

Exponent®
Engineering & Scientific Consulting

Marta Villarraga, Ph.D., RAC

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Professional Profile

Marta Villarraga, Ph.D., RAC, is a principal in Exponent's Biomedical Engineering & Sciences practice with over 25 years of experience in medical device consulting. She specializes in evaluating device performance across the product lifecycle, regulatory strategy, compliance, quality control, and life sciences due diligence across various medical device types, including general surgery, orthopedic, spine, women's health, and diagnostics.

Dr. Villarraga has provided technical support for regulatory submissions, risk management, postmarketing surveillance, product development, and government investigations. She has conducted failure analyses, root-cause analyses, and compliance evaluations related to medical device recalls. She has also served as an expert witness in product liability, intellectual property, contract disputes, trade secret, and arbitration matters involving medical devices.

Dr. Villarraga's research experience and interests include spine biomechanics; implant and tissue retrieval analysis, including the use of microscopic (SEM) and tissue analysis techniques (ICP, histology); use of animal models for evaluating orthopedic/spinal device performance; and the use of experimental and finite element stress analysis techniques to characterize the mechanical behavior of bone, other biological structures, and orthopedic/spinal implant devices. She has been a reviewer for the Journal of Biomechanical Engineering, Clinical Orthopedics and Related Research, Clinical Biomechanics, Clinical Neurology and Neurosurgery, Journal of Engineering in Medicine, and the Journal of Biomedical Materials Research.

Medical device total product lifecycle consulting

Dr. Villarraga advises MedTech clients on technical and regulatory issues throughout the total product lifecycle. This has included working with client teams during risk management file development and developing and conducting medical device performance evaluations during pre- and postmarket stages, as well as assessments related to quality and compliance requirements.

Medical device performance evaluation

Dr. Villarraga has expertise in developing unique methodologies for evaluating medical device performance during the premarketing and postmarketing stages. These evaluations have included assessments used as part of verification and validation and in support of durability and/or reliability studies, utilizing industry standards as guides or developing unique methodologies when necessary. She has experience with orthopedic, spinal, plastic and reconstructive surgery, urology, urogynecology, general surgery, women's health, and diagnostic medical devices.

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Medical device regulatory strategy and compliance

As a Regulatory Affairs Certified (RAC-US, Devices) professional, Dr. Villarraga uses her knowledge and experience with U.S. Food and Drug Administration regulations and the EU Medical Deice Regulation (EU MDR) requirements to develop regulatory strategies for novel products, contribute to or prepare regulatory submissions, interact with regulatory bodies, and support identifying, developing, and justifying technical evaluations for premarket assessments and postmarket compliance matters. Additionally, as a certified lead ISO 13485 auditor, she is able to leverage her experience to address regulatory and compliance issues that may arise during the total product development cycle, including internal audits and regulatory body inspections.

Medical device quality control

Dr. Villarraga has experience in identifying scientifically justifiable methodologies for assessment of quality control issues as applied to medical devices, combination products, and pharmaceuticals, medical device quality systems compliance (gap analysis), contamination, manufacturing compliance, and finished device evaluations.

Life sciences due diligence

Dr. Villarraga has provided technical and regulatory expertise as part of due diligence efforts associated with potential acquisitions. These efforts have leveraged the multidisciplinary expertise of Exponent colleagues while providing targeted technical and regulatory perspective from her decades of consulting with medical device clients.

Academic Credentials & Professional Honors

Ph.D., Biomedical Engineering, Tulane University, 1996

M.S., Biomedical Engineering, Tulane University, 1992

B.S., Biomedical Engineering, Tulane University, 1990

American Association of University Women (AAUW) Selected Professions Fellow

National Science Foundation Minority Graduate Fellow

Sigma Xi (Scientific Research Society)

Alpha Eta Mu Beta (Biomedical Engineering Honor Society)

Tau Beta Pi

2000 Harold Levey Award (Tulane School of Engineering: In recognition of professional achievement to an alum)

Licenses and Certifications

Certified ISO 13485 Lead Auditor

ISO 14971:2019 - Application of risk management to medical devices

Regulatory Affairs Certification (RAC: Devices)

Regulatory Affairs Certification (RAC: US)

Academic Appointments

Research Assistant Professor, School of Biomedical Engineering, Science and Health Systems at Drexel University, Philadelphia

Previous Academic Appointments

Adjunct Professor in the Department of Mechanical Engineering at Temple University, Philadelphia

Visiting Lecturer in Mechanical and Aerospace Engineering at Princeton University, 2000-2006

Adjunct Assistant Professor in the Department of Biomedical Engineering at Tulane University, New Orleans

Prior Experience

Visiting Assistant Professor, Department of Biomedical Engineering, Tulane University, New Orleans, LA, 1998-1999

Post-doctoral Research Fellow, Department of Biomedical Engineering, Tulane University, New Orleans, LA, 1996-1997

Professional Affiliations

Regulatory Affairs Professionals Society (member)

Women in Bio (member Philadelphia Chapter)

MedTech Women (member)

ChIPs® (Chiefs in Intellectual Property) (member)

Medical Device Innovation Consortium (MDIC), Case for Quality

Food and Drug Law Institute (Corporate Member), 2020 & 2021 Annual Meeting Planning Committee, 2023 Enforcement, Compliance and Litigation Planning Committee

Orthopaedic Research Society (member)

ASTM International (member), Subcommittees F04.25: Spinal Devices, F04.15: Material Test Methods, F04.18: Device Retrieval Analysis

Life Sciences PA (Corporate Member), 2019 Life Sciences Future, MedTech Planning Committee

The Forum of Executive Women (member), 2021 DEI Committee

Philadelphia Biotechnology & Medical Device Seminar Series, Co-Founder 2004

Languages

Spanish

Patents

US 7,186,254 B2 "Methods and Apparatus for Promoting Fusion of Vertebrae", March 6, 2007

Publications

Meng, L, Frohbergh, M, Villarraga, M, Sundaram, S, Roffidal T, Fodor, W. Biomechanics of regenerated esophageal tissue following the implantation of a tissue engineered Cellspan™ Esophaeal Implant. J. Biomech. 2022 Jul (140): 111162.

Villarraga, ML. Enhancing Engineering Approaches to Understand and Treat Women's Health, Guest Editor's Note, Engineering for Women's Health, The Bridge, April 25, 2022, 52(1): 7-9.

Sjovold SG, Zhu Q, Bowden A, Larson CR, de Bakker PM, Villarraga ML, Ochoa JA, Rosler DM, Cripton PA. Biomechanical evaluation of the Total Facet Arthroplasty System ® (TFAS ®): Loading as compared to a rigid posterior instrumentation system. Eur Spine J 2012 Aug; 21(8):1660-1673.

Ong KL, Villarraga ML, Lau E, Carreon L, Kurtz SM, Glassman S. Off-label use of bone morphogenetic proteins in the United States using administrative data. Spine 2010; 35(19):1794-1800.

Villarraga ML, Guerin HL, Wood, JM. Five year review of Class I medical device recalls: 2004-2008. Food Drug Law J 2009; 64(4):663-676.

Steffey D, Ostarello A, Clevenger J, Villarraga M. Troubleshooting analyses of production data. Int J Indust Eng 2009; 16(3):206-213.

Bowden AE, Guerin HL, Villarraga ML, Patwardhan AG, Ochoa JA. Quality of motion considerations in numerical analysis of motion restoring implants of the spine. Clin Biomech (Bristol, Avon) 2008; 23(5):536-544.

Khanna AJ, Lee S, Villarraga M, Gimbel J, Steffey S, Schwardt J. Biomechanical evaluation of kyphoplasty with calcium phosphate cement in a 2-functional spinal unit vertebral compression fracture model. Spine J 2008; 8(5):770-777.

Villarraga ML, Guerin HL, Lam T. Medical device recalls from 2004 to 2006: A focus on Class I recalls. Food Drug Law J 2007; 62(3):581-592.

Kobayashi N, Ong K, Villarraga M, Schwardt J, Wenz R, Togawa D, Fujishiro T, Turner AS, Seim HB, Bauer TW. Histological and mechanical evaluation of self-setting calcium phosphate cements in a sheep vertebral bone void model. J Biomed Mat Res 2007; 81(4):838-846.

Kurtz S, Van Ooij A, Ross E, de Waal Malefijt J, Peloza J, Ciccarelli L, Villarraga M. Polyethylene wear and rim fracture in total disc arthroplasty. Spine J 2007; 7(1):12-21.

Villarraga M, Cripton P, Teti S, Steffey D, Krisnamuthy S, Albert T, Hilibrand A, Vaccaro A. Wear and corrosion in retrieved thoracolumbar posterior internal fixation — Response to Letter to the Editor (Asher MA and Carson WL). Spine 2007; 32(7):831-832.

Villarraga ML, Cripton PA, Teti SD, Steffey DL, Krisnamuthy S, Albert T, Hilibrand A, Vaccaro A. Wear and corrosion in retrieved thoracolumbar posterior internal fixation. Spine 2006; 31(21):2454-2462.

Kurtz S, Siskey R, Ciccarelli L, Van Ooij A, Peloza J, Villarraga M. Retrieval analysis of total disc replacements: Implications for standardized wear testing. J ASTM Int 2006; 3(6):1-12.

Kurtz S, Peloza J, Siskey R, Villarraga M. Analysis of a retrieved polyethylene total disc replacement component. Spine J 2005; 5:344-50.

Villarraga M, Bellezza A, Harrigan T, Cripton P, Kurtz S, Edidin A. The biomechanical effects of kyphoplasty on treated and adjacent non-treated vertebral bodies. J Spinal Disorders Tech 2005; 18(1):84-91,

Kurtz S, Villarraga M, Zhao K, Edidin A. Static and fatigue mechanical behavior of bone cement with elevated barium sulfate content for treatment of vertebral compression fractures. Biomaterials 2005; 26:3699-3712.

Villarraga M, Most E, Kurtz S. Risk communication of medical device failures. Update (FDLI): Food and Drug Law, Regulation and Education 2004; 5:18-31.

Villarraga M, Cripton P, Bellezza, A, Berlemann U, Kurtz S, Edidin A. Bone and bone cement stresses in the thoraco-lumbar spine following kyphoplasty: A finite element analysis. Zeitschrift Der Orthopade (Special Issue Concerning Cementing Techniques) 2004; 33(1):48-55.

Villarraga M, Kurtz S, Herr M, Edidin A. Multiaxial fatigue behavior of conventional and highly crosslinked UHMWPE during cyclic small punch testing. J Biomed Mat Res 2003; 66A:298-309.

Harris M, Chang D, Shilt J, Villarraga M, Thomas K, Stelly M. Modeling of the naked facet sign in the lumbar spine. J Spinal Disord Tech 2002; 15(6):495-501.

Kurtz S, Villarraga M, Herr M, Bergstrom J, Rimnac C, Edidin A. Thermomechanical behavior of virgin and highly crosslinked ultra high molecular weight polyethylene used in total joint replacements. Biomaterials 2002; 23(17):3681-3697.

Edidin A, Herr M, Villarraga M, Muth, J, Yau S, Kurtz S. Accelerated aging studies of UHMWPE. I: Effect of resin, processing, and radiation environment on resistance to mechanical degradation. J Biomed Mat Res 2002; 61:312-322.

Edidin A, Villarraga M, Herr M, Muth, J, Yau S, Kurtz S. Accelerated aging studies of UHMWPE. II: Virgin UHMWPE is not immune to oxidative degradation. J Biomed Mat Res 2002; 61:323-329.

Harris M, Stelly M, Villarraga M, Schroeder A, Thomas K. Modeling of the naked facet sign in the thoracolumbar spine. J Spinal Disorders 2001; 14(3):252-258.

Villarraga M, Anderson R, Hart R, Dinh D. Contact analysis of a posterior cervical spine plate using a three-dimensional canine finite element model. J Biomech Eng 1999; 121(2):206-214.

Martinez (Villarraga) M, Anderson R, Bundy, K, Dinh D. Titanium metal release after posterior cervical spine plate placement in a canine model. J Long Term Effects of Medical Implants 1995; 5(3):185-208.

Book Chapters

Villarraga ML, Kurtz SM, Clinical performance of UHMWPE in the spine. In: The UHMWPE Biomaterials Handbook, 3rd Edition. Kurtz S (ed), Academic Press, New York, NY, 2016.

Villarraga M, Day J. Risk management during the design process: The role of medical device failure analysis. In:Bringing Your Medical Device to Market, Third Edition. Reiss J (ed), FDLI, Washington, DC, 2013.

Villarraga M, Butchko H, Ong K. Understanding, anticipating, and preventing medical device recalls. In: Bringing your medical device to market, Third Edition. Reiss J (ed), FDLI, Washington, DC, 2013.

Kurtz SM, Villarraga ML, Ianuzzi A. Clinical performance of UHMWPE in the spine. In: The UHMWPE Biomaterials Handbook, 2nd Edition. Kurtz S (ed), Academic Press, New York, NY, 2009.

Kurtz S, Van Ooij A, Peloza J, Villarraga M. Retrieval analysis of arthroplasty devices. In: Spinal arthroplasty, the preservation of motion. Vaccaro A, Papadopoulos S, Traynelis V, Haid R, Sasso R (eds), Philadelphia, PA, 2007.

Villarraga M, Mazzucco D. Medical device failure considered in the design process. In: Bringing Your Medical Device to Market. Reiss J, Armon B (eds), Food and Drug Law Institute, Washington, DC, 2006.

Butchko H, Villarraga M. Understanding, anticipating, and preventing medical device recalls. In: Bringing Your Medical Device to Market. Reiss J, Armon B (eds), Food and Drug Law Institute, Washington, DC, 2006.

Villarraga M. Historical review of spinal instrumentation for fusion: Rods, plates, screws and cages. In: Spine Technology Handbook. Kurtz S, Edidin A (eds), Academic Press, New York, NY, 2006.

Villarraga M. Clinical performance of rods, plates, screws, and cages. In: Spine Technology Handbook. Kurtz S, Edidin A (eds), Academic Press, New York, NY, 2006.

Villarraga M, Cripton P. The clinical performance of UHMWPE in the spine. In: The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement. Kurtz S (ed), Academic Press, New York, NY, 2004.

Villarraga M, Kurtz S, Herr M, Edidin A. Multiaxial fatigue behavior of oxidized and unoxidized UHMWPE during cyclic small punch testing at body temperature. In: Highly Crosslinked and Thermally Treated Ultra-High Molecular Weight Polyethylene For Joint Replacements. STP 1445. Kurtz S, Gsell R, Martel J (eds), American Society for Testing and Materials, West Conshohoken, PA, 2003.

Villarraga M, Ford C. Applications of bone mechanics. In: Bone Mechanics Handbook. Cowin S (ed), CRC Press, Inc., Boca Raton, FL, 2001.

Villarraga M, Anderson R, Hart R, Bundy K, Dinh D. Mechanisms of titanium release from posterior cervical spine plates in a canine model based on computational and biocompatibility studies. In: Functional Biomaterials. Soboyejo W (ed), Trans Tech Publications Ltd., Winterthur, Switzerland, 2001.

Villarraga M, Rice D. Personal information management systems. In: Encyclopedia of Electrical and Electronics Engineering, John Wiley & Sons, Inc., New York, NY, 1999.

Martinez (Villarraga) M, Anderson R. Models of the upper cervical spine. In: Frontiers in Head and Neck Trauma: Clinical and Biomechanical. Yoganandan N, Pintar F, Larson S, Sances A (eds), IOS Press, Netherlands, 1998.

Published Abstracts of Presentations

Siskey RL, Villarraga M. Fatigue and wear evaluation of nucleus pulposus replacements. ASTM Symposium on Static and Dynamic Spinal Implant: Are We Evaluating Them Appropriately? San Antonio, TX, November 16, 2010.

Shah P, Villarraga M, Siskey RL, Guerin H. Validation of a physical intervertebral disc model with surrogate endplate material for multidirectional wear and fatigue testing of nucleus pulposus replacements. Poster 349, 10th Annual SAS Global Symposium on Motion Preservation Technology, New Orleans, LA, April 27-30, 2010.

Shah P, Villarraga M, Siskey R, Guerin H. Validation of a physical intervertebral disc model with surrogate endplate material for multidirectional wear and fatigue testing of nucleus pulposus replacements. Poster No. 1580, 56th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, March 6-9, 2010.

Heinly J, Guerin H, Auerbach J, Siskey R, Villarraga M. The use of ATR-FTIR to correlate proteoglycan content to degenerative grade of the human intervertebral endplate. Poster No. 1466, 56th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, March 6-9, 2010.

Ong KL, Lau E, Villarraga ML, Glassman S, Kurtz SM. Evaluating on-label and off-label use of BMP in the U.S. using administrative data. Scientific Exhibit No. 71, 77th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, March 9-13, 2010.

Ong KL, Lau E, Villarraga ML, Glassman S, Kurtz SM. Evaluating on-label and off-label use of BMP in the U.S. using administrative data. Paper No. 19, 77th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, March 9-13, 2010.

Ong K, Villarraga M, Lau E, Carreon L, Kurtz S, Glassman S. Evaluating on-label and off-label use of BMP in the U.S. using administrative data. Poster No. 1406, 56th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, March 6-9, 2010.

Shah P, Villarraga M, Siskey R, Guerin H. Validation of a physical intervertebral disc model with surrogate endplate material for multidirectional wear and fatigue testing of nucleus pulposus replacements. 5th Annual Philadelphia Spine Research Symposium, University of Pennsylvania, December 9, 2009.

Ong KL, Lau E, Villarraga ML, Glassman S, Kurtz SM. Evaluating on-label and off-label use of BMP in the U.S. using administrative data. 5th Annual Philadelphia Spine Research Symposium, University of Pennsylvania, December 9, 2009.

Ong KL, Lau E, Ianuzzi I, Kurtz S, Villarraga M, Future Demand in Cervical, Thoracic, and Lumbar Spine Fusions: U.S. Projections to 2020, E-Poster P114, Proceedings, North American Spine Society, San Francisco CA, November 10-14, 2009.

Siskey RL, Villarraga ML, Guerin H. Wear and fatigue characterization of a nucleus pulposus replacement using a surrogate annulus and the ISO 18192 duty cycle. Transactions of the Spine Arthroplasty Society; 562, London, UK, April 28-May 1, 2009.

Siskey R, Villarraga ML, Guerin HL. Wear and fatigue characterization of a nucleus pulposus replacement using a surrogate annulus. 55th Annual Meeting of the Orthopaedic Research Society, 33:24, Las Vegas, NV, February 22-25, 2009.

Steffey D, Ostarello A, Clevenger J, Villarraga M. Troubleshooting analyses of production data. 13th Annual International Conference on Industrial Engineering Theory, Applications and Practice, Las Vegas, NV, September 8-10, 2008.

Siskey RL, Villarraga M, Guerin H, Shah P, Kurtz SM. Developing a surrogate annulus fibrosus model for nucleus pulposus replacement wear and fatigue characterization. Transactions of the Spine Arthroplasty Society; 85, Miami, FL, May 6-10, 2008.

Guerin HL, Heinly J, Auerbach J, Siskey R, Lonner B, Villarraga M, Kurtz S. Identifying appropriate interventional timepoints for nucleus pulposus replacements: Impact of degeneration-dependent mechanical properties of the cartilaginous endplate. Transactions of the Spine Arthroplasty Society; 72, Miami, FL, May 6-10, 2008.

Ong K, Lau E, Ianuzzi A, Villarraga M, Kurtz S. Future demand in spine fusions: U.S. projections to 2030. Scientific Exhibit SE64. 75th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, CA, March 5-9, 2008.

Bowden A, Guerin H, Villarraga M, Patwardhan A, Ochoa J. Higher order validation metrics are required when numerically modeling physiologic motion of the spine. Poster No. 1360. 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, March 2-5, 2008.

Guerin H, Heinly J, Auerbach J, Siskey R, Lonner B, Villarraga M, Kurtz S. Human intervertebral disc cartilaginous endplate tensile mechanical properties are anisotropic and degeneration dependent. Poster No. 1444. 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, March 2-5, 2008.

Ianuzzi A Kurtz S, Van Ooij A, Bindal R, Ross E, Bohinski R, Kane W, Siskey R, Shah P, Villarraga M. In vivo deformation, surface damage, and biostability of retrieved dynesys components for posterior dynamic stabilization. Poster No. 1325. 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, March 2-5, 2008.

Siskey R, Villarraga M, Guerin H, Shah P, Kurtz S. Design and validation of a surrogate annulus fibrosis model for nucleus pulposus replacement wear and fatigue characterization. Poster No. 1924. 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, CA, March 2-5, 2008.

Khanna J, Lee S, Villarraga M, Gimbel J, Schwardt J. Kyphoplasty with calcium phosphate is biomechanically similar to PMMA in a 2-FSU spine fracture model. Paper No. 222. 74th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Diego, CA, February 14-19, 2007.

Kurtz SM, Patwardhan A, van Ooij A, Lorenz M, Zindrick M, Oleary P, Peloza J, Ciccarelli L, Villarraga ML. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? Paper No. 437. 74th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Diego, CA, February 14-18, 2007.

Guerin H, Baxter S, Nguyen A, Elliot D, Villarraga M, Kurtz S. Human intervertebral disc cartilaginous endplate biphasic mechanical properties. Poster No. 1135, 53rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, February 11-14, 2007.

Kurtz S, Van Ooij A, Ross E, De Waal Malefijt J, Isaza J, Peloza J, Ciccarelli L, MacDonald D, Villarraga M. Clinical significance of polyethylene oxidation for total disc arthroplasty. Poster No. 1130. 53rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, February 11-14, 2007.

Ong K, Lau E, Kurtz S, Chin K, Ianuzzi A, Villarraga M. Cervical, thoracic, and lumbar fusion rates in the U.S.: Perspective from two health databases. Poster No. 1016. 53rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, February 11-14, 2007.

Ong K, Lau E, Kurtz S, Chin K, Ianuzzi A, Villarraga M. Projections to 2030 of the prevalence of primary and revision spine fusions in the U.S. Poster No. 107. 53rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, February 11-14, 2007.

Villarraga M, Teti S, Kane W, Steffey D, Campbell P, Hilibrand A, Albert T, Vaccaro A. What is the impact of wear and corrosion seen on retrieved spine implants? Poster No. 1068. 53rd Annual Meeting of the Orthopaedic Research Society, San Diego, CA, February 11-14, 2007.

Day J, Villarraga M, Teti S, Graber M, Schwardt J. Does MicroCT provide clinically relevant information on vertebral compression fractures? E-Poster P136. Proceedings, North American Spine Society, Seattle, WA, September 26-30, 2006.

Bowden A, Villarraga M. In situ biomechanics of total facet replacement using finite element analysis. SIPP #4, 140. Proceedings, North American Spine Society, Seattle, WA, September 26-30, 2006.

Kurtz S, Van Ooij A, Ross R, Ciccarelli L, Zeiger A, Villarraga M. Analysis of textured endplates and bone ongrowth in retrieved charité total disc replacements. E-Poster P113. Proceedings, North American Spine Society, Seattle WA, September 26-30, 2006.

Kurtz S, Patwardhan A, Van Ooij A, Lorenz M, Zindrick M, O'Leary P, Peloza J, Ross R, Ciccarelli L,

Siskey R, Villarraga M. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? SIPP #1, 87. Proceedings, North American Spine Society, Seattle, WA, September 26-30, 2006.

Kurtz S, Van Ooij A, Peloza J, Ross E, Ciccarelli L, Siskey R, Villarraga M. Impact of in vivo oxidation on the clinical performance of total disc replacements. E-Poster. 13th International Meeting on Advanced Spine Techniques (IMAST), Athens, Greece, July 12-15, 2006.

Kurtz S, Patwardhan A, Van Ooij A, Lorenz M, Zindrick M, O'Leary P, Peloza J, Ross E, Ciccarelli L, Siskey R, Villarraga M. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? Paper #38. 13th International Meeting on Advanced Spine Techniques (IMAST), Athens, Greece, July 12-15, 2006.

Kurtz S, Patwardhan A, Van Ooij A, Lorenz M, Zindrick M, O'Leary P, Peloza J, Ciccarelli L, Villarraga M. What is the correlation of in vivo wear and fracture patterns with in vitro TDR motion response? 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006.

Van Ooij L, Ciccarelli L, Kurtz S, Villarraga M. Analysis of textured endplates and bone ongrowth in retrieved charité total disc replacements. 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006.

Van Ooij A, Peloza J, Ciccarelli L, MacDonald D, Topper J, Kurtz S, Villarraga M. The impact of polyethylene oxidation on the long-term clinical performance of total disc replacements. 6th Annual Meeting of the Spine Arthroplasty Society, Montreal, Canada, May 9-12, 2006.

McCombe P, Ciccarelli L, Villarraga M, Kurtz S, Chan F. Analysis of In Vivo wear mechanisms in maverick total disc arthroplasty. Poster No. P398. 73rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Chicago, IL, March 22-26, 2006.

Ong K, Chin K, Lau E, Mowat F, Kurtz S. Changes in revision spine fusion rates at all levels in the United States from 1990-2003. Poster No. P394. 73rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Chicago, IL, March 22-26, 2006.

Van Ooij A, Peloza J, Ciccarelli L, Kurtz S, Villarraga M. Polyethylene wear and rim fracture in total disc arthroplasty. Paper No. 108. 73rd Annual Meeting of the American Academy of Orthopaedic Surgeons, Chicago, IL, March 22-26, 2006.

Ong K, Chin K, Lau E, Mowat F, Kurtz S, Villarraga M. Age and gender prevalence of revision spine fusion rates in the United States from 1990 to 2003. p. 1265. In: Trans. Orthopaedic Research Society, Volume 31, March 19-22, 2006.

Kurtz S, Van Ooij A, Van Rhijn L, Peloza J, Ciccarelli L, Villarraga M. PE wear, rim fracture, and osteolysis in retrieved total disc replacements. p. 117. In: Trans. Orthopaedic Research Society, Volume 31, March 19-22, 2006.

Kurtz S, Van Ooij A, Peloza J, Ciccarelli L, Zeiger A, Villarraga M. Central core and rim damage in retrieved polyethylene total disc replacement components. Paper #17. Proceedings, North American Spine Society, Philadelphia, PA, September 28-October 1, 2005.

Kurtz S, McCombe P, Ciccarelli L, Villarraga M, Chan F. Retrieval analysis of short-term implanted maverick total disc arthroplasty. Paper #124. Proceedings, North American Spine Society, Philadelphia, PA, September 28-October 1, 2005.

Bowden A, Edidin A, Villarraga M, Kurtz S. Advanced numerical modeling of spinal biomechanics. Philadelphia Spine Research Symposium, Philadelphia, PA, September 27, 2005.

Villarraga M, Ong K, Chin K, Lau E, Mowat F, Kurtz S. Age and gender prevalence of revision spine fusion rates in the United States from 1990 to 2003. Philadelphia Spine Research Symposium, Philadelphia, PA, September 27, 2005.

Villarraga M, Day J, Teti S, Graber M, Schwardt J. Does the resolution of MicroCT provide any clinically relevant information on vertebral compression fractures? Philadelphia Spine Research Symposium, Philadelphia, PA, September 27, 2005.

Villarraga M, Bowden A, Kurtz S, Edidin A. Numerical simulation of vertebral body collapse. Philadelphia Spine Research Symposium, Philadelphia, PA, September 27, 2005.

Kurtz S, Van Ooij A, Peloza J, Ciccarelli L, Zeiger A, Villarraga M. Polyethylene wear and rim fracture of retrieved total disc arthroplasty. Paper #41. Annual Meeting of the Spine Society of Europe, Barcelona, Spain, September 21-24, 2005.

Kurtz S, Van Ooij J, Peloza J, Ciccarelli L, Zeiger A, Villarraga M. Polyethylene wear analysis of retrieved total disc arthroplasty. 12th International Meeting on Advanced Spine Techniques (IMAST), Banff, Alberta, Canada, July 7-9, 2005.

Kurtz S, McCombe P, Ciccarelli L, Villarraga M, Chan F. In vivo wear mechanisms of a retrieved metal-on-metal total disc replacement. 12th International Meeting on Advanced Spine Techniques, Banff, Alberta, Canada, July 7-9, 2005.

Kurtz S, Van Ooij A, Peloza J, Ciccarelli L, Zeiger A, Villarraga M. Wear and surface damage analysis of retrieved charité total disc replacements. Spine Arthroplasty Society Global Symposium, New York, May 4-7, 2005.

Kurtz S, McCombe P, Ciccarelli L, Villarraga M, Chan F. Analysis of in vivo wear mechanisms in a retrieved total disc arthroplasty. Spine Arthroplasty Society Global Symposium, New York, May 4-7, 2005.

Bowden A, Bergstrom J, Villarraga M, Kurtz S. Biomechanical analysis of polyethylene stresses in charité total disc replacement. Spine Arthroplasty Society Global Symposium, New York, May 4-7, 2005.

Ong K, Villarraga M, Teti S, Sankaran M, Turner A, Seim III H, Schwardt J. Vertebral augmentation with calcium phosphate cements: Bioceramic integration characteristics and compressive strength in ovine vertebral bodies. Paper No. 272. Annual Meeting of the Orthopaedic Research Society, Washington, DC, February 20-23, 2005.

Ong K, Villarraga M, Mazzucco D, Jaekel D, Kurtz S, Edidin A. Mechanical properties of freshly-procured and previously-frozen human cadaveric nucleus. Poster P319. 72nd Annual Meeting of the American Academy of Orthopaedic Surgeons, Washington, DC, February 23-27, 2005.

Villarraga M, Bellezza A, Harrigan T, Cripton P, Kurtz S, Edidin A. The biomechanical effects of kyphoplasty on adjacent non-treated vertebral bodies: A finite element analysis. Proceedings, 50th Annual Meeting of the Orthopaedic Research Society, Volume 29, p. 1141, San Francisco, CA, March 7-10, 2004.

Villarraga M, Bellezza A, Harrigan T, Cripton P, Kurtz S, Edidin A. Biomechanical evaluation of kyphoplasty on treated and adjacent vertebral bodies. Poster P422. 71st Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, CA, March 10-14, 2004.

Villarraga M, Cripton P, Vaccaro A, Hilibrand A, Albert T, Turner J, Boatwright J, Smith T. Engineering analysis of retrieved spine implants. p. 669. In: 29th Annual Meeting and Exposition of the Society of Biomaterials, Volume 26, Reno, NV, 2003.

Villarraga M, Kurtz S, Cripton P, Edidin A. The biomechanical effects of kyphoplasty on single thoraco-

lumbar vertebrae: A parametric finite element analysis. Proceedings, 49th Annual Meeting of the Orthopaedic Research Society, Volume 28, p. 29, New Orleans, LA, February 2-5, 2003.

Villarraga M, Vaccaro A, Cripton P, Albert T, Hilibrand A. Improvement of spine implant performance through analysis of retrieved implants. Proceedings, 30th Annual Meeting of the Cervical Spine Research Society, Miami, FL, December 5-7, 2002.

Villarraga M, Vaccaro A, Cripton P, Hilibrand A, Albert T, Turner J, Daffner S. Analysis of retrieved scoliosis instrumentation. Proceedings, 37th Annual Meeting of the Scoliosis Research Society, Seattle, WA, September 19-22, 2002.

Villarraga M, Vaccaro A, Hilibrand A, Cripton P, Turner J, Boatwright J, Albert T. Improvement of spine implant performance through analysis of retrieved implants: Preliminary results. Proceedings, 28th Annual Northeast Bioengineering Conference, p. 159, Philadelphia, PA, April 20-21, 2002.

Villarraga M, Kurtz S, Herr M, Ciccarelli L, Edidin A. The effect of body temperature on the multiaxial fatigue behavior of virgin and highly crosslinked UHMWPE. p. 402. In: 28th Annual Meeting and Exposition of the Society for Biomaterials, Volume 25, Tampa, FL, April 24-27, 2002.

Villarraga M, Kurtz S, Ciccarelli L, Herr M, Rimnac C, Edidin A. The role of shear in the wear mechanisms of UHMWPE. p. 186. In: 28th Annual Meeting and Exposition of the Society for Biomaterials, Volume 25, Tampa, FL, April 24-27, 2002.

Kurtz S, Villarraga M, Herr M, Ciccarelli L, Bergstrom J, Rimnac C, Edidin A. Effect of temperature on the mechanical behavior of highly crosslinked UHMWPE. p. 57. In: 28th Annual Meeting and Exposition of the Society for Biomaterials, Volume 25, Tampa, FL, April 24-27, 2002.

Edidin A, Villarraga M, Herr M, Ciccarelli L, Hozack W, Turner J, Kurtz S. Relationship between clinical performance and mechanical behavior of retrieved UHMWPE acetabular liners. p. 25. In: 28th Annual Meeting and Exposition of the Society for Biomaterials, Volume 25, Tampa, FL, April 24-27, 2002.

Edidin A, Hozack W, Villarraga M, Ciccarelli L, Kurtz S. Evaluation of wear in short term implanted highly crosslinked UHMWPE inserts. p. 27. In: 28th Annual Meeting and Exposition of the Society for Biomaterials, Volume 25, Tampa, FL, April 24-27, 2002.

Villarraga M, Kurtz S, Herr M, Ciccarelli L, Edidin A. Multiaxial fatigue behavior of virgin and highly crosslinked UHMWPE at body temperature. p. 1035. In: 48th Annual Meeting of the Orthopaedic Research Society, Volume 27, Dallas, TX, February 10-13, 2002.

Kurtz S, Villarraga M, Herr M, Ciccarelli L, Bergstrom J, Rimnac C, Edidin A. Thermomechanical behavior of highly crosslinked UHMWPE: Effect of remelting vs. annealing. p. 1026. In: 48th Annual Meeting of the Orthopaedic Research Society, Volume 27, Dallas, TX, February 10-13, 2002.

Villarraga M, Kurtz S, Edidin A. Fatigue punch testing of virgin and crosslinked UHMWPE under cyclic multiaxial loading conditions. Annual Meeting and Exposition of the Society for Biomaterials, St. Paul, MN, April 25-29, 2001.

Villarraga M, Kurtz S, Edidin A. Fatigue response of virgin and crosslinked UHMWPE to cyclic multiaxial loading. p. 1020. In: 47th Annual Meeting of the Orthopaedic Research Society, Volume 25, San Francisco, CA, February 25-28, 2001.

Villarraga M, Anderson R, Hart R, Bundy K, Dinh D. Metal release from Ti-6Al-4V posterior cervical spine plates: A computational and experimental study in the canine model. ASME 2000 Congress and Exposition, Symposium on Functional Biomaterials: Joint Replacement, Orlando, FL, November 7, 2000.

Villarraga M Pope R, Aitken E, Rice J, Didier P. Evaluating the compositional and structural changes in

female rhesus monkey lumbar cancellous bone as a potential model for aging. p. 719. In: Trans. 46th Annual Meeting of the Orthopaedic Research Society, Volume 25, Orlando, FL, March 2000.

Bellezza A, Hart R, Villarraga M, Burgoyne C. Effects of ocular dimensions on IOP-related stress within the optic nerve head and posterior scleral shell. Proceedings, Annual Meeting of the Biomedical Engineering Society, Atlanta, GA, October 1999.

Villarraga M, Aitken E, Colberg A, Pope R, Didier P. Mechanical behavior of rhesus monkey lumbar vertebrae as a model for osteoporosis. Experimental Biology Meeting, Washington, DC, April 1999.

Villarraga M, Colberg A, Frazine R, Sampson K, Didier P. Mechanical properties of rhesus femoral cortical bone as determined by three-point bending and ultrasound tests. Experimental Biology Meeting, Washington, DC, April 1999.

Villarraga M, Anderson R, Hart R. Load sharing in a simplified cervical spine vertebral body model under compressive loading. p. S1. In: Annual Meeting of the Biomedical Engineering Society, Annals of Biomedical Engineering, Volume 26, Cleveland, OH, October 1998.

Martinez (Villarraga) M, Bellezza A, Hart R, Burgoyne C. IOP-related stress within the load-bearing connective tissues of the scleral canal wall is substantial at even low levels of IOP by preliminary finite element modeling. p. 4. In: Annual Meeting of the Association for Research in Vision and Ophthalmology, Volume 39, Ft. Lauderdale, FL, May 1998.

Martinez (Villarraga) M, Bellezza A, Hart R, Burgoyne C. An idealized model of the posterior eye and scleral canal. p. S1. In: Annual Meeting of the Biomedical Engineering Society, Volume 25, San Diego, CA, October 1997.

Anderson R, Martinez (Villarraga) M, Anderson R, Hart R, Dinh D. Validation of a 3-D finite element model of a plated canine cervical spine including contact nonlinearities. ASME Summer Bioengineering Conference, Sun River, OR, June 1997.

Martinez (Villarraga) M, Erickson, G, Anderson R. A validated dynamic continuum finite element model representing a simplified cervical spine motion segment. ASME Summer Bioengineering Conference, Sun River, OR, June 1997.

Martinez (Villarraga) M, Anderson R, Hart R, Bundy K, Dinh D, Hew M, Aydin F. Titanium release from Ti-6Al-4V cervical spine plates: A computational and experimental study in the canine model. p. 215. In: Trans. 43rd Orthopaedic Research Society, Volume 22, San Francisco, CA, February 1997.

Martinez (Villarraga) M, Anderson R, Bundy K, Dinh D. Titanium trace metal analysis of tissue overlaying cervical spine plates in dogs. 14th Southern Biomedical Engineering Conference, Shreveport, LA, April 1995.

Martinez (Villarraga) M, Anderson R, VanBuskirk W. Theoretical three dimensional stress analysis of the human mandible. Proceedings, 18th Annual Session of the American Association for Dental Research, San Francisco, CA, March 1989.

Selected Invited Presentations

Villarraga, M. Collaboration and Multi-Generational Relationships for Long-Term Success in Technical Scientific Consulting, SHPE 2025 National Convention, Philadelphia, PA, October 29- November 1, 2025.

Villarraga, M. (Panelist), AI Trends in Medical Devices: Global Developments, FDA Policies and Software as a Medical Device, FDLI Annual Conference, Washington DC, May 15- 16, 2025.

Villarraga, M. (Panelist), Courtroom Feud: Survey Says… Juror Psychology Matters! ABA 2025 Litigation

Section Annual Conference, Chicago, IL, April 30-May 2, 2025.

Villarraga, M. (Panelist in Roundtable), Navigating the Legal & Regulatory Complexities of the Femtech Market, Women's Health Innovation Summit, Boston, MA, September 23-25, 2024.

Villarraga, M. (Moderator Fire Side Chat), A Journey Through Women's Health with a Focus on the Later Decades, Women's Healthy Aging Innovation Summit, San Diego, CA, November 9-10, 2022.

Villarraga, M. (Moderator), Advancing Women in STEM, Forum of Executive Women (virtual), November 3, 2022

Villarraga, M. (Panelist), Do you Recall? When and How to Issue a Product Recall, and How to Handle the Aftermath, ABA Women in Product Liability CLE, Los Angeles, CA, October 20, 2022.

Villarraga, M. (Topic Facilitator), EU MDR: How are these regulations impacting the Med Dev industry? FDLI Annual Meeting (virtual), May 18-20, 2021.

Villarraga, M. (Panelist). Navigating the Intersection Between Litigation Tactics and Regulatory Issues. FDLI Enforcement, Litigation, and Compliance Conference. Washington, DC, December 11-12, 2019.

Villarraga, M. (Panelist). Diversity and Inclusion Initiatives: How Are They Changing The Mindset and Actions of Women in Products Liability? ABA 2019 Women in Litigation Joint CLE Conference. Chicago, IL, November 13-15, 2019.

Villarraga, M. BMES Celebration of Minorities in BME Luncheon Speaker. 2019 Annual Meeting of the Biomedical Engineering Society. Philadelphia, PA, October 17, 2019.

Villarraga, M. (Panelist). FDA Evidence in Device Cases: Friend or Foe? DRI Drug and Medical Device Litigation Seminar. Washington DC, May 16-17, 2019.

Villarraga M. (Panelist). Minimizing the Impact of "Bad" Company Documents. ABA Environmental & Energy, Mass Torts, and Products Liability Litigation Committees' Joint CLE Seminar. Whistler, BC, January 25-27, 2018.

Villarraga M. (Panelist). Medical Devices: Do I need to open a CAPA? FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Medical Device, Food, and Tobacco Industries. Washington DC, December 7-8, 2017.

Villarraga M. (Panelist). Preparing for and Responding to FDA Enforcement Actions- Advanced Topics: Medical Products. FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Medical Device, Food, and Tobacco Industries. Washington DC, December 6-7, 2016.

Villarraga M. (Panelist). The FDA and Medical Devices. ABA Current Issues in Pharmaceutical, Medical Device, and Biotech Litigation. Philadelphia, PA, November 4, 2016.

Villarraga M. Postmarketing Issues. FDLI's Introduction to Medical Device Law and Regulation: A program on how the medical device industry is regulated, Washington, DC, April 12-13, 2016.

Villarraga M. Postmarketing issues (Medical Device track). FDLI's Introduction to Law and Regulation-Drug and Medical Device, San Francisco, November 9-10, 2015.

Villarraga M. (Panelist). Industry Reactionary Panel to Acting FDA Commissioner. FDLI Annual Meeting. Washington, D.C., April 20, 2015.

Villarraga M. (Panelist). He says, she says, but who says it best? Gender of your expert in an IP case. 30th Intellectual Property Law Conference. Bethesda, MD, March 25-27, 2015.

Villarraga M. An introduction to health hazard evaluation (HHE). Medical Device Complaints, MDRs, and Reports. AdvaMed MTLI, Alexandria, VA, March 18-19, 2014.

Villarraga M (Moderator). Litigation: Key cases in 2014. FDLI's Medical Device, Key Legal and Regulatory Developments Conference, Washington, DC, February 27, 2014.

Villarraga M (Moderator). Hot topics in enforcement: Lessons learned (Part II), Enforcement, Litigation and Compliance Conference, FDLI, December 10-11, 2013.

Ahlin C, Mellow MA, Villarraga M, Woolf L (Panelists). Evidence testing following a client's crisis. Women in Products Liability, 14th Annual WIPL Regional CLE Workshop, ABA, New York City, November 15, 2013.

Villarraga M, Brennan J. How to leverage science and engineering consultants in the MedTech industry. World Medtech Forum Lucerne, Lucerne, Switzerland, September 17-19, 2013.

Villarraga M, Shaffer B, Phillips P (Panelists). Litigation: Products liability and key cases in 2013, strategic considerations, and avoidance techniques. Medical Device Compliance, Regulation and Litigation Conference, FDLI, The Westin Georgetown, Washington, DC, March 4, 2013.

Villarraga M, Vahey K. Failure investigations: Principles, procedures, and best practices. School at the Summit, Medical Device Summit Webinar, December 18, 2012.

Villarraga M, Brennan J, Soderborg N. Why should you think about the end first? An overview of DFx as applied to Medical Devices. Workshop at MD&M East, Philadelphia, PA, May 23, 2012.

Villarraga M, O'Shea S, Mittelman M. Combination products. Exponent Webinar, May 17, 2012.

Villarraga M. Postmarketing issues. FDLI's Introduction to Medical Device Law and Regulation: A program on how the medical device industry is regulated, Washington, DC, March 13, 2012.

Villarraga M. Case studies in consulting in biomedical engineering. Department of Biomedical Engineering Seminar, City College of New York, New York, NY, December 7, 2011.

Villarraga M. Medical device overview: Product development and role of consulting. West Chester University, Pharmaceutical Development Program, November 15, 2011.

Villarraga M. Panel participation in "Managing News From Post-Approval Studies." Medical Device Reports, Complaints, Product Recalls and Disclosures to Shareholders (and Investors). Philadelphia Medical Device Seminar Series, Philadelphia, PA, Friday, November 11, 2011.

Villarraga M. MeDevice Forum, San Diego, CA, September 13-14, 2011, Conference Chair.

Villarraga M. Panel participation in "Witness Preparation." Philadelphia Bar Institute, Philadelphia, PA, June 23, 2011.

Villarraga M. Postmarketing challenges: Failure analysis tools for combination medical products. Combination Devices: Challenges and Opportunities, MD&M East, New York, NY June 9, 2011. Also Organizer and Session Chair for Combination Products session.

Villarraga M. Preventing and managing recalls. OrthoTec, Warsaw, IN, May 24-25, 2011.

Villarraga M. Postmarketing issues. FDLI's Introduction to Medical Device Law and Regulation: A program on how the medical device industry is regulated, Washington, DC, February 18, 2011.

Villarraga M. Postmarketing challenges: Failure analysis tools for combination medical products. Combination Devices: Challenges and Opportunities, MD&M West, Anaheim, CA, February 9, 2011. Organizer and Session Chair for Combination Products session.

Villarraga M. Five year review of Class I Medical Device Recalls: 2004-2008. 6th Annual CBI Product Recalls Summit, Bethesda, MD, September 30, 2010.

Villarraga M. Best practices for selecting, retaining, and working with experts in patent cases. Panel in American Bar Association 25th Annual Intellectual Property Law Conference, Arlington, VA, April 8, 2010.

Villarraga M. Postmarketing issues. FDLI's Introduction to Medical Device Law and Regulation: A program on how the medical device industry is regulated. Washington, DC, March 8-9, 2010.

Villarraga M. Gender and the perception of experts in IP cases. Women in IP Subcommittee, Philadelphia Bar Association, Philadelphia, PA, October 14, 2009.

Villarraga M. Postmarketing issues. FDLI's introduction to medical device law and regulation: A program on how the medical device industry is regulated. Washington, DC, February 27, 2009.

Villarraga M. Lessons learned from spine retrieval analyses. Philadelphia Spine Research Symposium, Philadelphia, PA, November 13, 2008.

Villarraga M. Use historical Class I medical device recall information to enhance internal quality practices: A four year overview. 4th Annual CBI Product Recalls Summit, Tysons Corner, VA, September 26, 2008.

Totten J, Villarraga M. Due diligence: Evaluation methodologies that mitigate risk. Medical Devices Mergers & Acquisitions Conference, Palo Alto, CA, August 25-26, 2008.

Villarraga M. Overview of regulatory process for scientific inventors. Coulter Foundation Early Career Award Meeting, Ft. Lauderdale, FL, August 7, 2008, August 12, 2009, August 9, 2011.

Villarraga M, YshkolnikovY. FMEA: Risk management and prioritization in medical device design. Thompson Interactive Audio-Conference, July 17, 2008.

Villarraga M. Combination products. Panel at 51st Annual Meeting of Food Drug and Law Institute, Washington, DC, March 26, 2008.

Siskey R, Villarraga M, Guerin H, Shah, P, Kurtz S. Design and validation of a surrogate annulus fibrosus model for nucleus pulposus replacement wear and fatigue characterization. Philadelphia Spine Research Symposium, October 9, 2007.

Villarraga M, Bowden A, Guerin H, Patwardhan A, Ochoa J. Effect of soft tissue mechanical properties on validated quality of motion of the spine. Philadelphia Spine Research Symposium, October 9, 2007.

Guerin H, Heinly J, Auerbach J, Villarraga M, Siskey R, Lonner B, Kurtz S. Degeneration and anisotropy affect tensile properties of human intervertebral disc cartilaginous endplate. Philadelphia Spine Research Symposium, October 9, 2007.

Villarraga M, Teti S, Kane W, Steffey D, Campbell, P, Hilibrand A, Albert T, Vaccaro A. What is the impact of wear and corrosion seen on retrieved spine implants? Philadelphia Spine Research Symposium, October 9, 2007.

Ciccarelli L, MacDonald, D, Siskey R, Villarraga M, Kurtz S. International spine implant retrieval program. Philadelphia Spine Research Symposium, October 9, 2007.

Ianuzzi A, Kurtz S, Van Ooij A, Bindal R, Ross R, Bohinski R, Kane W, Siskey R, Shah P, Villarraga M. In

vivo deformation, surface damage and biostability of retrieved dynesys components for posterior dynamic stabilization. Philadelphia Spine Research Symposium, October 9, 2007.

Villarraga M. Post-marketing warnings. Panel in Current Issues in Medical Device Litigation, Section of Litigation, American Bar Association, New Orleans, LA, October 5, 2007.

Villarraga M. CAPA systems in post marketing surveillance. Compliance Online Webinar, September 4, 2007.

Villarraga M. Risk communication of medical device failures. Compliance Online Webinar, August 7, 2007.

Villarraga M, Shkoknikov Y. Failure analysis during the design process of medical devices. Compliance Online Webinar, July 19, 2007.

Villarraga M. Medical device recalls. Compliance Online Webinar, June 7, 2007.

Villarraga M. Biomaterials for vertebral body augmentation. Spine Pain: Origins and Treatment Strategies, Society for Biomaterials 2007 Annual Meeting, Chicago, IL, April 21, 2007.

Villarraga M. Orthopaedic biomechanics, mechanical engineering. Temple University, Philadelphia, Pennsylvania, March 30, 2009, March 26, 2007, March 21, 2005, April 5, 2004, March 24, 2003, March 4, 2002, February 12, 2001, March 27, 2000.

Villarraga M. Medical devices and radiological health. Fundamentals of Food and Drug Law and Regulation, FDLI, Washington, DC, October 31, 2006.

Villarraga M. Failure analysis of medical devices during the design process. FDA News Audioconference, August 17, 2006.

Villarraga M. Hazard analysis of medical devices during the design process. Product Development Course, Drexel School of Biomedical Engineering, Philadelphia, PA, May 2, 2006, March 3, 2007, May 6, 2009, May 5, 2010, May 4, 2011, May 9, 2012, May 15, 2013, May 2014, May/June 2015-2026

Villarraga M. CAPA systems: Evaluating the root cause with failure analysis methods. Medical Device Recall Workshop, ACI Drug and Medical Device Conference, Chicago, IL, June 28, 2006.

Villarraga M. Case studies in orthopaedic bioengineering. Mechanical Engineering, Princeton University, Princeton, New Jersey, April 23, 2009.

Villarraga M. Orthopaedic bioengineering. Mechanical Engineering, Princeton University, Princeton, New Jersey, April 2006, April 24, 2003.

Villarraga M. Overview of medical device law and regulation. Introduction to Medical Device Law and Regulation Workshop, FDLI, Washington, DC, November 16, 2004.

Villarraga M. Adverse events product problems. Introduction to Medical Device Law and Regulation Workshop, FDLI, Washington, DC, November 17, 2004.

Villarraga M. Total artificial disc replacements. Orthopaedic Research Laboratory, University of Pennsylvania, August 5, 2004.

Villarraga M. Experimental spine biomechanics. Mechanical Engineering, Princeton University, Princeton, New Jersey, April 24, 2002, and April 16, 2001.

Villarraga M. Implant research opportunities. School of Biomedical Engineering, Science and Health

Systems, Drexel University, Philadelphia, PA, December 7, 2001.

Villarraga M. Biomechanics consulting: Legal and medical technology development applications. City College of New York's Center for Biomedical Engineering, New York, NY, November 21, 2001.

Villarraga M. Experimental and computational evaluation of metal release from spine implants in a canine model: Further applications. In Vivo. Synthes Spine, Paoli, Pennsylvania, December 9, 1999.

Project Experience

Medical device total product lifecycle consulting

Conducted Risk Analyses for Risk Management File development in support of:

- Device being marketed under EU MDR.
- Wearable device in support of software component for regulatory submission.
- Device component of a combination product in support of responding to a complete response letter for an Abbreviated New Drug Application (ANDA) submission.

Evaluated medical device performance as part of root-cause analysis during an investigation into devices that were being considered for a recall. This included:

- Leading a team of Exponent colleagues who were conducting several parallel technical investigations to understand the effect of the change to a material specification that had been overlooked during the due diligence of an acquisition.
- Providing supporting evidence about specific criteria of device performance that enabled the client to resume distribution of the medical device.

Medical device performance evaluation

Medical device performance evaluations associated with:

- Mechanical performance assessments of tissue derived device to generate data in support of burst and suture retention requirements for design verification and in support of a regulatory submission.
- Assessment of durability of medical device to generate data in support of an appeal for a reimbursement code denial for durable medical equipment.
- Device evaluations as part of retrieval programs associated with a clinical study or with returns associated with reported complaints

Medical device regulatory strategy and compliance

Developed a regulatory strategy for a sponsor who was interested in using an existing authorized medical device for a new indication as part of a co-packaged kit with other medical devices.

Evaluated stability and suitability of hundreds of medical devices and medical device/drug kits to withstand temperature fluctuations outside of labeled temperature indication as part of an investigation associated with a potential recall.

Supported clients with preparation of materials and interaction with FDA for various presubmission meetings associated with:

- Investigational Device Exemption updates for a new indication for use.
- Choice of predicate for a 510(k) submission.
- Biocompatibility assessments in support of a 510(k) submission.

Conducted a gap analysis of the regulatory submission for a new sterilization wrap on behalf of an investment firm. Reviewed existing test reports and product description information provided by the medical device company. The assessment included:

- Identifying specific opportunities to add information to the regulatory submission, including the need for additional validation testing, details on the sterilization parameters for the wrap's intended use statement, and performance data for the wrap compared to the predicate device.
- Providing input to update the regulatory submission, leading to the sterilization wrap being cleared within the 90-day goal set by FDA's Medical Device User Fee Amendments (MDUFA).

Medical device quality control

Supported client team investigating out of specification finished device inspections and failed validation release testing of pharmaceutical products.

Worked with client teams to resolve technical challenges associated with root-cause investigations as part of CAPA files, while identifying additional candidate analyses for augmenting internal investigations to finalize CAPAs.

Life sciences due diligence

Conducted technical due diligence of a medical device imaging system to assess the technical advantages and overlap with competing technologies for the same indication. The due diligence approach included:

- Developing a framework to assess the unique capabilities of the medical imaging system, in comparison to competitors.
- Evaluating design options in the early stages of design to identify potential overlaps, gaps, and risks of implementation.
- Issuing a comprehensive report to investment banker group for consideration as part of their due diligence activities.

Other technical experience

Reviewed design documentation of medical devices to evaluate the design process, design verification and validation activities relative to typical industry practices.

Reviewed manufacturing documentation of medical devices to evaluate the manufacturing process and assess the various in process and finished device inspections.

Developed unique test methodologies to evaluate whether certain medical devices met criteria specified in claim elements of patents.

Additional Education & Training

Leading Strategic Growth, Columbia Business School, Executive Education ExecOnline, June 2021

Advisory Appointments

Department of Biomedical Engineering, Tulane University, Board of Advisors

Food and Drug Law Institute, Member of Board of Directors, January 2024-present