

Korina Akhondzadeh, senior regulatory consultant, KARA & Associates, Inc.

Akhondzadeh has extensive experience working for Notified Bodies and in the medical industry in several quality/regulatory-related roles including assisting, training, auditing and providing expertise to medical companies involved in the design, development, manufacturing, servicing, repairs, logistics and contract manufacturing of medical devices. Her expertise includes thorough knowledge of: ISO 13485:2003, FDA (QSRs), and 21 CFR 820, elements of the *Sherman Antitrust Act*, European Directives (MOD, AIMDD, and IVDD), JPAL MO, CMDR SOR/98-282, TGA and ISO 14971:2007. Akhondzadeh is also involved in the preparation of international and domestic product submissions including technical files, 510(k) and design dossiers.

Chuck Blevins, director, office of program management, Lifescan

Blevins has served Johnson & Johnson for more than 10 years and has been a leader in developing various new medical device products for more than 18 years. His passion is products that improve the quality of life for patients, specifically in helping patients to receive the appropriate product as quickly as possible. Blevins is a member of PDMA, PMI, ASQ, New York Academy of Sciences and Sigma Xi, the Scientific Research Society. He holds 11 US patents.

Peggy Carter, PhD, RAC, regulatory affairs manager, Ventana Medical Systems Inc.

Carter has been a regulatory affairs manager with Ventana Medical Systems Inc., a member of the Roche Group, for more than three years and has more than seven years experience in the IVD industry with a focus on design control, regulatory submissions and compliance. Carter holds a PhD in biochemistry and molecular biology from LSU Medical Center. Ventana develops and manufactures medical diagnostic instruments and reagent systems that provide leading-edge automation technology for use in slide-based tissue diagnosis of cancer.

Pierre Cassigneul, president & CEO, XDx, Inc.

Cassigneul previously served as a partner with the consulting firm, Stone Bridge and vice president diabetes management at Becton Dickinson where he led the company's efforts in entering the blood glucose monitoring market. Cassigneul also worked at Bayer where he was senior vice president and general manager of the diabetes business unit, at Ortho (J&J) where he was vice president and general manager of the AIDS and Hepatitis Business Unit, and at Abbott where he held several US and European general management and marketing positions. Cassigneul has a management degree from the ESC Reims.

Gary Cederwall, director, regulatory affairs, Thoratec Corporation

Cederwall has worked in the medical device industry since 1979 and at Thoratec Corporation, a manufacturer of ventricular assist devices in Pleasanton, CA, for the last 16 years. Cederwall began work in the product development engineering group at Thoratec and moved into regulatory in 1989.

Robert Church, partner, Hogan and Hartson LLP

Church is a partner in the Los Angeles office of Hogan & Hartson whose practice focuses on assisting pharmaceutical and biotechnology companies in translating US Food and Drug Administration (FDA) regulatory requirements into corporate operational standards and actions. He assists clients of all sizes on clinical trial issues; laboratory practice standards; and the array of issues that arise in research, development and product approval. Church worked for eight years in senior positions at Amgen Inc., most recently, as executive director and head of Amgen's global research and development compliance department, where he was responsible for all quality assurance and compliance activities. Before joining Amgen, Church worked in FDA's Office of the Chief Counsel for five years serving as associate chief counsel for drugs, advising the agency's Center for Drug Evaluation and Research on legal and policy issues related to drug development, approval and marketing. He also served as associate chief counsel for enforcement, prosecuting violations of the *Federal Food, Drug, and Cosmetic Act*.

Christopher Devine, senior program manager, Boston Scientific Corporation

Devine has worked at Boston Scientific for 11 years and has 30 years of experience with quality assurance in several industries. Currently, he manages the recertification of Boston Scientific medical devices sold outside the US; and was one of the principle contributors in the development of the Boston Scientific Supplier Quality System. Prior to his current assignment, Devine was the quality control manager for Boston Scientific's EP Business Unit located in San Jose. Additionally, Devine is a senior member of ASQ, and is in the process of completing his doctoral dissertation; "Examining the Value of Defensive- Receiving Inspection" at Northcentral University (Prescott Valley, Arizona). Devine holds a graduate degree in organizational management (MAOM) and an undergraduate degree in business administration (BSBM).

Neal E. Fearnot, PhD, president, MED Institute Inc

In Fearnot's current role at MED Institute Inc, a medical device research and development firm located in West Lafayette, Indiana, and a subsidiary of Cook Group Incorporated, he helps develop medical device prototypes, performs preclinical evaluation, conducts clinical studies and prepares regulatory submissions to FDA and other regulatory agencies. Fearnot's responsibilities include the executive management of regulatory affairs and clinical trials worldwide for Cook medical companies, including a recent emphasis on expediting regulatory approval of Cook products in Asia. Currently, Fearnot is active in several initiatives to promote harmonization of Japan-US device regulations. These include US FDA think tanks, the Harmonization by Doing (Duke) initiative and the Midwest US-Japan Association Conference. Fearnot has represented the Cook Group on government and industry task forces for improving federal medical device legislation, high technology workforce development and streamlining FDA processes.

Ralph Hall, JD, attorney, Baker & Daniels LLP

Ralph Hall, JD, has extensive experience in the areas of FDA and healthcare law, specifically with the medical device regulatory system, and in the design and implementation of regulatory compliance programs, FDA enforcement actions, managing complex patent litigation and licensing matters and general corporate counseling. Prior to rejoining Baker & Daniels, Hall served as senior vice president and deputy general counsel, litigation and compliance, special counsel to the Board of Director's compliance committee and to the compliance office and general counsel of the Cardiac Rhythm Management group at Guidant Corporation. Prior to joining Guidant, Hall served in a number of legal roles, including chief environmental counsel at Eli Lilly & Company. He is a visiting professor at the University of Minnesota Law School and CEO of the start-up medical device company, MR3 Medical LLC. Hall speaks frequently at legal seminars.

Matthew G. Hillebrenner, chief, Circulatory Support and Prosthetics Branch, US Food and Drug Administration, Center for Devices and Radiological Health

Matthew G. Hillebrenner supervises a staff of engineers, scientists and clinicians in the premarket review of various medical devices, including percutaneous heart valves, ventricular assist and CPR devices. He began his career as a scientific reviewer at the US Food and Drug Administration in 2003 after receiving his master's degree in biomedical engineering from Tulane University. Initially assigned to pacemakers, defibrillators and cardiac resynchronization therapy devices, Hillebrenner eventually found a niche as lead reviewer for a range of heart failure devices before moving into his current position in May 2007.

Steven Hoff, PhD, RAC, president, Hoff Consulting LLC

Hoff's experience includes more than 30 years in biomedical research, including 17 years working directly in regulatory including preparing various INDs, NDAs, supplemental NDAs and pediatric programs, along with 510(k)s for devices. Hoff has coordinated major meetings and teleconferences with FDA and worked on various due diligence and divestiture efforts for several products. He received his pharmacy degree from the University of the Pacific, and his PhD in cell biology from the University of California at Los Angeles.

Tom Kahrmann, senior medical device manager, BSI IRCA lead auditor/RAB lead auditor, BSI PS Healthcare

Kahrmann is an RABQSA and IRCA lead auditor. He has been with BSI for more than 12 years, and is recognized throughout the organization as an expert in quality systems and regulatory requirements for medical devices. Kahrmann established a supply chain involving four countries and more than 8,000 people that resulted in a design and manufacturing capability of 1.4 million components per week. He managed quality requirements at the factories and selected and qualified subcontractors, which led BSI to ISO 9001 certification. Kahrmann frequently teaches BSI medical device courses such as CE, CMDCAS and JPAL and he created BSI's program for training and certification to the 14971:2007 risk management standard. He is BSI's supervisor of the Accredited Person's Program and has recently published articles on ISO 13485:2003 and subcontracting of medical devices.

Mary Beth Kepler, president/private consultant, MBK Biomedical Consulting LLC

Mary Beth Kepler has more than 15 years of regulatory, bioengineering and clinical affairs experience in cardiovascular devices. She has served as the clinical manager on the total artificial heart program at the University of Arizona and her clinical management experience includes work with several cardiac device companies, including the Novacor division of Baxter Healthcare. Kepler was the principal instructional consultant and clinical program manager in heart failure and associated CRT devices for Medtronic and later director, clinical studies and product manager at Terumo Corporation. Kepler participated in a bioengineering internship at the Cardiovascular Labs at the National Institutes of Health. She currently provides private clinical and regulatory consultant services to support activities for companies seeking US approval. Kepler holds a BS in bioengineering from Texas A&M and an MBA in healthcare finance.

Irina Kulinets, RAC, vice president of regulatory and clinical affairs, Anika Therapeutics

Kulinets has 17 years of experience in the medical device industry with large and small manufacturers including Boston Scientific, Johnson & Johnson/DePuy and OmniGuide, where she served in various regulatory affairs, clinical affairs and quality assurance technical, management and executive roles. Previously, Kulinets served as a medical regulatory reviewer and lead medical auditor for the Notified Body, TUV America. Certified by FDA as a third party 510K reviewer and investigator, Kulinets holds an MS and BS in mechanical engineering from Belarus Polytechnic Academy and an MS in quality assurance from California State University, Dominguez Hills. She also holds a PhD in Health Sciences from TUI University. Kulinets is RAC and ASQ certified, Six Sigma Black Belt and an ASQ Certified Quality Engineer.

Bob Kroslowitz, vice president, clinical affairs, Berlin Heart Inc.

Kroslowitz has more than 10 years of marketing and clinical affairs experience in the cardiovascular industry. His role at Berlin Heart Inc., the US subsidiary of Berlin Heart GmbH, a global leader in both the adult and pediatric ventricular assist device market, involves working effectively with FDA to develop and gain approval for the first pediatric ventricular assist device clinical trial in the US, which is now well underway. Previously, Kroslowitz held clinical and marketing positions with Jostra. He also served as chief of pediatric perfusion where he was instrumental in establishing a pediatric cardiac surgery program in Orlando, Florida, and held clinical and research positions in the divisions of clinical perfusion and pediatric cardiac surgery at Columbia Presbyterian Medical Center in New York. Kroslowitz has published and presented many articles and case studies. He holds active membership in several medical and professional associations and is past president of the American Academy of Cardiovascular Perfusion. Kroslowitz serves on the board of directors for Heart Care International and is active in other organizations that provide volunteer cardiac surgical services to underserved areas in third world countries. He holds a BS in perfusion technology from Quinnipiac College.

Patrick Lee, MD, MBA, radiologist and principal, Palo Alto Investors

Lee joined Palo Alto Investors in 2001 as an investment analyst covering the healthcare sector. His prior experience includes a consulting role at McKinsey & Company, where he advised top-10

pharmaceutical companies on management and product strategy. Lee holds a Doctor of Medicine from Duke University and is a practicing board certified radiologist.

Christina Markus, JD, partner, King & Spalding

Markus is a partner in the Washington, DC, office of King & Spalding LLP and serves as deputy chair of the FDA/Healthcare Group. Markus' practice focuses on the regulation of drugs, biologics, and other products regulated by the US Food and Drug Administration, the US Drug Enforcement Administration (DEA) and related state agencies (e.g., boards of pharmacy). Markus represents health product and technology manufacturers, distributors and related service providers in a range of regulatory compliance, enforcement and business transactions involving product development and approval, safety, labeling and advertising and supply chain.

Annette Mathisen, PhD, QST Consulting Ltd.

Mathisen has more than 30 years experience in the pharmaceutical industry working for American, British and Japanese companies as head of statistics and data management departments. Mathisen has participated in regulatory meetings and interactions with FDA, EMEA and Health Canada. Her current responsibilities include building and submitting eCTDs. She also teaches a course in clinical trials at Grand Valley State University. Mathisen holds a PhD in statistics.

Eileen McCall, PhD, associate director, intercontinental regulatory affairs, Eli Lilly & Company

McCall joined Eli Lilly in 1996 after completing her postdoctoral training at the University of California and Loyola University. Since joining Lilly she has held positions in cardiovascular research and regulatory affairs, focusing on affiliate registration planning and maintenance for the intercontinental region for the Neuroscience therapeutic area. Eileen received her doctorate in physiology from the University of Leeds, England.

Denise McEachern, vice president global regulatory affairs, Bausch & Lomb

With more than 25 years of experience in the medical device, diagnostic and pharmaceutical industries, McEachern has a track record of fostering product innovation and global commercialization. She has developed and implemented regulatory strategies for the approval and launch of new products in the global environment including collaboration and utilization of new and novel approaches to regulatory approval, which resulted in best-in-class "time to market cycle" and first of a kind product claims. McEachern's current role involves corporate regulatory responsibility for worldwide business. Past roles include worldwide vice president of regulatory & development affairs and other senior executive positions in quality and compliance for LifeScan, Inc, (Johnson & Johnson). She entered the regulatory field with Alcon Laboratories and also served as director of regulatory and clinical affairs for Vistakon (Johnson & Johnson) prior to joining LifeScan.

David McGrath, KARA & Associates, Inc.

McGrath is a quality and regulatory professional with 20 years experience in the application of risk analysis and risk management tools and techniques to complex engineered systems, designs and processes. He provides consulting services through KARA and Associates, which provides a broad range of regulatory, quality assurance, and engineering consulting as well as regulatory and quality assurance training. McGrath also serves as director of regulatory affairs and quality assurance for a medical device company in Carlsbad, CA. David holds an MS in reliability engineering and a Six Sigma Black Belt.

David McIntyre, assistant general counsel, Johnson & Johnson

For almost 20 years, McIntyre has handled a wide variety of patent, trademark and copyright infringement litigations, as well as product liability and compliance matters, for Johnson & Johnson and other companies in the healthcare, and high technology fields. He has served as a judicial law clerk for the Honorable William H. Timbers of the US Court of Appeals for the Second Circuit and the Honorable Irma E. Gonzalez of the US District Court for the Southern District of

California in San Diego. McIntyre earned his JD from Fordham University School of Law, where he was senior articles editor for the Fordham Law Review, and holds a BS in biology from Cornell University. He is a member of the New York, California and Patent Bars, and is admitted to practice before a number of Federal Courts in New York and California.

Murray Malin, MD, MBA, medical officer, Center for Devices and Radiological Health, US Food and Drug Administration

Dr. Murray Malin provides clinical guidance to the office and center on device safety and is responsible for conducting risk assessments of postmarket device failures and recalls. Prior to joining FDA, Malin designed and developed clinical information systems and has a particular interest in the safe use of software and other medical devices in the operating room and critical care environments. Malin completed his undergraduate studies at the University of Michigan and received his MD from the Medical College of Ohio. He is a board certified anesthesiologist, completing his residency in anesthesiology and Fellowship in cardiac anesthesiology at the Georgetown University Hospital in Washington, DC. Upon completion of his formal training in anesthesiology, Malin was in private practice for 15 years. He holds an MBA from the George Washington University, concentrating his studies on information technology, finance, statistics and HIPAA.

Ann Meeker-O'Connell, MS, compliance and quality management consultant

Meeker-O'Connell has over twelve years of pre-clinical and clinical research experience in academia and industry. Presently, Ann is pursuing a law degree at the University of California-Berkeley. Prior to law school, Ann worked in the global R&D compliance department at Amgen. At Amgen Ann was responsible for collaborating with the company's corporate compliance department in efforts to develop an enterprise-wide compliance risk management program. Prior to joining Amgen, Ann spent four years as a clinical quality auditor and clinical study monitor for companies including Pfizer and Genentech. Ann received her masters degree in Pharmacology and her bachelor's degree in Biological Anthropology and Anatomy from Duke.

William Mendez, director business development & alliance management, SymCare Personalized Health Solutions Inc.

Mendez has more than 16 years of professional experience with 11 years focused on the pharmaceutical and OTC industries. Prior to joining LifeScan, he was the director of business development supporting Johnson & Johnson's consumer healthcare and OTC global business units in Europe, where he was responsible for directing and executing acquisitions, licensing and integration activities across the region, including the acquisition and integration of Pfizer Consumer Health in Europe, the Middle East and Africa. Before joining Johnson & Johnson in 2005, Mendez was with Hoffmann La Roche for seven years, where he held various roles in internal audit, finance and business development. With Hoffmann-La Roche, he relocated to Switzerland and led the divestment of Roche Consumer Health, the largest transaction in OTC history at that time.

Keith Morel, PhD, project manager, KEMA Medical

Morel is a lead auditor for CE and ISO 13485:2003 audits (including CMDCAS) and also performs design dossier reviews for clients. Prior to joining KEMA, Morel worked in R&D in the medical device industry as engineer, manager and director, for various technologies including IVUS catheters and super-oxidized water products. He holds a PhD in plasma physics (nuclear fusion) from the Imperial College of Science, Technology and Medicine in the UK.

Robert North, PhD, chief scientist, Human Centered Strategies

Robert North, PhD, is a recognized industry leader in the application of human factors engineering for the control of use-related risks in medical devices. His industry experience includes management of Medtronic's Cardiac Rhythm Management usability engineering group, and more than 20 years with Honeywell International's aerospace and control products groups. For the past six years, he has worked as a consultant with the Human Factors group at the US Food and Drug Administration's Center for Device and Radiological Health, developing methods

of classifying and analyzing medical device use errors related to device design problems. North is a member and co-author of the new human factors standard, HE-75, which will be published by AAMI in late 2009. In 2008, he was named to MD&DI's list of Top 100 Notable People in the Device Industry. North holds a doctorate in engineering psychology from the University of Illinois at Urbana-Champaign, and is chief scientist of Human Centered Strategies.

Steven Oh, microbiologist, CBER, US Food and Drug Administration

Oh's areas of expertise at the Food and Drug Administration's Center for Biologics Evaluation and Review (CBER) include biologic-device combination products and tissue engineered medical products with therapeutic or regenerative indication. He actively participates in submission reviews, policy development and staff training for these combination products in the Office of Cellular, Tissue and Gene Therapies (OCTGT). Oh spent some time at the Center for Devices and Radiological Health as a visiting review scientist from CBER. This experience taught Oh about balanced approaches to biologic and device reviews. He continues in his effort to harmonize review practices for biologic-device combination products currently regulated by OCTGT.

Niamh Pellegrini, general manager, global institutional business and vice president of strategic alliances, Lifescan Inc.

Niamh Pellegrini manages the LifeScan business in multi-patient settings around the world, with a particular focus on the hospital marketplace. She is also responsible for creating and managing strategic alliances for the North American market across institutional and consumer business. Pellegrini joined LifeScan in 1988 and has held a variety of key management roles, most recently vice president of consumer and professional sales, vice president US marketing and vice president of global strategic marketing. LifeScan manufactures and markets blood glucose monitoring systems used in the care of people with diabetes. Pellegrini began her career with Johnson & Johnson in finance and has worked in information management and a variety of marketing and sales roles, including assignments in Europe and Asia Pacific. Pellegrini holds a BS in finance and an MBA from Santa Clara University.

John Plewes, MD, medical advisor, neurosciences, Eli Lilly and Company

Plewes served in the US Army for 25 years; his last assignment was chair of the department of psychiatry and neurology at Womack Army Medical Center, Fort Bragg, NC. Plewes was psychiatry consultant to 18th Airborne Corps and Special Operations Command at Fort Bragg, and the forensic psychiatrist for five courts-martial jurisdictions. After retiring from the Army, Plewes joined Eli Lilly and Company, working with the company's global organization and LillyUSA, and he continues to do forensic and clinical trials work for the company. He has served as faculty for several medical schools and as an examiner for the American Board of Psychiatry and Neurology for more than 10 years.. Plewes graduated from the University of Texas HSC San Antonio; and completed a Psychiatry Residency at Walter Reed Army Medical Center and a Fellowship in Forensic Psychiatry at the University of Virginia.

Stuart Portnoy, MD, senior consultant, Biologics Consulting Group

Portnoy advises medical device manufacturers regarding regulatory strategy, clinical trial design issues and technical considerations to gain FDA market-approval. He previously worked as a consultant at PharmaNet for five years and spent eight years with FDA, including positions of branch chief of interventional cardiology devices and acting deputy director of the division of cardiovascular devices. While at FDA, Portnoy performed the clinical review of a wide range of cardiac devices and was an agency leader in developing the now well-established multicenter review practices for evaluating drug-eluting stents and other combination products. Portnoy is a graduate of George Washington University School of Medicine and holds an MS in bioengineering from the University of Pennsylvania.

Miriam Provost, PhD, senior consultant, medical devices, Biologics Consulting Group

Prior to joining Biologics Consulting Group, Provost worked at FDA's Center for Devices and Radiological Health for more than 13 years, holding the positions of deputy director for science

and engineering review in the Office of Device Evaluation and scientific reviewer and manager in areas including gastroenterology and renal devices, cardiovascular, general and plastic surgery, orthopedics, neurology and restorative devices. Provost has received several honors, including FDA Engineer of the Year and the FDA Scientific Achievement Award for Excellence in Review Science. She holds a BS in chemical engineering from the University of Dayton and an MS and PhD in chemical engineering from the University of Pennsylvania.

Linda Ricci, biomedical engineer, Center for Devices and Radiological Health, US Food and Drug Administration

Linda Ricci is a premarket scientific reviewer for devices including cardiac ablation catheters and generators, cardiac monitors and heart failure diagnostics. She also specializes in the premarket review of software contained in medical devices. Before joining FDA, Ricci was involved in the design and development of various cardiac monitoring equipment including 12-lead ECG, stress test monitors, and external defibrillators. She holds a master's degree in medical engineering from the University of Washington in Seattle.

Mohamed Rizk, senior manager, regulatory affairs, Amgen Inc.

Mohamed Rizk has more than 20 years of regulatory experience. He began his career in the chemical industry, focusing on regulatory affairs, operations and business development. He later worked at Univar USA Inc., leading the regulatory and business development efforts at their global headquarters. Rizk worked at Univar USA Inc. for 13 years before joining Amgen Inc., where he now focuses his efforts on regulatory affairs and clinical trials registrations and results disclosures.

Erica Rogers, vice president and general manager, medical devices, Nanosys

Erica is an experienced medical technology senior executive and entrepreneur and has founded two companies including Nanosys, which is an industry-leading nanotechnology company developing, manufacturing and selling products based on a technology platform of high performance inorganic nanostructures. Erica holds over 15 patents in fields ranging from nanotechnology to ophthalmology and cardiovascular devices. She spent over 12 years at Boston Scientific and was instrumental in the global acceptance of intracranial aneurysm coiling technology. Erica has experience in interventional radiology, cardiology, neurosurgery, ophthalmology, plastic and reconstructive medicine, dermatology and otolaryngology. She holds a BS degree in Zoology.

David Sampson, PhD, regulatory affairs manager, SRA Global Clinical Development Ltd

Sampson's experience prior to entering the field of regulatory affairs was in drug discovery, focused on combinatorial and medicinal chemistry. His previous experience and current responsibilities at SRA Global Clinical Development include European Phase 3 clinical trials, Marketing Authorisation Applications and post-licensing work. He is also a core member of the eCTD team that has focused on successfully introducing eCTD capabilities into the organization. Sampson holds a PhD in organic chemistry.

Ekkehard Stösslein, PhD, head active medical devices department, Federal Institute for Drugs and Medical Devices

Ekkehard Stösslein, PhD, has been with the Medical Devices Department of BfArM since its establishment in July 1994. He has held several positions within the department and is also a member of Study Group II of the Global Harmonisation Task Force (Post Market Surveillance and Vigilance), the Medical Devices Experts Group and Medical Devices Experts Group on Vigilance. He was the chair of the working group on the latest revision of the Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12/1 rev.5). Previously, he conducted research on the haemodynamics of artificial heart valves and hearts. Stösslein joined public service to start the implementation of the *Active Implantable Medical Devices Directive* and later the *Medical Devices Directive* in Germany. He studied physics and biophysics at the Humboldt-University, Berlin.

Michael Swit, Esq., vice president, The Weinberg Group

Swit's expertise includes product development strategies, compliance and enforcement initiatives, recalls and crisis management, submissions and related FDA regulatory activities, labeling and advertising and clinical research efforts for all types of life sciences companies. Swit has 25 years of experience addressing critical legal and regulatory issues, both in private practice with McKenna & Cuneo and Heller Ehrman; and as vice president, general counsel & corporate secretary of Par Pharmaceutical, a prominent generic and specialty drug company. He also served from as CEO of FDANews.com, a premier publisher of regulatory newsletters and other information products for the life sciences. Swit holds an AB, magna cum laude, from Bowdoin College, his law degree from Emory University, and he belongs to the DC, Virginia and California Bars.

Erica Takai, PhD, biomedical engineer, CDRH, US Food and Drug Administration

Takai is a scientific reviewer in the Interventional Cardiology Devices Branch in the Division of Cardiovascular Devices at FDA's Center for Devices and Radiological Health. She is responsible for the review of premarket submissions and is involved in various regulatory initiatives, including Harmonization by Doing, aimed at harmonizing US and Japanese regulatory processes, as well as scientific working groups. Takai holds a doctoral degree from Columbia University, and was a post-doctoral fellow at the National Institutes of Health.

Paul Tan, FRACP, chief operating officer, Living Cell Technologies

Tan has 14 years experience in the biotechnology industry and has been involved with the manufacture of therapeutic products for early human trials in the US, UK and Australia. He has developed research products for Phase I/II clinical trials in the US, New Zealand, the Philippines and Brazil. Tan was the founding deputy director and head of the health division at Genesis Research & Development Corporation Limited, Auckland and served as CEO of CenTec Ltd, Sydney. Prior to entering the biotechnology industry, Tan was an associate professor in immunology at the University of Auckland and a consultant physician rheumatologist at Auckland Hospital. He holds patents relating to the therapeutic uses of microbial and cell-based products. At LCT, he oversees the GMP plant for encapsulated pancreatic islets developed by LCT and the regulatory requirements for the first-in-class product.

Reed Tarwater, PhD, RAC, director, pharmaceutical services, The Anson Group

Tarwater is both the regulatory scientist and project manager responsible for leading multifunctional project teams to develop new pharmaceuticals and biotechnology products in his current role with The Anson Group. He brings extensive experience in managing major new drug development projects from a distinguished three-decade career in medical technology, including 26 years at Eli Lilly and Company. His background encompasses all aspects of the complex FDA processes for evaluating and approving new and improved pharmaceutical products. In addition, Tarwater serves as a visiting lecturer at Purdue University's MS program dedicated to regulatory and quality compliance.

Patricia Teden, principal, Teden Consulting LLC

Patricia Teden specializes in clinical trial disclosure strategy and operations and strategic project management for global clinical trial operations. Teden has 20 years of experience conducting global clinical trials, pharmacovigilance, alliance management, clinical data management, developing and implementing IT projects and leading change management initiatives for global pharmaceutical companies. As senior director of strategic business functions for Pfizer, Teden was responsible for implementing the company's clinical trial disclosure processes so IFPMA commitments were met. She is a founding member of the DIA SIAC for Clinical Trial Disclosure, and a frequent speaker at industry conferences. Teden holds a BA in biology from Cedar Crest College and an MBA from the Harvard Business School.

Kimberly Trautman, medical device quality expert, CDRH, US Food and Drug

Administration is FDA's Expert on Medical Device GMPs and Quality Systems. She was responsible for writing the final Quality System regulation and preamble published in 1996. She

reviews inspection reports of foreign and domestic medical device manufacturers to identify violations of the Good.

Chang Hong Whitney, MBA, president, Whitney Consulting Ltd

Whitney has consulted for international medical companies since 1994. Specialized in SFDA, AQSIQ and other government regulations pertaining to the medical industry, Whitney provided China regulatory support, up to date information and China regulatory guidance to key players in the Chinese medical market. She has written more than 20 articles and presented at numerous professional conferences. Whitney holds an MBA from Babson Graduate School of Business and undergraduate degrees in electrical engineering and international business.

Rebecca Williams, PharmD, assistant director, clinical trials.gov, National Library of Medicine

In William's capacity at the National Library of Medicine, she is involved with policy issues and outreach activities related to registration and results reporting of clinical trials. Previously, she was a regulatory affairs consultant with SAIC and held reviewer and supervisory roles at the US Food and Drug Administration in the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications (DDMAC). Rebecca holds a PharmD from the University of Wisconsin–Madison.