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Where Safe Names Begin!

EMA NRG, FDA DMEPA & Health Canada MHPD Naming Officials Join Drug Safety Institute in 2017

José-Ángel Ferrero, Pharm.D., M.Sc.

Vice President, EU Regulatory Affairs & Safety Research - London

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 (brand) 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 labelling specialist, he was responsible for the management of the labelling review and Quality Review of Documents (QRD) standards' check of Summaries of Product Characteristics, Labelling 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."

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

Carol Holquist, R.Ph.

Vice President Global Naming, Labeling & Human Factors - Rockville

Ms. Holquist joined DSI – Rockville in 2017 as Vice President, Global Naming, Labeling and Human Factors. Prior to joining DSI, Ms. Holquist recently retired as Deputy Director of the Office of Regulatory Operations in the Office of Generic Drugs at the Food and Drug Administration (FDA), Center for Drug Evaluation & Research (CDER). **She was responsible for the final evaluation and approval of all abbreviated new drug applications (ANDAs).** She has 24 years of FDA experience, 14 of which are in the field of medication error prevention. For 9 years she was Division Director, 2 years as Deputy Director, and 3 years as Safety Evaluator for the Division of Medication Error Prevention and Analysis (DMEPA) in OMEPRM, CDER, FDA. She was **responsible for the final approval of manufacturer's drug/biologic brand names, and human factors/medication error evaluation of 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.

Scott Sawler, B.Sc., LL.B., LL.M., M.B.A.

Managing Director, Canadian Regulatory Affairs - Ottawa

Mr. Sawler joined DSI - Ottawa as Managing Director, Canadian Regulatory Affairs in 2017. 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 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.

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