DIA

Regulatory Submissions, Information, and Document Management Forum

Virtual Short Course February 9 | Virtual Short Course February 10 | In-Person Primer February 12
Forum February 13-15

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Overview

The last few years have shed light on the importance of operational efficiency of the management of regulatory information to ensure quality regulatory submission to health authorities. We have seen how the ability to perform at this level has allowed drug companies to bring therapeutics and vaccines to patients faster. At DIA's Regulatory Submissions, Information, and Document Management (RSIDM) Forum, we will hear from industry and regulatory stakeholders working across the scope of regulatory information to examine current and evolving data standards and requirements and effective regulatory information management approaches to align related people, processes, and technology. The Forum presents four tracks: Regulatory Informatics Business, Regulatory Informatics Technology, Trial Master File (TMF) Inspection Readiness and Electronic Document Management, and Electronic Regulatory Submissions. Cross-track sessions provide the opportunity to discuss key connection points across major components of regulatory information, and plenary sessions featuring regulatory intelligence updates by FDA and other regulatory authorities are offered each day.

This Forum provides multiple opportunities for networking, knowledge sharing, and education for both business and technology-focused attendees.

Event Goals and Offerings

- **Gather insights** to hot topics impacting regulatory information in life sciences research and development
- Hear directly from **global regulators** on regulatory plans, priorities, and updates to incorporate into your everyday work and processes
- Identify how **advanced technologies and innovation** can be applied to impact functions and processes within regulatory affairs

Why You Can't Miss it

- **Network** with like-minded professionals focused on regulatory information in life sciences research and development to discuss best practices and lessons learned
- Learn how to apply successful **use cases**, real-world examples, and practical outcomes into your own company or organization
- Gain insights and discuss how stakeholders are impacted by everyday challenges and **how they overcome** these challenges
- Evaluate **future applications** of regulatory informatics, trial master file inspection readiness, electronic document management, and electronic regulatory submissions

Meeting Designed for

- Regulatory Affairs and Operations
- Regulatory Information Management
- Regulatory Informatics
- Submissions and Global Submissions Management/Project Management
- Medical, Technical, and Regulatory Writers
- TMF and eTMF Management
- Informatics/Bioinformatics Professionals
- Clinical Data/Data Managers
- Information Technology and Support Personnel
- Document and Records Management/ Specialists
- Essential Document Process and Business System Owners
- Regulatory Standards Implementation Specialists and Associates
- Clinical Operations and Processes
- Quality Management
- Quality Assurance/Quality Control and Compliance Professionals
- Strategic Planning and Operations
- Contract Research and Service Support Providers
- Emerging Pharmaceutical/Biotech/ Device Professionals
- Outsourcing/Clinical Outsourcing
- Vendor Relationship Managers

Schedule-At-A-Glance

Track Key: Track 1: Regulatory Informatics Business **Track 2:** Regulatory Informatics Technology
Track 3: Trial Master File (TMF) Inspection Readiness and Electronic Document Management (EDM)
Track 4: Electronic Regulatory Submissions (ERS)

VIRTUAL SHORT COURSE | THURSDAY, FEBRUARY 9

Sessions are held in ET

10:00AM-2:00PM	**Short Course:** The Future of Documents: Deep-Dive into Structured Content **Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	

VIRTUAL SHORT COURSE | FRIDAY, FEBRUARY 10

10:30AM-2:00PM	**Virtual Short Course:** Structured Data: IDMP is Not the Goal **Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend**	

IN-PERSON PRIMER | SUNDAY, FEBRUARY 12

10:00AM-5:00PM	**Regulatory Content and Submission Primer:** Content from Authoring to Archive Registration (In-Person Exclusive) **This Primer Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	**Forest Glen Foyer (Lower Level)**

DAY ONE | MONDAY, FEBRUARY 13

11:30AM-5:25PM	**Forum Registration**	**Ballroom Foyer (Upper Level)**
1:00-1:25PM	**Welcoming Remarks and Presentation of the Excellence in Service Award** **Congratulations to our 2023 Excellence in Service Awardees!**  **V. "Bala" Balasubramanian, PhD, MBA**, Senior Vice President and Global Head, Healthcare and Life Sciences, Orion Innovation  **Mark Gray**, Senior Project Manager, DSB, CBER, FDA	**Ballroom E-H**
1:25-2:00PM	**Session 1:** Keynote Address  **Ulo Palm, MD, PhD, MBA**, Chief Medical Officer, Vaxxinity	**Ballroom E-H**
2:00-2:45PM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
2:15-2:45PM	**SPONSORED SESSION:** Case Study hosted by Court Square Group/Adlib Software The "Easy" Button for eTMF Classification: Using AI to Streamline Classification of Clinical Trial Documents	**Forest Glen**
2:45-4:00PM	**Session 2:** FDA Plenary: PDUFA VII Information Technology and Bioinformatics	**Ballroom E-H**
4:10-5:00PM	**Session 3:** FDA: Ask the Regulators	**Ballroom E-H**
5:00-6:00PM	**Networking Reception in the Exhibit Hall**	**Ballroom A-D**

DAY TWO | TUESDAY, FEBRUARY 14

7:30AM-5:30PM	**Registration**	**Ballroom Foyer**
7:30-8:00AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:00-9:15AM	**Session 4:** FDA Plenary: Electronic Submissions Update	**Ballroom E-H**
9:25-10:40AM	**Session 5:** International Regulatory Authority Updates	**Ballroom E-H**
10:40-11:15AM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**

10:45-11:15AM	**SPONSORED SESSION:** Case Study hosted by Calyx A Guide to Bringing Regulatory Publishing In-House – Key Questions to Ask	**Forest Glen**
11:15AM-12:30PM	**Session 6:** BREAKOUT SESSIONS	
	Track 1: Driving Performance from RIM	**Ballroom FGH**
	Track 2: Optimizing Regulatory Operations Through the Application of Advanced Technologies	**White Flint (Lower Level)**
	Track 3: Advancing Inspection Readiness Through Data Driven Planning and Continuous Process Improvement	**Brookside (Lower Level)**
	Track 4: Submissions Are Data – Changing Formats and Improving the Submission Process	**White Oak (Lower Level)**
12:30-2:00PM	**Networking Luncheon in the Exhibit Hall**	**Ballroom A-D**
12:14-1:45PM	**SPONSORED LUNCH AND LEARN:** Hosted by Genpact (INVITATION ONLY)	**Forest Glen**
2:00-3:15PM	**Session 7:** BREAKOUT SESSIONS	
	Track 1: New Developments in RIM Reference Model	**Ballroom FGH**
	Track 2: Is it Time to Streamline Your Processes with Structured Content Management?	**White Flint**
	Track 3: Regulatory Submissions: Special Requirements in Europe and China	**Brookside**
	Track 4: Pairing Strategic Vision With Innovation To Support Regulatory Processes	**White Oak**
3:15-4:15PM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
3:30-4:15PM	**SPONSORED SESSION:** Case Study hosted by IQVIA: Reduce Time, Cost and Risk, from Drug Discovery Through Post-Registration	**Forest Glen**
4:15-5:30PM	**Session 8:** BREAKOUT SESSIONS	
	Track 1: IDMP Ontology: Semantic Interoperability Throughout the Entire Medicinal Product Lifecycle	**Ballroom FGH**
	Track 2: Business Benefits and Insights Gained from Regulatory Intelligent Automation Implementations	**White Flint**
	Track 3: The Evolution of Documents to Digital –New Solutions Using Emerging Technologies	**Brookside**
	Track 4: Submission Quality	**White Oak**
5:30-6:00PM	DIA EDM Structured Submission Reference Model Kick-off	**Forest Glen**

DAY THREE | WEDNESDAY, FEBRUARY 15

7:30AM-2:00PM	**Registration**	**Ballroom Foyer**
7:30-8:30AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:30-9:45AM	**Session 9:** BREAKOUT SESSIONS	
	Track 1: Regulatory 3.0 - A Data Driven Perspective	**Ballroom FGH**
	Track 2: Advancing Data Based RIM Based on Lessons Learned and the Practical Application of Governance Frameworks	**White Flint**
	Track 3: Using Automation to Replace Manual Documentation Processing, Realize Resource Efficiencies, and Gain Valuable Insights Into Your Data	**Brookside**
	Track 4: Dynamic Submission Planning - Plan, Replan, and Execute	**White Oak**

9:45-10:30AM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
10:00-10:30AM	**SPONSORED SESSION:** Case Study hosted by ArisGlobal: Revolutionize Management of Global Lifecycle Submissions	**Forest Glen**
10:30-11:45AM	**Session 10:** BREAKOUT SESSIONS	
	Track 1: "Good RIM" – Key Considerations on Establishing Comprehensive Data Readiness, Governance & Quality Management	**Ballroom FGH**
	Track 2: Along the Path of Drug Approval; A Hodgepodge of IDMP, EMA Support for SMEs, and ICH M11 CeSHarP	**White Flint**
	Track 3: How Innovative Collaboration Supports Compliance Across the Regulatory Ecosystem	**Brookside**
	Track 4: Transformation in Submission Management: Current Activities and Future Trends	**White Oak**
11:45AM-1:15PM	**Networking Luncheon in the Exhibit Hall**	**Ballroom A-D**
1:15-2:00PM	**Session 11:** FDA - Ask the Regulators	**Ballroom E-H**
2:00-2:15PM	**Closing Remarks**	**Ballroom E-H**
2:15PM	**Forum Adjourns**	

Learning Objectives

At the conclusion of this forum, participants should be able to:

- Explain and gain insights on regulatory updates from global regulatory health authorities
- Apply insights from the PDUFA reauthorization and explain selected key data standards initiatives for the US
- Describe eCTD v4.0 and its implementation in various regions
- Identify KPI metrics to demonstrate RIM performance and describe a valuable roadmap to high RIM performance
- Identify how advanced technologies can be applied to impact functions and processes within regulatory affairs
- Describe the key requirements for regulatory submissions in Brazil, China, Europe, Japan, and the US
- Recognize common electronic submission errors and identify tools and techniques to avoid and/or solve them
- Describe and understand how team collaboration and an effective team strategy achieve submission goals
- Describe the practicalities and benefits of structured content management
- Identify practical aspects of implementing content authoring automation for regulatory submission documents and the process improvements needed to streamline those processes
- Apply insights and implementation guidelines to increase IDMP adoption success
- Discuss approaches for implementing and scaling intelligent automation technologies, the value in doing so, and how to deal with challenges along the way
- Evaluate the impacts of digital transformation on the regulatory workforce
- Evaluate how to gain intelligent insights from aggregated data
- Describe the key elements of establishing a data governance program, the approaches to data unification and its sustainability without system integration, and the impact of implementing RIMS with poor data quality
- Describe the current deliverables and the latest developments on the ICH M11 guideline, protocol template and technical specification

Track Descriptions

Track 1: Regulatory Informatics Business - addresses the governance, processes and standards around life cycle management of regulatory data, including key challenges shaping the global regulatory and business environments.

Track 2: Regulatory Informatics Technology - covers (emerging) technologies and solutions for data management and analytics to support efficient data control and quality, including hot topics such as Artificial Intelligence (AI) and Structured Content Management (SCM)

Track 3: Trial Master File (TMF) Inspection Readiness and Electronic Document Management (EDM) - track examines the processes, systems, and best practices for content management across the product lifecycle, including alignment with RIM systems for optimal use of regulatory information as well as the downstream impact on Inspection Readiness in the Trial Master File.

Track 4: Electronic Regulatory Submissions (ERS) - explores best practices, innovations, and future trends for creating and managing quality global submissions in an evolving regulatory landscape.

Continuing Education Credit

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As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to **.8*** CEUs for this program.

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IACET CEUs will be offered if you attend the live virtual Short Courses on February 9 & 10, 2023.

Credit will not be awarded for attending the Primer and Forum sessions.

Continuing Education Credit Allocation

February 9, 2023 – Virtual Short Course #1:

The Future of Documents: Deep Dive into Structured Content: .4 CEUs

February 10, 2023 – Virtual Short Course #2:

On the Road to an EU Filing: Getting Familiar with Critical EMA IT Systems: .4 CEUs

February 12, 2023 – Primer:

Regulatory Content and Submission Primer: Content from Authoring to Archive: No CEUs

February 13-15, 2023

Regulatory Submissions, Information, and Document Management Primer & Forum: No CEUs

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual short course, you must virtually attend the short course(s), in their entirety, achieve a passing score of 80% or better on the post-assessment, and complete the program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Monday, February 13, 2023**.

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Disclosure statements are included with each speaker's biographical sketch.

DIA staff members have no relevant financial relationships to disclose.

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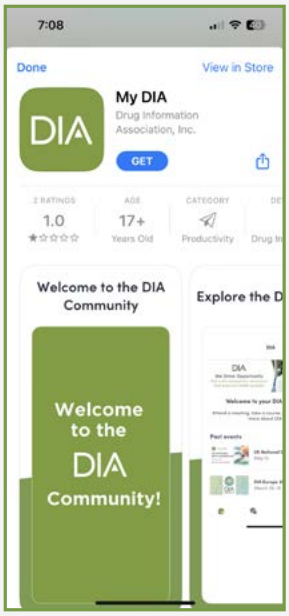

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Exhibitor Directory

Regulatory Submissions, Information, and Document Management Forum

February 13-15, 2023

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

DIA

ArisGlobal, LLC

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EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and provide solutions covering the entire regulatory landscape: Planning & Tracking, Document Management, Submission Management, Safety Management, and Product Registration. Check out www.extedo.com and visit our booth #213. Looking forward to seeing you!

Generis

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LORENZ Life Sciences Group

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LORENZ Life Sciences Group (www.lorenz.cc) has been developing and marketing software solutions for the life sciences market since 1989. LORENZ offers a range of Regulatory Information Management (RIM) solutions for industry, health authorities and academia to be globally compliant. LORENZ's RIM system allows solutions to be combined depending on the functionality required. Interoperability with third-party solutions and the ability to automate processes enable improved operational efficiency.

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February 13-15, 2023

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ArisGlobal, LLC — Booth 105

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Court Square Group, Inc. — Booth 100

Contact: Keith Parent
Phone: 413.746.0054
Email: info@courtsquaregroup.com
Website: *https://www.courtsquaregroup.com/*
LinkedIn: *https://www.linkedin.com/company/court-square-group*

Court Square Group is a leading managed services technology company dedicated to empowering those who change lives. Our Audit Ready, Compliant Cloud (ARCC) infrastructure provides Life Science companies with the highest level of data integrity from pre-clinical to clinical and regulatory approval through manufacturing. We manage the 21CFR Part 11 validated infrastructure so you can focus on secure Clinical Collaboration & Content Management.

DDi LLC — Booth 210

Contact: Subrata Biswas
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Email: info@ddismart.com
Website: *https://www.ddismart.com*

DDi is an innovative Technology partner for BioPharma and Medical Device companies of various sizes, providing innovative Technology products and Automation/AI solutions that are fit-for-purpose, compliant, and cost effective. DDi serves technology needs of our clients in Clinical, Regulatory, Labeling and Enterprise domains.

DocShifter — Booth 109

Contact: Geert van Peteghem (CEO) &
Paul Ireland (VP Life Sciences)
Phone: 9 242 87 39
Email: geert.vanpeteghem@docshifter.com
Website: *https://www.docshifter.com*
LinkedIn*: https://www.linkedin.com/company/docshifter*

Accelerate time to market through automated document conversion, validation and report generation. Compliant, fast, automated, and scalable file format conversion for the regulated enterprise. On-premise or in your private/hybrid cloud. We support +300 file formats. Leading pharmaceutical companies rely on DocShifter software for high-quality conversion of all their digital files. Easily convert thousands or even millions of files in a digital file format of your choice.

Docxonomy — Booth 112

Contact: Bryan Reynolds
Phone: 73327182272
Email: bryan.reynolds@docxonomy.com
Website: https://www.docxonomy.com
LinkedIn: https://www.linkedin.com/company/docxonomy/

Docxonomy is an intelligent insight solution for enterprise that crawl and analyze unstructured and structured data behind the firewall regardless of where it is stored. We leverages AI and machine learning to analyze all types of files, including Office documents, PDFs, videos, audio and images. We draw context and meaning through this analysis, including industry terminology, enabling the platform to automatically classify files, identify entities, recognize similarity and answer questions.

Ennov — Booth 101

Contact: Chet Shemanski
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Website: https://en.ennov.com/
Twitter: https://twitter.com/EnnovGroup
LinkedIn*: https://www.linkedin.com/company/ennov*
Facebook: *https://www.facebook.com/profile.php?id=100063464291433*

Headquartered in Paris, with offices in the US and UK, Ennov provides the most original, comprehensive, and cost-effective suite of software solutions for the life sciences industries. We proudly serve over 250 companies and 250,000 users globally. For more than 20 years, we have been developing innovative, powerful and easy-to-use Enterprise Document Management, Submission Publishing, Regulatory Information Management software based on our unified compliance platform.

EXTEDO — Booth 213

Contact: Andrew Skopek
Phone: 855.328.3500
Email: skopek@extedo.com
Website: *https://www.extedo.com/*
Twitter: *https://twitter.com/extedo*
LinkedIn: *https://www.linkedin.com/company/extedo/*

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and provide solutions covering the entire regulatory landscape: Planning & Tracking, Document Management, Submission Management, Safety Management, and Product Registration. Check out www.extedo.com and visit our booth #213. Looking forward to seeing you!

fme US — Booth 202

Contact: Rene Rosenberg
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Website: https://fme-us.com
Twitter: *https://twitter.com/fmeUS_LLC*
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fme Life Sciences is a leading provider of business and technology services, Content Services, and ECM solutions to the Life Sciences Industry. We are trusted advisors and systems integration specialists across the Clinical, Regulatory and Quality and Manufacturing domains in Europe and North America. We do not exclusively recommend or promote any platform or vendor, but rather focus on providing our clients with an independent perspective of the solutions available.

FTI Consulting — Booth 212

Contact: Pat Shafer
Phone: 646.379.8307
Email: pat.shafer@fticonsulting.com
Website: https://www.*fticonsulting.com*

FTI Consulting's world-class capabilities across pharmaceuticals, biotechnology, medical technology and the healthcare ecosystem enable us to assist clients to solve their most complex challenges, capitalize on opportunities and achieve their strategic and operational objectives. FTI collaborates with our clients to assess their regulatory capabilities, streamline their regulatory processes and strengthen the integration among regulatory affairs, the business, and the healthcare ecosystem.

Generis — Booth 013

Contact: Karolina Rogowska
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Email: info@generiscorp.com
Website: https://www.caralifesciences.generiscorp.com/
Twitter: https://twitter.com/Generis_Cara
LinkedIn: https://www.linkedin.com/company/1567663/

Generis is a UK-headquartered developer of world-class data, content and business process management for regulated industries globally. 60% of the top 20 life sciences companies rely on Generis' flagship CARA™ Life Sciences Platform, including AbbVie, Biogen, Reckitt, BMS, Bayer, Pfizer, and Merck KGaA. Today Generis serves more than 750,000 users worldwide, across use cases ranging from RIM, Regulatory / R&D and Safety use cases to Clinical, Non-clinical, Quality GxP, CMC, PV and more.

Genpact — Booth 108

Contact: Padmanabham Navuluri (Paddy)
Phone: 203.690.7954
Email: event.marketing@genpact.com
Website: *https://www.genpact.com/*
Twitter*: https://twitter.com/genpact*
LinkedIn*: https://www.linkedin.com/company/genpact/*
Facebook: *https://www.facebook.com/pages/Genpact/105635026136729*

Genpact is a global professional services firm delivering outcomes that transform business and shape the future. Guided by our experience redesigning and running thousands of processes, global companies partner with us to drive innovation and turn insights into action and outcomes. We create lasting competitive advantage for clients through our digitally enabled operations and Data-Tech-AI services. See how we're in relentless pursuit of a world that works better for people at genpact.com

Gens & Associates, Inc. — Booth 209

Contact: Gens & Associates
Phone: 267.614.0935
Email: corporate@gens-associates.com
Website: *https://gens-associates.com/*
LinkedIn: *https://www.linkedin.com/company/42081581/admin/*

Gens & Associates is a boutique Life Science benchmarking and advisory firm specializing in operational performance improvement, benchmarking, World Class RIM?, and organizational transition. Our focus is the regulatory domain and how it connects with clinical, commercial, safety, quality, and health authorities. Our mission is to help the regulatory eco-system improve their performance through our recognized research platform that brings precision to the most effective changes and investments.

inSeption Group, LLC — Booth 208

Contact: Brian Sulpizio
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Email: Bsulpizio@inseptiongroup.com
Website: *https://www.inseptiongroup.com*
Twitter: *https://www.twitter.com/PrimeVigilance*
LinkedIn*: https://www.linkedin.com/in/sulpizio*

inSeption Group, an outsourcing organization built upon a culture of exceptional service and quality, provides medical writing, QC, and regulatory operations/publishing services for a variety of clinical/regulatory deliverables. inSeption's highly experienced, dedicated team members integrate with clients to seamlessly manage the complexities of timeline management, resourcing, document interdependencies, quality control, submission compilation, and transmission to regulatory agencies.

IQVIA — Booth 204

Contact: Scott Higgins
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Email: ScottM.Higgins@iqvia.com
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Twitter*:* https://twitter.com/iqviacompliance
LinkedIn: https://www.linkedin.com/showcase/iqvia-global-compliance

IQVIA provides regulatory, scientific, and medical advisory services supported by our data and RIM Smart technology to enhance customer journeys from early drug development through submissions and post-registration.

IRISS Forum — Booth 211

Contact: Kelly Hnat
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LinkedIn*: https://www.linkedin.com/company/iriss-forum*

IRISS Forum is a non-profit dedicated to advancing Implementation of Regulatory Information and Submission Standards for life sciences globally.

Kivo — Booth 200

Contact: Theresa Pinnell
Phone: 617.320.3663
Email: theresa@kivo.io
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LinkedIn*: https://www.linkedin.com/company/kivoio*

Kivo's regulatory platform is built for how you work. Our core document management solution has been on the market for over nine years, with new leadership and funding, we have expanded into eTMF and submission support business processes. Author, review, collaborate, approve

and e-sign drug development documents in a secure validated workspace. Share and distribute as required to regulatory agencies, clinical teams or partners. We strive to provide value-based solutions that fit the needs of dynamic life science organizations. Kivo complements its strong product offerings with exceptional customer support.

KPMG — Booth 012

Contact: Brian Williams
Phone: 312.995.3582
Email: bewilliams@kpmg.com
Website: *https://www.kpmg.us/insights/2022/regulatory-affairs-services-life-sciences.html*
Twitter*: https://twitter.com/KPMG*
LinkedIn: https://www.linkedin.com/company/kpmg-us/

KPMG is a leading professional services firm, with over 200,000 employees globally. Our Life Sciences consulting practice has focused teams serving Regulatory Affairs and related functional areas. We aim to help clients improve Regulatory Affairs activities through process optimization, technology/digital changes, and regulatory strategy enablement. These initiatives help bring products to market more quickly, while reducing compliance risk and enabling a sustainable approach to key activities.

LORENZ Life Sciences Group — Booth 201

Contact: Yaprak Eisinger
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LinkedIn*: http://www.lorenz.cc/linkedin*

LORENZ Life Sciences Group (www.lorenz.cc) has been developing and marketing software solutions for the life sciences market since 1989. LORENZ offers a range of Regulatory Information Management (RIM) solutions for industry, health authorities and academia to be globally compliant. LORENZ's RIM system allows solutions to be combined depending on the functionality required. Interoperability with third-party solutions and the ability to automate processes enable improved operational efficiency.

MMS Holdings — Booth 010

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Email: drobinson@mmsholdings.com
Website: *https://www.mmsholdings.com/*
Facebook*:* https://www.facebook.com/mmsholdings/
Twitter: https://www.twitter.com/mmsholdings
LinkedIn: *https://www.linkedin.com/company/mms-holdings-inc-/mycompany/*

MMS Holdings (MMS) is an innovative, data-focused CRO that supports the pharmaceutical and biotech industries with a proven, scientific approach to complex trial data and regulatory submission challenges. Strong industry experience, technology-enabled services, and a data-driven approach to drug development make MMS a valuable CRO partner, creating compelling submissions that meet rigorous regulatory standards. With a global footprint across 4 continents, MMS maintains a 97% satisfaction rating.

NNIT — Booth 107

Contact: Toni Lakin-Ritter
Phone: 484.631.3030
Email: nnitcontact@nnit.com
Website: https://www.nnit.com
LinkedIn*: https://www.linkedin.com/company/nnit*

NNIT provides a wide range of IT and consulting services to the global life sciences industry and has been a trusted partner to life sciences companies for +25 years. We are a leading global RA advisory and consultancy unit committed to digitally transform Regulatory Affairs into an influential strategic and data driven business unit. We leverage thought leadership knowledge and the newest technology, with implementation excellence and successive maintenance service.

OpenText — Booth 110

Contact: Robin Gellerman
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Email: rgellerm@opentext.com
Website: https://www.opentext.com/products/documentum-for-life-sciences
Twitter: https://www.twitter.com/OpenText
LinkedIn*: https://www.linkedin.com/company/opentext/*

For more than 30 years, OpenText Documentum has helped Life Sciences organizations accelerate clinical trials, improve regulatory submission quality, and ensure manufacturing process compliance across the extended enterprise. OpenText Documentum continuously improves upon its comprehensive solutions that leverage agency guidance and industry leading practices while providing the most mature and proven products in the cloud as a validated solution.

PharmaLex GmbH — Booth 207

Contact: Piet Lesange
Phone: 621.181.5380
Email: contact@pharmalex.com
Website: https://www.pharmalex.com
Twitter: https://www.twitter.com/OpenText
LinkedIn*: https://www.linkedin.com/company/pharmalexglobal/*

PharmaLex is a leading provider of specialized services for the pharma, biotech and medtech industries. We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and

post-approval/maintenance post-launch activities. Our experts use technology enabled solutions to support you through the entire product lifecycle.

Qdossier - a Celegence company Booth 102

Contact: Matthew Tyler
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Email: mtyler@celegence.com
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LinkedIn: *https://www.linkedin.com/company/celegence/*

Qdossier, a Celegence company, provides the pharmaceutical industry with regulatory consulting services such as Publishing & Submission, Labelling, RIMS, IDMP, Medical Writing, & Regulatory Strategy. Our advanced technology platform - Dossplorer™ is a cloud-based dossier management solution, allowing clients to share, review, and manage eCTD and other dossier formats. Dosscriber™ eCTD document templates also enable clients to author right first time documents and optimize lifecycle management.

Red Nucleus Booth 106

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LinkedIn*: https://www.linkedin.com/company/red-nucleus/*

Bringing a wealth of diverse expertise across the life science industry; to support our clients as they navigate the market realities of today and tomorrow. By integrating our deep scientific, process, training, and market access knowledge with unmatched creativity and digital innovation, we are your trusted partner in developing meaningful strategies, products, and solutions that provide actionable insights and measurable results.

Veeva Systems, Inc. Booth 111

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Facebook*:* https://www.facebook.com/VeevaSystems
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Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,000 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. More than 350 companies are transforming regulatory operations with Veeva Vault RIM Suite applications to speed execution and keep pace with evolving health authority requirements.

ZS Booth 104

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ZS is a management consulting and technology firm focused on transforming global healthcare and beyond. We leverage our leading-edge analytics, plus the power of data, science and products, to help our clients make more intelligent decisions, deliver innovative solutions and improve outcomes for all. Founded in 1983, ZS has more than 12,000 employees in 35 offices worldwide. To learn more, visit https://www.zs.com/or follow us on Twitter and LinkedIn.

DIA

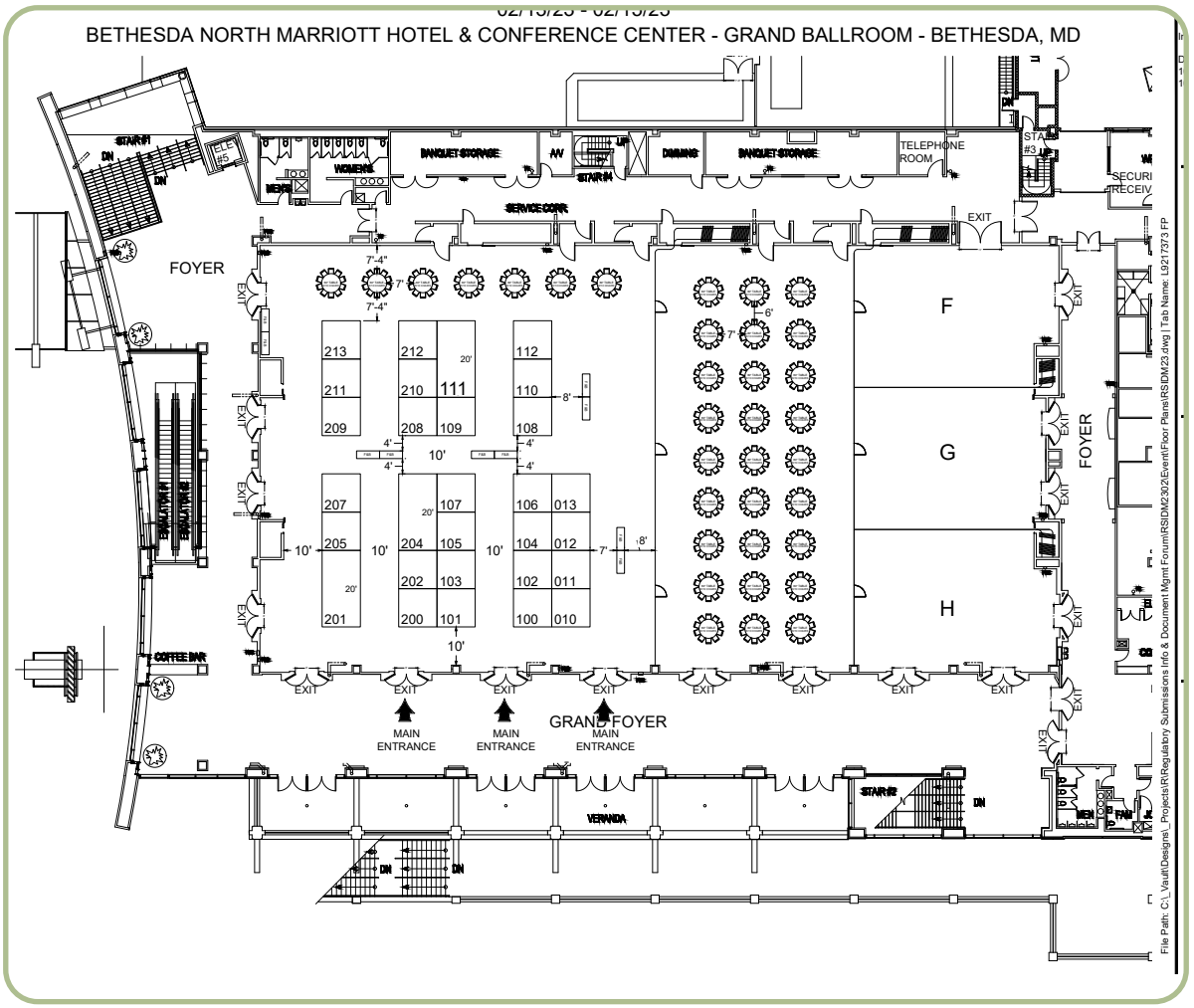
Regulatory Submissions, Information, and Document Management Forum

Exhibitor Directory

February 13-15, 2023

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

Floorplan



Exhibiting Companies

010	MMS Holdings
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012	KPMG
013	Generis Enterprise Technology Ltd
100	Court Square Group, Inc / RegDocs365
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207	PharmaLex GmbH
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Exhibitors by Services

AADE Evaluation / Drug Safety Assessment

ArisGlobal, LLC Booth 105

Adverse Event Management / Software

Docxonomy Booth 112

Generis Booth 013

Case Report Forms

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DocShifter Booth 109

Change Management / Implementation

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Veeva Systems, Inc. Booth 111

Chemistry / Manufacturing / Controls

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Medical Communications

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Medical Devices / Combination Products

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Medical Writing

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Pharmacokinetic / Pharmacodynamic Modeling

Certara Booth 011

Pharmacovigilance

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Preclinical Development Services

IQVIA Booth 204

Process Validation

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LORENZ Life Sciences Group Booth 201
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Programming (Database, SAS, etc)

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Translations

Docxonomy Booth 112

Trial Management

Ennov Booth 101

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