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BRANDNEWS

DrugSafetyInstitute
A Subsidiary of BRAND INSTITUTE, inc.
Where Safe Names Begin!

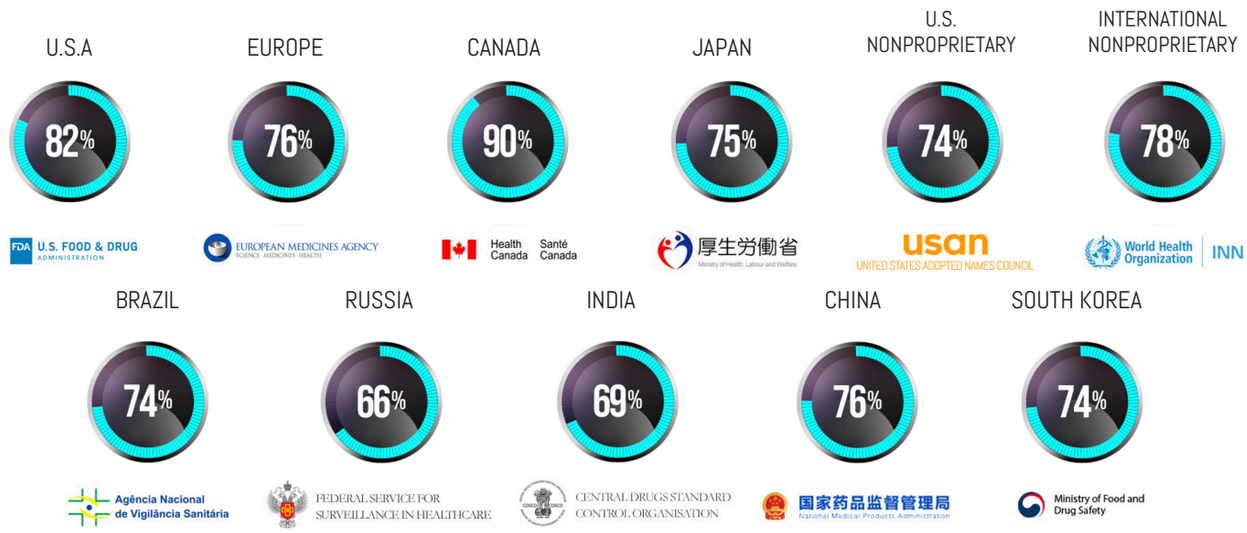
Brand Institute is proud to have partnered with 850 healthcare companies on over 3,100 names, including 25 FDA approved biological suffixes!

Highlighted by select experience listed below:

Genentech POLIVY™ polatuzumab vedotin-piiq "piiq" Oncology	Celltrion Herzuma® (trastuzumab-pkrb) "pkrb" Oncology	Pfizer Ruxience™ rituximab-pvvr "pvvr" Oncology
Pfizer Zirabev™ bevacizumab-bvzr "bvzr" Oncology	Aimmune Palforzia™ Peanut (*Arachis hypogaea*) Allergen Powder-dnfp "dnfp" Immunology	AveXis zolgensma® (onasemnogene abeparvovec-xioi) "xioi" Gene Therapy
Portola Andexxa® Coagulation Factor Xa (Recombinant), Inactivated – zhzo "zhzo" Hematology	Endo Global Aesthetics Qwo™ collagenase clostridium histolyticum-aaes "aaes" Aesthetics	Biomarin Palynziq® (pegvaliase-pqpz) Injection "pqpz" Immunology
Novartis Beovu® (brolucizumab-dbll) "dbll" Ophthamology	Horizon Therapeutics Introducing TEPEZZA™ teprotumumab-trbw "trbw" Ophthamology	Viela Bio uplizna™ inebilizumab-cdon "cdon" Ophthamology

Contact your local Brand Institute Office to discuss our experience and capabilities in developing biological suffixes, brand names, devices, programs and more!

BRAND INSTITUTE/DRUG SAFETY INSTITUTE 2019 GLOBAL SHARE OF MARKET NAME APPROVALS



DRUG SAFETY INSTITUTE (DSI) NAMING EXPERTS

Global Regulatory Expert

Todd Darwin Bridges, R. Ph.
Global President
Drug Safety Institute

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 a B.S. in Pharmacy from Virginia Commonwealth University's Medical College.

U.S. Regulatory Experts

Nora Roselle, Pharm.D.

President, U.S. Regulatory Affairs
Drug Safety Institute

Dr. Roselle joined DSI - Rockville as Managing Director of U.S. Regulatory Affairs in 2007, promoted in 2012 to Vice President, Global Regulatory Affairs and most recently promoted to President, U.S. 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.

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).

U.S. Regulatory Experts (cont.)

Cristina Milesi, Pharm.D.

Vice President, Safety Research
Drug Safety Institute

Dr. Cristina Milesi joined BI - Miami in 2014 as a Drug Safety Evaluator. Prior to joining Brand Institute she worked in various roles in retail pharmacy in Italy. In 2017, Dr. Milesi was promoted to Manager of Safety Research and to her current position of Vice President of Safety Research.

Dr. Milesi received her PharmD from the University of Milano, College of Pharmacy.

Europe Regulatory Experts

Ioannis (Nakos) Balamotis, Pharm.D.

President, EU Regulatory Affairs
Drug Safety Institute

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

Europe Regulatory Experts (cont.)

José-ángel Ferrero, Pharm.D., M.Sc.

Vice President, EU Regulatory Affairs & Safety Research
Drug Safety Institute

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. 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.

Dr. Ferrero earned a post-graduate Pharm.D. degree in Clinical Pharmacy (secondary care) from the University of Bradford, UK and a 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.

Baptiste Lacoustille, Pharm.D., M.S.

Drug Safety Evaluator
Drug Safety Institute

Dr. Lacoustille joined BI - Basel in 2017 as Vice President, Brand Development and was promoted to Drug Safety Evaluator in 2019. Prior to joining BI, he worked in the Labeling Review and Standards Office at the European Medicines Agency (EMA) in London, UK. In this role Baptiste participated in Name Review Group (NRG) meetings, and was responsible for researching, analyzing and preparing for the review and acceptability of invented names for medicinal products according to the EMA 2014 NRG Guidelines. Baptiste reported directly to the NRG Chairperson, the head of the division responsible for evaluating and approving invented names submitted to the agency via the centralized procedure.

Dr. Lacoustille's additional responsibilities at the EMA included reviewing the quality of product information (SmPC, package leaflet, labeling) according to QRD (Quality Review of Documents) standards for centrally authorized medicines in different therapeutic areas. He was appointed "Labeling Specialist" for the Immunosuppressants Product Portfolio where he served as an integral member of an "EMA Product Team" made up of various experts, providing labeling advice to pharmaceutical companies at pre-submission, assessment and post-authorization stages. Prior to his time at the EMA, he served in Regulatory Affairs at GlaxoSmithKline and in Regulatory Compliance at LFB Biomédicaments.

He earned his Pharm.D. and Master's degree in "International Regulatory Environment of Healthcare Industries and Health Products" from Montpellier University (UM).

Latin & South American Regulatory Expert

Domenica Redeschi, R.Ph.

Director, Brazil & Latin America Regulatory Affairs
Drug Safety Institute (DSI)

Dr. Redeschi joined BI - Miami as a Drug Safety Evaluator in 2015 and was promoted to Coordinator, South American Division in 2018. Prior to joining BI, she was in retail pharmacy with CVS for ten years. She graduated from UMC Pharmacy School in São Paulo, Brazil in 2000, and became a registered pharmacist in the United States in 2009. In 2012, she received her Consulting Pharmacist license and, in early 2018, she became certified in Brazilian Regulatory Affairs. In April 2019, Ms. Redeschi was a speaker at the OTC Seminar promoted by Anvisa and ABIMIP and in October of that year she was a speaker at the Naming Development Seminar promoted by Anvisa and Sindusfarma.

Dr. Redeschi has led the regulatory and safety research efforts for dozens of Brazilian and Latin American projects, highlighted by recent ANVISA approvals that include GSK's Trelegy, EMS' Bexai, Seqirus' Flucelvax, and Daiichi-Sankyo's Lixiana.B.Sc. from the Centro Universitário São Camilo.

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Canada Regulatory Expert

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

President, Canadian Regulatory Affairs
Drug Safety Institute

Mr. Sawler joined Brand Institute's regulatory subsidiary, Drug Safety Institute (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.

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.

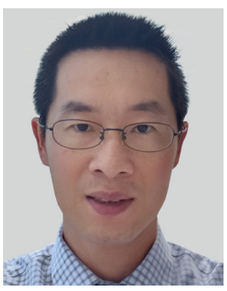
Japan Regulatory Expert

Shimpei Miyano, Pharm.D., M.P.A.

Director, Safety Research
Drug Safety Institute

Dr. Miyano joined Brand Institute -Tokyo as Director in 2015 and joined the DSI team at the Miami Headquarters office as Drug Safety Evaluator in 2016. He was promoted to Team Lead in 2018 and Director of Safety Research in 2020. Dr. Miyano is bilingual in Japanese and English and provides pharmaceutical regulatory strategy and guidance for products submitted to Ministry of Health, Labour and Welfare of Japan. In addition, he coordinates market & safety research projects for Brand Institute's 17 BI global offices. Prior to joining Brand Institute, he worked in various roles of retail pharmacy in Iowa, Missouri and Illinois. He earned his Doctor of Pharmacy (Pharm.D.) and Master of Public Administration (MPA) from Drake University.

China Regulatory Expert



Charles Wang, Pharm.D., R.Ph., M.B.A.

China, Drug Safety Evaluator, Team Lead
Drug Safety Institute

Dr. Wang joined DSI – Miami as a Drug Safety Evaluator in 2018. Dr. Wang was promoted to Drug Safety Evaluator Team Leader in 2019. In this role, his responsibilities include the review and management of drug nomenclature safety research projects. Charles also provides regulatory strategy and guidance to the pharmaceutical industry for products submitted to China's National Medical Products Administration. He is fluent in Mandarin and provides name transliteration and/or translation for products that will be marketed in China. Prior to joining DSI, Charles was employed by Johnson & Johnson in Taipei, Taiwan and has retail pharmacy practice experience in California and Florida. Dr. Wang earned a Doctor of Pharmacy from Nova Southeastern University, M.B.A. from University of Illinois at Chicago, and B.S. in Pharmacy from National Taiwan University.

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