Commitment to Continuing Education

Paladin Medical is committed to continuing education, both as a presenter and as a participant. Participation at seminars and courses assures that our clients receive the latest technical and regulatory information. Presentations extend the services Paladin Medical offers to the medical device community, thus clients benefit directly from our continuing commitment to education. Recertification as a Regulatory Professional (RAC) also depends upon continuing education. For brevity, only recent selected examples are provided here. To request additional information and training before 1997, visit our website at www.paladinmedical.com.

Presentations and Speeches

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

Managing Regulatory Uncertainty. Orthopaedic Research Society (ORS) 2011 Annual Meeting. Long Beach, CA, January 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 Symposium. Salt Lake City, UT, Nov 30-Dec 1, 2007.

IRB and FDA: Roles and Impacts. Barney Clark Commemorative Symposium. University of Utah, November 30-December 1, 2007

Shelf-life aging. Client training. September 2007.

Navigating Standards & Regulations for Medical Textiles. IFAI Medical Textile Symposium. October 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. Medical Alley, March 13, 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.

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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. AnokaRamsey 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 Sponsors of Pre-clinical 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. Podium Paper, World Congress of Biomaterials. May 19, 2000, Kona, Hawaii

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. University of Kentucky. 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

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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. September 1996, Phoenix, AZ

Deciding When to Submit a 510(k) for a Change to an Existing Device. Medical Alley Regulatory Committee. 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. Faculty; Mechanical Engineering Seminar and UNITE. 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

Continuous Service Improvements: Selected Examples 2012-1997

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

FDA Webinar, FDA, August 31, 2010

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

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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 Internatoinal, 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, Philadelpia, 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 Foundation – 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

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

Medical Device Directives- IVDD, & Submissions, TUV Rheinland 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 of the National and Local Processes, Medical Alley, February 3, 2000, St. Louis Park, 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, St. Louis Park, MN

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

Strategies for Integrating Regulatory, Reimbursement, and Outcomes Research for Effective Market Introduction, *Medical Alley, April 6, 1999, St. Louis Park, MN*

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

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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 Drug, Biologic and Medical Device 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 International Research Conference - 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: Private and Public Payer Perspectives on Insurance Coverage Decision Making, Medical Alley, May 12, 1998, St. Louis Park, MN

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

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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, Mpls, MN

Articles and Book Chapters

S. Martin, E. Duncan, Implantable sensor systems: Considerations for sterilisation: Implantable sensor systems for medical applications Chapter 12, Woodhead Publishing Innovation: In Press- 2012.

Duncan, E. Ch11 The Regulatory Environment for Biotextiles: Biotextiles as Medical Implants, Editors: Dr. Martin W. King and Dr. Bhupender S. Gupta Woodhead Publishing Innovation: In Press- 2012

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

Duncan, E. Good Laboratory Practices for Testing Biomaterials, *Biomaterials Forum*, September- October 2001.

Duncan, E. Combination Products and Design Control. SurFACTS in Biomaterials, Spring, 2001.

Duncan, E. Surface Modifiers Need to Speak up About Reuse Now. SurFACTS in Biomaterials, 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, Vol. 4, Issue 2, Summer 1999.

Duncan, E. Regulatory Update for SurFACTS Readers. Vol. 3, Issue 3, p. 7, 1998.

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

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.

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

Duncan, E. Seeking Biocompatibilty. MD&DI Magazine, September 1990.

Duncan, E. Biostability, Stability and Controlled Instability. MD&DI Magazine, May 1990.

Duncan, E. What is a Biomaterial? MD&DI Magazine, March 1990.

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