique understanding of the due-diligence required for mergers and acquisitions within the medical industry. Ms. Duncan works with clients to define the best regulatory approach for new products, helping companies to develop IDE trials and nonsignificant risk studies for premarket submissions.

Clients with concerns for biomaterials selection and biocompatibility analysis, including combination products and tissue engineering, will find Elaine's experience extremely helpful. Elaine also has in-depth experience in pre-clinical testing and GLP regulations. She has had broad experience in diverse areas, including artificial hearts, vascular grafts, spinal implants, and various disposable sterile products. Please see Profiles of Success for additional information.

In 1992, Elaine Duncan received the Medical Alley Outstanding Contribution to the Health Care Industry Award. Her service as the editor of Biomaterials Forum for over 12 years was recognized in 1999, with the C. William Hall Award from the Society For Biomaterials. In addition, Elaine has served on the board of directors and in other leadership positions of the Society For Biomaterials. She is a member of numerous biomedical organizations, including AAMI, ASTM and AIMBE as well as a frequent contributor to industry publications. In April 2000, Elaine was honored with induction into the University of Kentucky College of Engineering Hall of Distinction, in 2007, as a member of the Quadrangle Society and continues to serve as a member of the Dean's Advisory Committee of the Pigman College of Engineering at the University of Kentucky. In 2019 she was named to the AIMBE College of Fellows. Elaine was named Fellow of Biomaterials Science and Engineering (2024).

"We serve a global clientele who produce their products for the worldwide medical device community. We assist U.S. device manufacturers in understanding requirements for the European Union and Canada and preparing their documentation for assessment by a Notified Body to obtain the CE Mark and/or assessment by a Canadian Registrar for licensing in Canada. Risk management and device validation are universal expectations. "I have a real- world, pragmatic understanding of how to translate device requirements into product qualification in order to assure products meet user needs."

Curriculum Vitae

October 2024

Elaine Duncan MSME., RAC, FAIMBE, FBSE

CURRENT POSITIONS

PRESIDENT of PALADIN MEDICAL℠, Inc. -present

Paladin Medical℠, Inc., established in 1987, provides regulatory and clinical consulting, as well as contract technical management to emerging medical product programs. Services include engineering and process analysis, clinical/regulatory affairs consulting, and medical product new-business assessment. Please see PROFILES for specific device experience.

ADJUNCT PROFESSOR OF BIOMEDICAL ENGINEERING July 2018-present

Appointment to the F. Joseph Halcomb III, M.D. Department of Biomedical Engineering, College of Engineering at the University of Kentucky. Curriculum consulting and ad-hoc teaching.

FORMER POSITIONS

VICE PRESIDENT of NEW VENTURES, Possis Medical, Inc., Minneapolis, MN.

V.P. of RESEARCH and DEVELOPMENT

V.P. of PRODUCT QUALITY ASSURANCE

Responsible for identifying new business opportunities; including establishment of alternative biomaterial for graft project and new product opportunities. Reported to CEO of Possis/PMI and President of PMI and Board of Directors. Responsible for development of new vascular graft program; including successful joint venture negotiations with major medical firm. Developed polyurethane microfiber and ePTFE grafts. Designed and developed unique mock-circulatory loop. Directed regulatory approval and animal research. Established product assurance department/materials qualification and testing capabilities.

DIRECTOR of REGULATORY AFFAIRS and QUALITY ASSURANCE,
Kolff Medical, Inc. (Symbion, Inc.), Salt Lake City, Utah

Responsible for clinical programs and regulatory submissions of JARVIK-7 artificial heart and cochlear prosthesis. Instituted GMP and GLP programs. Coordinated artificial heart training program for surgeons. Analyzed failure of the Shiley heart valves. Qualified use of Medtronic valve. Planned and budgeted contract animal implant studies, biocompatibility and physical testing for 5-year program. Assisted in taking the company through first public stock offering. Reported to President/CEO (R. Jarvik) and Vice-president/COO.

SR. RESEARCH ENGINEER, 3M Health Care Group (Orthopedic & Med/Surg), St. Paul, MN.

Responsible for new product development and new technology assessment/acquisition teams. Successfully acquired and integrated first implantable products: silicone hydrocephalic shunt, intraocular lens, mammary prosthesis, cardiac assist products, collagen products, new vascular and dental prosthetic materials. Developed patented disposable wound drainage system, non-woven vascular prosthesis, and implantable magnetic material. Assessed percutaneous access technology/market potential. Lead for acquisition of bone growth stimulator and bone growth materials. Reported to Technical Director; major acquisitions, reported directly to Division Vice-president.

EDUCATION

Master of Science, Mechanical Engineering/Minor: Biomedical University of Minnesota, 1981;
Bachelor of Science, Mechanical Engineering/Minor: Biomedical
University of Kentucky, 1974 (Engineering Honors Fraternity)

MAJOR PROFESSIONAL AFFILIATIONS and RECOGNITION

FELLOW: Biomaterials Science and Engineering (FBSE)

FELLOW: The American Institute for Medical and Biological Engineering (FAIMBE)

Society For Biomaterials:
- Former Editor of ***Biomaterials Forum***.
- Council member 1981-2000.
- Nominated for President
- *Journal of Biomedical Materials Research*, Editorial Review Board.
- Numerous committees and Special Interest Groups

Association for the Advancement of Medical Instrumentation (AAMI)
American Society for Testing Materials (ASTM):- F-4 Committee (medical device standards)
Regulatory Affairs Professional Society—Certified (RAPS)

Retired Memberships-Held More than 10 years
Biomedical Engineering Society
Academy of Surgical Research-
International and American Society for Artificial Internal Organs
Medical Alley

PROFESSIONAL CERTIFICATION

Regulatory Affairs Certified by the Regulatory Affairs Professionals Society,
Original certification: November 1994. Renewed through 2027

ACADEMIC ADVISORY BOARD POSITIONS and CONGRESSIONAL COMMITTEE

College of Engineering Dean's Advisory Committee, University of Kentucky
Biomedical Engineering Department, University of Kentucky
(Formerly)-Biomedical Engineering Center, University of Minnesota
Dingell Committee: FDA Oversight for Shiley Heart Valve and 1996 Regulation Revisions

AWARDS

Outstanding Contribution to the Healthcare Industry, Medical Alley 1992
C. William Hall Award for Service to the Society For Biomaterials, 1999
Hall of Distinction, University of Kentucky, College of Engineering, 2000
Society for Biomaterials Award for Service, 2022.

PATENTS

US 4257422, Closed Wound Drain;
US Design: 260,177 & 260,433 Drainage Bottles

PUBLICATIONS and PRESENTATIONS

Articles and Book Chapters Does not include Paladin Medical, Inc. Website Blog Articles

Chapter 3.1.7: Regulatory Constraints for Medical Products Using Biomaterials in Biomaterials Science: An Introduction to Materials in Medicine, 4th edition, Eds. Wagner, Sakiyama-Elbert, Zhang & Yaszemski, Elsevier, ©2020

Chapter 3.1.3: Safety and Risk Considerations in Medical Device Development in Biomaterials Science: An Introduction to Materials in Medicine, 4th edition, Eds. Wagner, Sakiyama-Elbert, Zhang & Yaszemski, Elsevier, ©2020

Chapter 3.1.2: Total Product Lifecycle for Biomaterial-Based Medical Devices in Biomaterials Science: An Introduction to Materials in Medicine, 4th edition, Eds. Wagner, et.al. Elsevier, ©2020

"Standard Procedure: Strategic Requirements for US Regulatory Assessment"; Medical Device Developments Magazine; vol 2, 2016; Global Trade Media, London, UK.

Duncan, E. Ch 7 The Regulatory Environment for Biotextiles: Biotextiles as Medical Implants, 1st edition, Editors: Dr. Martin W. King and Dr. Bhupender S. Gupta Woodhead Publishing Innovation: 2013.

S. Martin, E. Duncan, Implantable sensor systems: Considerations for sterilisation: Implantable sensor systems for medical applications Chapter 12, Woodhead Publishing Innovation: 2013.

Duncan, E. *Development and Regulation of Medical Products Using Biomaterials*, Biomaterials Science, Third Edition.2012

Duncan, E . 123:: Development and regulation of Medical TEXnology, Industrial Fabric Products Review November 2006.

Duncan, E. Good Laboratory Practices for Testing Biomaterials, *Biomaterials Forum*, Newsletter of the Society For Biomaterials, September- October 2001.

Duncan, E. Combination Products and Design Control. SurFACTS in Biomaterials, Newsletter of the Surfaces in Biomaterials Foundation, Spring, 2001.

Duncan, E. Surface Modifiers Need to Speak up About Reuse Now. SurFACTS in Biomaterials, Newsletter of the Surfaces in Biomaterials Foundation Winter 1999.

Duncan, E. In-vitro Simulations– Critical to Design Control and Risk Analysis. Endurance Technology News, Vol. 1, No. 1, Fall 1999.

Duncan, E. Combination Products Can Create Combination Compliance Headaches. SurFACTS in Biomaterials, Newsletter of the Surfaces in Biomaterials Foundation Vol. 4, Issue 2, Summer 1999.

Duncan, E. Regulatory Update for SurFACTS Readers. Newsletter Surfaces in Biomaterials Foundation Vol. 3, Issue 3, p. 7, 1998.

Duncan, E. The Value of a Risk Management Approach to Clinical Trial Design and Management. Critical Reviews™ in Biomedical Engineering, Vol. 25, Issue 2, pp. 84-85, 1997.

Duncan, E. Custom Devices: Until FDA Finalizes a Guidance, What Can You Do? The Validation Consultant, Vol. 4 No. 9, September 1997.

Duncan, E. Implant Tracking, Surveillance, and Retrieval, Medical Device and Diagnostic Industry Magazine, Canon Communications, Inc. April 1991.

Duncan, E. Performance Testing,. Medical Device and Diagnostic Industry Magazine, Canon Communications, Inc. November, 1990

Duncan, E. Seeking Biocompatibility, Medical Device and Diagnostic Industry Magazine, Canon Communications, Inc. Sept 1990

Duncan, E. Pitfalls in Processing Biomaterials, Vol 12, No. 3, pg 94, Medical DDI Magazine, Canon, March 1990

Biostability, Stability and Controlled Instability, May 1990 Medical DDI Magazine, Canon Communications, Inc.

Duncan, E. What is a Biomaterial? Vol. 12, No. 1, pg 138,; Medical DDI magazine, Canon Communications, Inc. January, 1990

Duncan, E. Potential Impact of Regulatory Changes on Medical Devices. New Venture Review Minnesota. Vol. 1, pp 395-397, Sept/Oct 1988.

Drasler, J.W., M.L. Jenson, S.A. George, E.I. Protonotarios, R. G. Dutcher, P.E. Duncan, et.al. A Unique Vascular Graft Concept for Coronary and Peripheral Applications, Vol. XXXIV, pp 769-772, Transactions, ASAIO, 1988.

Presentations, Speeches and College Instruction*-

Webinar: Navigating the Bumpy Road of Medical Device Commercialization; Society For Biomaterials, June 27, 2024

The Saga of Silicone Breast Implants- 3M, Me and More, BME 350 UK COE, February 6, 2024

Podcast: ABC's of Medical Device Development for Office of Technology and Commercialization, U of Ky, October 26, 2023

Invited Lecture: Dean's Leadership Class 2022 ENG 490 Leadership Class "Reflections on Leadership", University of Kentucky College of Engineering April 26, 2023.

Regulatory for Medical Device Investors: 1) "How to Swim with Whales without Getting Swallowed, 2) Drugs and Stuff, 3) Swimming with whales without getting EATEN, 3 session series for i2e:On-LINE, May 2023.

Invited Lecture: "How This Little Girl Became and Engineer", Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 350 February 16, 2023

Biocompatibility: Concepts Effect on Assessments, Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 488/688, November 22, 2022

Safety and Risk Analysis of Biomaterials, Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 488/688, November 29, 2022

Examples of Regulatory Constraints on Biomedical Engineering Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 30, 2 29 September 2022

Biocompatibility: Concepts and Assessment; Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 488/688, November 23, 2021

Safety and Risk Analysis; Adjunct Professor, U of Ky, Dept. Biomedical Engineering BME 488/688, November 30, 2021

Regulatory Constraints on Biomedical Engineering; Adjunct Professor, University of Kentucky BME 201/301 September 2020.

Assessment of Biocompatibility, Risks Analysis, Total Product Lifecycle, Three Class Lecture Series; Adjunct Professor, University of Kentucky Department of Biomedical Engineering BME 488-661: Fall Semester 2020.

Medical Textiles and Regulatory Approvals, The Advanced Textiles Conference, IFAI EXPO Orlando, Florida, October 1, 2019

Three class lecture series: ***"Ethics in Biomedical Engineering", "Why This Little Girl Became an Engineer" and Why this Little Girl Became an Entrepreneur",*** Adjunct Professor, Department of Biomedical Engineering, U of Ky, September 2019

Society For Biomaterials: Session Organizer, 1) Panel Discussion: Regulatory Translational Science Focused on Commercialization Challenges for Surface Modification and the Characterization: SIG-SQUARED***, Moderator Presenter 2):*** SFB Business Plan Competition; *and* ***Presenter, 3)*** Panel Discussion: Biomaterials in Industry: Past, Present and Future; April 3-6, Washington State Conference Center, Seattle, WA.

Regulatory Challenges Facing New Medical Textiles: TECHTEXTIL North America, Raleigh, NC, February 26, 2019.

Spinal Implants vs Spine Biomechanics University of Kentucky*:* Adjunct Professor, Department of Biomedical Engineering, University of Kentucky, Lecture BME 472/672 February 21, 2019

*Three-class lecture series****: "What makes it Bio" for Biomaterials Science- Materials,*** Adjunct Professor, Department of Biomedical Engineering, University of Kentucky, September 2018

Medical Device Woes- Case Presentations, lecture to Ethics in Biomedical Engineering BME 640, Adjunct Professor, Department of Biomedical Engineering, University of Kentucky, September 2018

A glimpse of Standards and Regulations of Medical Devices: Introduction to Biomedical Engineering, BME 301 Adjunct Professor, Department of Biomedical Engineering, University of Kentucky, September 2018

Dental/Craniofacial Arena: Opportunities, Regulations and Minefields in the pathway from Benchtop to Commercialization: Co-Chair and organizer, Society for Biomaterials Annual Meeting, April 12, 2018

How do Industry Standards Fit into Your Regulatory Strategy? Benchtop to Bedside Series: We'll Get you There, Society For Biomaterials Annual Meeting, Minneapolis, MN April 18, 2017.

The Breast Implant Saga: Lecture: University of Kentucky Medical Center; Hangin' with Zwish lecture series, April 18, 2017

FDA Panel: Chairperson and organizer. 28th Annual Meeting for the International Society for Ceramics in Medicine, Charlotte, NC, October 17, 2016.

Biomaterials and medical products commercialization: regulatory case studies- how to get to market, Panelist, 10th World Biomaterials Congress, Montreal, Canada, May 20, 2016.

Biocompatibility: The Purloined Threshold for Clinical Entry, 10th World Biomaterials Congress, Montreal., CAN, May 19, 2016.

Controlled Release Science-in-industry-Chair, 10th World Biomaterials Congress, Montreal., Canada, May 19, 2016.

Running the FDA RTA & E-copy Gauntlet; Smoldering Submission Issues, Life Science Alley, MN, October 26, 2014.

Leaping the Hurdles of Medical Textile Devices, IFAI Advanced Textile Expo, Minneapolis, MN October 14, 2014.

Regulatory 10: Quality Systems in 30 Minutes, Life Science Alley Instructor, Minneapolis, MN, March 26, 2014

Ethics in Biomedical Engineering: Case Presentation-Sulzer Heart Valve University of Kentucky College of Engineering Invited Lecture September, 21, 2013.

Shepherding Device Applications through Regulatory Process: Standards, Society for Biomaterials, Boston, MA, April 10, 2013

Regulatory 101: Quality Systems Life Science Alley, Minneapolis, MN March 14, 2012

Delivering What Sponsors Need for GLP, Wake Forest University, Wake Forest, NC, June 26, 2012.

Strategies for a Biomaterial World. Material and Processes for Medical Devices (MPMD) Conf. and Exposition. Minneapolis, MN, August 8, 2011

Managing Regulatory Uncertainty. Orthopaedic Research Society (ORS) 2011 Annual Meeting. Long Beach, CA, Jan 14, 2011

UK Clinician Innovation Day: regulatory issues for medical devices. Lexington, KY, August 4, 2009.

Design Control for Professors. University of Kentucky Engineering. Lexington, KY, June 2009.

Engineering Senior Leadership. University of Kentucky College of Engineering. Lexington, KY, April 2009.

Shelf-life aging. Client training. Boulder, CO, September 2008.

How Barney Clark's broken heart valve changed medical device regulations. 25th Commemorative Sym. Salt Lake City, UT, Nov 30-Dec 1, 2007.

IRB and FDA: Roles and Impacts. Barney Clark Commemorative Symposium. University of Utah, Nov 30-Dece, 2007

Shelf-life aging. Client training. September 2007.

Navigating Standards & Regulations for Medical Textiles. IFAI Medical Textile Symposium. Oct 31, 2006

GLPs for Medical Device Sponsors and Combination Products. CRL, August 25, 2005.

Biomaterials Qualification and Selection for Spinal Implants. MDM Conference, November1, 2005

Practical Tips for Regulatory Compliance: Top Guidance and Website Help. AusBiotech in Sydney Australia, April 22, 2004.

Regulatory Changes Impacting Medical Device Development: The Good, the Bad and the Ugly. U of MN Annual Medical Device Design Conference, April 25, 2003.

GLP Compliance for Combination Products. November 18, 2002, Barnett International, Philadelphia, PA.

Surface Analysis: Tales of Woe & Lessons From the Past for the Future. MDM Minneapolis. October 22-24, 2002. Anaheim, CA, February 2003.

GLP Training for Sponsors: Corporate Forum (Workshop). Society for Biomaterials. April 24, 2002.

Customized GLP Training for Sponsor. Anoka Ramsey County College Education Grant. January 25, 2002

Regulatory Affairs Professional Certification Instructor for PMA, Manufacturing and Quality Training- Compare and Contrast Drugs to Devices. Medical Alley Workshop. October 10, 2001

Good Laboratory Practices Training for Preclinical Trials Workshop with Charles River Labs. Society for Biomaterials. April 25, 2001

Hazard Analysis & Risk Assessment as an Effective Tool for Modifications to Approved and Investigational Medical Devices. Workshop, Biomedical Focus '00. July, 2000, St. Paul, MN

Benefit Analysis and the Benefit/Risk Ratio. Kona, Hawaii**,** World Congress of Biomaterials. May 19, 2000,

Workshop: Part 1: Hazard Analysis and Risk Assessment as a Tool for Pre-Clinical Study Planning and Part 2: Optimizing Study Design Through Risk Control: Animal Study Planning. World Congress of Biomaterials: Jointly with PRIMEDICA. May 16, 2000, Kona, Hawaii

Risk Assessment as a Tool for Planning Pre-Clinical & Clinical Studies. Medical Alley. February 9, 2000, St. Louis Park, MN

The Standardization of Biomedical Products: Finding the Good Among the Bad and the Ugly. U of Ky. October 7, 1999, Lexington, KY

Design Control and Review Workshop, and Hazard Analysis and Risk Assessment Workshop. Society For Biomaterials Conference. April 28, 1999, Providence, RI

Introduction to Biomaterials: Regulatory and Standards Issues. University of Washington. March 18, 1999, Seattle, WA

Design Planning & Design Review Workshop. Medical Alley. October 14, 1998, St. Louis Park, MN

Utilizing Investigator and Institution Selection and Management Strategies. Institute for International Research Conference. June 23, 1998, Minneapolis, MN

Design Control & Review: Case Study of Material Change. Society For Biomaterials. April 22, 1998, San Diego, CA

Designer Surfaces on Biomaterials; Regulatory Case Study Workshop. Society For Biomaterials. April 22, 1998, San Diego, CA

Risk Management With and Within Clinical Trials. Medical Alley Seminar, May 13, 1997.

Design of Clinical Trials Workshop; Planning and Managing Clinical Studies-Addressing your Questions. ASAIO 43rd Annual Conference. April 30, 1997, Atlanta, GA

Reaction to Activities of the FDA-ODE from the Perspective of our Town. Medical Alley**.** December 1996, Minneapolis, MN

Surfaces in Biomaterials 1996 Symposium. Surfaces in Biomaterials Foundation. Sept, 1996, Phoenix, AZ

Deciding When to Submit a 510(k) for a Change to an Existing Device. Medical Alley, February 14, 1996, St. Louis Park, MN

Testing Medical Devices on Human Subjects: What Your Company Needs to Know to Work with the Physician and/or Inventor. Medical OEM Exposition. November 1995, Minneapolis, MN

Roadblocks in the Submissions Process. HIMA Fifth Annual Device Submissions Workshop, Panelist. July 1995, Washington, D.C.

Regs, Risks, and Responsibilities. Presented to the University of Minnesota IRB Human Subjects Committee. June 1, 1995, Minneapolis, MN

Selection of Biomaterials and Presentation of Data to FDA. Discussion Leader. Sponsored by Medical Alley Regulatory Committee, February 1995, St. Louis Park, MN

Medical Device Development: Regulatory Risk Management. Sponsored by University of Minnesota, January 1995, Minneapolis, MN

Requirements for Monitoring Clinical Trials. Faculty; Short Course: Approaches to the Clinical Evaluation of Medical Devices. Sponsored by the Society for Biomaterials, Dec. 1994, Rockville, MD

Device Labeling Changes, presented, Medical Alley, Minneapolis, MN, August 1993.

Controversial Issues in Biomaterials for Medical Devices, presentation, Biomedical Focus VII / ASQC, Minneapolis, MN, July 1993.

Medical Entrepreneurial: Practical Solutions for Starting Your Business, presentation, Minneapolis, MN, May 1993

Implant Retrieval Symposium, presentation, co-chairman of symposium, St. Charles, IL, September 1992.

Modifying Existing Biomaterials, presentation, chairman MD&M East 10th Anniversary, New York, NY, June 1992.

Strategic Planning for Clinical Trials, presentation, Biomedical Focus V / ASQC, Bloomington, MN, July 1991.

Technical, Industrial, Regulatory Aspects of Biocompatibility Testing Materials Qualification, , co-chair Workshop, May 1991.

Medical Devices: New Regulatory Environment for Manufacturers and Healthcare Professionals "Perspective on the Impact of the Revised Legislation", presentation, December 1990.

Performance Testing of Biomaterials, presentation, Biomedical Focus IV / ASQC Biomedical Div., Mpls MN, July 1990.

Biomaterials: Selection and Analysis, Workshop Chair, Medical Design and Manufacturing Conference, New York, June 1990.

Polymer Matrix Rare-earth Magnets for Medical Applications, Oral Presentation and Abstract, Advances in Biomedical Polymers, Royal Australian Chemical Institute Meeting, Perth, Australia, February 1989.

Device Reliability and Failure Analysis: Appropriate Measures for Your Product, panel chairman Medical Design and Manufacturing West Conference, Anaheim, CA, January 1989, and New York, June, 1989.

Circulatory Simulator for Analysis of Vascular Augmentation. Abstract, ASAIO. 1987.

Metallurgical and Thermal-Wave Failure Analysis of Two Bjork-Shiley Spherical Disk Valves Used in JARVIK-7 Total Artificial Hearts. World Biomaterials Congress April, 1984. Oral Presentation.

Choice of the Medtronic-Hall Valve in the JARVIK-7 Total Artificial Heart. Abstract. ASAIO, 1984.

**May not include presentations at client facilities*

Continuous Training and Service Improvements: Selected Examples

Due Diligence Decoded: M&A Success in the FDA-Regulated Industry, Gardner Law Firm Webinar, September 20, 2024

FDA Road Show- Upping Your Conformity Assessment Game: Putting Standards to Work to Streamline Device Review; Twin Cities RAPS Chapter. St. Paul, MN, May 30, 2024

Human Factors/Usability Studies following ISO62366, FDA guidance, Compliance4all Learning, August 28, 2023.

RAPS Webcast: Making Successful FDA eSTAR Submissions, May 5, 2023.

Legal Regulatory Update from Medical Alley, Gardner Law, Stillwater, MN, May 19, 2022

The Regulatory Consultant's Guide to ISO 10993 Updates: Webinar by Wuxi AppTech, January 8, 2019

Orthopedic Research Society Annual Meeting, and AAOS Exhibition, March 5-8, 2016

Biocompatibility and Performance of Medical Devices, NAMSA, Minneapolis MN May 14, 15, 2013

FDA's Financial Disclosure Guidance for Clinical Investigators, FOI Teleconferences, February 6, 2012

LifeScience Alley Conference and Expo 2010, LifeScience Alley, Minneapolis, MN, December 8, 2010

Symposium on Static and Dynamic Spinal Implants, ASTM, San Antonio, TX, November 16-17, 2010

NASS 25th Annual Meeting, North American Spine Society, Orlando, FL, October 6-9, 2010

Congressional Field Hearing, Congressman Erik Paulsen, Plymouth, MN, August 24, 2010

SAS 10th Annual Global Symposium on Motion Preservation Technology, Spine Arthroplasty Society, New Orleans, LA, April 27-30, 2010

CDRH Town Hall Meeting**,** US FDA Sponsored, Bloomington, MN May 18, 2010.

MedTec Ireland**,** Canon Communications, Galway, Ireland, September 23-24, 2009

Materials and Processes for Medical Devices, ASM International, Minneapolis, MN, August 2009

Under Attach or On the Attack?- The 510(k) Program, LifeScience Alley, St. Louis Park, MN, April 29, 2009

SAS 8, The Spine Arthroplasty Society, Miami, FL, May 6-9, 2008

NASS 22nd Annual Meeting, North American Spine Society, Austin, TX, October 23-27, 2007

MD&M Minneapolis Conference, Medical Design & Manufacturing, Minneapolis, MN, October 16-18, 2007

RAPS 2007 Annual Conference and Exhibition, RAPS, Boston, MA September 23-26, 2007

Developments in Medical Device Testing, NAMSA, Minneapolis, MN, May 17-18, 2007

Investigational Testing of Medical Devices in Canada, Advamed, September 7, 2006

AAOS, Chicago, IL March 21-25-2007

7th World Congress of Biomaterials, Sydney, Australia, May 17-21, 2004

Litigation Exposures in Clinical Trials, Medical Alley, January 21, 2004

HIPPA Update, Medical Alley, September 26, 2002, Minneapolis, MN

Data Management Process for Clinical Trials, Medical Alley**,** August 21, 2002, Minneapolis, MN

Good Laboratory Practices- Professional Training Course, IQPC, July 24-25, 2002, Philadelphia, PA

21 CFR Part 11- Electronic Records; Electronic Signatures, Medical Alley, April 5, 2002, Mpls. MN

An FDA ODE Update, Medical Alley, December 2001, Mpls, MN

Roadmap to Successful Development of Regulatory Approval of Medical Devices, Surfaces in Biomaterials – August 2001. Scottsdale, AZ

Carbon in Biomaterials, Workshop, Carbon Society, July 2001, Lexington, KY

FDA's Bioresearch Monitoring Program, Medical Alley, August 15, 2001, Mpls, MN

Combination Device Workshop, Medical Alley, January 10, 2001, Mpls, MN

E-Regulatory: Managing Submissions & Web Presence, Medical Alley, Dec 13, 2000, Mpls, MN

Medical Device Directives- IVDD, & Submissions, TUV Rhineland of North America, Inc. August 16, 2000, Mpls, MN

Pre-Clinical Trials and Animal Testing, Medical Alley, March 14, 2000, St. Louis Park, MN

Clinical Research 101, Medical Alley, February 16, 2000, St. Louis Park, MN

Medicare Coverage Decision-Making: Examining the Strengths and Weaknesses, Medical Alley, February 3, 2000, MN

FDA Financial Disclosure Rule and Guidance, Medical Alley, January 19, 2000, St. Louis Park, MN

Electronic Records and Signatures, Medical Alley, January 13, 2000, St. Louis Park, MN

Do's and Don'ts When Writing Clinical Research Contracts, Medical Alley, Dec. 15, 1999, Mpls, MN

Methods Used to Evaluate Medical Device Package Integrity, Medical Alley, Nov. 10, 1999, Mpls, MN

Proposed FDA Strategy-Reuse of Single-Use Medical Devices, Medical Alley, Nov. 10, 1999, Mpls, MN

Briefing- the Japanese Medical Products Market, Minnesota Trade Office, Nov. 8, 1999, St. Paul, MN

Quality System Inspection Technique Workshop, Medical Alley, October 21, 1999, St. Louis Park, MN

FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Medical Alley, September 14, 1999, St. Louis Park, MN

Software Regulations and Standards, Medical Alley, September 7, 1999, St. Louis Park, MN

The Status of Global Harmonization, Medical Alley, July 21, 1999, St. Louis Park, MN

Proposed Reengineering of the FDA Medical Device Registration and Listing System, Medical Alley, July 15, 1999, MN

Worldwide Clinical Trials, Medical Alley, April 21, 1999, St. Louis Park, MN

Integrating Regulatory, Reimbursement, and Outcomes for Effective Market Introduction, Medical Alley, April 1999, MN

Fundamentals of Medical Device Regulatory Requirements, Medical Alley, March 24, 1999, Mpls, MN

Designing Efficient Case Report Forms, Medical Alley, March 17, 1999, St. Louis Park, MN

Planning and Protocols for Preclinical and Clinical Testing, Medical Alley, March 10, 1999, Mpls, MN

BiMo Auditing, Medical Alley, February 17, 1999, St. Louis Park, MN

Clinical Standard Operating Procedures, Medical Alley, January 20, 1999, St. Louis Park, MN

The Role of Data Safety Monitoring Boards in Clinical Trials, Medical Alley, January 13, 1999, Robbinsdale, MN

510(k) Submission/Documentation, Medical Alley, December 9, 1998, St. Louis Park, MN

Quality Systems Inspection Techniques, *Medical Alley, December 8, 1998, St. Louis Park, MN*

Medical Device/Vigilance Reporting Update, Medical Alley, November 11, 1998, St. Louis Park, MN

Stent Grafts-An Interdisciplinary Workshop, FDA, October 5, 1998, Washington, DC

Exports/Imports and Device Updates, Medical Alley, September 9, 1998, Robbinsdale, MN

The Humanitarian Device Exemption Process, Medical Alley, August 19, 1998, Minneapolis, MN

Premarket Updates: IVDs, 510(k) & Emerging Issues, Medical Alley, July 15, 1998. Robbinsdale, MN

Global Clinical Trial Strategies for Medical Devices & Diagnostics, Institute for Research- June 22 24, 1998, Minneapolis, MN

Design Control Inspections, Medical Alley, June 18, 1998, St. Louis Park, MN

CE Mark for Inactive Implantable Medical Devices, Medical Alley, June 10, 1998, St. Louis Park, MN

Case Studies: Building a Bridge to the FDA, Medical Alley, June 3, 1998, Robbinsdale, MN

A Changing Landscape: Payer Perspectives on Insurance Coverage Decision Making, Medical Alley, May 12, 1998,

FDA Policy on Promoting & Advertising Medical Devices, Medical Alley, April 8, 1998, Mpls, MN

Clinical Database Solutions I, Medical Alley, March 18, 1998, St. Louis Park, MN

Medical Device Aspects of the FDA Modernization Act, Medical Alley, Feb. 25, 1998, Mpls, MN

Clinical Study Designs Used in Medical Device Trials, Medical Alley, February 18, 1998, Mpls, MN

Quality System Regulation Workshop, Medical Alley, December 18, 1997, Minneapolis, MN

Strategic Approaches to Regulatory Affairs, Medical Alley, December 10, 1997, Minneapolis, MN

Medical Device Aspects of the FDA Modernization Act, Medical Alley, Dec. 3, 1997, Minneapolis, MN

Surfaces in Biomaterials '97 Symposium, September 3-6, 1997, Minneapolis, MN

***Biomedical Focus '97,* 11th Annual Conference & Exposition**, July 28-30, 1997, Minneapolis, MN

FDA-Industry Design Control Training, Medical Alley, May 21-22, 1997

FDA Clinical Trials & Statistics-The Secrets of Success, May 14, 1997, Minneapolis, MN

Clinical Trial Design for Medical Devices, Medical Alley, April 16, 1997, Minneapolis, MN

The Nuts & Bolts of Preparing a Design Dossier for CE Marking of Medical Devices, Medical Alley, March 12, 1997, MN

Training events prior to 1997 omitted for brevity. Available upon request

Artificial Hearts, Heart Assist and Heart Valves

- Heart valves
- Durability testing, Failure analysis
- Flow simulation

- Pericardial heart valve animal testing
- Artificial heart clinical research and IDE submissions
  - Jarvik-7
  - Dayton Axial-flow pump
  - 3M/Pierce-Donachy, Milwaukee Heart

Biomaterials: Polymers, Surface Modifications and Combination Products

- Qualification and validation strategies for new and replacement biomaterials
  - Silicones
  - Polyurethanes
  - Surface coatings
  - PMMA
  - Polyester
- Combination drug/device
- ISO-10993 biocompatibility testing optimization for all types of devices
- Surgical mesh materials, physical, animal, clinical testing, premarket applications,
- Expert Witness concerning design control and review compliance for mesh implant trials
- Cranioplasty plates, 3D manufacturing.

Bone Graft Substitutes, Restorative Materials and Devices, Implants

- Orthopedic and dental biomaterial applications, clinical trial, IDE and premarket submissions
  - Coatings
  - Bone graft substitutes
    - Hydroxyapatite
    - Calcium sulfate and variations
  - Artificial ligaments
  - Cranial Plates
  - Artificial joints
  - Wedge osteotomy PEEK implant and instrumentation
  - Bone growth stimulation
  - Foot reconstruction systems
  - Hip implants and joint resurfacing
  - Intramedullary rod alternatives
  - Foot implant for Correction of Hallux Vagus deformity
- Spinal implant technologies in clinical trial, IDE applications and premarket submissions
  - Rods and screw
  - Total artificial disc
  - Spinal nucleus devices

Dental

- Bone and Defect Filler
- Dental Implants

Electrophysiology – Cardiovascular and Neurological

- Implantable defibrillators
- AED and multifunctional electrodes
- ECG Electrodes
- Pacemakers
- Leads and electrodes

- Wearable external pacemakers
- Electrophysiology stimulators
- Ablation catheters
- Guidewires and catheter navigation systems
- Pacing systems for congestive heart disease
- Bone and muscle electrical stimulation
- Hyperthermia System using Airflow
- Cerebral Spinal Fluid Filtration
- Automated ankle/brachial pressure index measuring device
- Intercranial neurological interface device
- Cranial replacement device
- Mechanical tapping device
- Plethysmographs

In-vitro fertilization products

In-vitro diagnostics

- Autism diagnostic using eye-tracking technology

Minimally Invasive Technology

- Laparoscopic, arthroscopic, spinal and other minimally invasive technologies 510(k) notifications
- Qualification of unique materials and design features
- Protocol development and testing requirements
- Animal and clinical evaluations
- Specialty Surgical Instruments
- Reusability protocols for cleaning and sterilization validation

Ophthalmology and Otolaryngology

- Selection of biomaterials, device qualification, and clinical trials
- Comparative testing of lenses for optical quality related to clinical outcomes.
- Cochlear implant devices investigational applications

Oral Appliances

- Qualifying biomaterials and device designs
- Premarket notification [510(k)] for Australian and US clients
- Bite guards, TMJ and bruxism

Powered Mobility, Prosthetics and Physical Medicine

- Powered stand-up wheelchair.
- Physical medicine devices for the home
- Materials qualification for prosthetic interface

Reusability of Devices and Instrumentation

- Validated cleaning and/or sterilization studies
- Durability and reuse testing protocol development

Surgical Robotic System

- 510(k) application with software validation

Safety Syringe and PPE

- Clinical usability testing
- Premarket notification [510(k)]
- Nitrile gloves

Software, Electronics, Internet Medicine

- Implantable electronic device premarket notification [510(k)]
- Data storage systems
- Cybersecurity, software submission requirements
- Imaging diagnostic systems, such as gamma camera
- Radiology quality system device
- Software-based medical systems
- Hololens2 display/3D imaging
- Tablet-platform multiple diagnostic systems
- Internet-based home medical services

Sterility and Shelf-life Testing

- Shelf-life testing and expiration-date labeling protocols
- Qualifying materials and devices for use in alternative sterilization methods

Urological and Dialysis

- Clinical trial management, auditing and reporting
- Design qualification and review for numerous
- IDE applications and FDA interactions
- Premarket notification [510(k)] catheters
- FDA clearance of novel PU improved Foley catheter
- Biomaterials qualification
- Percutaneous implant port for bladder
- Anti-infective coatings and surface modifications
- Testing to voluntary standards

Usability Studies

- Protocol development and field testing for user manual validations
- Usability studies for “over-the-counter” products
- Usability studies for safety syringes

Vascular Grafts and Stents

- Peripheral vascular grafts
- Coronary artery bypass grafts
- Vascular stents technology
- Cell-seeding technology
- Tissue-derived vascular prostheses

Miscellaneous Regulatory Services

- Regulatory Assessment-New Technologies
- Regulatory Assessment-Cosmetics
- US. Agent
- Registration and Listing Assistance
- Medical Device Adverse Event Reporting
- Expert Witness
- Due Diligence/Forensic Regulatory