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Your Local Brand Institute Account Management Team

7 Years with BI

Kyu (Kurt) Yoon, R.Ph. - Vice President, Brand Development

Kyu (Kurt) Yoon, R.Ph. - Vice President, Brand Development Mr. Yoon joined BI - Seoul in 2015 as Associate Director, Brand Development. Prior to Brand Institute, Mr. Yoon was a Global Regulatory Affairs Manager at Daewoong Pharmaceutical and a Licensing & Business Development Manager at Kukje Pharmaceuticals. Mr. Yoon earned his B.S in Genetics, PGDip-Sci and Bachelor of Pharmacy from the University of Otago. He is a registered Pharmacist in Australia and New Zealand. He has led over70 Nonproprietary (USAN/INN) projects, including efineptakin alfa, fexuprazan, rivoceranib, and timbeta-sin, and 52 Global Brand Naming projects, highlighted by Celltrion's biosimilar brands Yuflyma, Remsima, Herzuma and Truxima.

6 Years with BI

Joohan (John) Song, Pharm.D., M.S. - Vice President, Brand Development

Joohan (John) Song, Pharm.D., M.S. - Vice President, Brand Development Dr. Song joined BI - Seoul as Associate Director, Brand Development in 2016, and was promoted to Vice President, Brand Development in 2019. Prior to Brand Institute, Dr. Song was a Clinical Project Leader at Daewoong Pharmaceutical and a Clinical Pharmacist at Seoul National University Hospital. He earned his B.S. in Pharmaceutical Science and Doctor of Pharmacy (Pharm.D.) from the University of Con-necticut and his M.S. in Clinical Pharmacy from the Seoul National University. He is a registered Pharmacist of the Republic of Korea and United States of America. He has led over 70 Nonproprietary (USAN/INN) projects, including delpazolid, epaminurad, mosedipimod, olinvacimab, and telacebec, and 52 Global Brand Naming projects, including the biosimilar brands of Prestige Bio Pharma and umbrella vaccine brands for Green Cross.

Your Brand Institute Full-Time Operations Project Team

18 Years with BI

Jerry Phillips, R.Ph. - President, Regulatory Strategy

Mr. Phillips created and opened Brand Institute's (BI) regulatory subsidiary, Drug Safety Institute (DSI), in 2004 as President& CEO. Since joining BI he has worked on approximately 9,000 naming and regulatory projects with our clients and has continuously expanded DSI to be fully compliant with FDA, EMA, Health Canada, and other regulatory authorities' guidance. Prior to joining BI, he worked at the FDA for 16 years where he became the spokesman for FDA in preventing medication errors related to naming and labeling issues. He also became a Division Director approving generic drug products and became the first Division Director of what's known today as DMEPA, establishing FDA's original brand name testing methodology. In 2018, Mr. Phillips was promoted to President, Regulatory Strategy, providing assistance and expertise to our clients and BI's 20 global local account teams with worldwide regulatory issues related to strategy and submission requirements. Mr. Phillips earned a B.S. in Pharmacy from the University of Houston.

3 Years with BI

Joe Bazerghi - Vice President, Commercial Research & Strategy

Mr. Bazerghi joined BI - Miami as Vice President, Brand Development in 2020 and was recently promoted to Vice President, Commercial Research & Strategy. Prior to joining Brand Institute, Mr. Bazerghi was Vice President of Marketing at Alker-mes where he was the commercial lead for marketing, brand strategy and lifecycle development for numerous brands, including the Brand Institute partnered brands Aristada and Aristada Initio. Prior to that, he served as Senior Director of New Product Planning, responsible for integrating Therapeutic Thought Leader involvement in product planning decisions and serving as the commercial lead for multiple clinical-stage medicines in Addiction, Schizophrenia, Major Depressive disorder, Bipolar I disorder, Binge Eating disorder, Pain, Multiple Sclerosis, Opioid-induced Constipation and Parkinson's disease. Earlier in his career, he worked in award-winning marketing strategy and product management roles at Gilead Sciences, Abbott Laboratories (now AbbVie) and GSK, partnering on and overseeing the commercial development and marketing activities of numerous Brand Institute partnered brands, including the antiviral brands Hepsera, Viread, Norvir, Epivir, Kaletra and Synagis, the cardiovascular brand Tricor, the blockbuster brand Humira, the anti-infective brand Biaxin, and the anti-migraine brand Imitrex. He earned a B.B.A. from Université du Québec, Montréal, Canada.

19 Years with BI

Scott Piergrossi - President, Creative

Mr. Piergrossi joined BI - Miami in 2003. As President, Creative, Mr. Piergrossi is Brand Institute's lead creative naming and brand name strategy official. He has led over 5,400 branding and naming initiatives during his 19 years with Brand Institute, developing creative nomenclature for a multitude of large, midsize and startup healthcare and consumer/B2B clients. He is proficient in the disciplines related to the creation and marketing of brands, including strategy, positioning, trademark law and regulatory affairs. In his previous role as President, Operations & Communications, Mr. Piergrossi led Brand Institute's Miami-based operations and global corporate communications. He continues to serve as head of media relations for BI. Mr. Piergrossi received his B.A. in Advertising from Barry University in Miami.

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Your Brand Institute Full-Time Operations Project Team (Cont.)

9 Years with BI

Alexa Lash - Senior Vice President, Creative Nomenclature

Ms. Lash joined BI - Miami in 2013 and serves as both a leader in innovation across the company, and as an expert in specialty creative projects ranging from brand strategy recommendations to live creative sessions. Ms. Lash has led over 2,700 creative naming, brand architecture and naming strategy projects during her tenure with Brand Institute. Before joining BI, she worked as a Social-Media & Marketing Coordinator and as a freelance writer and editor. She has a Bachelor of Arts degree in Creative Writing from the University of Central Florida, and her Master of Arts degree in Publishing and Writing from Emerson College in Boston.

14 Years with BI

Sanae Suga, LL.B., M.B.A. – Vice President, Creative Nomenclature

Ms. Suga joined BI - Miami in 2008 and serves as a leader in the department, and as the foremost expert in name development for Japan, specializing in any projects that require katakana transliteration and language translation. Ms. Suga is bilingual, speaking and writing fluently in English and Japanese, and has spearheaded 2,200 creative naming and brand strategy recommendations for hundreds of Japanese name-related projects over the course of her tenure. In addition to her work with Japan, she also supports all global projects across the company. Ms. Suga earned her Bachelor's Degree in Law from Rissho University, Japan, and her Master of Business Administration in International Business from Florida Metropolitan University, US.

21 Years with BI

Rogelio Reyes, Esq. - General Counsel & Head of Trademarks

Mr. Reyes joined BI - Miami in 2001. He oversees Brand Institute's trademarks department. He has led over 5,000 branding initiatives during his 20 years with Brand Institute for a multitude of large, midsize and startup healthcare and consumer/B2B clients. Mr. Reyes received his B.A. from the University of Chicago and J.D. from Tulane University School of Law in New Orleans.

1 Year with BI

Timothy J. Gaul, Esq. - Vice President, Intellectual Property Strategy

Mr. Gaul joined Brand Institute as Vice President, Intellectual Property Strategy and has over 33 years of experience as in-house intellectual property counsel in the pharmaceutical industry where he worked on over 150 nomenclature assignments. His career started at Bristol-Myers Squibb where he spent 9 years as a patent attorney. Then for the next 24+ years he was with Amgen where he rose to the role of Associate General Counsel and Executive Director. There he worked on trademark development, clearance, prosecution, opposition, and regulatory submission for some of Amgen's biggest brands including Enbrel, Neulasta, Prolia, Xgeva and Aranesp to name a few. He also has extensive experience regarding patents, nonproprietary names, clinical trial names, copyrights, internet domains, and intellectual property licensing and acquisition agreements. He earned a B.S. from Pennsylvania State University and a J.D. from the Dickinson School of Law.

2 Years with BI

Steve Anderson - Vice President, Trademarks & Brand Development

Mr. Anderson joined BI - New York as Vice President, Trademarks & Brand Development in 2021. He is an expert in brand establishment, IP product management, IP software solutions and pharmaceutical name clearance. He has extensive experience, both inside and outside the pharmaceutical industry, developing customer-focused solutions and technologies that automated project workflows and improved the trademark filing and clearance process. Prior to joining Brand Institute, he served for 12 years at Corsearch, most recently as Director of Product Management, where he directed product development and lifecycle initiatives globally and set forth the vision and strategy for Corsearch's online trademark screening global platforms. He served for 7 years at Pfizer/Wyeth, as Senior Trademark Specialist and Trademark Analyst.

During his time at Pfizer and Wyeth, he was recognized for his innovation in technology workflow solutions in the pharmaceutical trademark establishment process, and administrated large trademark portfolios, working on major brands such as CELEBREX, EFFEXOR, ADVIL, ENBREL, PREMARIN, CENTRUM, ZOSYN, PROTONIX, RAPAMUNE, PREVNAR, and many others. Steve has collaborated on numerous product naming projects with cross-functional teams as a trademark professional and product manager. He earned a B.A. from University of Iowa, received his Master's Certification in Applied Project Management from Villanova University, and has a level 6 Pragmatic Marketing certification.

9 Years with BI

Luisanna Mejia, M.B.A. - Vice President, Brand Development & Market Research

Ms. Mejia joined BI - Miami in 2013 as an Administrative Assistant. In November of 2014 Ms. Mejia joined the Market Research team as a Market Research Analyst and was later promoted to Market Research Team Lead. In 2017 she was promoted to Vice President of Market Research, where she oversaw research projects worldwide. During her tenure at Brand Institute, Ms. Mejia has worked on 3500+ global nonproprietary and brand name development initiatives encompassing multiple therapeutic areas and industries. In 2022, Ms. Mejia was promoted to Vice President, Brand Development. Ms. Mejia earned a B.A. in Public Relations and a M.B.A. in Advertising from Barry University.

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Your Brand Institute Full-Time Operations Project Team (Cont.)

8 Years with BI

Cristina Milesi, Pharm.D. - Vice President, Safety Research

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, Safety Research working on over 2,500 safety research initiatives. Dr. Milesi received her Pharm.D. from the University of Milano, College of Pharmacy.

22 Years with BI

Amauris Diaz - Senior Vice President, Visual Identity

Mr. Diaz joined BI – Miami in 2000 as Creative Assistant Manager and then moved to Senior Webmaster in 2004. Mr. Diaz was promoted to Senior Vice President, Visual Identity in 2019 and oversees a team of creative designers and has been involved in over 750 logo, packaging and website development projects. Mr. Diaz has over 20 years of experience in Art & Advertising Design and website development.

16 Years with BI

Juan Guillen - Vice President, Visual Identity

Mr. Guillen joined BI - New York in 2006. As Design Director, Visual Identity, Mr. Guillen has successfully orchestrated a team of talented graphic designers in developing over 600 global pharmaceutical and consumer brands. He has a robust background in logo development, identity system, branding, strategic design, presentations and packaging. With 15 years of experience, Mr. Guillen has designed prestigious brands that include, ViiV healthcare, Johnson & Johnson's Triple Baby Protection, Seqirus, Rezurock, DayClear's product line, and most recently Organon. He earned his B.A. in Electronic Design and Multimedia from The City College of New York.

5 Years with BI

Beckem Lacayo – Vice President, Digital Media & Design

Mr. Lacayo joined BI - Miami in 2017 as a Digital Design Director and was promoted to Vice President, Digital Media & Design in 2022. Mr. Lacayo has worked on numerous website including the development and processes of websites at BI. He has an extensive knowledge of Digital Media and has helped in brining animation and videos to life at Brand Institute. With 15 years of website experience and 8 years of Digital Media experience. He earned his B.A. in Information Technology from Florida International University.

Your Drug Safety Institute Full-Time Operations Project Team

4 Years with BI

Todd Darwin Bridges, R. Ph. - Global President

Mr. Bridges joined Drug Safety Institute (DSI) - Rockville, the Regulatory Affairs subsidiary of Brand Institute (BI) 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 FDA's DMEPA, Mr. Bridges supervised the review of approximately 500 proprietary names each year, and since joining DSI has overseen 1,119 brand naming projects.

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 guidance 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.

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Your Drug Safety Institute Full-Time Operations Project Team (Cont.)

15 Years with BI

Nora Roselle, Pharm.D. - President, U.S. Regulatory Affairs

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).

8 Years with BI

Ioannis (Nakos) Balamotis, Pharm.D., B.Sc. - President, EU Regulatory Affairs

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

5 Years with BI

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 (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 Salamanca, Spain and his BSc in Pharmacy from the University of Bradford, UK. Prior to joining EMA, he accomplished senior clinical pharmacist roles at Sheffield Teaching Hospitals, UK.

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Your Drug Safety Institute Full-Time Operations Project Team (Cont.)

5 Years with BI

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

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 stream¬lined 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.

17 Years with BI

Sophia Fuerst, M.S., M.B.A. - President, Nonproprietary Names Division

Ms. Fuerst joined Drug Safety Institute's Nonproprietary (USAN/INN) Names Division as Managing Director in 2005, and was promoted to President in 2007. Ms. Fuerst was formerly Director of the USAN Program at the American Medical Association (AMA) and served in various positions during her 18-year tenure with the Program, including AMA senior staff scientist in the area of Drug Nomenclature. She was involved in negotiations between the USAN Council, pharmaceutical manufacturers, and foreign nomenclature agencies. From 1986 to 2005, Ms. Fuerst was responsible for reviewing submissions, classifying compounds, creating new stems when appropriate and approving and adopting new USAN names. Ms. Fuerst worked as a consultant, from 1999-2000, to the Secretariat of the INN Programme at the World Health Organization (WHO/INN) in Geneva, Switzerland. Ms. Fuerst holds a B.S. in Biology/Chemistry (pre-med) from St. Joseph's College, an M.S. in Medicinal Chemistry from the University of Chicago and an M.B.A. from Governor's State University in Illinois.

16 Years with BI

Sandra Van Laan, B.S. - Vice President, Regulatory Affairs, Nonproprietary Names Division

Ms. Van Laan joined Drug Safety Institute's Nonproprietary (USAN/INN) Names Division as Vice President, Regulatory Affairs, Nonproprietary Division in 2006, and was promoted to Senior Vice President, Regulatory Affairs, Nonproprietary Names Division in 2022. Prior to joining DSI, she worked for 26 years at the American Medical Association (AMA). Ms. Van Laan was the Associate Secretary to the United States Adopted Names (USAN) Council and a Senior Research Associate at the AMA within the Division of Science and Technology where she provided pharmaceutical expertise to AMA staff for several publications including Current Medical Information and Technology (CMIT), Current Procedural Technology (CPT) and the Journal of the American Medical Association (JAMA). In her role with the USAN Program she provided structural and mechanistic compound analysis to accurately categorize newly submitted names into the appropriate stem classification and shared the responsibility for devising new stems within the taxonomy of nomenclature, when appropriate. The AMA USAN Program is responsible for evaluating and approving nonproprietary names. She supplied guidance to pharmaceutical companies on the preparation of submissions to the USAN Council and negotiated name candidates with the members of the USAN Council and INN Expert Committee to obtain scientifically appropriate nonproprietary names for worldwide use. Ms. Van Laan has worked closely with the Food and Drug Administration (FDA), Center for Biologics, Evaluation and Research (CBER), and the United States Pharmacopeial (USP) Convention for the standardization of nonproprietary nomenclature and has participated in regulatory strategic planning sessions and intellectual property protection discussions pertaining to nonproprietary names. Ms. Van Laan co-chaired the Pronunciation Committee that developed the USAN Pronunciation Guidelines that are in use today.

BRAND INSTITUTE'S 2021 GLOBAL SHARE OF MARKET NAME APPROVALS