Medical and Scientific Communications 2013 Annual Forum

PROGRAM COMMITTEE



MEDICAL COMMUNICATIONS TRACK:

Maureen Baldwin, MSN, RN Associate Director Pfizer Inc.

David Bowers, PharmD Director, Medical Communications PPD

Alicia Alexander Cadogan, PharmD Director, Team Lead, Oncology Pfizer Medical Information Pfizer Inc.

Nicole Corder, RPh, MBA Director, The Lilly Answers Center Lilly USA, LLC

Lesley Fierro, PharmD, MS Associate Vice President, Medical Information Services sanofi-aventis

Stacey Fung, PharmD Associate Director, Medical Communications Genentech, A Member of the Roche Group

Pete Guillot President CenterFirst Consulting, LLC

Leena Jindia, MS, PharmD Director, Medical Information Janssen Scientific Affairs

Monica Kwarcinski, PharmD Executive Director, Medical Services Purdue Pharma LP

Sharon Leighton, PhD Consultant Sharon Leighton Consultancy Ltd.

Julia Petses, PharmD Director, Oncology/Urology Medical Information Services sanofi-aventis

Patrick Reilly Vice President, Global Medical Information Bristol-Myers Squibb

Mary Sendi, PharmD Senior Director, Team Lead, Medical Information Pfizer Inc.

Iris Tam, PharmD Director, Managed Care Medical Communication Genentech, A Member of the Roche Group

Jim Wilkinson, PhD Executive Director, Medical Communications Amgen Scientific Affairs

MEDICAL WRITING AND PUBLICATIONS TRACK:

Julia Cooper, PhD Senior Director, Worldwide Head of Medical Writing Services PAREXEL International Ltd.

Matthias Dormeyer, PhD Managing Director MDC RegAffairs GmbH

Barbara Godlew, RN President The FAIRE Company, LLC

Noah M. Gourlie, MS Senior Medical Writing Program Manager Astellas Pharma Global Development

Klaus J. Hermann, PhD President ClinCoRep LLC

Darryl Zachary L'Heureux Medical Writer CSL Behring AB

Wendi Lau, MS Senior Director, Global Medical Writing Astellas Pharma Global Development, Inc

Nimita Limaye, PhD Vice President, Biometrics and Medical Writing Tata Consultancy Services

Michael John Mihm, PhD Associate Medical Writing Program Director Astellas Pharma Global Development

Peter Riebling, MS Manager, Medical Writing Daiichi Sankyo, Inc.

Jennifer L. Riggins, PharmD Director, Global Information Disclosure Eli Lilly and Company

Lili Fox Vélez, PhD Science Writer Center for Food Safety and Applied Nutrition

Susan Vintilla-Friedman Principal Vintilla Communications LLC

Linda Fossati Wood, RN, MPH President MedWrite, Inc.

MEDICAL SCIENCE LIAISONS TRACK:

Vickee Altman, RN, BSN, MEd MSA National MSL Manager Roche Diagnostics

J. Lynn Bass, PharmD Director, Medical Scientists Jazz Pharmaceuticals

Edward Bezarro, RPh Medical Affairs Professional

Rachel Couchenour, PharmD, MBA Director, Medical Affairs Chelsea Therapeutics

David L. Cram, PharmD Director, Medical Affairs Corcept Therapeutics

Edmund J. Cunningham, PharmD Director, Specialty Care MSLs, Medical Affairs Eisai Inc.

Anselm D'Costa, PhD Executive Director, Field Medical Affairs Daiichi Sankyo, Inc.

Edith Eby, PharmD Executive Director, Medical Relations & Governance Pfizer Inc.

Eric Jozefiak, PharmD Director, Field Medical Science, CV/Metabolics Bristol-Myers Squibb

Craig J. Klinger, RPh Medical Liaison Operations Consultant – Trainer Lilly USA, LLC

Hilary D. Mandler, PharmD Director, Global MSL Operations Shire

Carrie C. Murray, MSN, NP Director, Global MSL Excellence Bayer HealthCare Pharmaceuticals

Beth A. Price Executive Vice President The Medical Affairs Company

Muriel Siadak Director, Medical Affairs Seattle Genetics

Christina Cognata Smith, PharmD, MBA Executive Director, Medical Affairs Medicis Pharmaceutical Corp





Natalie Gearhart, PharmD Associate Director, Medical Information Janssen Scientific Affairs, LLC

Janssen Scientific Affairs, LLC Natalie Gearhart is as Associate Director in Medical Information with over 11 years of Medical Information and Medical Call Center experience at Janssen Scientific Affairs. She currently manages a call center team of healthcare professionals who respond to medical information requests and handle complaint reporting for the Internal Medicine and Cardiovascular franchises. She has served on the DIA Medical Communications SIAC and DIA Planning Committees for 7 years. She received her Doctor of Pharmacy degree from the University of Pittsburgh.



Sara Doshi, PharmD Manager, Global Medical Information Strategy <u>Eli Lilly and Company</u>

Sara Doshi, Manager Medical Information Strategy, Global Medical Information, Eli Lilly and Company Dr. Sara Doshi graduated with a Doctor of Pharmacy degree from Butler

University in May of 1999. Following graduation, she completed the Purdue University/Eli Lilly and Company ASHP accredited Drug Information Residency in June 2000 and then accepted a full time position with Global Medical Information (GMI) at Lilly. In 2003, Sara transitioned to a full time remote working arrangement with GMI. She has supported numerous products and therapeutic areas in a traditional medical information role. Sara continues to hold a position in GMI, but is currently in a management position focused on business process improvements, quality, systems, project management, training and development, and six sigma projects.

Maureen Baldwin, MSN, RN Associate Director Pfizer Inc.

Maureen Baldwin MSN, RN is an Associate Director, Medical Customer Interface, US Medical Information at Pfizer. In her current role she is involved in several global initiatives related to Contact Centers. Prior to joining Pfizer, Maureen worked in the Medical Communications Contact Center at Wyeth for 9 years where she held various positions within the US Contact Center. Maureen has led or participated in several key contact center initiatives such as business continuity planning and implementation, telecommuting, customer satisfaction survey development, the development of a new orientation program and core competencies for Contact Center Specialists. She received her BSN from Widener University and her MSN from East Carolina University. She has also held positions during her career as a Registered Nurse in the areas of cardiovascular critical care, cardiovascular rehabilitation, a position as a Cardiovascular Clinical Nurse Specialist, and was an adjunct faculty member at East Carolina University.



David Bowers, PharmD Director, Medical Communications PPD

David Bowers has 15 years of experience managing pharmaceutical contact center programs at PPD. As Director of Operations, David supports global medical information for pharmaceutical, biotechnology and medical device clients. He has a background in pharmacy, with a Doctorate of Pharmacy from the University of North Carolina. During his time at PPD, David has worked with over 30 client contact center programs providing medical information, pharmacovigilance and product complaint processing, persistency programs, REMS support and other services. David's recent experience includes implementing contact center operations in Europe, Mexico and Brazil to support European and Latin American pharmaceutical client operations. David has successfully implemented numerous telephony systems and contact center databases. He has survived (and occasionally enjoyed) multiple client and other audits. Presently David works directly with approximately ten pharmaceutical contact center clients. David enjoys sharing his expertise and professional advice, so feel free to contact David directly with any questions about operational challenges that your contact center is facing.



Alicia Alexander Cadogan, PharmD Director, Team Lead, Oncology Pfizer Medical Information Pfizer Inc.

Alicia is currently a Director, North America Team Lead, and Global Therapy Area Team Lead for Oncology in Medical Information at Pfizer Inc. Before becoming a part of Pfizer Inc, Alicia spent 6 years in Medical Communications at Wyeth Pharmaceuticals with responsibilities for Women's Health Care and eventually Vaccines. Prior to joining Wyeth, she spent 5 years as a Medical Director at CoMed Communications (a Medical Communications and Advertising agency in Philadelphia, PA) where her responsibilities included providing medical direction to the development of continuing education materials, product launches, and promotional materials for several pharmaceutical companies. Alicia has been an active member of the DIA for several years; participating in the Core Curriculum as faculty for 2 years, and chairperson for 2 years. In 2010, she had the honor of serving as chairperson of the Medical Communications Workshop. Alicia received her Bachelor of Science degree in Pharmacy from St. John's University in Queens, NY, and her Doctor of Pharmacy degree from Albany College of Pharmacy in Albany, NY. She completed a 2-year clinical research fellowship in Nephrology at the University of Pittsburgh School of Pharmacy, followed by 2 years at the same school as an Assistant Professor of Pharmacy and Therapeutics, specializing in Nephrology.



Nicole Corder, RPh, MBA Director, The Lilly Answers Center Lilly USA, LLC

Nicole Corder RPh, MBA is the Director of Operations for The Lilly Answers Center (TLAC) at Lilly USA, LLC. Nicole has worked in the Contact Center for 10 years and has been in her current role since January 2006. Her responsibilities include supporting various therapeutic areas that include Diabetes, Neuroscience, Men's Health, Musculoskeletal, Cardiovascular/Critical Care, Oncology, and marketed devices associated with these pharmaceutical products. She has also been actively involved in the management and partnership of TLAC's outsourced vendor relationships. Nicole has been a Registered Pharmacist for 25 years graduating from Butler University and completed her MBA in 2006. Before joining Lilly in 2002, Nicole worked as a Pharmacy Consultant for a Managed Care Physician Network specializing in Anticoagulation and Lipid Clinics. Nicole has been involved in DIA activities for many years and served in several capacities supporting the annual meeting.



Lesley Fierro, PharmD, MS Associate Vice President, Medical Information Services sanofi-aventis

Lesley Fierro is Associate Vice President, Medical Information Services at sanofi-aventis, US in Bridgewater, New Jersey, where she oversees a staff of professionals dedicated to providing accurate, unbiased, and balanced Medical and Pharmaceutical product information. Dr. Fierro received her BS degree in Pharmacy from Rutgers College of Pharmacy, her Masters degree in Drug Information from Arnold and Marie Schwartz College of Pharmacy, and her PharmD degree from the University of Illinois. Lesley has over 25 years of experience in the pharmaceutical industry including 12 years with sanofiaventis. Prior to joining sanofi-aventis, Dr. Fierro worked for 12 years in the Medical Information Department at Parke-Davis, Division of Warner-Lambert and 6 years in the Regulatory Department at Parke-Davis where she was responsible for labeling as well as advertising and promotion review processes. Preceding her employment in industry, Lesley worked as a staff Pharmacist in several hospitals.



Stacey Fung, PharmD Associate Director, Medical Communications Genentech, A Member of the Roche Group

Stacey M. Fung, PharmD is an Associate Director in Medical Communications at Genentech, a member of the Roche group. Prior to joining Genentech, she held positions in the Medical Affairs departments of Chiron Therapeutics and Protein Design Labs. She has also practiced in the hospital and retail pharmacy settings. Stacey has presented on various topics as well as chaired meeting sessions at industry-focused workshops and annual meetings. She has authored several clinical, scientific, and pharmaceutical industryfocused articles.

Pete Guillot President CenterFirst Consulting, LLC

Pete Guillot started CenterFirst in 2004 with the mission of helping pharmaceutical companies navigate the strategic, operational, and regulatory requirements of today's contact centers. In the 8 years since its start, CenterFirst has worked with the leadership of a broad range of bio-pharmaceutical and medical device clients, including 10 of the world's top 20 pharma companies. Pete has an MBA from The University of Texas and lives in Indianapolis, Indiana with his wife Simone and 3 children.



Leena Jindia, MS, PharmD Director, Medical Information Janssen Scientific Affairs

Leena is Director, Medical Information for Internal Medicine franchise at Janssen Pharmaceutical Companies of Johnson & Johnson. She has been with J&J since 2000. In her current role, Leena is responsible for managing Medical Information support, defining processes, developing strategies, integrating technology to create innovative customer response solutions and executing projects. Leena earned her Doctor of Pharmacy degree from Rutgers College of Pharmacy, New Jersey, in 2000.

Leena has been an active member of DIA Medical Communications SIAC since 2005 and is a member of the DIA Planning Committee since 2009. She lives in Tewksbury, NJ, with her husband and two children.

Monica Kwarcinski, PharmD Executive Director, Medical Services Purdue Pharma LP

Monica Kwarcinski is the Ex. Director of the Medical Services Department at Purdue Pharma. She leads the department that is responsible for responding to medical inquires, the medical review of promotional materials, and training the field force on the company's products. Prior to joining Purdue in 1998, Monica held various positions with increasing responsibilities within Abbott Laboratories Medical Services Department. Monica Kwarcinski received her PharmD from Creighton University in Omaha, NE in 1992 followed by a Drug Information Residency at Glaxo and University of North Carolina, Chapel Hill. She has been a member of DIA for 20 years and is actively involved in the DIA Medical Communications SIAC.



Sharon Leighton, PhD Consultant Sharon Leighton Consultancy Ltd.

Sharon runs a successful consultancy, training and mentoring business helping busy managers in medical information to achieve their business goals. She regularly presents at professional meetings on quality management, organisational change, service development and social media. Sharon is a Past President of PIPA (Pharmaceutical Information and Pharmacovigilance Association) and past co-chair of the DIA Medical Communications SIAC. Collaborating and working with like-minded people is her passion, which finds a creative outlet in her blog on our profession, a widely read email newsletter for pharmaceutical managers and a social media presence on Facebook and Twitter. She has over 25 years Medical Information experience, working for major companies such as AstraZeneca, Merck Inc. and Glaxo (now GSK) in leadership, senior management and training roles.

Julia Petses, PharmD Director, Oncology/Urology Medical Information Services sanofi-aventis

Julia Petses, PharmD is Director of Oncology/Hematology and Urology Medical Information Services for Sanofi U.S. Prior to joining Sanofi in 2002, Dr. Petses completed a Drug Information Residency at Schering-Plough. She received both her BS degree in Pharmacy and Doctor of Pharmacy degree from St. John's University in New York.

Patrick Reilly



Vice President, Global Medical Information Bristol-Myers Squibb

Patrick Reilly is currently the Vice President of the Global Medical Information at Bristol-Myers Squibb. Patrick has spent the past 25 years at BMS within the R&D/Medical organization. During his tenure at BMS, Patrick has worked in a variety of leadership roles with a focus on building and enhancing organizational capabilities like the R&D clinical research monitors; the US Oncology & ImmunoScience field medical, as well as the global field medical organizations. In his current role, he is leading the global transformation of Medical Information, building foundational capabilities to enable the exchange of medical and scientific information through innovative and more customer centric channels. Patrick is a graduate of St. Louis University Physician Assistant program, where he spent the early part of his professional career in clinical research. He implemented and managed a clinical research group, conducting both investigational (Phase II-III) and post marketing clinical trials in Infectious Diseases. Patrick also has a Masters Degree in Business.

Mary Sendi, PharmD Senior Director, Team Lead, Medical Information Pfizer, Inc.

Mary is Regional Therapy Area Lead (RTAL) in Medical Information at Pfizer, Inc. Mary is accountable for implementing MI global and regional strategies related to product support for Pfizer's Immunology and Inflammation Therapy Areas. Mary is also responsible for MI Immunology Inflammation therapy area operations across Canada and the United States. Mary graduated from the Philadelphia College of Pharmacy of Science (Philadelphia, PA) with a B.S. in Pharmacy. Mary earned her Doctor of Pharmacy degree through Shenandoah University (Winchester, VA). Mary has been a member of DIA for several years.



Iris Tam, PharmD

Director, Managed Care Medical Communication Genentech, A Member of the Roche Group

Iris Tam, Pharm.D. is Director of the Managed Care Medical Communications Group at Genentech. She manages and oversees the provision of relevant, timely, and balanced evidence-based scientific and clinical information in response to unsolicited requests from health care professionals responsible for making drug coverage, policy, and formulary decisions. Responsibilities in her area also include the development and handling of product dossiers in the AMCP Format for Formulary Submissions and other formats, the evaluation and submission of clinical data to drug information publishers, and the creation, review, and coordination of clinical presentations to payors and health systems. Prior to joining Genentech in 2002, Dr. Tam was a managed care clinical pharmacist for PacifiCare of California where she built, serviced, and managed relationships between the health plan and contracted medical groups. Previous to managed care, Dr. Tam was Assistant Pharmacy Director at a community hospital where she ran the P&T Committee, implemented new clinical pharmacy programs, and oversaw inpatient pharmacy operations. Dr. Tam received her Doctor of Pharmacy degree from the School of Pharmacy at the University of California, San Francisco, and her Bachelor of Arts degree in Microbiology and Immunology at the University of California, Berkeley. She completed a Clinical Pharmacy Practice Residency and a Pharmacy Administration Specialized Residency at California Pacific Medical Center, San Francisco.



Jim Wilkinson, PhD Executive Director, Medical Communications <u>Amgen Scientific Affairs</u>

Jim Wilkinson, Ph.D. is a Director of Medical Communications in the Global Scientific Affairs Department at Amgen, Inc. In this role, he manages multiple teams responsible for the development and implementation of high-quality medical communication materials and programs that support global initiatives across several functional departments and therapeutic areas. Activities include global publication planning, congress strategies and execution, global and regional scientific advisory boards, creation of Medical Science Liaison (MSL) resources, promotional review committee participation, and development of online scientific content. This also includes an extensive working knowledge and understanding of the commercialization process, best practices for product launches, new product acquisition integration, joint ventures, legal and regulatory guidelines, clinical development and vendor management (including developing off-shore capabilities). Jim has been with Amgen for over 11 years and prior to his current position worked in Amgen's Medical Information Department where he was responsible for responding to medical inquiries and participated in two additional product launches. Before joining the biotechnology industry, Jim received his B.S. in Biochemistry from the University of Wisconsin-Madison and his Ph.D. from the University of Minnesota-Minneapolis in the Department of Biochemistry, Molecular Biology & Biophysics. After receiving his Ph.D., he completed a post-doctoral fellowship with research focused on gene therapy approaches to treat acute lymphoblastic leukemia (ALL) in the Pediatric Hematology-Oncology and Blood/Marrow Transplantation Program at the University of Minnesota Cancer Center.



David Clemow, PhD Senior Clinical Research Scientist Lilly USA LLC

David is a Clinical Research Scientist at Eli Lilly with over 13 yrs of scientific communications experience in the pharmaceutical industry within regulatory, publications, and promotional areas. His work includes document authoring, team management, operations consulting, and clinical research.



Tolu Taiwo, PharmD Director, Medical Information Horizon Pharma

ToluTaiwo PharmD. MBA, a Medical Communications expert, began her career in North Carolina as a Clinical Pharmacist at Durham Regional Hospital and later CVS Pharmacy and the University of North Carolina at Chapel Hill Health Systems. After relocating to Chicago, she worked as a Clinical Pharmacist at Mount Sinai Hospital Medical Center, before joining Hospira Inc. as a Senior Medical Communications Specialist in 2006. Tolu was appointed Group Leader and Manager in the Medical Communications Department in 2008, and managed a multidisciplinary team of Pharmacists and Nurses at the Hospira Corporate Headquarters in Lake Forest, IL and the Global Communications Center in Cebu, Philippines. She is currently the director of Medical Information at Horizon Pharma, a biopharmaceutical company located in Deerfield IL. Tolu Taiwo holds a Bachelors of Science in Botany from the University of Ibadan, Nigeria, a Doctor of Pharmacy (Pharm.D) from the University of North Carolina, Chapel Hill, and a Masters of Business Administration (MBA) from the University of Illinois, Urbana Champaign. She lives with her family in Lake Forest, IL.



Julia Cooper, PhD Senior Director, Worldwide Head of Medical Writing Services PAREXEL International Ltd.

Julia Cooper, PhD, is Senior Director, Worldwide Head of Medical Writing Services at PAREXEL International Ltd. Since 2002, she has been responsible for leadership of the global PAREXEL Medical Writing department and all its deliverables, from clinical protocols and study reports, through to CTD/NDA and pharmacovigilance documents. Dr. Cooper began her career at the Technische Universität München, Germany, followed by a research position at Bayer AG. She later moved to Hoechst Marion Roussel as a medical writer, joining PAREXEL in 1998. Dr. Cooper received a BA and MA in Natural Sciences, and a PhD in biotechnology, from the University of Cambridge, UK. She has served the European Medical Writers Association (EMWA) in various board positions, and is the approved leader of the EMWA workshop on Development Safety Update Reports.

Matthias Dormeyer, PhD Managing Director MDC RegAffairs GmbH

Matthias Dormeyer is working as a consultant and service provider in the fields of regulatory affairs and drug development since autumn 2006. In his work he has focused on designation, development and authorization of orphan drugs in the EU and US. Another area of expertise are paediatric drugs (including drafting and submission of Paediatric Investigations Plans (PIPs) and Request for Waiver) and management of marketing authorization applications under the centralized procedure. His expertise comprises small molecules, protein drugs as well as advance therapies for the treatment of a wide variety of diseases including for example cancer, autoimmune diseases, ophthalmological conditions, infectious diseases. After finishing his doctorate he worked at Knoll AG (now Abbott) in the field of early ADME. In January 2000 he joined 4SC AG, a biotech in Martinsried/Munich. His initial assignment was to set up to biological department and screening facilities. He then moved into project management and was among other responsible for the transition of projects from research to development and non-clinical and early clinical development of 4SC's pipeline projects. He started his career as independent consultant and service provider after he left 4SC. Matthias Dormeyer is a chemist by training and holds a PhD in biochemistry as well as a Master in Drug Regulatory Affairs (MDRA).



Barbara Godlew, RN President The FAIRE Company, LLC

Barbara Godlew is an independent consultant who provides senior-level consulting to pharmaceutical/biotechnology industry and academic medical centers on clinical trial disclosure policy and process development, operations implementation and management, gap analyses, compliance measures, and quality assurance services. Barbara is a founding member of the DIA Clinical Trial Disclosure SIAC and is past Chair of the SIAC. Having worked in the clinical trial disclosure space since 2004 and in medical writing since 1994, Barbara is a frequent speaker at industry and academic educational programs.

Noah M. Gourlie, MS Senior Medical Writing Program Manager Astellas Pharma Global Development

Astellas Pharma Global Development Noah M. Gourlie, MS, has worked in medical writing in the pharmaceutical industry for seven years. He has supported the document development needs of multiple global project teams and has contributed to multiple marketing applications.



Klaus J. Hermann, BScPharm, PhD President ClinCoRep – LLC

Dr. Klaus J. Hermann received his degree in Pharmacy from the University of Freiburg, Germany. After practicing pharmacy for some years he went to graduate school at the University of Heidelberg where he received his PhD at the Department of Pharmacology. He was a postdoctoral fellow at the Department of Physiology, University of Florida, College of Medicine in Gainesville, Fla. He worked as an Assistant/Associate Professor at the University of Munich and Hamburg, Germany, investigating anaphylactic/anaphylactoid reaction induced by insect venoms, food and food additives, drugs, and chemicals. At the University of Hamburg he received his Habilitation in Experimental Medicine. His professional interests include Cardiovascular Medicine, Anaphylaxis, Allergy & Immunology, Inflammation, Dermatology, and Clinical Diagnostics. Dr. Hermann's publications include papers, abstracts, and book chapters in various scientific disciplines. He is a member of the American Medical Writers Association, Drug Information Association, and an editor Biomedworld Bioscience. In his spare time, he likes to do sports, watch movies, and play the guitar.

Darryl Z. L'Heureux Medical Writer CSL Behring

Dr. Darryl Z. L'Heureux is a new member to the Drug Information Association (DIA) and has started his DIA affiliation as an active and engaged member. He is a member of several DIA Community forums (formerly SIACs), including Medical Communications (MC) and Medical Writing (MW), in addition to other communities. At the Medical and Scientific Communications 2013 Annual forum, Dr. L'Heureux is speaking and chairing two sessions, which include Patient-Reported Outcomes and Publication Safety Writing. Dr. Darryl Z. L'Heureux received his PhD in Cancer Biology and a Masters in Pharmacy in Quality Assurance and Regulatory Affairs from Temple University in Philadelphia, Pennsylvania, USA. Upon graduation, he continued his research in oncology and has worked across different Cooperative Groups of the National Cancer Institute and within academic partnerships to develop biomarkers for early diagnosis and disease surveillance. Currently, Dr. L'Heureux has returned to his earlier research interest in protein chemistry and works at CSL Behring, a company dedicated to the development, manufacturing, and marketing of protein-based therapies for bleeding disorders, wound healing, and other therapeutic needs. Combining his interest in drug development and education, Dr. L'Heureux has presented his research at oncology conferences and continues to lecture at universities in the Philadelphia area.



Wendi Lau Senior Director, Global Medical Writing Astellas Pharma Global Development, Inc.

Wendi Lau has over 20 years of clinical research experience within the pharmaceutical industry, including work across multiple compounds and stages of drug development within data management, clinical research and medical writing. Within the Medical Writing realm, Wendi has worked on a multitude of regulated documents, including study reports, INDs, briefing documents and summary/submission documents.



Nimita Limaye, PhD Vice President, Biometrics and Medical Writing Tata Consultancy Services Pvt Lt.

Dr. Nimita Limaye serves as the Vice President, Biometrics and Medical Writing, at Tata Consultancy Services Pvt. Lt., India and contributes domain expertise and leadership to the life sciences business. She has 17 years of experience working across the Pharma and CRO sector, working with companies such as SIRO Clinpharm, Altana Pharma (now acquired by Takeda) & Quintiles India, in diverse functional areas. She is the past chair of SCDM (Society of Clinical Data Management), head-quartered in the US. She is also the past-chair of the DIA India Medical Writing Working Group, represents India on the SIAC Leadership Council and is the Program Co-Chair for the DIA India Annual Conference. In addition, she is the member of the National Committee on Drugs and Pharmaceuticals (2012-2013) of the Confederation of Indian Industries. She has also co-chaired the DIA India Annual Conference, 2012 and is co-chairing the SCDM Asia Annual Conference in May 2013.

She has presented at various national and international meetings on topics related to outsourcing strategy, data management and medical writing and has several publications to her credit. She has been invited by the International Women's Forum to the 'World Cornerstone Conference' at Hong Kong in May'09 to speak on 'Healthcare Beyond Borders'. She was also invited to co-lead a workshop on 'Advanced Medical Writing' at Turkey and at Bangalore in April'08 and conducted a workshop on 'The Essentials of Medical and Regulatory Writing' at the DIA conference in Delhi in Nov'09. She has earlier been responsible for establishing key strategic partnerships which have been presented by her leadership as success stories at the DIA at San Diego in June'09 - 'Establishing Successful Medical Writing Partnerships" and at the DIA at Mumbai in 2011 - 'Best Practices in Offshoring Scientific Programming'. Trained as a black belt in Lean Six Sigma, she has also contributed to innovation and operational excellence.

Michael John Mihm, PhD Associate Medical Writing Program Director Astellas Pharma Global Development, Inc

Dr. Michael John Mihm is currently an Associate Medical Writing Program Director at Astellas Pharma Global Development, Inc. Michael has 17 years of drug development experience in academia and the pharma industry, and over 100 peer-reviewed publications in the areas of diabetes and cardiovascular medicine.

Peter Riebling Manager, Medical Writing Daiichi Sankyo Pharma Development

Peter Riebling is currently a Manager, Medical Writing at Daiichi-Sankyo Pharma Development. Prior to joining Daiichi-Sankyo Pharma Development, he served as Associate Director, Regulatory and Medical Writing at PTC Therapeutics. He also has worked in regulatory affairs for Strides Inc, a generic drug manufacturer, and began his career as a reporter for FDAnews.com. He holds an MS degree in Biotechnology Studies from the University of Maryland University College and an MFA degree in Creative Writing from George Mason University. His professional certifications include the Regulatory Affairs Certified (RAC) designation and a Certificate in Biostatistics from the University of California-San Diego.



Jennifer L. Riggins, PharmD Director, Global Information Disclosure <u>Eli Lilly & Company</u>

Jennifer Riggins graduated with honors from Butler University College of Pharmacy with her Doctor of Pharmacy degree and joined Eli Lilly and Company in 1993. Jennifer currently serves as Director, Global Information Disclosure. Jennifer and her team have responsibility for innovating the delivery of medical content to customers in preferred ways, creating and implementing impactful information disclosure solutions, and understanding and influencing the external environment as it relates to medical affairs and e-capabilities. Jennifer's prior Lilly experience includes roles in Global Medical Customer Solutions, Global Medical Communications (GMC), the GMC Business Office, and Global Medical Information (GMI) in regulatory, medical, and the clinical development organizations of the company.

Throughout her career, Jennifer has provided active involvement and leadership to numerous cross-functional and global projects within GMI and GMC including strategy development and implementation, tools and technology, people development, six sigma, metrics, outsourcing, and external outreach. Jennifer has been an active and engaged member of the Drug Information Association (DIA) since 1995. She is a member of both the Medical Communications (MC) and Medical Writing (MW) Communities. Through the years, Jennifer has been a devoted volunteer serving as an author, speaker, session chair, program chair, Community Chair, Community core committee member, MC Workshop program chair, MC annual meeting track chair and on numerous program committees and task forces. She served as the Advisory Council of North America (ACNA) representative on the DIA Board's strategic committee on Global Community Development and as the MC Representative to the ACNA. Jennifer currently serves as the Chair of the ACNA, a member of the DIA Board of Directors, co-Chair of the Member and Volunteer Engagement Committee, Member of the Finance Committee, and as a Board Representative to the Digital Initiative.

Lili Velez, PhD Science Writer Center for Food Safety and Applied Nutrition

Lili Fox Vélez, PhD, works as a Science Writer at the Center for Food Safety and Applied Nutrition, and as a freelance educator. In her industry life she has worked in medical publications, market access, and medical education. As an academic, she has designed and taught University classes in medical communications, scientific writing, environmental science and creativity. In 1997, she founded the MS program in Biomedical Writing at the University of the Sciences in Philadelphia. Her other research projects have investigated ways to improve the writing and critical thinking skills of molecular biology and environmental science students.

Susan Vintilla-Friedman Principal Vintilla Communications LLC

Susan Vintilla-Friedman is the principal for Vintilla Communications LLC, a firm specializing in writing, project management, and website development. She provides consulting services to biotech, pharmaceutical, educational, and engineering firms. Her work in pharmaceuticals includes clinical and technical writing, training, and electronic submissions development.



Linda Fossati Wood, RN, MPH President

MedWrite, Inc.

Linda has provided regulatory writing services to the pharmaceutical, biotechnology, and medical device industries for 22 years as President of MedWrite, Inc., a contract writing company. She specializes in strategic development of regulatory documents, using techniques that improve the speed and quality of submissions. Linda co-authored the first comprehensive book on regulatory writing, Wood L, Foote MA *Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics*. Basel, Switzerland: Birkhäuser; 2008. She is also winner of the 2010 Will Solimene Award for Excellence in Medical Communication from the New England Chapter of the American Medical Writers Association. She founded the DIA's Medical Writing Special Interest Area Community, is past President of the New England Chapter of the American Medical Writer's Association, and was part of the team that initiated the effort to update ICH E3, the guideline for clinical study reports. She is currently Track 6 Co-chair for the June 2013 DIA Annual Meeting.

Linda received her Master's Degree in Chronic Disease Epidemiology and Biostatistics from Yale University.

Medical Science Liaison Track



Rebecca Vermeulen R.Ph. Senior Director, BioOncology Medical Science Liaisons Genentech - A member of Roche Group

Rebecca Vermeulen brings a variety of experiences and capabilities to her role as Senior Director, Medical Science Liaisons at Genentech. A licensed pharmacist, she has spent 20 years in the pharmaceutical industry leading teams across Medical Affairs. She has served in a variety of functions including Sales, Clinical Research, Medical Communications, Medical Science Liaisons and Six Sigma.

Rebecca is recognized for her strategic planning and operational management skills. In addition, she has expertise in compliance, regulatory, medical education, medical communication, social media, and six sigma methodology. Rebecca has lead teams of more than 150 people spanning multiple organizational units and has been responsible for creating global standards for information exchange with healthcare professionals. Having coordinated more than 75 six sigma projects with a team of 21 black belts, she knows how to increase efficiency in research and reduce the number of days it take to bring new medicines to patients.

Currently, Rebecca is the Senior Director for the BioOncology MSL organization and is leading teams across 5 tumor areas to positively improve the lives of patients in this important therapeutic area.

Medical Science Liaison Track

Ramineh Zoka, MS, PharmD Senior Director, Clinical Science Liaison, Medical Affairs Janssen Services, LLC

Ramineh Zoka started her industry career at Janssen Pharmaceutical, Titusville, New Jersey in 1994, and worked in several positions through Medical Affairs. Her last position at Janssen was Senior Director, Medical Services, where she was responsible for an internal and field based team, providing medical information support within one of the company franchises. In 2003, she moved to Centocor, Inc. as the Senior Director of the Clinical Scientist/Medical Science Liaison team. In 2009, her responsibilities at expanded and she is now leading the Medical Science Liaison teams across various therapeutic areas at Janssen Services, LLC. Prior to working in the pharmaceutical industry, Ramineh held a position at the Albert Einstein Medical Center, in Philadelphia, as the Pharmacy CQI/Staff Development Coordinator. She also served as a Clinical Pharmacist at Temple University Hospital. Ramineh received her Pharm.D. degree, then completed the ASHP accredited residency program and a M.S. degree in Hospital Pharmacy Administration at Temple University. Ramineh and her family reside in Lower Gwynedd, Pennsylvania.



Vickee Altman, RN, BSN, MEd MSA National MSL Manager Roche Diagnostics

Vickee Altman is the MSA Manager for the Medical Scientific Liaisons. Mrs. Altman is responsible for the management of 12 Medical Scientific Liaisons. The MSL team is responsible for medical and clinical professional education, dissemenation of scientific information within compliant and ethical standards, and the facilitation of peer to peer professional exchantges. Mr. Altman has over 35 years of nursing experience including Critical Care, Emergency Department and Flight Nursing. Her professional experience also includes administration and nursing education.



J. Lynn Bass, PharmD Director, Medical Scientists Jazz Pharmaceuticals

Lynn serves as Director, Medical Scientists, at Jazz Pharmaceuticals and focuses within the narcolepsy therapeutic area. Prior to this position, Lynn has served as an Associate Director, MSLs at Baxter and as Sr. MSL at both Amgen and Eli Lilly. In total, Lynn has over 15 years of experience in the MSL profession. She has managed and coached numerous liaisons and has led a variety of projects throughout her tenure within these companies. Lynn has been active within the Drug Information Association and serves as a Core Member of the Medical Science Liaison Community. She has co-authored an annual Medical Science Liaison Survey, currently in its eighth year. Prior to joining the pharmaceutical industry, Lynn held Clinical Pharmacist positions at Kaiser Permanente and the Department of Defense. Lynn holds B.S. degrees in Biology and Medical Technology. In addition, she received her B.S. in Pharmacy from the Medical College of Virginia and her Doctor of Pharmacy degree from the University of South Carolina.

Edward Bezarro, RPh Medical Affairs Professional

Ed Bezarro has spent the past 15 years as part of Medical Affairs organizations within Pharma. His most recent role was that of Regional Director for Medical Development at Amylin Pharmaceuticals where he was responsible for leading a team of 11 Medical Science Liaisons focused on the treatment of diabetes. Ed joined Amylin in 2003 as the MSL for the Northeast region and was promoted to Regional Director in 2007. From 1997 to 2003 Ed was a Clinical Liaison for Roche Pharmaceuticals working in infectious Diesease, Cardiovascular, Metabolic and CNS therapeutic areas. Prior to joining industry, Ed's career was focused in the acute care hospital setting where he held positions of Clinical Pharmacist, Clinical Coordinator and Director of Pharmacy. Ed guaduated from Northeastern University with a BS in Pharmacy in 1981.

Rachel Couchenour, PharmD, MBA Director, Medical Affairs Chelsea Therapeutics

Rachel Couchenour, PharmD, MBA has more than 15 years' experience combined in pharmacy academia and the pharmaceutical industry. Dr. Couchenour joined Chelsea Therapeutics in January 2011 and currently serves as Director, Medical Affairs. Dr. Couchenour completed her undergraduate studies in Pharmacy at the University of North Carolina at Chapel Hill. Her Doctor of Pharmacy degree was conferred by the Medical University of South Carolina (MUSC) where she stayed to complete a specialty residency in ambulatory care.

She has a diverse background in the pharmaceutical industry. She has experience in field medical affairs, head quarter based medical affairs leadership, advocacy and corporate affairs. Prior to joining the pharmaceutical industry she had a clinical practice in the area of ambulatory care along with faculty appointments @ St. Louis College of Pharmacy (1997 – 1999) and the Medical University of South Carolina (1999 – 2001).

David L. Cram, PharmD Director, Medical Affairs <u>Corcept Therapeutics</u>

Dr. Cram has over 20 years of experience in healthcare that includes clinical practice, academia and the pharmaceutical industry.

Edmund J. Cunningham, PharmD Director, Specialty Care MSLs, Medical Affairs Eisai Inc.

Ed Cunningham, PharmD is the Director of Specialty Care Medical Science Liaisons (MSLs) at Eisai Inc. Ed is based in Milwaukee, WI, and is responsible for overseeing the US Neuroscience and Metabolic MSL teams at Eisai. Ed obtained his PharmD degree from Philadelphia College of Pharmacy and completed a 1-year Drug Information Residency with Janssen Pharmaceutica. Ed has been in the pharmaceutical industry for 10 years, working as both a direct contributor and a team leader in a variety of Medical Affairs functions, including Medical Information, Medical Education, Investigator Initiated Studies, and MSLs.

Anselm D'Costa, PhD Executive Director, Field Medical Affairs Daiichi Sankvo

Anselm is the Executive Director of Field Medical Affairs at Daiichi Sankyo, Inc., a role in which he oversees the Medical Science Health Outcome Liaisons. He has over 14 years Pharmaceutical Industry experience which has primarily revolved around the Medical Science Liaison role. He started as a MSL in Bristol Myers Squibb supporting their Cardiovascular and Metabolic products before taking on managerial and leadership roles supporting MSL teams Wyeth. In this capacity, Anselm lead the Hemophilia and Oncology Medical Communications department which included MSL and Medical Information services. He was the National Director of the Medical Science Liaison team at the Johnson and Johnson company, Tibotec Therapeutics supporting the HIV franchise before joining Daiichi Sankyo Inc. Anselm has a doctoral degree in Pharmacology from Wake Forest University.

Edith Eby, PharmD Executive Director, Medical Relations and Governance Pfizer

Edith Eby is the Medical Relations & Governance (MR&G) Group Lead responsible for Global Field Based Medical Governance, Global Investigator Initiated Research, Medical Education Grants and Medical Grant Management Japan. Since joining Pfizer in 2002, Edith's roles have included Oncology RMRS, Oncology RMRS Team Leader and Global Field Based Medical Governance Lead. She obtained a BS in Pharmacy and PharmD from the University of Texas and completed an Oncology Specialty Residency at MD Anderson Cancer Center. Prior to joining Pfizer, Edith practiced for 10 years as a pediatric oncology pharmacist at Baylor University, Texas Children's Cancer Center. She enjoys spending time with family, watching her husband and son play hockey and her daughter horseback ride.



Eric Jozefiak, PharmD Director, Field Medical Science, CV/Metabolics Bristol-Myers Squibb

Eric Jozefiak is currently the Director, Field Medical Science, CV/Met, Bristol-Myers Squibb. In this position, Eric is responsible for leading a team of 60 Field Medical Science Liaisons (MSL's) through the delivery of medical strategy across the Cardiovascular and Metabolics organizations. In this role, Eric works closely with different Alliance partners to align Field Medical Services across the partnerships.

Eric has been with BMS for fifteen years, has served as an MSL Field Manager, Medical Information Director and an MSL Director in the Immunoscience, CV/Met and Neuroscience organizations, respectively. In his most recent role, Eric led the Neuroscience MSL team and was responsible for piloting a combined Customer Facing Team that consisted of Neuroscience Field Medical and Medical Information.

Previously, Eric was the US Medical Information (MI) Director for Cardiovascular/Metabolic products. Prior to heading up this team, Eric was the East Regional Associate Director for Immunoscience Medical Science Liaisons (MSL). He was involved with the development of this new MSL team and managed the team through a Product launch. Among other roles within BMS, Eric was a Medical Director, Patient Marketing, Compliance and Persistency. There he assessed and developed several pilots designed to improve medication non-adherence. Eric has also held various other positions in the Cardiovascular/Metabolic Therapeutic area including Global and US Medical & Marketing roles.

Eric received a B.S. in Pharmacy from the Massachusetts College of Pharmacy and a Doctor of Pharmacy degree from Duquense University. Prior to joining Bristol-Myers Squibb Company in 1997, he held academic appointments as an Assistant Professor of Pharmacy at Rutgers University and at the Philadelphia College of Pharmacy. During that period, Dr. Jozefiak helped developed several pharmacy-based lipid and anticoagulation clinics, was involved with various research trials and publications.

Craig J. Klinger, RPh Medical Liaison Operations Consultant - Trainer Lilly USA. LLC

Craig has been an employee of Eli Lilly and Company for 22 years. He has worked in various positions while at Lilly in multiple therapeutic areas including neuroscience, diabetes and women's health. Craig was a founding member of the Medical Science Liaison program at Lilly where he was a Senior Consultant Medical Liaison for Musculoskeletal Health in the New York City Metropolitan area for over 13 years. Craig currently is the Medical Liaison Trainer for Lilly USA. Craig has been very active in developing benchmarking survey data on MSL standards across the pharmaceutical industry. He has presented and published this data at DIA meetings and in the DIJ. Craig has been a frequent speaker at various meetings, such as CBI, eXI Pharma, and the Drug Information Association on medical liaison practices and standards. Craig currently serves on the DIA planning committee for its Medical Liaison Community.

Hilary D. Mandler, PharmD Director, Global MSL Operations Shire

Dr. Hilary Mandler is currently the Director for Global MSL Operations at Shire Pharmaceuticals, located in Wayne, PA. Hilary received her Bachelor of Science in Pharmacy from the University of Pittsburgh, a Doctorate of Pharmacy from the Philadelphia College of Pharmacy and Sciences (now University of the Science in Philadelphia), and completed a 2-year Post-Doctoral Fellowship in Infectious Diseases at the University of Rhode Island. Hilary began her clinical pharmacy career at Hahnemann Hospital in Philadelphia, where she was a Clinical Pharmacist/Educator in Infectious Diseases and the Pharmacy Residency Program Director. She was adjunct professor of pharmacy and medicine at numerous Philadelphia institutions, including Philadelphia College of Pharmacy, Temple University School of Pharmacy, and Hahnemann University School of Medicine (now known as Drexel University). Hilary transitioned into the pharmaceutical industry as a MSL for Bristol-Myers Squibb in their Anti-infective franchise. Due to reorganization, she took a position a ViroPharma, Inc. to lead a new MSL organization in Antiviral therapy followed by an opportunity to start up a new MSL organization at Shire. Over the past 10 years at Shire, Hilary has taken on additional leadership responsibilities and most recently, was the Senior MSL Director for US & Canada.

Carrie Murray

Director, Global MSL Excellence Bayer HealthCare Pharmaceuticals

Carrie has been with Bayer HealthCare Pharmaceuticals since 2008 and started the women's health care MSL team there. She has a decade of experience as an MSL and MSL manager and most recently became part of a Global Medical Affairs team. Carrie has vast experience in the MSL role, including development and execution of MSL SOPs, metrics, objectives setting, strategic planning and professional development. Carrie practiced as an OB/GYN nurse practitioner before making the transition to the pharmaceutical industry. She received her master's degree in nursing from Vanderbilt University in Nashville, TN and holds a bachelor's degree in psychology from Hartwick College in Oneonta, NY. She is currently pursuing a doctorate degree at the University of Colorado, College of Nursing.

Beth A. Price Executive Vice President The Medical Affairs Company

Beth Price is Executive Vice President of Business Development, Marketing and Communications at The Medical Affairs Company (TMAC). Beth is the key driver behind business development and customer service for all TMAC clients.

Beth is a pharmaceutical industry veteran with greater than 20 years of experience, most of which *have* been in the outsourced Medical Affairs arena. Her intimate *involvement* at an executive *level* with scores of field-based medical and medical communications programs makes her uniquely qualified for her key responsibility of ensuring all TMAC-outsourced programs are strategically aligned with the business objectives of the client company. Beth's true talent is exploring new and innovative solutions to support and enhance TMAC client's existing Medical Affairs programs. Her relentless drive, attention to detail and commitment to excellence has made her a valuable resource to all TMAC clients. Prior to joining TMAC, Beth was Executive Vice President at SOS and for *over* 10 years was instrumental to the success of the company. She helped secure more than 75 new clients and enhanced client relationships by providing invaluable insight and support.

Prior to that, Beth held a number of management positions within the healthcare communications industry *(Nelson* Communications, KPR, Becker, McAdams) providing pharmaceutical and biotech clients with strategic marketing solutions.

Beth is a renowned speaker on topics related to outsourced Medical Affairs, regularly conducting workshops and presentations at industry meetings and conferences. She is an active member of the DIA and Healthcare Businesswomen's Association (HBA) Atlanta chapter and is a preceptor for fourth year pharmacy students attending the Mercer University Leadership Pharmacy Management Program



Muriel Siadak Director, Medical Affairs Seattle Genetics

Muriel Siadak, PA-C is currently a Director of Medical Science Liaison for Seattle Genetics in Medical Affairs. A physician assistant by training, Muriel received her PA degree from the University of Washington in Seattle. She has extensive clinical experience in oncology and bone marrow transplantation. With over 10 years of leadership experience in the pharmaceutical industry, Muriel has functioned in a number of roles. She has worked at Immunex, Berlex Oncology, Bayer, Zymogentics and Seattle Genetics. In addition to extensive medical affairs experience, she also has had experience as Medical Monitor for Phase II and Phase II studies.

Christina Cognata Smith, PharmD, MBA Executive Director, Medical Affairs Medicis, A Division of Valeant

Christina Cognata Smith PharmD. MBA, a Medical Affairs expert, began her career in Chicago as a Critical Care Pharmacist within the Northwestern Integrated Delivery Network and later relocated to serve as Director of Clinical Services at Health Services Corporation of America, a nationwide group purchasing organization headquartered in St. Louis, MO. After moving back to Chicago, she started her career in the pharmaceutical industry as a Medical Science Liaison with Janssen, a Johnson & Johnson Company where she was promoted to regional and national director in various therapeutic areas. While at Janssen, also was advanced to the position of Clinical Operations Lead for two large phase 3 trials. Christina left Janssen to work at Bristol Myers Squibb as National Director, Field Medical Science. In that capacity she worked in multiple therapeutic areas, across multiple alliance agreements, and lead the field based Health Economics and Outcomes Research team. Christina was promoted to the Medical lead for Bristol Myers Squibb neuroscience franchise where she led the US and Global medical matrix teams. She is currently the Executive Director. Medical Affairs at Medicis. A Division of Valeant located in Scottsdale. AZ. Christina Cognata Smith holds a Bachelors of Science in Pharmacy from St. Louis College of Pharmacy, a Doctor of Pharmacy (Pharm.D) from St. Louis College of Pharmacy, and a Masters of Business Administration (MBA) from Lindenwood University, St. Louis, MO. She completed her residency in Internal Medicine, with an emphasis in Critical Care at St. Joseph's Hospital in Belleville, IL. In addition to her role at Medicis, A Division of Valeant, she is currently adjunct faculty at the University of Arizona School of Pharmacy and Midwestern University.