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Global Labeling Conference

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Print Agenda

Day 1 Apr 03, 2025

10:00 AM — 2:00 PM

Global Labeling – The Basics of Core Datasheet

Session Chair(s)

Gerrit Nijveldt, MS, MSc

Global Labeling Consultant
Opus Regulatory Inc., United States

Gerrit Nijveldt is currently Labeling consultant with Opus Regulatory. Gerrit has more than 25 years of experience in Global labeling. He has a broad experience in developing and maintaining Company Core Data Sheets, US Prescribing Information and EU Summary of Product Characterisation, including the labeling for multiple development products (early phase to approval) and labeling for devices. Gerrit was also an associate adjunct professor for Temple University School of Pharmacy teaching Global Labeling in the RA/QA

Master's Program till 2022. Gerrit earned his MSc in Medical Biology from University of Utrecht in the Netherlands

Day 2 Apr 07, 2025

7:30 AM — 5:35 PM Ballroom Foyer

Meeting Registration

7:30 AM — 8:15 AM Ballroom Foyer

Networking Breakfast

8:15 AM — 8:30 AM F. Fitzgerald Ballroom CDE

Welcome and Opening Remarks

8:30 AM — 10:00 AM F. Fitzgerald Ballroom CDE

Session 1: Last One Mile for e-labeling: Accelerating Health Innovation with e-labeling and Healthcare Interoperability

E-labeling initiatives have seen significant acceleration across regions with a focus on leveraging international common electronic standard to advance health innovation and enhance healthcare interoperability. In the US, FDA has developed SPL-FHIR Implementation Guide and is planning to implement FHIR e-labeling. Similarly, in the EU, the technical pilot for FHIR e-pi concluded in 2024, with its implementation currently in planning. Other regions, such as Jordan, have also made considerable progress in FHIR e-labeling adoption.

This session will provide a comprehensive update on the latest advancements in FHIR e-labeling initiatives for FDA SPL-FHIR and EMA's e-pi implementations. Global progress in e-labeling adoption will also be explored, along with practical insights into what the industry needs to prepare for the FHIR e-labeling implementation. In addition, the session will discuss the broader applications e-labeling and healthcare interoperability to foster health innovation.

Learning Objective :

- Describe the current status of FDA and EMA's FHIR e-labeling initiatives
- Gain insights into the progress of FHIR e-labeling initiatives worldwide
- Identify industry preparation steps for the upcoming implementation of FHIR e-labeling
- Discuss the utilization of e-labeling and healthcare interoperability for driving health innovation

Track: General Session

Session Chair(s)

Rie Matsui, RPh

Senior Director, Regional Labeling Head for APAC, International Labeling
Pfizer R&D Japan G.K., Japan

Rie Matsui is Senior Director, Regional Labeling Head for APAC, International Labeling Group, Global Regulatory Science, Pfizer Japan. She is also the Head, External Engagements for ILG. She is the founder of Asia Labeling Hub at Pfizer that has created various local label updates for more than 25 countries in Asia. She was a member of the Advisory Council of DIA Japan until 2020 and received the DIA Japan regional award in 2015. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. She is the vice chair of the 2021 DIA Japan Annual Meeting Program Committee. She received DIA Global Inspire Award Connector in 2022. She is teaching at Keio University and Chiba University and is a pharmacist.

Deborah Bebbington

Head Global Labeling
Bayer Plc, United Kingdom

Deborah has been working in the Pharmaceutical Industry for over 25 years. She began her career in Research before moving into Regulatory Affairs. During her tenure at Bayer Deborah worked in the UK affiliate, as an EU liaison, set up a new global RA department focusing on the RA support for Mature products and headed the International RA department before moving to her current position 12 years ago. She is currently VP and Head of Global Labeling at Bayer.

Speaker(s)

FHIR ePI Implementation: Present and Future Progress

Craig Anderson

Director, R&D Labeling Lead, International Labeling
Pfizer Inc , Canada

As Director, R&D Lead at Pfizer, Craig Anderson is responsible for research, development, business and process-related functions across the International Labeling organisation. This includes topics such as electronic labelling, medicinal product information, digital health, and data standards. Craig is also Co-lead of HL7's Vulcan accelerator project for electronic Product Information (ePI) and co-lead for HL7's Pharmaceutical Quality (Industry) project.

How will ePI Enable Patient Centricity?

Juan Garcia-Burgos, MD, PhD

Head of Public and Stakeholders Engagement Department
European Medicines Agency, Netherlands

Juan García Burgos is a Qualified Medical Doctor from Autonoma University in Madrid, specialised in urology. Juan worked as a urologist surgeon at the Maranon hospital in Madrid. He joined the European Medicines Agency in 2002 and was responsible for coordinating the preparation of EU clinical guidelines for drug development. In 2005 he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and Healthcare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences. In 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.

Electronic Product Information · ePI

Rabi Mohd, PharmD

IT Specialist · Drug Directorate
Jordan Food and Drug Administration, Jordan

Mohd Rabi works for Jordan FDA, the comprehensive consumer protection agency in Jordan that manages and regulates pharmaceutical industry. Rabi supervises IT related operations in the drug directorate. He has over 25 years of experience as full-stack developer. Artificial Intelligence (AI) and Image Processing are the main fields of interest. Rabi is currently working on the ePI project, which provides access to official, up-to-date, and approved medicinal information.

10:00 AM — 10:45 AM Ballroom Foyer

Refreshments, Exhibits, and Networking Break

10:05 AM — 10:35 AM F. Fitzgerald Ballroom B

Non-CE: Case Study Spotlight by Dr. Evidence – How BioNTech Uses AI-Enabled Labeling Intelligence to Drive Global Strategy

Regulatory Affairs leaders play a central role in shaping strategy to get products to market and maintain them there. This session will explore how the strategic use of an AI-enabled landscape intelligence platform supports Global Regulatory and Labeling professionals in their roles as leaders and effectively supports other key departments such as Safety in their work. Dr. Suzette Hildenbrand, Vice President, Global Regulatory Affairs, Head of Global Labeling for BioNTech, will

educate the audience on how to leverage an AI-enabled solution to develop a global labeling strategy across the entire product lifecycle, to ensure you are prepared and proactive in your approach to Health Authorities, and to more rapidly and confidently generate comprehensive and accurate insights for internal and external stakeholders.

Featured Topics

- How to leverage an AI-enabled landscape labeling intelligence solution to lead the organization more broadly and drive global Labeling strategy
- How to successfully introduce an AI-enabled solution to deliver significant tactical efficiencies in generating landscape intelligence
- How to more effectively engage Health Authorities and de-risk your approach based on a comprehensive and contemporary view of the global landscape

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Speaker

Suzette Hildenbrand, PharmD

Vice President, Global Regulatory Affairs, Global Labeling
BioNTech, United States

Suzette Hildenbrand is a strategic Labeling leader with over 25 years of experience in the pharmaceutical industry. She established and currently leads the GRA Global Labeling function at BioNTech. Prior to that she was at Wyeth then Pfizer for over 20 years and has a proven track record of driving the strategic direction of product information across the product lifecycle. With expertise in Labeling Strategy, she has set a high standard for managing Labeling and has led many cross-functional and global Labeling initiatives. Suzette leads with a clear vision, ensuring compliance and timely updates of robust product information and champions the resolution of critical issues through fostering collaboration with Health Authorities globally.

10:45 AM — 12:00 PM F. Fitzgerald Ballroom CDE

Session 2: Patient Centric Labeling for Shared Decision-making in Healthcare

Nowadays patients often search for product information online, where they may encounter inaccurate and outdated information, since the sources are not always reliable. To empower patients to be active participants in their healthcare

plan and enable shared decisions with their healthcare providers, it is essential to develop patient-centric labeling that prioritizes health literacy. This session will explore the patient needs for product information and discuss the best practices for developing patient-centric labeling that incorporates health literacy principles. In addition, this session will also highlight the importance for leveraging digital labeling initiatives to enhance patient access to reliable information in a patient friendly method.

Learning Objective :

- Discuss the components and best practices for incorporating health literacy testing into labeling
- Describe the strategies for effective utilization of digital patient labeling
- Identify the current challenges in ensuring patients receive accurate and accessible information through active patient participation and digital initiatives

Track: General Session

Session Chair(s)

Rie Matsui, RPh

Senior Director, Regional Labeling Head for APAC, International Labeling
Pfizer R&D Japan G.K., Japan

Rie Matsui is Senior Director, Regional Labeling Head for APAC, International Labeling Group, Global Regulatory Science, Pfizer Japan. She is also the Head, External Engagements for ILG. She is the founder of Asia Labeling Hub at Pfizer that has created various local label updates for more than 25 countries in Asia. She was a member of the Advisory Council of DIA Japan until 2020 and received the DIA Japan regional award in 2015. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. She is the vice chair of the 2021 DIA Japan Annual Meeting Program Committee. She received DIA Global Inspire Award Connector in 2022. She is teaching at Keio University and Chiba University and is a pharmacist.

Brandon Stempo, MS

Practice Leader Regulatory Labeling
Opus Regulatory Inc, United States

Brandon has spent more than 15 years in the life sciences industry with most of his experience focused on global labeling. Prior to joining Opus, he was the head of global labeling at Ultragenyx where he implemented end-to-end global labeling processes, led label content generation and oversaw global regulatory approvals for multiple programs starting from CCDS development through lifecycle management. He has worked at companies including Sanofi, Daiichi Sankyo and Amicus Therapeutics which has helped him develop labeling expertise across a broad range of therapeutic areas.

Speaker(s)

Labeling People Does Not Help Medicine Labeling

Karel Martinus van der Waarde, PhD, MA

Lecturer
Lucerne University of Applied Sciences and Arts, Switzerland

Karel van der Waarde studied graphic design in the Netherlands (The Design Academy, Eindhoven), and the UK (Leicester and Reading). He started in 1995 a design - research consultancy in Belgium. Most of the projects are related to information about medicines for patients, doctors and pharmacists. (www.graphicdesign-research.com). In 2023 he teaches at BA, MA, and PhD level at the Lucerne University of Applied Sciences and Arts (Switzerland), and University of Hasselt (Belgium). He is a board member of International Institute for Information Design (IIID, Vienna, Austria) and the International Plain Language Federation (IPLF), and editorial board member of Information Design Journal, Hyphen, She Ji, and Visible Language.

Patient-Centric Labeling: Empowering Shared Decision-Making in Healthcare

Marva Schodel, MBA, MS

Senior Director of Regulatory Affairs, Global Labeling Therapeutic Area Lead, an
Merck & Co., United States

With over 18 years in the pharmaceutical industry and more than 16 years in regulatory affairs, Marva Schödel is the Senior Director of Regulatory Affairs, Global Labeling Therapeutic Area Lead, and Health Literacy Lead at Merck & Company. She is committed to developing patient-centric labeling strategies that enhance health literacy across diverse populations. Marva leads cross-functional teams to ensure clarity and compliance in product information, focusing on improving patient outcomes. As an advocate for clear labeling, she emphasizes the role of health literacy in supporting informed patient decisions. By integrating these principles into regulatory practices, Marva focuses on inclusive communication that fosters accessibility.

DCI Network's EMPATHICA: A Chatbot for Enhancing Medication Communication to Patients

Yuri Quintana, PhD

Chief, Division of Clinical Informatics
Beth Israel Deaconess Medical Center, United States

Yuri Quintana, Ph.D., is Chief of the Division of Clinical Informatics at Beth Israel Lahey Health and Assistant Professor of Medicine at Harvard Medical School. His research focuses on learning health networks and online platforms that empower patients, families, and health professionals. He developed InfoSAGE, a mobile app for home-based coordination for medication and symptom management, and Alicanto Cloud, an online platform for learning and collaboration to disseminate best healthcare practices and virtual consultations. Quintana obtained his engineering degrees from the University of Waterloo in Electrical and Computer Engineering and Systems Design Engineering. More at http://www.yuriquintana.com and on Twitter at @yuriquintana.

12:00 PM — 1:00 PM Ballroom Foyer

Luncheon, Exhibits, and Networking Break

Session 3: Ensuring Excellence in Safety Labeling: Strategies, Collaboration, and Global Best Practices

This session will focus on ensuring excellence in safety labeling, including strategies, collaboration and global best practices. Key topics include developing safety text for the CCDS, while balancing the need for to maintain global alignment with region-specific regulatory requirements and managing deviations. Emphasis will be placed on effective collaboration with cross-functional stakeholders (e.g., safety, commercial) through defined roles and responsibilities. The session will also feature case studies to showcase safety labeling practices across therapeutic areas and drug categories.

Learning Objective :

- Integrate knowledge of regional guidelines on safety text in labeling to develop compliant and globally aligned safety text for the CCDS
- Define the roles and responsibilities of various cross-functional stakeholders that participate in and/or implement safety labeling decisions
- Develop safety labeling text by applying insights and best practices shared during the case studies

Track: General Session

Session Chair(s)

Kelly Treonze, MS

Head, Global Labeling Strategy
Merck & Co., Inc., United States

Kelly M. Treonze, MS, Head, Global Labeling Therapeutic Area, Merck & Co., Inc. Kelly leads the Global Labeling Therapeutic Area at Merck which is part of Global Regulatory Affairs and Clinical Safety. In this role, Kelly leads a team of 50+ labeling professionals who support the labeling strategy and development for Merck's marketed and developmental products. This includes the early developmental labeling and life cycle management of Core Labeling, US Labeling, and Local Labeling for Merck's products globally. Kelly began her career at Merck within Discovery as a bench scientist, after working in academia. Kelly received her M.S. in Molecular Biology from Lehigh University and her B.S. in Biology from Boston College.

Hayley Parker, PhD, MSc

Senior Vice President
Pepgen Inc., United States

Hayley received her MSc., and PhD from Imperial College, London. She began her career as a research scientist (studying HCV, HIV, respiratory viruses) at Cambridge University and then GSK, moving to Regulatory in 2004. In 2009, Hayley began working at Biogen in the ALP department in the UK, eventually transferring to the USA to head up Global Labeling. In 2016 Hayley moved to Vertex Pharmaceuticals Inc., in Boston, and as part of the Regulatory Leadership Team built the Global Labeling department, as well as being a Therapeutic Strategy Head. From there she became VP of Regulatory Strategy at Scholar Rock and then PepGen Inc. Hayley is now part of the Executive Team at PepGen Inc., as SVP of Regulatory Affairs and Medical Writing.

Speaker(s)

Considerations in the Transfer from CCSI to CCDS Based Documentation

Vladimir Penkrat, MBA

Associate Vice President of Regulatory Affairs
Indegene, United States

Vladimir Penkrat is AVP of Regulatory Affairs at Indegene. With an MBA in International Business, Vladimir has provided strategic leadership throughout his career across clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vlad worked across top pharma, biotech startups, CROs, and consulting firms. Within the recent 10 yrs, Vlad's passion for regulatory excellence has established process leadership in Regulatory Writing, Submissions Management, Publishing, Labelling, CTT, Consulting, & GenAI innovation as a business. Vlad's leadership has enabled businesses to prepare for digital adeptness & as a business leader he has scaled R&D operations to >500 FTE.

Proactive Communication with Health Authorities for an Effective Labeling Change Process

Patricia Ann Fraser, MD, MPH, MS

Vice President, Head of Pharmacovigilance
PepGen, United States

Pat is a board-certified rheumatologist with 20 years of pharmaceutical industry experience in various stages of the life cycle management for biologics in immune mediated diseases and fertility, small molecules for immuno-oncology, cardiovascular, hematologic malignancies, enzyme replacement therapies and anti-sense oligonucleotides for rare disease indications. She has served at levels of increasing responsibility in PV at Genzyme, EMD Serono, Sanofi, Ionis and Nimbus Therapeutics. She currently serves as VP Pharmacovigilance at PepGen Inc in Boston.

Advancing Safety Label Change (SLC) Tracking

Jackie Mowry

Global Team Lead, Director, Labeling Compliance
Novartis, United States

Jackie Mowry is the Global Labeling Compliance Director at Novartis, leading a team with responsibilities including oversight of safety label change implementation, driving process improvements, audit and inspection readiness, and ensuring continued compliance. Prior to joining Novartis in 2015, Jackie held the role of Artwork Compliance Director at Merck, where she oversaw the development of artwork to ensure regulatory compliance and consistency across Merck brands, as well as key initiatives including implementation of serialization and anti-counterfeiting measures. With over 20 years of experience in labeling, Jackie remains focused on compliance, regulatory excellence, and fostering a collaborative and performance-driven team.

2:15 PM — 3:00 PM Ballroom Foyer

Refreshments, Exhibits, and Networking Break

2:20 PM — 2:50 PM F. Fitzgerald Ballroom B

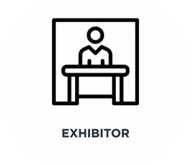
Non-CE: Case Study Spotlight by Glemser: Structured Content AI and ePI Conversions

A London-based global pharmaceutical company needed an ePI conversion provider with proven success and a rapid startup timeline. Glemser supported the client in converting over 1500 labels in six languages, including right-to-left scripts, for submission to 12 markets—all within a three-month timeframe. This transition to structured digital formats, including ePI Pharmaledger, ePI FHIR, and Structured Product Monograph (SPM), improved accessibility for patients and healthcare professionals while ensuring compliance with evolving regulatory mandates. By centralizing labeling conversions with Glemser, the client established a scalable process for future updates, reducing both complexity and cost. This approach positions them to quickly adapt as additional health authorities move toward structured data standards.

Featured Topics

- Process existing unstructured labeling content into structured XML
- Convert newly structured XML data into compliant labeling submissions
- Perform automated document comparison to ensure data integrity between the source document and newly generated structured output

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

Speaker

Jamie Morisco

Vice President
Glemser Technologies, United States

Jamie is the Director of Client Success at Glemser Technologies. He advises clients on innovation strategies and enterprise wide cloud technology transformations that save time, save money, increase compliance, and improve quality. Jamie has deep technology, business transformation, and benefit realization, experience across the life

science and healthcare industries. Jamie is a proven leader who has run large scale, multi-year enterprise engagements across complex ecosystems.

3:00 PM — 4:15 PM F. Fitzgerald Ballroom CDE

Session 4: End-to-End (E2) Labeling Process, Concepts, and Initiatives

This session will cover a few important labeling end-to-end fundamental concepts. The start of the session will cover ownership, governance, and process alignment concepts to ensure quality deliverables related to labeling. Session 4 will also define the meaning of a company core position and what happens when there is a local deviation. It is important for an accurate understanding of what constitutes a deviation, with an assessment of the core position and subsequent tracking and documentation methodologies. The session will conclude with global compliance and PV readiness in relation to audits and inspections.

Learning Objective :

- Demonstrate a clear understanding of labeling governance principles and their practical applications
- Explain the definition of a company core position and downstream process deliverables related to a local labeling deviation
- Identify the core fundamentals of audit and inspection criteria and organization readiness

Track: General Session

Session Chair(s)

Gerrit Nijveldt, MS, MSc

Global Labeling Consultant
Opus Regulatory Inc., United States

Gerrit Nijveldt is currently Labeling consultant with Opus Regulatory. Gerrit has more than 25 years of experience in Global labeling. He has a broad experience in developing and maintaining Company Core Data Sheets, US Prescribing Information and EU Summary of Product Characterisation, including the labeling for multiple development products (early phase to approval) and labeling for devices. Gerrit was also an associate adjunct professor for Temple University School of Pharmacy teaching Global Labeling in the RA/QA Master's Program till 2022. Gerrit earned his MSc in Medical Biology from University of Utrecht in the Netherlands

Sylvie Pujol, MSc

Senior Director, Head of Global Labeling, Global Regulator Affairs
Ipsen, France

Sylvie is the Head of Global Labeling at Ipsen, based in France, where she leads a team responsible for managing Company Core Data Sheets and overseeing End-to-end labeling. She has been working for over 25 years in the pharma industry at large & small companies, with 15 years in labeling, at Sanofi

Aventis and then GSK where she was strategic labeling lead for worldwide and EU-US region. While labeling became a true passion, she brings also experience from Quality Assurance as she worked previosuly as a GCP auditor and adpromo global Compliance. Sylvie is passionate about developing her team, enjoy process optimization and multidisciplinary interactions.

Speaker(s)

Ownership, Governance, and Ownership

Megann Looker

Executive Director, Head of Global Labeling
Jazz Pharmaceuticals, United Kingdom

Megann Looker (BA Hons) is Head of Global Product Labelling at Jazz Pharmaceuticals, based in Oxford, UK, overseeing a global remit. Having graduated from the University of Reading in 2001 after studying Classics, English Literature and Sociology, Megann found her way into Regulatory Affairs whilst planning a career in teaching. Over the past 23 years, Megann has held key roles: previously the lead for Regulatory Labeling at Celgene for the EMEA region from 2009-2016, and prior to this, Regulatory Affairs at Wyeth and Apotex. She has served as a KOL member of LabelNet for over 12 years, and was formerly a member of ePI and IDMP Task Forces across Europe.

CCDS Deviations, Safety Signals, and Compliance

Yaroslav Ivanov, PharmD

Senior Director, Global Labeling Strategy
Bristol Myers-Squibb, United States

Yaroslav Ivanov is a Senior Director of Global Labeling Strategy, Team Lead, Marketed Product Development at Bristol Myers Squibb Company (BMS), with 14 years of labeling experience in the pharmaceutical industry. In this role, Yaroslav is responsible for leading the team of global labeling strategists responsible for developing labeling content for all BMS approved products. Prior his current position, Yaroslav was a Director, Global Labeling Lead for Immunology and Rare Blood Diseases products at Sanofi. Prior to labeling, he completed a Fellowship program in Global Medical Safety at Johnson & Johnson. Yaroslav has a PharmD and a Bachelor of Arts in Biology degrees from Rutgers University.

Labeling Audit Preparation and Readiness

Tara D Baer

Head of Labeling
Gilead Sciences, United States

Tara is the Head of Global Labeling at Gilead Sciences, bringing over 25 years of global experience in pharmaceutical and medical device labeling. She has held key roles at industry leaders such as Takeda, PRA (ICON), AbbVie, Boston Scientific, and Wyeth (Pfizer), where she developed a strong passion for End-to-End Labeling Management, from safety through distribution. As a member of Gilead's Innovation, Content, and Operations Leadership Team, Tara is dedicated to driving labeling innovation and continuous improvement in labeling strategy, content, and process. She is the founder of Leaders in Labeling, a collaborative network of thought leaders in labeling for regulated products, including pharmaceuticals, biologics, and medical devices.

4:20 PM — 5:35 PM F. Fitzgerald Ballroom CDE

Session 5: Packaging Label Insights

While primarily a vehicle for product protection and delivery, pharmaceutical packaging delivers benefits beyond protecting the integrity of medications. Packaging offers opportunities to enhance patient safety, ensure compliance with regulations, and contributes positively to the overall healthcare experience. In this session, we will explore innovations and insights related to packaging and their positive impacts on compliance, supply chain efficiency, and customer experience.

Learning Objective :

- Describe ways in which packaging enhances safety, compliance, and customer use and experience
- Explain the innovations and technological advances in packaging enabling supply chain efficiency related to movement and traceability of products from manufacture to distribution
- Identify opportunities and challenges related to packaging development within the end-to-end labeling process

Track: General Session

Session Chair(s)

Kathleen Salazar, MA, MBA

Head, Global Labeling Operations
Johnson & Johnson Innovative Medicine, United States

Kathy Salazar is the Head of Global Labeling Operations at Johnson & Johnson Innovative Medicine. She has over 28 years of labeling experience within J&J, including artwork development, end-to-end tracking, labeling implementation management, and labeling compliance. Kathy has an undergraduate degree from the University of Pittsburgh, graduate degrees from Rutgers and Fairleigh Dickinson University, and is recognized as a Certified Packaging Professional by the Institute of Packaging Professionals.

Speaker(s)

NFC Technology in Pharmaceutical Packaging

Hemant Patel, MS

Advisor - Regulatory – Drug Delivery and Digital Health
Eli Lilly and Company, United States

Hemant Patel is Regulatory Scientist at Eli Lilly and Company. With over 15 years of experience in the field product development, Hemant has led numerous projects with regulatory compliance in the pharmaceutical and aerospace industry. He received a MSEE from Purdue University, holds several patents related to medical devices and is an active AAMI member. He is an advocate for staying up to date and researching how technology can be utilized in pharmaceutical product development while meeting the latest regulatory standards.

Impact of Label and Packaging Design on Medication Safety

Rita Jew, PharmD, MBA

President
Institute for Safe Medication Practices, United States

Rita K. Jew, PharmD, MBA, BCPPS, FASHP is President at the Institute for Safe Medication Practices (ISMP), a nonprofit organization devoted entirely to preventing medication errors. Prior to ISMP, Dr. Jew spent over 25 years in the acute care setting as a neonatal/pediatric specialist and held various leadership positions including Director of Pharmacy at UCSF Health, Executive Director of Pharmacy & Clinical Nutrition Services at CHOC Children's and Clinical Manager at Children's Hospital of Philadelphia. She received her PharmD from University of California at San Francisco and MBA from the Wharton School, University of Pennsylvania, and completed an ASHP-Accredited Residency in Clinical Pharmacy at Thomas Jefferson University Hospital.

Artwork & Labeling Management: A Package Design and Development Perspective

Jim Regan

Head of Packaging Consulting Services, Pharmaceutical
Adept Group, United States

Jim recently joined Adept Group as Head of Packaging Consulting Services, Pharmaceutical. He is a global leader with 35 years of package design and development experience in the pharmaceutical and OTC products industry. Jim recently retired from Pfizer as the Senior Director of Pfizer's Package Design and Development organization. He has experience with many types of packaging components and systems, site operations and artwork management. Jim's teams have developed packaging for many known consumer and pharmaceutical products around the world. Jim holds a BS is Packaging Science from The Rochester Institute of Technology.

5:35 PM — 6:35 PM Ballroom Foyer

Networking Reception

Day 3 Apr 08, 2025

7:30 AM — 3:45 PM Ballroom Foyer

Meeting Registration

7:30 AM — 8:15 AM Ballroom Foyer

Networking Breakfast

8:15 AM — 9:30 AM F. Fitzgerald Ballroom CDE

Session 6: Professional Development for Labeling: Building Skills for Cross-Functional and Digital Success

This session will discuss several strategies to support the professional development of a labeling strategist. Topics will include managing cross-functional labeling committees, with emphasis on the key qualities required to effectively lead diverse teams and achieve functional alignment. Additionally, the session will cover the necessary skills required for effective labeling management, such as regulatory compliance, digital literacy, project management, negotiation, and cross-functional leadership. Attendees will also learn about the development of competency models, skill matrices, and training programs to foster professional growth, facilitate performance assessment, and ensure consistent skill-building across the labeling team.

Learning Objective :

- Define the key skills and qualities needed to fulfil the responsibilities of a labeling strategist
- Apply best practices for managing and leading cross-functional teams
- Identify competency models and skills matrices to support onboarding, professional growth, and consistent skill-building across labeling teams

Track: General Session

Session Chair(s)

Kelly Treonze, MS

Head, Global Labeling Strategy
Merck & Co., Inc., United States

Kelly M. Treonze, MS, Head, Global Labeling Therapeutic Area, Merck & Co., Inc. Kelly leads the Global Labeling Therapeutic Area at Merck which is part of Global Regulatory Affairs and Clinical Safety. In this role, Kelly leads a team of 50+ labeling professionals who support the labeling strategy and development for Merck's marketed and developmental products. This includes the early developmental labeling and life cycle management of Core Labeling, US Labeling, and Local Labeling for Merck's products globally. Kelly began her career at Merck within Discovery as a bench scientist, after working in academia. Kelly received her M.S. in Molecular Biology from Lehigh University and her B.S. in Biology from Boston College.

Gerrit Nijveldt, MS, MSc

Global Labeling Consultant

Opus Regulatory Inc., United States

Gerrit Nijveldt is currently Labeling consultant with Opus Regulatory. Gerrit has more than 25 years of experience in Global labeling. He has a broad experience in developing and maintaining Company Core Data Sheets, US Prescribing Information and EU Summary of Product Characterisation, including the labeling for multiple development products (early phase to approval) and labeling for devices. Gerrit was also an associate adjunct professor for Temple University School of Pharmacy teaching Global Labeling in the RA/QA Master's Program till 2022. Gerrit earned his MSc in Medical Biology from University of Utrecht in the Netherlands

Speaker(s)

Attracting, Onboarding, and Training Talent

Lori LaRosa, PharmD

Senior Director, Regulatory Affairs, Global Labeling
Merck, United States

Lori LaRosa holds a Doctor of Pharmacy degree from Mercer University and a Bachelor of Science in Industrial Chemistry from Middle Tennessee State University. Currently, she is a Senior Director of Regulatory Affairs, Global Labeling at Merck in the oncology therapeutic area. Lori has also held roles at Merck in promotion and advertising regulatory review and in global medical information. Her experience spans managing labeling strategies, training students, interns, and new employees, and ensuring compliance with regulatory standards. Prior to Merck, Lori worked as a clinical pharmacist at the Hospital of the University of Pennsylvania, focusing on anti-infective stewardship and clinical nutrition support.

Partnership of GRL and GLL

Maria Sandrino Meinz, MS

No Company Affliation, United States

Global Regulatory Affairs professional with large and mid-Pharma experience covering research, drug development and regulatory labeling strategy. Experienced in leading multi-disciplinary, geographically diverse teams.

Building Agility: Transforming Labeling with Flexible Resource Strategies

Julie Guery, PhD

Global Regulatory Affairs Labeling Head
Sanofi, United States

Julie Guery is the Global Regulatory Affairs Labeling Head at Sanofi, leading a team of 50+ professionals focused on Labeling Strategy, Innovation, and Operations. She supports a broad portfolio across Inflammatory & Immunology, Rare Diseases, Oncology, Vaccines, and General Medicine, from early development through lifecycle management. With 17+ years of experience in pharmaceuticals, consumer healthcare, and cosmetics, Julie has developed global

expertise, particularly in Europe, the US, and Asia. Holding a Ph.D. in Physical Chemistry, she combines scientific knowledge with strategic leadership to drive innovation and team development. Julie is committed to advancing public health and fostering excellence in the industry.

9:30 AM — 10:15 AM Ballroom Foyer

Refreshments, Exhibits, and Networking Break

9:35 AM — 10:05 AM F. Fitzgerald Ballroom B

Non-CE: Case Study Spotlight by Basil Systems: Unleash Oncology: Fast-Track Market Access with Unified Labeling

In the oncology sector, navigating complex regulatory requirements while reducing time-to-market is a major challenge. This case study examines how a unified labeling strategy streamlined cross-functional collaboration and regulatory submissions, significantly accelerating the drug launch process. By standardizing messaging and coordinating efforts between medical, legal, and marketing teams, the approach mitigated risks and ensured compliance, ultimately overcoming delays and expediting market access for the oncology drug.

Featured Topics:

- Unified Strategy Benefits: Understand how a cohesive labeling approach accelerates market entry and streamlines regulatory approvals
- Interdisciplinary Collaboration: Learn effective methods for aligning medical, legal, and marketing teams to ensure consistent and compliant messaging
- Risk Management: Gain insights into managing regulatory risks and addressing potential pitfalls specific to oncology labeling
- Process Optimization: Discover actionable strategies and best practices to reduce time-to-market without compromising safety or efficacy

Track: General Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Speaker

Sam Kay, MPharm, RPh, RAC

Vice President, Pharma
Basil Systems, United Kingdom

Sam Kay is a strategic Regulatory Affairs leader specializing in all things Pharma at Basil Systems. With over 12 years of experience, he has driven global labelling initiatives—from clinical development through commercialization—ensuring that products meet rigorous regulatory standards across key markets. A Master of Pharmacy graduate from Kingston University London, Sam has a proven track record engaging with Health Authorities such as the EMA, FDA, and MHRA. Passionate about leveraging technology to enhance regulatory practices, his innovative approach to labelling and compliance continues to set industry benchmarks and inspire forward-thinking solutions in pharmaceutical product development.

10:15 AM — 11:30 AM F. Fitzgerald Ballroom CDE

Session 7: Human Factors Testing to Core Device Label - Case Study

This session presents a case study of the development of labeling for a drug-device combination product, followed by a panel discussion consisting of experts in Global Regulatory Labeling and Human Factors engineering. The case study discusses an end-to-end process improvement project spanning from human factors testing through labeling development, submission, and implementation, focusing on ways to enhance collaboration between human factors engineers and global regulatory labeling colleagues during core device labeling development. The panel will provide both labeling and human factors engineer perspectives on potential areas of process challenges and ways to address them.

Learning Objective :

- Explain high level human factors testing for device constituent of drug led combination product Instructions for use, quick reference guide, carton and/or container label
- Describe optimized collaboration between a labeling department and human factor engineers to develop core device labeling
- Discuss a case study handling governance and early Ministry of Health (MOH) feedback to draft device constituent core device labeling

Track: General Session

Session Chair(s)

Gina Monteiro

Senior Director, Global Regulatory Affairs – Global Core Labeling
Eli Lilly and Company, United States

Gina Monteiro has 6 years of labeling management experience with Eli Lilly's Global Regulatory Labeling organization and currently in the Drug Delivery and Digital Health Global Regulatory Department. She has overseen the development of Core Data Sheets, US and Canadian labeling for Lilly's Bio-

Medicines, Oncology, Diabetes, Medical Device and Digital Health product portfolios. Prior to joining the global labeling organization, Gina held a number of previous positions at Eli Lilly including US Medical, Pharmacovigilance and US Regulatory, Advertising and Promotion Quality. Gina worked as a Clinical Research Associate (CRA) prior to joining Eli Lilly in 2001. Gina obtained her B.A. from The University of Michigan.

Mary Beth Wilusz

Head, Regulatory Labeling Operations and Compliance
Daiichi Sankyo, Inc., United States

Mary Beth is Head of Regulatory Labeling Operations and Compliance at Daiichi Sankyo, Inc. where she leads a team responsible for optimizing processes, implementing innovative technologies, monitoring compliance, developing packaging, and ensuring labeling quality for oncology and specialty medicine products. She has >30 years' experience in the pharma/bio industry at large & small companies, with >20 years in labeling. She previously led labeling strategy, operations, and compliance teams at Shire/Takeda and Merck & Co., Inc. Mary Beth is passionate about developing her team, collaborating globally to align processes, and exploring ways to utilize technology to optimize processes and enhance patient safety.

Speaker(s)

Human Factors Testing to Core Device Label - Case Study

Kathleen Johnson

Associate Director - Global Regulatory Affairs - Global Core Labeling
Eli Lilly and Company, United States

Kathleen began her career in the Pharmaceutical Industry at Eli Lilly and Company in 2011. She brings 9 years experience supporting global core, US, and Canada labeling for small molecules, biologics and combination drug labeling. Prior to transitioning to Regulatory Labeling, she helped build the Clinical Diagnostics Laboratory, spearheading the establishment of Lilly's first CLIA accredited laboratory. With a 22-year background in hospital regulated clinical laboratories, she held roles in multiple disciplines, collegiate allied health education, management and served as a US laboratory peer inspector for the College of American Pathologists. She has a dedication to quality, team success and a passion for innovative labeling solutions.

Speaker

Mark Jakubowski

Global Labeling Strategist
Bayer Corporation, United States

Mark has worked in the Medical Device Industry for over 20 years. He presently is working in the Pharmaceutical Industry and has so for the past 10 years. He is a Global Regulatory Affairs professional responsible for regulatory labeling strategy. He is experienced in combination products and worked with the Medical Device Excellence team at Bayer to develop the process for incorporating core device labeling into the pharmaceutical business.

Speaker

Young Ji Chun, PhD

Principal Research Engineer, Human Factors, Combination Product Development
AbbVie, United States

At AbbVie, Young is managing human factors engineering activities to design, test, and validate the combination products and medical devices as well as digital health. Prior to joining Abbvie, Young led the human factors team in Alexion Pharmaceuticals, a rare disease business subsidiary of AstraZeneca, and oversaw human factors engineering processes. Before Alexion, Young worked at Takeda, Shire, and Biogen in medical device and combination product development as a human factors lead. She holds a Ph.D. in Industrial Engineering specializing Human Factors from Texas Tech University and BS and MS in Industrial & Information Engineering from Hongik University, South Korea.

11:30 AM — 12:30 PM Ballroom Foyer

Luncheon, Exhibits, and Networking Break

12:30 PM — 1:45 PM F. Fitzgerald Ballroom CDE

Session 8: Will Artificial Intelligence (AI) Transform Drug Labeling Processes?

This session will examine the transformative role of artificial intelligence (AI), neuro linguistic programming (NLP), and machine learning (ML) in global regulatory labeling, highlighting opportunities to enhance efficiency, accuracy, and compliance. Speakers will discuss how these technologies can streamline processes, from automating label updates to analyzing health authority requirements, while addressing challenges such as integration and data privacy. Attendees will gain insights into how AI-driven innovations are reshaping labeling processes, future directions in the industry, and strategies for collaborating with health authorities to navigate the evolving regulatory landscape.

Learning Objective :

- Describe how to structure prompts to generate appropriate AI output
- Identify specific areas of the labeling process that can benefit from the use AI, NLP or ML
- Evaluate the future role and potential of AI in the regulatory labeling landscape

Track: General Session

Session Chair(s)

Deborah Bebbington

Head Global Labeling
Bayer Plc, United Kingdom

Deborah has been working in the Pharmaceutical Industry for over 25 years. She began her career in Research before moving into Regulatory Affairs. During her tenure at Bayer Deborah worked in the UK affiliate, as an EU liaison, set up a new global RA department focusing on the RA support for Mature products and headed the International RA department before moving to her current position 12 years ago. She is currently VP and Head of Global Labeling at Bayer.

Mary Beth Wilusz

Head, Regulatory Labeling Operations and Compliance
Daiichi Sankyo, Inc., United States

Mary Beth is Head of Regulatory Labeling Operations and Compliance at Daiichi Sankyo, Inc. where she leads a team responsible for optimizing processes, implementing innovative technologies, monitoring compliance, developing packaging, and ensuring labeling quality for oncology and specialty medicine products. She has >30 years' experience in the pharma/bio industry at large & small companies, with >20 years in labeling. She previously led labeling strategy, operations, and compliance teams at Shire/Takeda and Merck & Co., Inc. Mary Beth is passionate about developing her team, collaborating globally to align processes, and exploring ways to utilize technology to optimize processes and enhance patient safety.

Speaker(s)

Will Artificial Intelligence (AI) Transform Drug Labeling Processes?

Mike DeMarco, PharmD

Regulatory Advisory Services Leader
PwC, United States

Mike is a consulting professional with over 15 years of Healthcare and Pharmaceutical Industry experience. His range of experiences span from product development and Health Authority interactions to R&D functional strategy and management. Mike currently leads PwC's Regulatory Advisory Services team, supporting regulatory leaders across the life sciences industry address organizational priorities and navigate disruptive technologies. His areas of expertise include: organizational strategy, operating model design, technology enablement, and digital disruption.

Implementing AI in RA A Real-life Example

Irene Kuhlman, MSc

Global Labeling Strategist
Bayer Pharma NL, Netherlands

After obtaining her MSc in Biomedicine, Irene began her career in various science and health communication roles at non-profit organizations. She then transitioned to Regulatory Affairs, where she worked for 14 years as a local and EU Regulatory Manager at the Dutch Bayer affiliate, supporting various therapeutic areas. In 2023, she took on her current role in global labeling, where she leads initiatives on patient-friendly labeling and the implementation of AI in Regulatory Affairs. Irene is passionate about improving healthcare communication and leveraging technology to enhance regulatory processes.

Mastering AI in Labeling: Boost Efficiency, Innovation and Career Growth

Michelle Wu, MBA

Co-founder & CEO
NyquistAI, United States

Michelle Wu is the cofounder and CEO of NyquistAI, with over a decade of experience in pharmaceuticals, medical technology, and digital innovation. She has been featured by Forbes and has spoken at various conferences on AI in life science. Before founding NyquistAI, she was the youngest global strategy manager at Novartis, where she played a pivotal role in the industry's first and only asset swap deal between Novartis, Eli Lilly, and GSK. This experience highlighted the challenges of manual data research, sparking her vision to create NyquistAI. Before Novartis, she worked for BCG, advising major pharma and Medtech companies on their global product development and emerging market strategies. She holds an MBA from Stanford University.

1:45 PM — 2:30 PM Ballroom Foyer

Refreshments, Exhibits, and Networking Break

1:50 PM — 2:20 PM F. Fitzgerald Ballroom B

Non-CE: Case Study Spotlight by RWS: Navigating Complex Labeling with Structured Content & AI-driven Knowledge Portal

Using a document delivery portal that intuitively guides knowledge workers and customers to the right information fast. Rather than using the traditional, linear way of browsing content, you can look for answers with the help of two AI-driven interfaces: Trustable Chat and a brand-new navigation paradigm called Hexahops™.

Featured Topics

- How AI chat generates highly reliable responses using a technology called RAG (Retrieval-Augmented Generation)
- Understanding of smart recommendations with search results enhanced by semantic textual similarity
- Benefits of Structured Content for GenAI solutions

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

Speaker

Frank Barendregt

Technology Sales Director Life Sciences
RWS Group, Netherlands

2:30 PM — 3:30 PM

F. Fitzgerald Ballroom CDE

Session 9: Rare Diseases: Cell and Gene Therapy Considerations for Developing the Label and Your Stakeholders

There has been an increase in Cell and Gene Therapies (CGT) being developed and approved as novel treatments for rare diseases. Unique situations, challenges, and requirements face CGTs which require the labeling team to engage with a broad stake-holder network during development. Considerations such as safety concerns associated with CGTs (including benefit:risk considerations for specific populations), study expectations and design elements, alternative endpoints/data-sets informing the label, traceability, and planning of long-term follow-up requirements and supply chain. CGT examples and labeling themes and considerations to support the development of CGTs labels for rare diseases will be provided. The session will finish with a patient advocacy speaker for Friedreich ataxia (FA), a progressive neurodegenerative disorder that affects the nervous system. An opportunity to hear considerations, questions, support, communication and education requirements, that face the treatment journey for an individual with a rare disease which has the potential for treatment with a cell and gene therapy.

Learning Objective :

- Discuss some of the unique labeling requirements for Rare Diseases treated with CGT
- Identify best practices for supporting label development and life cycle management for Rare Diseases treated with CGT
- Recognize aspects of what the treatment journey may look like for someone considering receiving CGT treatment for a rare disease and how this might be considered when developing the CGT treatment label

Track: General Session

Session Chair(s)

Hayley Parker, PhD, MSc

Senior Vice President
Pepgen Inc., United States

Hayley received her MSc., and PhD from Imperial College, London. She began her career as a research scientist (studying HCV, HIV, respiratory viruses) at Cambridge University and then GSK, moving to Regulatory in 2004. In 2009, Hayley began working at Biogen in the ALP department in the UK, eventually transferring to the USA to head up Global Labeling. In 2016 Hayley moved to Vertex Pharmaceuticals Inc., in Boston, and as part of the Regulatory Leadership Team built the Global Labeling department, as well as being a Therapeutic Strategy Head. From there she became VP of Regulatory Strategy at Scholar Rock and then PepGen Inc. Hayley is now part of the Executive Team at PepGen Inc., as SVP of Regulatory Affairs and Medical Writing.

Speaker(s)

CAR T-cell Therapy: Labeling for Personalized Medicine

Urchena Tewari, MSc

Associate Director, Labeling Product Leader, Global Labeling
Johnson & Johnson Innovative Medicine, United Kingdom

Urchena Tewari is an Associate Director and Global Labeling Product Leader at J&J Innovative Medicine, where she is responsible for target label development and formulating labeling strategies to support new product filings. With a passion for labeling in Cell and Gene Therapy Products, she's currently leading an initiative focused on this innovative area. With over 20 years of experience in Global Labeling, Urchena began her career at the MHRA before joining GSK. She subsequently worked as a labeling consultant for over 10 years, contributing to diverse projects, including multiple global labeling compliance projects. Urchena joined J&J Innovative Medicine in 2021. She holds an MSci in Chemistry with Bioscience from King's College, London.

A Community Perspective

Kyle Bryant

Spokesperson
Friedreich's Ataxia Research Alliance (FARA), United States

Kyle Bryant is the founder and director of the bicycle ride fundraiser, rideATAXIA for the Friedreich's Ataxia Research Alliance (FARA). rideATAXIA has raised over $12 million for FA research since 2007. Despite his diagnosis of Friedreich's ataxia (FA) at the age of 17, Kyle has completed numerous long-distance bike rides including up The World's Highest Paved Road and successful completion of The World's Toughest Bike Race on a 4-man team, which is the subject of the award winning documentary, The Ataxian. He is co-host of the Two Disabled Dudes Podcast. He's the author of Shifting Into High Gear, which chronicles his first ride across the country when he was coming to grips with his rare disease diagnosis.

3:30 PM — 3:45 PM F. Fitzgerald Ballroom CDE

Closing Remarks

Closing Remarks

Track: General Session

Session Chair(s)

Sorcha McCrohan, MS

Scientific Project Manager
DIA, United States

Sorcha McCrohan is a Specialist of Scientific Programs for the Americas Region at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines Meningococcal franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

3:45 PM — 3:45 PM

Conference Adjourns