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Disclosure Statements and Biographies

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Maria Mota: is an employee and stock shareholder of AbbVie

Ana Padua: is an employee of ROCHE

Thomas Schreitmueller: is an employee of F. Hoffaman – La Roche Ltd./Pharmaceuticals

The following have nothing to disclose:

Ivana Antonacci

Daniela Decina

Maria Guazzaroni Jacobs

Justina Molzon

Prisha Patel

Mark Paxton

Ana Pineda

Balbiana Oliveria

Brenda Valente

Hans Vasquez

Mike Ward

DIA staff members have reported no relevant financial relationships to disclose.

FACULTY BIOGRAPHIES

Ivana Antonacci

Ivana Antonacci is an International Regulatory affairs professional Consultant who is multilingual and multicultural. She worked in the Pharmaceutical industry for over 30 years, in Regulatory Affairs, Clinical Affairs, Quality Control/Quality Assurance and Product development. She also obtained numerous product approvals in over 100 countries and leads the Regulatory activities for Latin America for Merck & Co Inc.

Daniela Decina

Daniela joined the World Health Organization in 2015 as a member of the Regulatory Systems Strengthening Team in the Department of Essential Medicines and Health Products, focusing on regulatory pathways for timely registration of medical products. She holds a Master's degree in Microbiology. She has more than 25 years of pharmaceutical industry experience and began her career in the Quality Control laboratory before entering Regulatory Affairs, with emphasis in Chemistry, Manufacturing and Controls (CMC). Prior to her current role Daniela was Director of Regulatory CMC at Amgen Canada with responsibility for Canada and Latin America.

Maria Guazzaroni Jacobs

Maria has more than 30 years Pharmaceutical industry experience mainly in Quality, both in Argentina and the U.S. She has been with Pfizer Inc since 1991; she managed analytical laboratories, including the Quality Control Laboratories, and was the Brooklyn Site Quality Operations Director, prior to assuming a Center position. In her current capacity, she is responsible for developing strategies to address emerging regulations and guidance documents in the areas of GMPs and pre- and post-approval filings (Chemistry Manufacturing and Control, CMC), and assisting in development of company positions and responses to proposed regulations and guidances. Her focus is mainly US and Latin America. She holds a degree in Pharmacy from the University of Buenos Aires, Argentina, and a Ph.D. in Organic Chemistry from New York University.

Justina Molzon

Justina Ann Molzon, Former Associate Director for International Programs, Center for Drug Evaluation and Research, US Food and Drug Administration, 1999-2014, is an expert in regulatory harmonization and capacity building of international drug regulatory authorities. She is also a career US Public Health Service officer serving for 30 years with a retired rank of Captain. Further credentials include: Juris Doctor, Illinois Institute of Technology Chicago-Kent College of Law, Chicago, Illinois, Master of Science in Pharmacy, University of Rhode Island, Kingston, RI—Pharmaceutics, Bachelor of Science, University of Rhode Island, Kingston, RI, graduated with honors and distinction and selected for Rho Chi.

Maria Mota

Cristina is currently Director at AbbVie where she coordinates regulatory policy and intelligence activities for Latin America. Cristina worked for Boehringer Ingelheim for 13 years in different roles including Quality, Validation and Regulatory Affairs. Cristina attended Universidad Nacional Autonoma de Mexico where she got her Pharmacy Degree and a Masters in Industrial Administration.

Balbiana Oliveira

Balbiana Oliveira has degree in Pharmacy and Biochemistry from Federal University of Minas Gerais, specialization in Sanitary Surveillance from Oswaldo Cruz Foundation - Fiocruz and master degree in Health Science from University of Brasilia. She has been working in Brazillian Health Regulatory Agency (Anvisa) since 2005 and was a member of the reviewer team of New Drugs Division from 2005 to 2013, working with the evaluation of clinical protocols and applications for development and registrations of innovative medicines. Along these years, she was coordinator of the Coordination of New Drugs for 2 years. Since 2013, she is working as Advisor of Director at Anvisa with good regulatory practices, regulatory harmonization and drug regulatory issues.

Ana Padua

Ana Padua has been working in pharmaceutical industry for 16 years, starting on analytical development in the first year and then moved to regulatory affairs area where she is up to now. In the last years she has been leading regulatory policy activities for LATAM region on chemical and bio-therapeutic products at Roche to drive science-based regulations, working actively in several industry associations (FIFARMA, BIO, EFPIA and local industry associations). Ana Padua is a pharmacist by training and has a Master Degree on Clinical Pharmacology.

Prisha Patel

Prisha Patel is the Manager for the Global Development programme at the Centre for Innovation in Regulatory Science (CIRS), London, focussing on emerging markets. Her responsibilities include managing the emerging markets industry benchmarking and agency benchmarking projects and working with regulatory agencies on special projects. Most recently Ms Patel served as a co-author of several publications including R&D Briefing 58: The changing regulatory environment in Latin America and along with Hashan, Aljuffali and Walker, The Saudi Arabia Food and Drug Authority: An Evaluation of the Registration Process and Good Review Practices in Saudi Arabia, published in Pharmaceutical Medicine in 2016.

Mark Paxton

Mark S. Paxton is the newly appointed CEO of RX-360, an international medical product supply chain consortium dedicated to patient safety by promoting practices to protect supply chains and distribution channels. RX-360 is based in Washington, DC. Prior to joining RX-360, Mark served as a Regulatory Counsel in the CDER Office of Compliance where he was responsible for developing supply chain security policies, both domestically and internationally, including serving as the overseer of a major global initiative under the auspices of Asia-Pacific Economic Cooperation (APEC) to establish best practices for ensuring product quality moving in international commerce. Before joining FDA, Mark served as Associate Vice-President, International Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America ("PhRMA"). In that capacity, Mark established a number of on-going dialogs and work programs with drug regulatory authorities throughout, Japan, China, East Asia, India, Europe and Latin America. These efforts were designed to assist regulators and constituent companies operating in these markets to better understand complex regulatory issues arising from the globalization of the pharmaceutical industry. Mark is a regulatory attorney by education, experience, and training, and prior to joining PhRMA was in private practice in Lexington, Kentucky where he focused his practice on food and drug law. Mark received his B.S. (1991) and M.S. (1993) degrees in Economics from the University of Kentucky, and his J.D. from the University of Dayton School of Law in 1998.

Ana Pineda

Ana Patricia Pineda is an International Regulatory Analyst for Medical Products in the U.S. FDA's Latin America Office since March, 2013. Ms. Pineda holds a BSc in Chemistry, Pharmacology and Biology from the UNAM and a Master of Science in Toxicology from the CINVESTAV. Ms. Pineda started her career in pharmaceutical manufacturing. In 2001, she joined the Ministry of Health of Mexico as Head of the Toxicology Department. Ms. Pineda also served as the Manager of International Affairs for Drugs and Chemicals with Mexico's COFEPRIS where she coordinated the Commission's participation and its representation in multiple international fora as well as developing new cooperation instruments.

Thomas Schreitmueller

Dr. Thomas Schreitmueller is biochemist by education and joined Roche in 1989 holding various leadership positions in the biotech area (e.g. Analytical R&D, Quality Control, Technical Project Management). As off 2010 Thomas became the global lead for international regulatory policy for biologics leading and coordinating the development of Roche positions on regulatory policy topics related to biotheapeutic and similar biotherapeutic products. Since 2015 Thomas is global head of regulatory policy leading and coordinating Roche's regulatory policy activities.

Brenda Valente

Mrs. Brenda Valente is a pharmacist and holds the position of Specialist in Regulation and Health Surveillance in the sanitary authority in Brazil, the Brazilian National Health Surveillance Agency (ANVISA). She has been working since 2005 as a reviewer at the department responsible for the assessment of marketing authorization and post registration

changes of biological products. She has participated in the elaboration and revision of regulation and guidelines regarding biological products in Brazil.

Hans Vasquez

Hans is General Director in Office for Research and Technology Transfer, in Peruvian National Institute of Health since 2014; this Office is in charge of national regulation for clinical trials and other activities regarding regulation and promotion research in the health sector. He was in National Regulatory Authority of Medicine, as clinical reviewer and clinical review coordinator from 2005 to 2014; in this position was responsible for coordinating new regulations of biological product. He is involved in national and international activities related to improve regulation of medicine and clinical research sponsored by PAHO.

Mike Ward

Mike Ward recently assumed the position of Coordinator, Regulatory System Strengthening, Essential Medicines and Health Technologies, Health Systems and Innovation Cluster, WHO Headquarters. Mike joined the WHO in 2015 as the Coordinator, Prequalification Team in the same Department. Mike previously worked within Health Canada for close to 30 years as GMP specialist, drug evaluator and manager, international policy analyst and for the past 15 years as Manager of the International Programs Division of the Therapeutic Products Directorate. Mike has extensive experience in the area of international regulatory cooperation, having served on numerous international harmonization steering committees. He was also responsible for helping launch the APEC Regulatory Harmonization Steering Committee, the International Generic Drug Regulators Pilot and the International Medical Device Regulators Forum. Mike started his professional career working in the areas of Quality Assurance and Production for Burroughs Wellcome, a former multi-national pharmaceutical firm based in the UK. Mike won the Regulatory Affairs Professional Society Global Leadership Award in 2012. Mike has a BSc in Physiology from McGill University.