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November 6, 2020 JANSSEN	October 26, 2020 NOVO NORDISK	October 13, 2020 ROCHE
October 10, 2020 SANDOZ	September 21, 2020 JANSSEN	September 9, 2020 JANSSEN
August 8, 2020 ASTRAZENECA	July 20, 2020 ALNYLAM	May 5, 2020 TAIHO
May 4, 2020 PFIZER	April 6, 2020 LUNDBECK	February 26, 2020 SEQIRUS

DRUG SAFETY INSTITUTE (DSI) NAMING & LABELING EXPERT SPOTLIGHT



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.



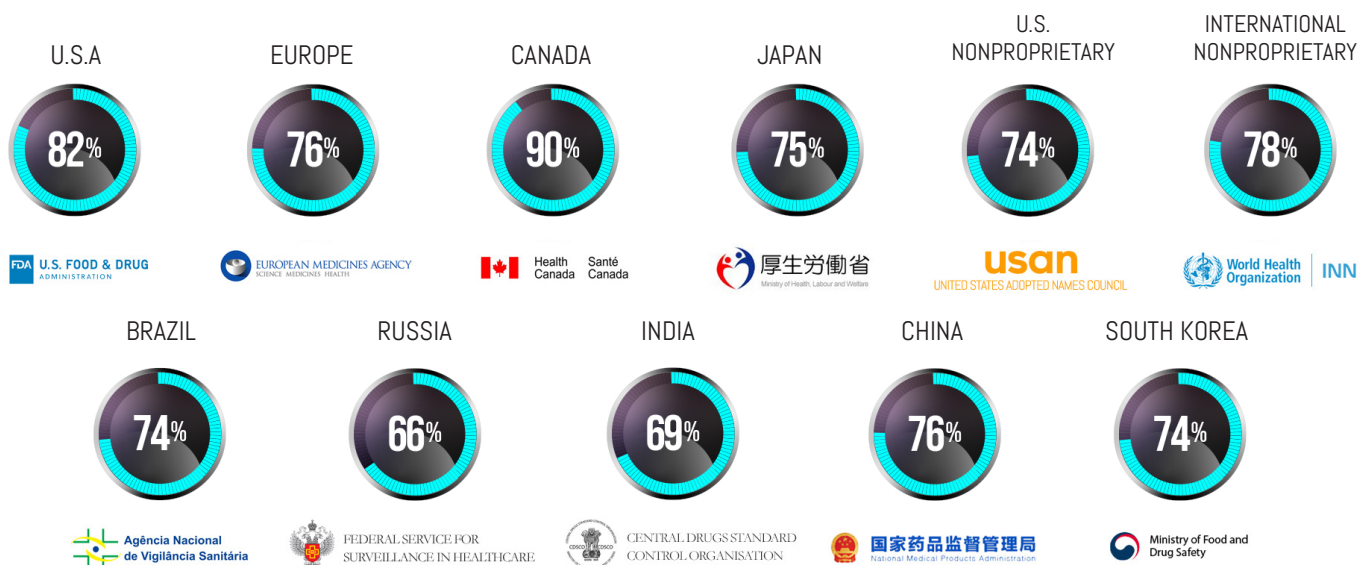
Domenica Redeschi, R.Ph.

Director, Brazil & Latin America Regulatory Affairs
 Drug Safety Institute

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' Flucelvac, and Daiichi-Sankyo's Lixiana. B.Sc. from the Centro Universitário São Camilo..

BRAND INSTITUTE'S 2019 GLOBAL SHARE OF MARKET NAME APPROVALS



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OTTAWA (613) 482-1333	RALEIGH-DURHAM (919) 572-9311	ROCKVILLE (301) 984-1055	SAN FRANCISCO (415) 421-3200	SÃO PAULO +55 11 945-364-083	SEATTLE (206) 204-5111	SEOUL +82 6433-9555	TOKYO +81(03) 6861-7517	TORONTO (416) 622-5777