Sheraton Pentagon City Hotel

Mar 14, 2024 7:30 AM - Mar 15, 2024 4:15 PM

900 South Orme Street, Arlington, VA 22204, USA

Global Labeling Conference

Join speakers from around the world sharing their labeling – Germany, Japan, Belgium, UK, Canada and more!

Print Agenda

Day 1 Mar 14, 2024

7:30 AM — 5:05 PM — Main Lobby, outside North/South Ballrooms

Meeting Registration

7:30 AM — 8:30 AM — North Ballroom

Networking Breakfast

8:30 AM — 8:45 AM — South Ballroom

Welcome and Opening Remarks

8:45 AM — 10:00 AM South Ballroom

Session 1: Global Regulatory Updates

The global regulatory environment in the pharmaceutical industry is dynamic, especially in light of the growth of new product modalities and the continued evolution of transformative technologies and practices for product and labeling development. Health Authorities are engaged with these changes and providing input and feedback in the face of emerging developments and their application to labeling. In this session, we will review some areas of change and how Health Authorities are responding.

Learning Objective : At the conclusion of this session, participants should be able to:

- Identify area of emerging change related to new drug modalities and technologies impacting labeling
- Review Health Authority input and actions in face of emerging changes
- Identify best practices in the use of new technology and data sources

Track: General Session

Session Chair(s)

Kathleen Salazar, MA, MBA

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

Kathy Salazar is the Head of Global Labeling Implementation at Johnson & Johnson Innovative Medicine. She has over 27 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.

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)

US: Utilization of RWE in Labeling

Jennifer Sekawungu, MS

Global Labeling Product and Initiative Lead
Johnson & Johnson Innovative Medicine, United States

Jennifer Sekawungu is a Director, Global Labeling Product & Initiative Leader at Johnson & Johnson Innovative Medicine, Real World Evidence (RWE) Initiatives leader. Jennifer is responsible for building capabilities within Global Labeling to drive labeling content strategies for New Molecular Entities and Line Extensions, incorporating RWE to support regulatory submissions. Jennifer is a seasoned labeling professional with 25 years of experience in the pharmaceutical industry of which 16+ years have been in Global Labeling. She started her labeling career at Merck & Co., Inc. before joining Janssen in 2016. Jennifer holds a Master's Degree in Biotechnology from Northwestern University.

Global Regulatory Updates – EU

Koen Nauwelaerts, PharmD, PhD, MBA

Regulatory Policy and Innovation Lead
Bayer AG, Belgium

Koen Nauwelaerts holds a Master's degree in Pharmacy from Leuven University, Belgium and a PhD in Drug Development from the same university. Further he obtained an MBA degree from Vlerick Business School and completed the technology immersion program at MIT. Koen is currently working at Bayer as RA Policy and Innovation Lead. He joined Bayer as head of regulatory affairs and quality for the Belgium/Luxemburg region and previously has been active within MSD and Medicines for Europe in different roles in Regulatory Affairs and Quality. Within his current role as RA Policy and Innovation Lead, Koen leads the internal global e-labeling initiatives at Bayer and is vice-chair of the Inter Association TaskForce (IATF) for ePI.

Introduction to Labelling Regulations in Japan

Mohamed Oubihi, DrSc, MSc

President and CEO
Yakumed limited, United Kingdom

Mohamed Oubihi is the President and CEO of Yakumed, a one-stop niche service provider that is fully specialized in the Japanese pharmaceutical market. Yakumed has supported over 70 pharmaceutical/biotechnology companies to strategize, develop, approve, and launch their drugs in Japan. Mohamed has 24 years of experience in the Japanese bio and pharmaceutical sector. Ex-Vice Chairman of the Japanese Association of Additives Enzyme committee. Ex-Head of Amicus Operations in Japan. He assumed leading positions in several pharmaceutical companies. Strong Negotiation Experience with PMDA/MHLW. Wide network in the Japanese pharmaceutical Industry. Mohamed served as an expert witness in international arbitrations involving Japanese companies.

10:00 AM — 10:40 AM North Ballroom

Refreshments, Exhibits, and Networking Break

Hosted Session/Non-CE: Case Study Spotlight hosted by Glemser: How Artificial Intelligence is Being Applied to Generate FHIR Outputs

The way we access and understand information about medications is undergoing a transformative shift. As we continue to embrace the digital age, the traditional regulatory content generation processes at pharmaceuticals are giving way to a more interoperable and technologically advanced solution – HL7 FHIR. Come see how Glemser is using automation to create FHIR outputs at scale.

- ePI
- PQ CMC
- Natural language technologies
- Generative AI
- FHIR
- Global labeling
- Structured content
- Clinical labeling

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Jamie Morisco

Director of Client Success
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.

Session 2: End-to-end Labeling Part 1: The Development Phase

To support end-to-end successful delivery of a product, when should you start developing your ‘label’ and how broad should the term ‘label’ be? Target Product Labels (TPL) have typically focused on the prescriber, but as the world of labeling becomes more complex, this session focuses on how the TPL could include packaging, instructions for use (IFUs), supporting software, risk minimization, patient materials, and the supply chain, to enhance supply of the product globally. This session will focus on some case-studies, examples, and considerations where factoring in these broader elements of labeling into the TPL process has been utilized to successfully optimize the supply of the product to the end user.

Learning Objective : At the conclusion of this session, participants should be able to:

- Evaluate opportunities to broaden the scope of the TPL to assist supply of the final product
- Identify additional stakeholders which may be required to support broader TPL development
- Discuss best practices and learnings when implementing a broader TPL process

Track: General Session

Session Chair(s)

Hayley Parker, PhD, MSc

Vice President Regulatory Affairs
PepGen, United States

Beginning her career at Cambridge University, Hayley began working in clinical research. Moving to GSK, continuing a career in clinical trials (HIV, respiratory viruses), Hayley began a part-time PhD and eventually transferred to Regulatory. Hayley joined the ALP team at Biogen Idec (UK) and then moved to the USA to lead Global Labeling. In 2016 Hayley joined Vertex Pharmaceuticals Inc., to lead and develop the Global Labeling function. Subsequently, Hayley joined Scholar Rock as VP of Regulatory Affairs as a therapeutic lead. Then she moved to her current position as VP Head of Regulatory Affairs and Medical Writing at PepGen Inc. a company developing treatments for rare neuromuscular diseases.

Lauren Brunke, PharmD, RPh

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

Lauren Brunke began her career in the Pharmaceutical Industry in 2012 when she joined Eli Lilly and Company as a fellow in the Visiting Scientist Program. Before transitioning to Regulatory Labeling, she worked as a Pharmaceutical Project Manager, where she supported products in Alzheimer’s Disease and Oncology, managed Global submission strategies, and led contractual and clinical start up activities for public-private partnerships. Currently, Lauren leads the Global Labeling Department within Global Regulatory Affairs where she oversees the development and maintenance of Core labeling and US and Canada labeling for drug and combination device products across the portfolio.

Speaker(s)

Speaker

Shaun Wallisa

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

Shaun Wallisa began his career in the Pharmaceutical Industry in 2000 when he joined Pharmacia and Upjohn as an Analytical Chemist and then moved to Eli Lilly and Company in 2002. Before transitioning to Regulatory Labeling, he held several technical and leadership positions within the manufacturing organization - Quality Assurance, Quality Control, Procurement, Continuous Improvement, and Technical Services. Currently, Shaun leads the Global Labeling Department within Global Regulatory Affairs where he oversees the development, implementation, and maintenance of Core labeling and US and Canada labeling for drug and combination device products across the product portfolio.

11:55 AM — 12:55 PM North Ballroom

Luncheon, Exhibits, and Networking Break

12:55 PM — 2:10 PM South Ballroom

Session 3: eLabeling: Regulatory Environment, Early-stage Developments, and Global Adoption

Various e-labeling initiatives are underway worldwide in the healthcare and pharmaceutical fields. This session will provide an overview of current developments in global e-labeling initiatives related to the electronic distribution of product prescribing and patient information, including: availability of labeling online (on a publicly accessible websites); use of machine-readable codes to provide access to user-friendly formats of labeling; and the elimination of paper labeling from commercial product packages. E-labeling should be structured content that utilizes the electronic common standard and eventually should be interoperable with the other healthcare system. The switch to e-labeling provides numerous benefits, including sustainability; however, it is not a simple change as it requires a change in regulations, processes, new ways of working across the organization, and new interactions with regulators. In this session, we will share lessons learned from markets who have made e-labeling happen and discuss best practices, including hearing the perspectives from the health authorities during review and implementation of e-labeling.

Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize global adoption trends of e-labeling initiatives
- Describe the best practices and challenges from e-labeling implementation
- Discuss the fit for purpose approach for e-labeling

Track: General Session

Session Chair(s)

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.

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.

Speaker(s)

e-Labelling Implementation in Malaysia: Journey and Experience

Maslinda binti Mahat, MSc, RPh

Head of Policy & Strategic Planning
National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia, Malaysia

Maslinda Mahat has dedicated nearly two decades of her professional career to working in the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia. She currently holds the position of Head of Policy and Strategic Planning at NPRA. Graduating as a pharmacist, she pursued her MSc in Pharmaceutical Biotechnology at De Montfort University of Leicester. Embracing the evolving landscape of pharmaceutical regulation, Maslinda Mahat has been deeply involved in the planning and implementation of e-labeling for pharmaceutical products in Malaysia since 2021. The journey commenced with the groundbreaking use of e-labels on COVID-19 vaccines, marking a significant leap forward in regulatory transparency and efficiency.

EMA-HMA-EC ePI: Piloting and Beyond

Elizabeth Scanlan, PhD, MSc

ePI Product Owner
European Medicines Agency, Netherlands

Elizabeth Scanlan joined the European Medicines Agency in 2016 where she is currently Product Owner for electronic product information (ePI). Prior to joining EMA, she worked in communication roles in the biotechnology industry and not-for-profit sector. Elizabeth holds a PhD in molecular biology from Trinity College Dublin.

2:10 PM — 2:50 PM North Ballroom

Refreshments, Exhibits, and Networking Break

2:15 PM — 2:45 PM Cavalier A

Hosted Session/Non-CE: Case Study Spotlight hosted by IQVIA: Ensuring Labeling Harmonization Amidst a Legal Entity Change

The success and safety of drug products heavily depend on an efficient labeling team, particularly during a legal entity change such as a merger, acquisition, or marketing authorization transfer. Such changes can pose compliance risks, leading to potential safety risks, product recalls, and brand damage. However, the development of new labels can be smooth with a well-planned strategy, timeline, and data transfers that follow both companies' regulations.

Successful labeling harmonization relies on a gap analysis that examines the labeling practices of both companies and identifies any discrepancies. This allows for the creation of a strategy that addresses these deviations and mitigates any compliance risk. If the labeling team lacks the ability to manage this additional workload, partnering with a vendor experienced in legal entity change procedures could be beneficial. The process begins with reviewing the steps to develop new, compliant labels, followed by identifying a strategy that aligns with the company's goal with a patient-centric approach.

Featured Topics:

- Impact Assessment and Gap Analysis
- Designin a Labeling Strategy
- Data Transfer
- Submission to Health Authorities
- New Label Implementation
- Using LLM, NLP, and Automated Label Text Comparison Technology

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Rama Mohan Rao Chikkam

Senior Director, Regulatory Affairs
IQVIA, United States

Kiran Chinnalla

Director, Product Manager - Regulatory Affairs
IQVIA, India

Kiran Chinnalla is Director at IQVIA and is responsible for managing product development and maintenance in regulatory affairs. He has over 16 years of experience in regulatory & labelling strategy, patient safety, project management, product strategy and consulting. Kiran is a pharmacist by qualification with a post-graduate in pharmacology.

2:50 PM — 4:05 PM

South Ballroom

Session 4: Panel Discussion: Impact of Company Size on Labeling Innovation

Pharmaceutical and biotech companies can have unique approaches to how they conduct research, development, and commercialization. How about labeling? This session will explore how company size and labeling organizational structure can impact current business needs and future innovation. It will include a panel of representatives from different companies sharing their perspectives on the following areas: (1) mergers, acquisitions, and co-development with external companies; (2) roles, responsibilities, and processes; and (3) technology.

Learning Objective : At the conclusion of this session, participants should be able to:

- Describe the role of the labeling function during mergers, acquisitions, and co-development with external companies
- Explain the impact that company size can have on an organization’s labeling processes and governance
- Discuss the impact that company size can have on labeling strategy and emerging technologies

Track: General Session

Session Chair(s)

Hayley Parker, PhD, MSc

Vice President Regulatory Affairs
PepGen, United States

Beginning her career at Cambridge University, Hayley began working in clinical research. Moving to GSK, continuing a career in clinical trials (HIV, respiratory viruses), Hayley began a part-time PhD and eventually transferred to Regulatory. Hayley joined the ALP team at Biogen Idec (UK) and then moved to the USA to lead Global Labeling. In 2016 Hayley joined Vertex Pharmaceuticals Inc., to lead and develop the Global Labeling function. Subsequently, Hayley joined Scholar Rock as VP of Regulatory Affairs as a therapeutic lead. Then she moved to her current position as VP Head of Regulatory Affairs and Medical Writing at PepGen Inc. a company developing treatments for rare neuromuscular diseases.

Lauren Brunke, PharmD, RPh

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

Lauren Brunke began her career in the Pharmaceutical Industry in 2012 when she joined Eli Lilly and Company as a fellow in the Visiting Scientist Program. Before transitioning to Regulatory Labeling, she worked as a Pharmaceutical Project Manager, where she supported products in Alzheimer's Disease and Oncology, managed Global submission strategies, and led contractual and clinical start up activities for public-private partnerships. Currently, Lauren leads the Global Labeling Department within Global Regulatory Affairs where she oversees the development and maintenance of Core labeling and US and Canada labeling for drug and combination device products across the portfolio.

Speaker(s)

Speaker

Ken Zerfass

Director of Global Packaging and Labeling Artwork Development
Eli Lilly, United States

I have a BS Degree in Chemistry and worked as a chemist in several industries on the east coast until I started in Pharmaceuticals at Merck. After a few years I moved to the Midwest with Eli Lilly and have been here 21 years. I have worked in Quality Assurance, Printed packaging labeling support, and have spent the last 11 years in the Global Packaging - Labeling organization. I work with a great team who support the strategy and overarching processes for Artwork Labeling development globally at Eli Lilly. We are passionate about excellence in all aspects of labeling processes as we pursue the lofty ideal of Best in Class.

Speaker

Nancy Cauwenberghs, PhD

Head Global Labeling, GRA

J&J Innovative Medicines, Belgium

Nancy is heading up the Global Labeling Organization, including the Global Labeling Content & Strategy group as well as Global Implementation, for J&J Innovative Medicines. The organization consists of the Global Labeling Product Leads in charge of target labels, primary labels and label updates for the different Therapeutic Areas (oncology, immunology, neuroscience, cardiovascular, pulmonary hypertension, global public health), as well as Global Implementation Managers. Prior to heading up Global Labeling, Nancy has been working within GRA in different functions, as GRA Head of Vaccines TA responsible for GRLs developing global regulatory strategies. Prior to J&J, Nancy worked at Merck and GSK Vaccines.

Speaker

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.

4:05 PM — 5:05 PM North Ballroom

Networking Reception

Day 2 Mar 15, 2024

7:30 AM — 4:15 PM Main Lobby, outside North/South Ballrooms

Meeting Registration

7:30 AM — 8:30 AM North Ballroom

Networking Breakfast

8:30 AM — 10:00 AM South Ballroom

Session 5: Patient Centric Labeling: Putting the Patient at the Heart of the Label

The importance of accessible patient-centric product information in helping patients understand and adhere to their treatment is becoming even greater. The overarching role of the patient in labeling, covering aspects such as health literacy, usability requirements, and patient consultations have been discussed increasingly. In this session, we will discuss the initiatives for patient-centric product information such as the PMDA's perspective, usability tests and the open publishing concept linking patient lay summaries with labels. There will also be discussions on strategies for involving patient insights into label development.

Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize the recent patient centric labeling initiatives
- Describe the concepts of health literacy and the role of usability requirements
- Discuss the global approaches to patient labeling within a company

Track: General Session

Session Chair(s)

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 since August 2016. She graduated from the University of Reading in 2001 after studying Classics, English Literature and Sociology, and found her way into Regulatory Affairs whilst planning a career in teaching. Megann was previously the lead for Regulatory Labeling at Celgene for the EMEA region from 2009-2016 and prior to this was in Regulatory Affairs at Wyeth and Apotex. She has served as a KOL member of LabelNet for over 8 years, and as part of the InterAssociation Task Force for IDMP, eLabelling, and DIA SIAC Patient Information.

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.

Speaker(s)

Regulator View: Risk Communication for Patients

Junko Sato, PhD

Associate Executive Director
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Dr. Sato joined the Pharmaceuticals and Medical Devices Agency (PMDA) in 1998, and she is currently the Associate Executive Director. She has work experiences in new drug review for 11 yrs, risk management for 3 yrs, and international area for 11 yrs. She also worked in U.S. FDA as a guest reviewer from 2002-2003, and in EMA as the Japan Liaison Officer from 2012-2014. She is actively involved in many academic societies, and contribute them as counselor, committee member, and a board member.

A Novel Approach to Improving Health Literacy: Plain Language Summary Publications and Open Access Publishing

Catherine Skobe, MPH

Senior Director, Publications Management Team Lead
Pfizer, Inc., United States

Catherine Skobe, Sr Director, has been the Publications Management Team Leader at Pfizer since 2017. Prior to joining Pfizer in 2007, she worked at IntraMed, Becton Dickinson, and at UNC Hospitals. Catherine is a member of ISMPP where she has held several roles and currently co-chairs the Patient Engagement Task Force. She is also a member of Open Pharma and sits on the Vision Task Force. Catherine received her MPH with a concentration in Community Health Education from Hunter College and earned a BS in Medical Technology from the University of North Carolina at Chapel Hill. She is a certified Medical Technologist (ASCP).

Get Messages to Medicines Users: How We Can Put Their Needs First in a Regulated World

David Patrick Samuel Dickinson, MA

Principal Consultant
Consumation Ltd, Consumer Information Design, United Kingdom

David is a health information designer from a consumer campaign background. He worked for the UK Consumers Association as editor of Health Which? magazine. As a founder of Consumation he then worked on patient advocacy projects including Ask About Medicines Week, and the Compliance to Concordance initiative. David and the team at Consumation were early practitioners of usability testing for patient information in Europe, following the work of David Sless and colleagues in Australia. Consumation has worked with government agencies, pharma firms and professional bodies to put across complex messages in simple language. In 2015 David was made an Honorary Member of the Faculty of Public Health.

10:00 AM — 10:40 AM North Ballroom

Refreshments, Exhibits, and Networking Break

10:05 AM — 10:35 AM Cavalier A

Hosted Session/Non-CE: Case Study Spotlight hosted by Perigord Life Science Solutions: Closing the Loop on Risk: Addressing the manual ways of working between the E2E Labeling and Artwork processes

Regulatory Affairs Professionals allocate a considerable amount of time to manually search for, download, compile, and update labeling and artwork files when considering the impact of safety related changes to Product Information content. This presentation explores the potential for automation to expedite the identification of Product Information change impacts, leading to a tenfold increase in delivery speed, a 50% enhancement in efficiency compared to current regulatory artwork change planning methods, and potential savings of up to 20% on manufacturing costs.
Featured Topics:

- Labeling Process Pain Points
- Key Regulatory Operational Challenges
- Solution
- Q&A

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Jim Chesterman

Senior Project Manager
Perigord Life Science Solutions, Ireland

Jim Chesterman is a labelling professional with over 25 years of consulting and international project management experience in the Pharma, Medical Devices and Consumer sectors, focusing on labelling, artwork, business process, solution design and system implementation and integration.

10:40 AM — 11:55 AM South Ballroom

Session 6: End-to-end Labeling Part 2: The Implementation Phase

This session aims to address the critical need for streamlined processes, enhanced traceability, and improved safety in the development of medicinal products information. Explore the significance and challenges of end-to-end tracking in ensuring product integrity, patient safety, and regulatory compliance across the internal content development processes and into the supply chain.

Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize the regional requirements for compliant management of iterative product information, including the role of audit and inspection
- Appraise the various industry approaches for tracking label content and content deviations
- Interpret the importance and impact to patients and caregivers

Track: General Session

Session Chair(s)

Gerrit Nijveldt, 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)

What To Track? Timeline Compliance and Content Deviations

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 since August 2016. She graduated from the University of Reading in 2001 after studying Classics, English Literature and Sociology, and found her way into Regulatory Affairs whilst planning a career in teaching. Megann was previously the lead for Regulatory Labeling at Celgene for the EMEA region from 2009-2016 and prior to this was in Regulatory Affairs at Wyeth and Apotex. She has served as a KOL member of LabelNet for over 8 years, and as part of the InterAssociation Task Force for IDMP, eLabelling, and DIA SIAC Patient Information.

BMS End-to-End Labeling Process Implemented Across Regulatory and Supply Chain

Wanda Rosado

E2E Labeling Process Lead
Bristol Myers-Squibb, United States

Wanda Rosado is the End to end Labeling Process Lead, in Global Strategic Regulatory Operations at Bristol-Myers Squibb. Her pharmaceutical career spans 35 years. Wanda has held positions in Clinical Biostatistics, Regulatory Operations and worked as an IT Business Partner facilitating strategic projects, driving process improvements, and supporting change management. Wanda is a Lean Six Sigma Black Belt and has a B.S. degree in Biomedical Computer Science from Rochester Institute of Technology. Within BMS she led RIM Services (using Veeva RIM Vault) and helped expand the E2E label tracking from HA Approval to Implementation in the market by deploying new processes in Supply Chain for Artwork Management and Implementation Planning.

U.S. Regulations Leveraging Product Labeling

Tracy Nasarenko, MBA

Vice President of Community Engagement, Healthcare
GS1 US, United States

Tracy Nasarenko, vice president of Community Engagement at GS1 US for Healthcare, has more than 20 years of experience in healthcare and pharmaceutical supply chain, finance, product management, marketing, and operations. Currently, she leads a collaborative healthcare industry group focused on addressing supply chain challenges and meeting the requirements of regulations like the Drug Supply Chain Security Act (DSCSA). Using GS1 Standards, the most widely used supply chain standards in the world, she guides the implementation of these standards to help the pharmaceutical industry deliver safe products to patients. She earned a bachelor's degree from Villanova University and a Master of Business Administration from West Chester University.

11:55 AM — 12:55 PM North Ballroom

Luncheon, Exhibits, and Networking Break

12:55 PM — 2:10 PM South Ballroom

Session 7: eLabeling: Patient Interactions, Advanced e-Labeling Initiatives, and Public/Private Consortia Insights

While a key focus of e-labeling is how and when labels are converted from paper to digital, important aspects of e-labeling and its adoption go beyond the conversion itself. A key measure of value is patient benefit, including accessibility of elabeling across patient populations, interoperability across various points of care and care providers, and personalization to the individual patient. And a key enabler to driving forward e-labeling is Health Authority engagement and support. This session will address regulator interactions, early-stage developments, and global adoption patterns around e-labeling as well as patient benefits and interactions through key e-labeling initiatives.

Learning Objective : At the conclusion of this session, participants should be able to:

- Discuss regulator interactions, early-stage developments, and global adoption patterns for e-labeling
- Identify key concepts and technologies related to interoperability across care platforms and within the end-to-end labeling process
- Describe select in-flight patient-focused e-labeling initiatives and their current status

Track: General Session

Session Chair(s)

Theresa Brunone, MLS, MS

Head-Labelling Compliance and Implementation, Global Labeling
GlaxoSmithKline, United States

Terry has been in the pharmaceutical industry since 1993. She has supported Regulatory Affairs and Product Information areas throughout that time. Since 2003, she has worked with US and Global Labelling in Operations and Compliance areas. Her current role of Compliance Director assures that regulatory labelling throughout the local operating companies within GSK are managing their compliance with labelling safety updates. Historical note: She led the Structured Product Labeling Working Group Leadership Team, a group representing manufacturers, vendors, downstream users and the FDA in the varied uses and challenges of SPL, through 2019.

Kathleen Salazar, MA, MBA

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

Kathy Salazar is the Head of Global Labeling Implementation at Johnson & Johnson Innovative Medicine. She has over 27 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)

Gravitate-Health... Unlocking the Value in Electronic Product Information (ePI) for the Patient – Taking a Global Approach

Giovanna Ferrari, PhD

Regional Labelling Lead, Senior Director
Pfizer Ltd, United Kingdom

Giovanna Ferrari is a Senior Director at Pfizer with over 15 years' experience working in the regulatory sector of the pharmaceutical industry, specialising in labelling & product information since 2009. She currently works within the Pfizer International Labeling Group with regional responsibility for Europe and is also the global business owner for the Pfizer process for management of country labeling documents. Externally, Giovanna has represented Pfizer in a wide range of industry forums over the last few years, in particular focussing on e-labelling, and is the industry lead for a highly innovative and patient-focussed digital health information project that is being progressed via an IMI public-private partnership – Gravitate Health

Co-Creating New Ways to Communicate Medication Information 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.

FDA SPL-on-FHIR: Opportunities for Modernization and International Harmonization of Product Information

G. Scott Gordon, PhD

Senior Health Informatics Officer, OSP, CDER
FDA, United States

Since 2016, Dr. Gordon has been a lead for data standardization efforts including those for pharmaceutical quality, manufacturing, and labelling, as well as real-world data derived from health information technology for use in clinical research and pharmacovigilance. Before arriving at FDA, Dr. Gordon received his core scientific training with a Ph.D.

in Molecular Microbiology from Tufts University Medical School, entered the public health domain in 2005 working on public health emergency preparedness and from 2011 with a focus on public health informatics.

2:10 PM — 2:50 PM North Ballroom

Refreshments, Exhibits, and Networking Break

2:15 PM — 2:45 PM Cavalier A

Hosted Session/Non-CE: Case Study Spotlight hosted by Dr.Evidence: The Label and Beyond – How to Accelerate Strategy, Planning and Approval with AI-enabled Technology

Regulatory Affairs leaders play the central role in shaping regulatory strategy. However, the demanding submission and approval process often consumes significant time as we seek market intelligence insights to guide the process. We're navigating multiple websites, combing through massive documentation, and putting together manual comparisons, leaving little time for strategic reflection. Embracing AI-enabled solutions can streamline these repetitive tasks, allowing us to allocate more time to strategy.

Hayley Parker, Vice President, Global Regulatory Affairs for PepGen, will tackle this important topic. She will illustrate how advanced technology can facilitate the rapid generation of side-by-side label comparisons and expedite searches within and across SBAs and EPARs. She'll highlight how applying Generative AI chat to SBA and EPARs content can accelerate insight generation, and how machine learning models help identify key data points in competitive clinical trials. And she'll advise how to integrate these insights to accelerate strategy, submission, and approval.

Featured Topics:

- What's in the Label and how to rapidly and effectively leverage that intelligence
- What's not in the Label and how to find those insights to inform a faster pathway to approval
- Putting it all together: accelerated impact with AI-enabled technology

Track: General Session

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

Hayley Parker, PhD, MSc

Vice President Regulatory Affairs
PepGen, United States

Beginning her career at Cambridge University, Hayley began working in clinical research. Moving to GSK, continuing a career in clinical trials (HIV, respiratory viruses), Hayley began a part-time PhD and eventually transferred to Regulatory. Hayley joined the ALP team at Biogen Idec (UK) and then moved to the USA to lead Global Labeling. In 2016 Hayley joined Vertex Pharmaceuticals Inc., to lead and develop the Global Labeling function. Subsequently, Hayley joined Scholar Rock as VP of Regulatory Affairs as a therapeutic lead. Then she moved to her current position as VP Head of Regulatory Affairs and Medical Writing at PepGen Inc. a company developing treatments for rare neuromuscular diseases.

2:50 PM — 4:05 PM South Ballroom

Session 8: Unveiling Precision: AI, ML, and NLP in Regulatory Labeling

Join us for an informative session to hear regulatory perspectives on the use of technological innovation in regulatory labeling. As industries navigate an increasingly complex regulatory landscape, the integration of artificial intelligence (AI), machine learning (ML), and natural language processing (NLP) has emerged as a transformative force in enhancing the efficiency, accuracy, and compliance of labeling processes. In this interactive session, industry experts will explore the latest advancements and practical applications of AI, ML, and NLP in the regulatory labeling domain. Participants will gain invaluable insights into how these technologies are reshaping the regulatory landscape, driving precision in compliance, and revolutionizing traditional labeling methodologies.

Learning Objective : At the conclusion of this session, participants should be able to:

- Identify how AI-driven tools can minimize risks associated with labeling errors, ensure product safety, and maintain regulatory compliance
- Explain the use of AI and ML to support the work of labeling professionals by streamlining regulatory labeling workflows and automating repetitive tasks
- Evaluate the potential of AI in their labeling processes based on case studies presented

Track: Hosted Session

Session Chair(s)

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.

Theresa Brunone, MLS, MS

Head-Labelling Compliance and Implementation, Global Labeling
GlaxoSmithKline, United States

Terry has been in the pharmaceutical industry since 1993. She has supported Regulatory Affairs and Product Information areas throughout that time. Since 2003, she has worked with US and Global Labelling in Operations and Compliance areas. Her current role of Compliance Director assures that regulatory labelling throughout the local operating companies within GSK are managing their compliance with labelling safety updates. Historical note: She led the Structured Product Labeling Working Group Leadership Team, a group representing manufacturers, vendors, downstream users and the FDA in the varied uses and challenges of SPL, through 2019.

Speaker(s)

AI, Write Me a Product Insert

Evi Cohen, MBA, MS, MSc

Industry Leader, Life Sciences
Appian, United States

Evi is the Life Sciences Industry Leader at Appian. He is an experienced pharmaceutical executive with an extensive background developing global business portfolios with emphasis on new products, technologies, and IP. Previously, as Global Head of Life Sciences at ServiceNow Evi lead the Life Sciences strategy and solutions approach to creating value for patients. Prior to ServiceNow Evi was VP Global Life Science & Healthcare at Appian, VP Global Innovation at Catalent and held roles in Legal Affairs, R&D, Clinical Operations, Quality, CSV, Regulatory Affairs, and Program Management. He holds an M.B.A. in Pharmaceutical Management, MIT Certification in AI, M.S. in Biotechnology, and a B.S. in Chemistry.

AI, Write Me a Product Insert

Juan Jiménez, MBA

Lead Software Engineer, Product Strategy
Appian, United States

Juan has been with Appian for four years and currently serves as the Process Automation Technology Lead for Product Strategy. Prior to joining Appian, Juan worked for over 15 years as a consultant and independent contractor, leading customized software development projects for medium and large organizations. He earned a B.S. in Electrical Engineering from the Polytechnic University of Puerto Rico and an M.B.A. from the University of New Orleans.

Structured Labeling Creation Supported by NLP and AI

Niklas Jaenich, PhD, RPh

Head of Global Labeling Operations and Digitization
Boehringer Ingelheim, Germany

Dr. Niklas Jänich is Head of Global Labeling Operations & Digitization at Boehringer Ingelheim. In this position Dr. Jänich is responsible for Labeling process, systems, compliance and digitization as well as for driving the implementation of structured content management in the GxP-regulated Labeling process. Dr. Jänich is a certified pharmacist and holds a PhD in medicinal chemistry and a Master of Drug Regulatory Affairs.

What Does a Labeling Professional do in These Disruptive Times?

Aliza Nathoo

Senior Business Transformation Leader
F. Hoffmann-La Roche Ltd., Canada

Aliza has over 20 years of experience in the biopharmaceutical industry. She is an expert in structured content authoring, component content management, and content reuse. Over the last several years, she has used her extensive and varied expertise to evolve a theoretical enterprise content strategy into sustainable content operations for the Roche pharma organization. She collaborates with various organizational units to standardize content practices, implement structured content management technology solutions, and drive results that align with future work paradigms.

4:05 PM — 4:15 PM South Ballroom

Closing Remarks

4:15 PM — 4:15 PM

Meeting Adjourns