Todd Darwin Bridges, R.Ph. - Global President - Rockville

Mr. Bridges joined DSI – Rockville in May 2018 as Global President. Prior to joining DSI, **Mr. Bridges was the Director of the Division of Medication Error Prevention and Analysis (DMEPA**) in the Office of Surveillance and Epidemiology at the **U.S. Food and Drug Administration (FDA)**. He has **more than thirteen years of DMEPA experience with three of those years as the Director of DMEPA**.

As Director of DMEPA, **Mr. Bridges was responsible for supervising the premarket review and approval of proposed proprietary/brand drug names, labels/labeling, packaging, product design, United States Adopted Names, biological product proper name suffixes, and human factors studies** in order to reduce the potential for medication errors with products regulated by the Center for Drug Evaluation and Research (CDER). DMEPA conducts review and analysis of post-marketing medication errors submitted to CDER to determine if regulatory action such as label/labeling revisions, names change, product redesign, or post-marketing communications to stakeholders is needed. DMEPA also works with external stakeholders, regulators, and researchers to better understand the causes of medication errors and the effectiveness of interventions at preventing them, and **provides guidance to the pharmaceutical industry on drug development considerations from a medication errors perspective.**

Mr. Bridges has contributed to FDA policy and guidances related to medication errors, represented FDA as a member of the National Coordinating Council for Medication Error Reporting and Prevention as well as the Joint Commission's Patient Safety Advisory Group, and was responsible for establishing FDA's ongoing membership with the International Medication Safety Network.

In addition to his FDA experience, Mr. Bridges has thirteen years of pharmacy practice and supervisory experience prior to joining FDA. He has also received specialty training in medication error prevention and analysis from the Institute for Safe Medication Practices. Mr. Bridges earned his B.S. in Pharmacy from Virginia Commonwealth University's Medical College.

Carol Holquist, R.Ph. - President, Human Factors & Labeling - Rockville

Ms. Holquist joined DSI – Rockville in 2017 as Vice President, Global Naming, Human Factors & Labeling and in 2018 was promoted to President, Human Factors & Labeling. Prior to joining DSI, Ms. Holquist retired (CAPT) from the U.S. Public Health Service at the **U.S. Food and Drug Administration (FDA)** as the **Deputy Director for the Office of Regulatory Operations in the Office of Generic Drugs**. She has 24 years of FDA experience in the Center for Drug Evaluation and Research (CDER) with more than 9 years as the **Director of the Division of Medication Error Prevention and Analysis (DMEPA)** and 2 years as the **Deputy Director of DMEPA** in the Office of Surveillance and Epidemiology (OSE). DMEPA is **responsible for the approval of manufacturer's drug/biologic brand names and human factors/medication error evaluation of drug and drug/device labeling, packaging, and product design to reduce medication errors.**

She has co-authored numerous articles and several key medication error prevention guidance's including FDA's Contents of a Complete Submission for Proprietary Names Guidance (2010), Safety Considerations for Container Labels and Carton Labeling (2013), and Safety Considerations for Proprietary Names (in clearance for 2013) to name a few. **She oversaw DMEPA Regulatory Briefings to inform FDA Senior Management on medication safety issues, led pre-and post-marketing negotiations of proprietary name and labeling changes, human factors studies, and coordinated DMEPA related responses to name decisions, rejections and approvals.** She represented FDA nationally as a member of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), U.S. Pharmacopeia Safe Medication Use Expert Committee (SMU) and CDER's Labeling and Nomenclature Committee. Internationally, she represented FDA as an expert Advisor to Health Canada regarding the Review of Health Product Names for LASA Confusability: Development of a Guidance for Industry and a HC SOP.

Ms. Holquist earned her B.S. in Pharmacy from Temple University.

Ioannis Balamotis, Pharm.D. - President, EU Regulatory Affairs - London

Dr. Balamotis joined DSI - London as Managing Director, EU Regulatory Affairs in 2014 and in 2018 was promoted to President, EU Regulatory Affairs. Prior to joining DSI, he was a Scientific Administrator for the **European Medicine Agency's (EMA) Name Review Group (NRG)**. NRG is **responsible for evaluating and approving invented names** submitted to the Agency via the centralized procedure. He played an integral role in the development of the EMA's 2014 NRG Guidelines, which were published in May 2014. Dr. Balamotis reported directly to the EMA's NRG Secretariat during his tenure with the agency. He participated in all name review meetings and communicated meeting outcomes with NRG affiliates. And, while working on the 2014 guidance document, he liaised with Member States and representatives of the Pharmaceutical Industry, coordinating information and input from all relevant parties. He assisted the EMA in conducting technical reviews of the Product Information (Summary of Product Characteristics, Labeling and Package Leaflets) according to QRD (Quality Review of Documents) standards and in evaluating mock-ups and specimens (packaging artwork). He was also involved in the implementation of the new Pharmacovigilance Legislation, which involved the electronic submission of substance data according to ISO IDMP standards in the first EMA's electronic medicinal dictionary (XEVMPD). Dr. Balamotis is a current member of the BHBIA (British Healthcare Business Intelligence Association) Ethics & Compliance Committee.

Dr. Balamotis earned his Doctor of Pharmacy from Carlo Bo University of Urbino, Italy and a B.Sc. in Chemistry at Aristotle University of Thessaloniki, Greece.

Scott Sawler, B.Sc., LL.B., LL.M., M.B.A. - President, Canadian Regulatory Affairs

Mr. Sawler joined DSI - Ottawa as Managing Director, Canadian Regulatory Affairs in 2017 and in 2018 was promoted to President, Canadian Regulatory Affairs. Prior to joining DSI, he was Director General (DG) of **Health Canada's Marketed Health Products Directorate (MHPD)**, which is **responsible for reviewing and approving proposed proprietary (brand) names**; conducting risk/benefit assessments of marketed health products; overseeing the advertising regulatory requirements of health products; providing policies to effectively regulate marketed health products etc.

Among his many roles and accomplishments as DG was leading the development of the 2014 Health Canada Guidance Document for Industry - Review of Brand Names (officially implemented in June of 2015), which provides direction on process and information to be submitted to Health Canada regarding the potential for a proposed name. He also oversaw significant changes to the regulatory framework governing health products that were adopted, especially those relating to the Brand Names, Labeling and Packaging of Drugs for Human use. Prior to this, Mr. Sawler was the DG of Health Canada's Natural and Non-prescription Health Product Directorate where he led the program through a transitional period. He re-established its strategic vision, overhauled its policies and streamlined management systems to put the program back on track. Mr. Sawler also has significant experience as an executive and counsel in clinical trial management, government, legal and regulatory affairs. His clients included pharmaceutical companies, health professional associations, and non-governmental organizations.

Mr. Sawler earned his LL.M. from Osgoode Hall at York University, an M.B.A. from the University of Laval, an LL.B. from the University of Ottawa, and a B.Sc. in Chemistry from the University of New Brunswick.

Nora Roselle, Pharm.D. - Vice President, Global Regulatory Affairs - Rockville

Dr. Roselle joined DSI - Rockville as Managing Director of U.S. Regulatory Affairs in 2007 and was promoted in 2012 to Vice President, Global Regulatory Affairs. Prior to DSI, she served as an officer (LCDR) in the U.S. Public Health Service. She joined the **U.S. Food and Drug Administration (FDA)** in 2001 as a Safety Evaluator in the **Division of Medication Errors and Technical Support (DMETS)**, in the Office of Drug Safety (ODS), renamed the **Office of Surveillance and Epidemiology (OSE)**, now known as the **Division of Medication Error Prevention and Analysis (DMEPA)**. DMEPA is **responsible for the approval of manufacturer's drug/biologic brand names** and human factors/medication error evaluation of drug and drug/device labeling, packaging, and product design to reduce medication errors.

In that role, she evaluated a multitude and diverse array of applications for brand names, line extensions and combination product names utilizing DMETS' name evaluation methodology. In July of 2006, she was promoted to a more senior management position as a Team Leader in DMETS. As Team Leader, Dr. Roselle managed DMETS safety evaluators, proprietary (brand, line extension, and combination product) name reviews, labeling and risk management consults. Dr. Roselle has published several articles on medication errors. Two of her most widely known name safety articles include "Metadate ER or Metadate CD?; Drug Topics 2004, Oct 11:62,64" and "Confusion between Methylphenidate and Methadone, Patient Care 2003, Jan 15:76."

Dr. Roselle earned a Doctor of Pharmacy from the University of Maryland (with Honors) and a B.S. in Biology with a Chemistry Minor from the University of Akron (Cum Laude).

José-Ángel Ferrero, Pharm.D., M.Sc. - Vice President, EU Regulatory Affairs & Safety Research

Dr. Ferrero joined DSI - London in 2017 as Drug Safety Institute - Vice President, EU Regulatory Affairs & Safety Research. Prior to joining DSI, he was a Labeling Specialist and Scientific Administrator of the **Name Review Group (NRG) – European Medicines Agency (EMA)** for over 5 years, the group that is **responsible for evaluating and approving invented names** submitted to the Agency via the centralized procedure. In his role at EMA, he was responsible for the drafting and handling of revision 6 of the 2014 "Guideline on the acceptability of names for medicinal products processed through the centralized procedure."

Dr. Ferrero managed all aspects related to the activities and work of the NRG, including the preparation of NRG meetings, support to the NRG Chair before, during and following NRG meetings, preparation of agendas and minutes, preparation of all internal/external correspondence and preparation of reports/memos on NRG related Member States correspondence for invented name submissions, reviews and approvals. He proposed and developed a decision tool for the evaluation/discussion of objections due to orthographic and phonetic similarity. This tool has led to a consistent approach to the discussion of objections with the NRG and was integrated in EMA's name review process in 2015. As labeling specialist, he was responsible for the management of the labeling review and Quality Review of Documents (QRD) standards' check of Summaries of Product Characteristics, Labeling and Package Leaflet for assigned product portfolio. He also drafted the EMA's policy "Quick Response (QR) codes in the labeling and package leaflet of centrally authorized medicinal products."

Dr. Ferrero earned his post-graduate Pharm.D. degree in Clinical Pharmacy (secondary care) from the University of Bradford, UK and his B.Sc. in Pharmacy from the University of Salamanca, Spain. Prior to joining EMA, he accomplished senior clinical pharmacist roles at Sheffield Teaching Hospitals, UK.