



Musculoskeletal Clinical
Regulatory Advisers, LLC

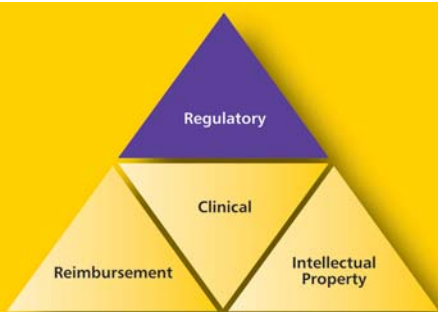
MANAGEMENT TEAM PROFILES

MCRA's the most experienced team guiding technologies through regulatory, reimbursement, clinical, intellectual property, quality assurance and international regulatory affairs initiatives.

MCRA currently employs 25 individuals, guiding technologies at any point in the device life-cycle; from pre-clinical testing, to FDA submission, to post-commercialization.

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U.S. & INTERNATIONAL REGULATORY TEAM

1st In Class Orthopedic Consulting Firm



Glenn Stiegman

Vice President, Regulatory Affairs

Mr. Stiegman manages and directs the regulatory affairs for MCRA and its clients. Mr. Stiegman is responsible for management of approximately 10 regulatory professionals at MCRA. Mr. Stiegman leads the firm's submission process, regulatory strategy, analysis and development: from pre-clinical testing, to FDA submissions, to market approval and post commercialization.

Prior to joining MCRA in February 2006, Mr. Stiegman served as the Chief of the Orthopedic Devices Branch for US Food and Drug Administration. As Branch Chief, Mr. Stiegman managed a team of scientists, clinicians, and engineers in the regulation of all orthopedic devices marketed in the United States. In addition, Mr. Stiegman was responsible for overseeing all FDA guidance documents and FDA policy determinations for orthopedic devices marketed in the US. Furthermore, he assisted in and oversaw all integrity, compliance, and monitoring issues regarding the orthopedic industry in collaboration with the Office of Compliance.

Mr. Stiegman was also a member of several leveraging groups such as the Orthopedic Device Forum and Orthopedic Surgical Manufacturer Association, where he represented the FDA. As the head of the Orthopedic Devices Branch, Mr. Stiegman pursued the advancement and consistency in the regulation of all orthopedic devices. This was evident by the pursuit of reclassifying several types of orthopedic devices, developing guidance documents on state-of-the-art orthopedic devices, and educating and assisting the orthopedic community in the regulatory strategies to get devices to market.

Prior to becoming Branch Chief, Mr. Stiegman was a reviewer in the Orthopedic Devices Branch where he was the team leader on many state-of-the-art spinal technologies. He was a leader in the field of artificial disc replacements, nucleus replacements, posterior stabilization systems, and many of the current widely used fusion spinal systems. He authored a guidance document for industry on spinal systems indicated for fusion, and he also developed documents that assisted companies in getting other devices to market such as artificial disc replacements, nucleus replacements, and posterior stabilization systems. Mr. Stiegman received his Bachelor in Science at Tulane University in Biomedical Engineering and his Master in Science at Clemson University in Bioengineering with a focus on biomaterials and biomechanics.



Kevin Ladd

Vice President, Quality Assurance & International Regulatory Affairs

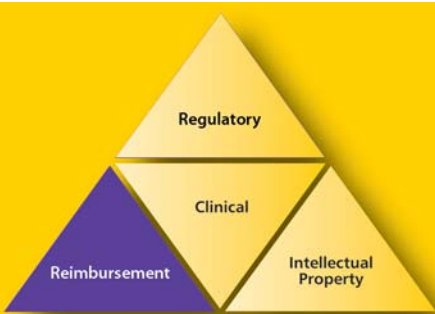
Mr. Ladd manages and directs the quality assurance and international regulatory affairs for MCRA and its clients. Mr. Ladd creates, modifies and implements quality systems for device manufacturers & developers. He also ensures compliance with FDA QSR systems, ISO 13485, European Medical Device Directives and other international regulatory agencies.

Since 2000, Mr. Ladd has provided engineering, quality system and international regulatory consulting services to 17 companies, 9 of which were in the orthopedic field. Most recently, Mr. Ladd has worked with a spine non-fusion company to create the quality system and obtain ISO 13485 and Medical Device Directive (MDD) certification in less than six months of the founding of the company. In addition to CE marking spinal devices for distribution in the European Union, Mr. Ladd has obtained registration approvals in more than 15 additional countries.

From 1998 to 2003, Mr. Ladd was a subcontractor for TÜV America, a subsidiary of TÜV SÜD AG. He performed over 200 compliance audits of more than 100 different companies (>450 days of auditing), and was lead auditor in approximately 85% of all audits. In addition, he performed more than 200 days of documentation review including the review of orthopedic design dossiers, technical files and procedures. He was certified by TÜV America as an auditor / lead auditor to ISO 9001, ISO 13485, MDD and CMDR, and was the US "expert" for orthopedic devices including trauma, hip, knee, shoulder and spine. Further, he was certified as an "expert" for review of sterilization validation and control (gamma, ethylene oxide and steam).

Mr. Ladd has worked in the medical device industry for more than 20 years. Prior to becoming a consultant, Mr. Ladd assisted the formation of CardioRhythm, a cardiac arrhythmia management company that was acquired by Medtronic. At CardioRhythm, Mr. Ladd was the Director of Instrument Systems and managed Design Engineering and Manufacturing. Mr. Ladd has worked at several other medical device companies including Advanced Cardiovascular Systems and EndoTherapeutics, typically as a design engineer.

Mr. Ladd received his Bachelor in Science in Material Science & Engineering in 1982 at the Massachusetts Institute of Technology.



REIMBURSEMENT TEAM

1st In Class Orthopedic Consulting Firm



Charles Schneider

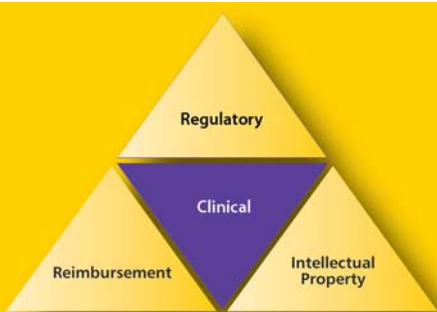
Vice President, Reimbursement

As a seasoned professional with more than 20 years of experience as an accomplished industry leader and author in reimbursement, health economics and governmental affairs, Mr. Schneider directs MCRA's reimbursement department for its clientele. Mr. Schneider is responsible for assisting companies in the preparation of a) coding applications, b) creating reimbursement pathways (Phase I through Phase IV), c) preparing submissions for use by commercial carriers (TriCare, Medicare, and fiscal intermediaries), and to d) support national coverage determinations by CMS. Working with MCRA's clinical and regulatory teams, the reimbursement division further supports client needs through coordination of health economic and utilization review outcomes and comparative effectiveness studies, whether it is within a FDA mandated or marketing study.

Mr. Schneider has held key positions with large and regional insurance carriers (Prudential, Blue Shield, Monarch), as well as holding to leadership positions within the medical device community (Cyberonics, Inc.). Furthermore, Mr. Schneider served as the former Chief Executive Officer of Provider Solutions, LLC, a diversified health care management consulting group. Mr. Schneider was the principle executive of Capital Claims Acquisition of America, a revenue cycle management consulting and patient account management firm representing providers throughout the United States.

Mr. Schneider has been an active participant within AdvaMed's Payment & Policy Work Group as well as other national and regional trade organizations. Mr. Schneider maintains relationships with key payors including CMS and State Medicaid programs. Drawing upon his experience with major commercial carriers, Mr. Schneider has been highly effective in working with commercial carriers, technology assessment and value analysis committees. Further, Mr. Schneider has authored numerous publications including instructional guides regarding reimbursement; pre-paid health care and finance solutions; revenue cycle management; as well as design, certification and management of Centers of Excellence.

Mr. Schneider graduated from the University of Southern California with a bachelor degree in Political Science.



CLINICAL TEAM

1st In Class Orthopedic Consulting Firm



Teresa Schroeder

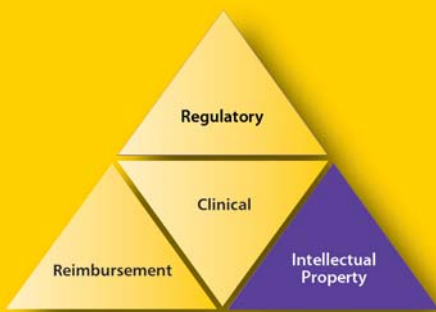
Director, Clinical Affairs

Ms. Schroeder is a dedicated and experienced clinician with more than 15 years experience managing CRO's, statisticians, investigators and IRB's. Ms. Schroeder leads a team of 4 clinical professionals executing clinical study & regulatory submission preparation, clinical study management, and clinical writing initiatives.

Prior to joining MCRA, Ms. Schroeder worked on clinical studies of several large orthopedic and medical device companies. In this role Ms. Schroeder acted as the expert in the development and release of a digital software measurement tool for both scoliosis and kyphosis. Additionally, Ms. Schroeder was instrumental in the development of two measurement manuals and was the Study Director for an international Prospective Pediatric Kyphosis outcomes study. From April 2000 to June 2005 Ms. Schroeder was Program Manager, Clinical Trials, in the Department of Orthopaedics at Walter Reed Army Medical Center. While her responsibilities included the management of all spine related clinical trials, Ms. Schroeder analyzed patient data for publication and/or presentation purposes. Most notably, the devices included Medtronic's Maverick Total Disc Replacement, DePuy Acromed's Titanium Surgical mesh and Moss-Miami Spinal Fixation pedicle screw system.

While serving in the US Army, Ms. Schroeder was a licensed Radiology Technologist where she worked in both Orthopaedics and Special Procedures. She is also an author on numerous peer-reviewed articles and national/international paper presentations. Many of these focused on degenerative disc disease in the spine, adolescent idiopathic scoliosis, pediatric kyphosis and other spinal disorders.

Ms. Schroeder received a Bachelors of Science degree in Parks and Recreation Management from West Georgia College and a Masters of Business Administration degree from the University of Central Florida.



INTELLECTUAL PROPERTY TEAM

1st In Class Orthopedic Consulting Firm



Tram Nguyen

Vice President, Intellectual Property

Ms. Nguyen manages and directs the intellectual property affairs for MCRA and its clients. Ms. Nguyen has more than ten years of intellectual property experience in medical device and life science technologies, particularly in the area of orthopedics.

Prior to joining MCRA, Ms. Nguyen was an Associate at the Cambridge, MA office of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, an international all-IP law firm, from August 2004 to February 2006. Ms. Nguyen's practice at Finnegan involved foreign and domestic patent prosecution, preparation of noninfringement, invalidity and/or product clearance opinions, patent infringement and reexamination proceedings, conducting intellectual property due diligences, and general patent counseling for small to mid-size medical device and orthopedic device companies. From August 2000 to July 2004, Ms. Nguyen worked in the Intellectual Property group of Nutter, McClennen & Fish, LLP, a Boston-based general practice law firm. While at Nutter, Ms. Nguyen focused on foreign and domestic patent prosecution of spinal implants and spinal support systems for a large Fortune 500 medical device and orthopedic company.

Prior to her law firm experiences, Ms. Nguyen served as a Patent Examiner from July 1996 to July 2000 at the U.S. Patent and Trademark Office in their Prosthesis art unit, primarily examining patent applications in the cardiovascular and orthopedics field, with a particular focus on spinal implants. Ms. Nguyen was the recipient of the Distinguished Graduate Recognition Award from the Patent Academy in 1996.

Ms. Nguyen received her Bachelor of Science in Biology and Minor in Chemistry from George Mason University in 1994, and Master of Science in Biotechnology from The Johns Hopkins University in 1996. She also received her Juris Doctor, with a focus in Intellectual Property, from George Mason University School of Law in 2001. Ms. Nguyen is a registered patent attorney, and is a member of the bar in Massachusetts, New Jersey and the District of Columbia.



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EXECUTIVE MANAGEMENT TEAM

1st In Class Orthopedic Consulting Firm



David Lown

General Manager

Mr. David W. Lown has more than 8 years of experience specific to the orthopedic industry and currently serves as General Manager for Musculoskeletal Clinical and Regulatory Advisers, LLC (MCRA). Mr. Lown is responsible for the operational execution and growth of MCRA's 5 service areas (regulatory, clinical, reimbursement, intellectual property, and quality assurance). Mr. Lown joined the firm in August 2006.

Prior to joining MCRA, Mr. Lown has been employed at Viscogliosi Brothers, LLC (VB), the first and premier merchant banking firm focused on the orthopedic industry. Mr. Lown has worked both for VB's merchant banking initiatives and as an operating employee within 3 of its portfolio companies. For VB's merchant banking initiatives, Mr. Lown has worked on the company's 6 venture funds performing portfolio company investment due diligence, financial and fund analysis, and both US and international deal structuring and transaction execution. Furthermore, Mr. Lown has been responsible in the creation of VB's 5 most recent company creations: Spine Solutions, Inc. (1999), Paradigm Spine, LLC (2004), Small Bone Innovations, Inc. (2004), and Musculoskeletal Clinical and Regulatory Advisers, LLC (2004) and Surgisoft, LLC (2006). Lastly, Mr. Lown has been responsible for oversight of VB's principal investments, including Spine Next, SA and Raymedica, Inc.

From an operational standpoint, Mr. Lown's most recent position has been as Director, Corporate Finance for Small Bone Innovations when he joined the company in August 2004. Mr. Lown was responsible for identifying and structuring mergers and acquisitions, licensing and other corporate-partnering activities, and as such assisted the CEO in the completion of 17 transactions in a two year period. Additionally, Mr. Lown managed a team of upwards of 7 analysts responsible for the company's financial projections, M&A due diligence, intellectual property, internal analytics, and industry research/competitive intelligence. Mr. Lown also served as a Financial Analyst for Spine Solutions, Inc., the developer of the ProDisc® Lumbar & Cervical total disc technologies that were sold to Synthes, Inc. for \$350 million in April 2003.

Mr. Lown graduated from Fordham University with a Bachelor of Science degree in Finance.



Amanda Briscoe

Vice President, Global Market Development

With more than 12 years experience as an accomplished entrepreneur, reimbursement professional, and sales and marketing leader, Ms. Briscoe manages and directs the Global Market Development department for MCRA. For MCRA, Ms. Briscoe is responsible for client relationship management, sales and marketing and new business opportunities.

Prior to joining MCRA in May 2007, Ms. Briscoe served as an executive with expertise in pharmaceutical and medical device sales and reimbursement. Ms. Briscoe's qualifications and accomplishments are exemplified through more than 10 years of dedicated work experience with Eli Lilly and Company, Johnson and Johnson, and Cyberonics, Inc. Ms. Briscoe's core competencies include retail and institutional sales, sales team development, organizational leadership, national sales operations, growth planning, product launches, market analysis and reimbursement/contract negotiations. Ms. Briscoe has been acknowledged for driving multi-million dollar annual revenue growth and is a recipient of multiple company reimbursement and sales awards.

Ms. Briscoe received her Bachelor of Science degree in pre-med biology from Wittenberg University and Master of Science degree from Tufts University School of Medicine with a concentration in health communication. Additionally, Ms. Briscoe is a certified professional reimbursement coder. She has had extensive working relationships with Medicare, Medicaid and commercial carriers, with the ability to process reimbursement denial, appeals and other third party correspondence.