DIA LEARNING

Achieving Excellence in Regulatory Information Management (RIM)

Venkatraman Balasubramanian (Bala), PhD, MBA

VB Insights

Bala heads VB Insights, an advisory firm for the Healthcare and Life Sciences sector. Bala brings over 35 years of experience, mostly in the pharmaceutical industry. During his long tenure, he has been responsible for the introduction of Web, document management, global team collaboration, and regulatory information management applications to large pharma. Until recently, Bala was Head of the Healthcare and Life Sciences Industry Solutions Group at Orion Innovation. As an entrepreneur and a thought leader, he has been involved in initiatives to transform regulatory affairs from a document-centric function to a data-driven function. Bala has been associated with DIA for more than 14 years, most recently as the DIA RIM Working Group subteam lead for the RIM Reference Model.

Segolene Balling, MBA

Merck & Co., Inc.

Segolene is an Associate Director for Global Labeling at Merck. Prior to joining Merck, she was a Life Sciences consultant focused on developing and implementing cross-functional programs driving regulatory process optimization. Her areas of expertise include electronic labeling implementation, labeling systems, and regulatory submission process.

Vanessa Brewer-Yizar

Gan & Lee Pharmaceuticals

Vanessa is a Senior Manager for Global Regulatory Affairs at Gan & Lee Pharmaceuticals USA Corp. Throughout her career in the life sciences arena, her experiences and expertise have been focused on providing regulatory functions and global strategic assessments for pharmaceutical and medical devices companies. She has aided these companies' expansion in medical and innovative technology, servicing in the areas of cardiovascular imaging, laboratory diagnostics, and molecular medicines.

Kathie Clark, MA

Kathie Clark Expert Services for Life Sciences

Kathie is currently President of Kathie Clark Expert Services for Life Sciences, LLC, specializing in pharmaceutical regulatory, clinical and quality technology. In her last position, she was Product Director, eTMF and CTMS at Ennov Software for Life. Previously, she was the Product Manager for IQVIA's eTMF, eREG, and ePromo promotional materials management solution. She was Director of Professional Services at GlobalSubmit, where she worked with the FDA on their eCTD submission validation and viewing requirements, and she managed the Subject Matter Experts group providing support for regulatory solutions at First Consulting Group.

Meghan Cox

KPMG LLP

Meghan is a director at KPMG with 10+ years of consulting and industry experience that she leverages when delivering regulatory affairs services to pharmaceutical, medical device, and biotechnology organizations. She is responsible for developing and expanding the Regulatory Information Management service offerings for KPMG's life sciences clients. In addition to RIM, she also supports her clients with regulatory operating model redesign and data modernization projects.

Joel Finkle

Retired Regulatory IT Expert

Joel is a retired IT/Regulatory expert who began his adventures with electronic submissions and RIM when the Regulatory Affairs team came down to IT and asked to convert all clinical reports to Word Perfect for the FDA, and said, “Let’s find out.” He split his career between sponsors (most recently BeiGene) and vendors (most recently IQVIA), developing tools for regulatory writing, RIM, and electronic submission, and was part of the team that developed the RPS standard planned for eCTD v4.0.

Steve Gens, MSOD

Gens & Associates

Steve is the founder and Managing Partner of Gens & Associates, a life sciences benchmarking and advisory firm specializing in regulatory benchmarking, performance improvement, regulatory information management, and organizational transition. He has 35 years of life sciences experience, having spent his early career at Johnson & Johnson in a variety of management positions. He then transitioned to consulting, where he led global life sciences consulting practices for First Consulting Group and Booz Allen Hamilton.

Vahé Ghahraman, PhD, MS

Apellis Pharmaceuticals, Inc.

Vahé has over 23 years of global regulatory operations, project management, and regulatory technology experience, with special focus on regulatory information management, data governance, business process optimization, regulatory intelligence, technology, medical imaging, and global submissions strategy. Vahé has held leading roles at Alexion, Takeda, Dyax, Millennium, Parexel, and Datafarm, and has also been involved in consulting activities. He established and heads the Global Regulatory Operations function at Apellis. Vahé is an active member of the DIA RIM Working Group subteam on RIM Reference Model and Intelligent Automation.

Shakul Hameed, MBA, MS

Sanofi CHC

Shakul is a seasoned Regulatory Operations/Regulatory Information Management (RIM) professional with over 18 years of experience in the pharmaceutical and contract research organization (CRO) industries. He is currently working at Sanofi CHC, where he serves as the Regulatory Information Management Digitalization Lead. He has held regulatory operations positions at Novartis, Baxter, Baxalta, Shire, Takeda, PRA, IQVIA, and BeiGene. Shakul's expertise includes leading and driving global strategies for GRA systems, global submission publishing and delivery, submission standards, document management, and regulatory information management (including XEVMPD and IDMP) as well as regulatory digitalization.

John Jones, MBA

Entitech Solutions

John is the founder and CEO of Entitech Solutions, a life sciences-focused systems integrator. John has 25+ years of experience in the pharmaceutical industry providing IT solutions in areas of Clinical Trials, Regulatory, Document Management, Supply Chain & Manufacturing, Commercial, and Medical Affairs. His most immediate and relevant initiatives are focused on helping life sciences companies build scalable solutions using best-of-breed systems and integration and API management solutions. John has also placed Entitech Solutions’ focus heavily on the generative AI space and is providing guidance and solutions for several customers in this area.

Renata Kover

Cencora, Inc.

Renata is the director of US CMC and Regulatory Affairs at Cencora PharmaLex. Renata has worked in industry for 20+ years in development, manufacturing, and leading the process for CMC registration of complex development programs specializing in a variety of therapeutic areas including small molecules, oncology, and radiopharmaceuticals.

Gerald Kukko

Johnson & Johnson

Gerald is a Business Outcomes and Delivery Manager for Global Regulatory Affairs at J&J Innovative Medicine. With decades of industry experience, he continues to bring insights that lead innovations to improve and evolve regulatory information management solutions.

Dominique Lagrave, PharmD

Accumulus Synergy, Inc.

Dominique has over 25 years of international regulatory affairs experience with the last 20 years spent in a global regulatory operations leadership role. Past experiences include work at Amgen, Novo Nordisk, Liquent-Parexel, Dendreon, and Galderma. Dominique joined Accumulus Synergy, a nonprofit organization, in 2022 as the SVP of Regulatory Innovation, where he supports the adoption of cloud technologies across the regulatory ecosystem. He also currently serves as a Board Member of the IRISS Forum.

Karl-Heinz Loebel

PharmaLex

For 19 years, Karl-Heinz has worked for PharmaLex, now Cencora PharmaLex, in leading roles in Regulatory Operations and Regulatory Informatics. His expertise includes electronic submissions, regulatory digitalization, and systems implementation in pharmaceutical companies. He supported global-scale electronic submissions on the operational, strategic, and project-management level and is currently leading the company's IDMP/SPOR activities.

Sheila Mahoney-Jewels, MBA

LifeSciHub

Sheila has spent over 20 years at the intersection of sponsor operations, life sciences R&D technology, and the drug development vendor ecosystem. Her industry-recognized thought leadership efforts include Co-Founder and Co-Chair of the Drug Information Association's (DIA) RIM Working Group, and Regulatory Team Lead for DIA's Framework for Paper Destruction v2.0. Sheila currently focuses on independent research in aspects of drug development agility, creative application of advanced data science and AI/ML throughout drug sponsor operations, and enabling drug sponsors to embrace and engage the "microvendor" (small, niche businesses) ecosystem.

Tris Nockles

Navitas Life Sciences, Inc.

Tris has led the Navitas Life Sciences Regulatory Industry Networks for the last four years. Prior to that, she worked for 18 years in Fortune 500 life sciences companies with experiences across pharmaceuticals, devices, and consumer products. She specializes in strategy, process improvement, and development initiatives focusing on regulatory, end-to-end labeling, and Regulatory Information Management (RIM). Tris also previously co-led the IRISS topic group on e-labeling.

Donald Palmer, MA

Numbers Unlimited, Ltd.

Prior to retiring in 2023, Donald was Senior Director of Regulatory Affairs for business transformation at IQVIA. During a 25-year career with sponsors, vendors, and a CRO, his experience has been in bridging the business and technology divide. He has been a strong proponent of standards and data governance.

Keith Parent

Court Square Group

Keith is the founder and CEO of Court Square Group, a life sciences-based managed service firm. Keith is a serial entrepreneur who also founded RegDocs365 and EmpiraMed among other companies focused on the pharmaceutical, biotech, and medical device arenas. He has worked in multiple DIA Working Groups including the Destruction of Paper, AI, and RIM Reference Model working groups. He also leads an IRISS group on Acquisitions, Mergers and Divestitures. His focus is on using technology to enable systemic change within the life sciences field.

Nirjhar Sarkar, MS

Independent Consultant

Nirjhar is a seasoned life sciences professional with over 20 years of experience. Driven by a passion for leveraging technology to enhance patient care, Nirjhar played a pivotal role in driving strategic initiatives and navigating regulatory complexities at leading companies like Novartis and EMC India. As a thought leader and trusted adviser, he consistently seeks innovative solutions to reimagine healthcare and transform patient outcomes.

Karin Schneider, MS

Janssen Research & Development

Karin, an experienced regulatory affairs professional at J&J Innovative Medicine, is a highly regarded thought leader in content management. Known for her innovative thinking and passion for pushing boundaries, she collaborates with other thought leaders to foster growth and generate new ideas. Karin strongly believes that the regulatory information management landscape is on the brink of transformative change.

Patterson Shafer

FTI Consulting

Pat leads the Regulatory and Quality Life Sciences practice at FTI Consulting. Throughout his career, he has helped large biopharma and medical device companies improve operations as well as build, launch, and grow pre-revenue innovators. In collaboration with the Medical Device Innovation Consortium, he has led multiple workstreams as part of the FDA's Case for Quality and is active in supporting regional and international medtech clusters. Pat also serves as an expert witness to help resolve disputes within the industry.

Cary Smithson, MBA

LeapAhead Solutions, Inc.

Cary is the Managing Partner of LeapAhead Solutions and has over 30 years of experience in life sciences focused on leading strategic initiatives to drive increased business productivity, enhance regulatory compliance, and simplify information management and the use of technology. Her areas of expertise include regulatory information management, intelligent automation, data strategy/governance, e-submissions, R&D and GxP content management, IT strategy, enterprise architecture, Agile, business process optimization, and project/program/portfolio management. Cary co-leads the DIA RIM Working Group, leads the DIA RIM Intelligent Automation Topic Team, and regularly serves as an industry thought leader.

Cheryl Tan, MS

FTI Consulting

With over five years of hands-on experience in the pharmaceutical, medical device, and foods for special dietary uses (FSDU) industries, Cheryl specializes in navigating regulatory challenges and developing comprehensive regulatory strategies. Her expertise in regulatory submissions, regulatory information management, and regulatory intelligence has enabled organizations to stay ahead of the curve and maintain their competitiveness.

Brian Williams

KPMG LLP

Brian is a leader in KPMG's Life Sciences Consulting practice, with a focus on serving the regulatory affairs function. He implements RA process and technology changes in order to help clients improve efficiency and enable compliance. His experience includes leading programs related to global RIM deployments, data modernization, RA operating model redesign, and implementation of Automation and AI in Regulatory processes.