

Regulatory Submissions, Information, and Document Management Forum

FEBRUARY 03-05, 2025 5701 MARINELLI ROAD NORTH BETHESDA, MD 20852



5701 MARINELLI ROAD, NORTH BETHESDA, MD 20852

February 03-05, 2025 Bethesda North Marriott Hotel and Conference Center



Booth #316

Website: https://alphalifesci.com/

Linkedin: https://www.linkedin.com/company/alphalife-sciences/

AlphaLife Sciences is revolutionizing the intersection of life sciences and advanced computer science with AuroraPrime, our premier GenAl-powered SaaS platform for clinical research. Our state-of-theart GenAl-driven medical writing solutions are trusted by leading pharmaceutical companies to enhance precision, streamline workflows, and accelerate drug development.



Chosen by 5 of the Top 10 Global Pharma!

Accelerate Regulatory and Medical Writing with Generative Al

Pre-clinical R&D & Regulatory Submission Clinical Trials & Regulatory Submission Phase IV & Marketing				
Literature	IB	CSR	Safety Summary	Package Insert
Synopsis	ICF	Patient Narratives	Efficacy Summary	Lay Summary
Protocol	CRF	SAP	Clinical Overview	ICSR/DSUR/ PSUR

Backed by







AuroraPrime Generative Al Powered Platform



Johnson & Johnson Innovation - JLABS

Industry Leadership











Website: https://astrixinc.com/

LinkedIn: https://www.linkedin.com/company/astrix-technology-group/

Astrix is the unrivaled market-leader in creating & delivering innovative strategies, solutions, and people to the life science community. Through world class people, process, and technology, Astrix works with clients to fundamentally improve business & scientific outcomes across many domains including the laboratory, clinical & regulatory, pharmacovigilance, R&D, and manufacturing. Founded by scientists to solve the unique challenges of the life science community, Astrix offers a growing array of strategic, application & platform, data transformation & analytics, change management, and staffing services designed to deliver immediate value to clients and solve their most complex technical and staffing challenges.







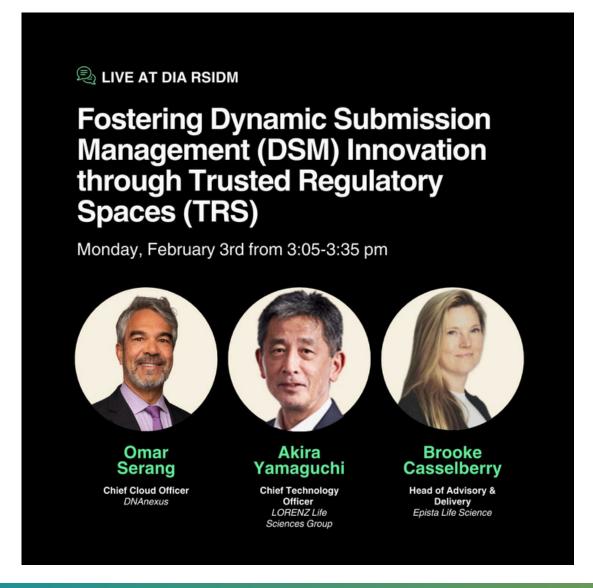
DNAnexus®

Booth #301

Website: https://www.dnanexus.com/

LinkedIn: https://www.linkedin.com/company/dnanexus/

DNAnexus, the enterprise platform for precision health, is on a mission to accelerate the development, approval and delivery of personalized treatments. Building on 15 years of bioinformatics innovation and genomics expertise, DNAnexus provides the cloud platform that centralizes and enriches multimodal omics data, supports an extensive suite of informatics use cases, and allows secure collaboration across the care continuum. DNAnexus powers a connected ecosystem trusted by the world's precision health leaders. This flexible ecosystem makes omics and real-world data accessible, actionable, and secure, while unlocking insights that improve patient lives. For more information, visit www.dnanexus.com or follow @DNAnexus on social media.









Website: https://dxc.com/us/en

LinkedIn: <u>https://www.linkedin.com/company/dxctechnology/</u>

DXC Technology (NYSE: DXC) helps global companies run their mission-critical systems and operations while modernizing IT, optimizing data architectures, and ensuring security and scalability across public, private and hybrid clouds. The world's largest companies and public sector organizations trust DXC to deploy services to drive new levels of performance, competitiveness, and customer experience across their IT estates.







Website: https://en.ennov.com/

LinkedIn: https://www.linkedin.com/company/ennov/

We have more than 450 clients worldwide (200+ in Life Science) and 20 years of experience serving the Pharmaceutical, Medical Device, Cosmetic and Healthcare Industries. Our single focus: delivering cost effective, best-of-breed, off the shelf, highly configurable, user friendly solutions to our clients. Ennov helps organizations comply with external and internal regulations to gain the true value of their business content. Highly scalable yet easily implemented, the Ennov product line requires minimal use of IT infrastructure and resources. All Ennov solutions include built-in electronic signature and audit trail compliant with the FDA 21 CFR Part 11, LDAP synchronization, scanner connector, email connector. Ennov solutions are web based solutions but can be installed on premise or used as cloud based solutions.







Website: https://www.extedo.com/

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:

- Master Data Management
- Content Management
- Quality Management
- Product Registration (XEVMPD & IDMP)
- Submission Management (eCTD, RPS, CTD, NeeS, IMPD, CTA, eCopy, DMF, ASMF, VNeeS, CADDY, ePRISM, eIndex)
- Pharmacovigilance Management and Drug Safety (SUSAR, ICSR, PSUR, DSUR, E2B, MedDRA, SMQ, GVP, CIOMS, MedWatch, R3)

Our mission of Effortless Compliance $^{\text{TM}}$ ensures that organizations are able to spend more time doing the things they want to do, rather than the things they have to do.







Website: https://www.fme-us.com/

LinkedIn: https://www.linkedin.com/company/fme-us-llc

fme Life Sciences is a global firm specializing in tailored business solutions for the life sciences industry, with a focus on data and document migration, enterprise content management, and business consulting. With the combination of our team of highly-skilled Life Science experts and industry-leading technology migration-center and dqMan, fme delivers unparalleled quality and accuracy in a fraction of the time. Let us efficiently guide your technology transformation into tomorrow's success.

Business Consulting and Technology Solutions for Life Sciences



Global partner for Regulatory, Quality & Clinical migrations

- Comprehensive business consulting, technical and migration services
- Experienced analysis, system selection, roadmapping and migrations from any source
- Certified experts in all leading platforms, dedicated to your success
- ✓ Industry-leading migration platform for seamless data and document migration

migration: center*

Visit us today at fme-LifeSciences.com





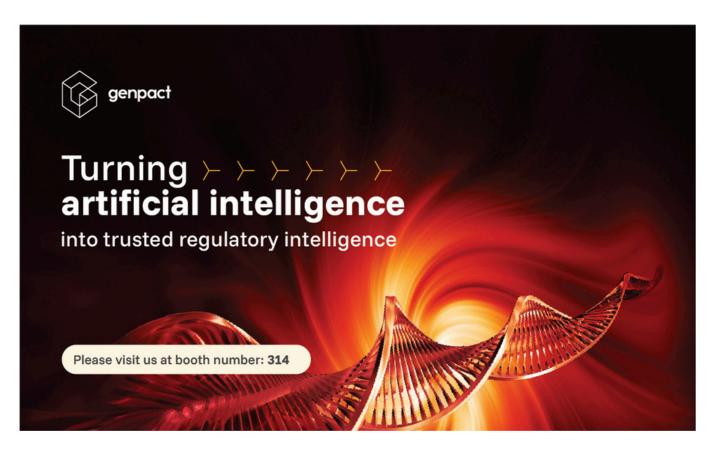


Website: https://www.genpact.com/

LinkedIn: https://www.linkedin.com/company/genpact/

Genpact (NYSE: G) is a global advanced technology services and solutions company that delivers unparalleled value for leading enterprises. Powered by our mix of deep business knowledge, operational excellence, and innovation, we help companies across industries reimagine finance and risk, supply chains, core industry operations such as regulatory affairs, and more. We use our innate curiosity and courage to relentlessly pursue a world that works better for people.

Genpact is a market leader in delivering regulatory affairs services to leading Life Sciences companies. With 20+ years of experience, we have built deep domain, data & technology experience in Regulatory Information Management, providing end to end support to our clients across their data journeys. We provide expertise in designing and managing client's migration & data enrichment strategy. We provide end to end support to our clients from strategy to implementation to post implementation services. Our innovative Regulatory Co-pilot brings the best of AI and augments regulatory professionals in their day-to-day activities.







Website: https://www.lorenz.cc/rim/

LinkedIn: <u>https://www.linkedin.com/company/lorenz-life-sciences-ltd-/</u>

LORENZ Life Sciences Group has been developing and marketing software solutions for the Life Sciences market since 1989. LORENZ has an array of Regulatory Information Management solutions geared towards industry, health authorities and academia that enable compliance enforcement globally. LORENZ' tried and tested portfolio offers Product Registration/IDMP, Submission Assembly, Validation and Management, Publishing/eCTD, Regulatory Planning and Tracking products and related services. Interoperability between LORENZ products and third party solutions, as well as the ability to automate processes, allow LORENZ customers to enhance operational efficiencies.









Website: https://www.main5.com/en/company.html

LinkedIn: https://www.linkedin.com/company/main5-gmbh/posts/?feedView=all

At MAIN5, we redefine consulting with a dynamic and forward-thinking approach, positioning ourselves as leaders in the ever-evolving landscape of the Life Sciences Industry. With over 60 dedicated professionals, we are committed to driving innovation and digital transformation for our clients.

Our Core Values: Innovation,

Expertise, and Excellence Innovation: In a world shaped by rapid advancements, MAIN5 stands at the forefront of industry trends. We embrace innovation as a guiding principle, ensuring our clients stay ahead in the competitive life science sector.

Our commitment to cutting-edge technologies is unwavering, making us your strategic partner in navigating the digital age. Expertise: With a team of seasoned professionals, MAIN5 brings unparalleled expertise to the table. Our consultants are adept in Regulatory Affairs, Quality, Safety, Clinical, and other critical areas along the R&D value chain. We provide tailored solutions that align with your unique challenges, leveraging our deep industry knowledge to drive success.









Website: https://rednucleus.com/

LinkedIn: <u>https://www.linkedin.com/company/red-nucleus/</u>

Advancing knowledge to improve lives.™

We are a global strategic partner with decades of experience across the entire life sciences product lifecycle. We excel in providing our clients with unique insights and efficiencies to support them in their journey to improve health outcomes and ultimately the quality of people's lives. By connecting our full suite of products and services from scientific and advisory services, market access, medical communications and learning and development, we are the "red thread" to lead our life sciences clients through transformational change to accelerate customer success.







Veeva

Booth # 212/212.5

Website: https://www.veeva.com/

LinkedIn: https://www.linkedin.com/company/veeva-systems

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 875 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Canada, Europe, Asia, and Latin America. Visit the Jobs section for open positions and remember that correspondence to new applicants and existing candidates will only come from an official @veeva.com email address.









Website: https://yseop.com/

LinkedIn: https://www.linkedin.com/company/vseop/

Yseop is the leader in Generative AI for regulated industries, changing the way content automation solutions are delivered with a human-centric, Al platform. Yseop is reimagining the future of scientific writing to get medicine into the hands of those who need it faster. With a suite of industry-specific applications and cutting-edge hybrid Natural Language Generation (NLG) technology that blends symbolic, machine learning, and LLM techniques, Yseop ensures that even the most demanding content automation tasks are met with ease, scalability and application security across the entire enterprise.

As the world's leading content automation solution for biopharmaceuticals, Yseop Copilot is a digital colleague that empowers scientific writers and addresses the unique requirements of regulated industries. Blending the power of large language models with customer data, Yseop Copilot delivers trusted and auditable content automation solutions in a closed, secure environment.

YSEOP COPILOT

Automate medical writing with an Al-powered digital colleague



Clients include 6 of top 20 pharma companies

Offices in Paris, Lyon, & NYC

Leverage a hybrid Al methodology Involved in more than 100+ clinical trials





Website: https://alphalifesci.com/

LinkedIn: https://www.linkedin.com/company/alphalife-

sciences/

AlphaLife Sciences is revolutionizing the intersection of life sciences and advanced computer science with AuroraPrime, our premier GenAl-powered SaaS platform for clinical research. Our state-of-the-art GenAl-driven medical writing solutions are trusted by leading pharmaceutical companies to enhance precision, streamline workflows, and accelerate drug development.

ARISGLOBAL LLC

Booth # 114

Website: https://www.arisglobal.com/

LinkedIn: <u>https://www.linkedin.com/company/aris-global/</u>

ArisGlobal is transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. Our end-to-end drug development technology platform, LifeSphere®, integrates our proprietary cognitive computing engine to automate all core functions of the drug development lifecycle. Designed with deep expertise and a long-term perspective that spans almost 40 years, LifeSphere® boosts efficiency, ensures compliance, and reduces cost through multi-tenant Software-as-a-Service (SaaS) architecture.

ARTOS AI

Booth # 112

Website: https://artos.us.com/

LinkedIn: https://www.linkedin.com/company/artos---

westover/?viewAsMember=true

Artos delivers Al-powered workflows tailored for regulatory affairs and medical writing teams. We help transform clinical data into regulatory submissions in days, not weeks. By automating repetitive tasks, our platform eliminates busywork, enabling you to focus on strategy and messaging. Reliable and efficient, Artos accelerates your processes, helping bring products to market faster.



Booth # 306

Website: https://astrixinc.com/

LinkedIn: https://www.linkedin.com/company/astrix-

technology-group/

Astrix is the unrivaled market leader in creating & delivering innovative strategies, technology solutions, and people to the life science community. Through world-class people, process, and technology, Astrix works with clients to fundamentally improve business, scientific, and medical outcomes and the quality of life everywhere. Founded by scientists to solve the unique challenges of the life science community,

Astrix offers a growing array of fully integrated services designed to deliver value to clients across their organizations. To learn the latest about how Astrix is transforming the way science-based businesses succeed today, visit www.astrixinc.com.

BIOVIA, A DASSAULT SYSTEMES COMPANY

Booth # 305

Website: https://www.3ds.com/

LinkedIn:

https://www.linkedin.com/company/dassaultsystemes/

BIOVIA, Systèmes Dassault supports science-based industries by providing a scientific collaborative environment for advanced biological, chemical and materials experiences. BIOVIA solutions including molecular modeling & simulation, data science, scientific and laboratory informatics, formulation design, quality & compliance and manufacturing analytics are used by more than 2,000 companies globally. For more information, please visit: https://www.3ds.com/products-services/biovia/

CELEGENCE

Booth # 106

Website: https://www.celegence.com/

LinkedIn: https://www.linkedin.com/company/celegence/

Optimizing your Team with Regulatory Services and Software.

Celegence uniquely combines operational, strategic, and scientific expertise with exclusive technology, to help pharmaceutical, medical device, and IVD clients achieve regulatory compliance in the most time and cost-efficient way

Having global presence and coverage, our highly educated and experienced consultants provide unparalleled quality of service for our customers, solving complex and burdensome regulatory challenges. Celegence allows our clients to focus on what matters most: providing exceptional patient value.

CERTARA

Booth # 204

Website: https://www.certara.com/

LinkedIn: https://www.linkedin.com/company/certara/

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include 2,000 biopharmaceutical companies, academic institutions, and regulatory agencies across 62 countries.

COURT SQUARE GROUP, INC.

Booth # 200

Website: https://courtsquaregroup.com/

LinkedIn: https://www.linkedin.com/company/court-square-

group/

Court Square Group is a leading provider of Audit Ready Compliant Cloud Infrastructure solutions for the Life Science Industry. At every stage of the development and manufacturing lifecycle Court Square's cloud, collaboration and regulatory submission solutions reduce costs, complexity and risks associated with sharing, storing, and submitting information for regulatory requirements.

Court Square Group's integrated, FDA 21 CFR Part11 compliant tools for Electronic Document Management System (EDMS), electronic Common Technical Documents (eCTD), LiMS, QMS software and regulatory submissions enables R&D groups of any size, CROs and sponsors to collaborate with confidence and meet regulatory body requirements.

DACHS COMPUTING & BIOSCIENCES GMBH

Booth # 308

Website: https://www.dachs.ch/

LinkedIn: https://www.linkedin.com/company/dachs-

computing

DACHS, with over 25 years of experience, takes pride in providing exceptional document improvement services and solutions accelerating medicines. We help pharmaceutical companies decrease their frustration when documenting their medical processes with reliable services and state-of-the-art technical solutions:

OnStyle, a revolutionary software designed to accelerate document authoring in MS Word. While boasting an intuitive user interface with numerous authoring tools, it effortlessly identifies and rectifies technical compliance issues, eliminating inconsistencies and inaccuracies.

OnTrack, an automated, browser-based PDF validation system, that proactively identifies more than 50 hard to find technical compliance issues within PDFs before they become part of dossiers.

DAELIGHT SOLUTIONS

Booth # 102

Website: https://daelightsolutions.com/

LinkedIn: https://www.linkedin.com/company/daelight-

solutions/

Daelight Solutions is an IT consulting company that is relentlessly focused on meeting Life Sciences' enterprise information challenges. Everything we do is centered around delivering real-world outcomes and ROI for clients. We take pride in the work we do, and strive every day to earn a reputation for quality, trustworthiness and honesty.



Booth # 301

Website: https://www.dnanexus.com/

LinkedIn: <u>https://www.linkedin.com/company/dnanexus/</u>

DNAnexus, the enterprise platform for precision health, is on a mission to accelerate the development, approval and delivery of personalized treatments. Building on 15 years of bioinformatics innovation and genomics expertise, DNAnexus provides the cloud platform that centralizes and enriches multimodal omics data, supports an extensive suite of informatics use cases, and allows secure collaboration across the care continuum. DNAnexus powers a connected ecosystem trusted by the world's precision health leaders. This flexible ecosystem makes omics and real-world data accessible, actionable, and secure, while unlocking insights that improve patient lives. For more information, visit www.dnanexus.com or follow @DNAnexus on social media.

DOCSHIFTER

Booth # 210

Website: https://www.docshifter.com/

LinkedIn: <u>https://www.linkedin.com/company/docshifter/?</u>

originalSubdomain=be

High volume, high-quality document conversion, on-premise or in the cloud. Automation, compliance, quality, speed, dynamic scalability, and configurability is why regulated enterprises choose DocShifter.

DOCUVERA

Booth # 307

Website: https://docuvera.com/

LinkedIn: https://www.linkedin.com/company/docuvera/

Docuvera is an intelligent, easy-to-use solution that combines AI + structured component authoring (SCA) to improve the efficiency and quality of pharma documentation. AI efficiently generates content and automates documentation processes, and SCA provides a framework of compliance and auditing throughout the content creation process. Docuvera automates complex document creation through automatic reuse of human-reviewed content and/or machine generation of high-quality, domain-specific content.

Effortlessly review and approve content leveraging audit trails that distinguish between human-reviewed and machine-generated content. Reduce errors and omissions through automated content integrity checks while maintaining a comprehensive audit trail of who changed what, when. Responsibly elevate your documentation process with Docuvera's straightforward solution that combines AI and SCA to make pharma content production efficient, compliant and, most importantly, trusted.



Website: https://dxc.com/us/en

LinkedIn:

https://www.linkedin.com/company/dxctechnology/

DXC Technology (NYSE: DXC) helps global companies run their mission-critical systems and operations while modernizing IT, optimizing data architectures, and ensuring security and scalability across public, private and hybrid clouds. The world's largest companies and public sector organizations trust DXC to deploy services to drive new levels of performance, competitiveness, and customer experience across their IT estates.



Booth # 206

Website: https://en.ennov.com/

LinkedIn: <u>https://www.linkedin.com/company/ennov/</u>

With offices in the US, UK, Europe, and Asia, Ennov provides the most original, comprehensive and cost-effective suite of software solutions for the Life Sciences industry. From leading pharmaceutical companies to emerging biotechs, we proudly serve over 450 Life Science companies and 500,000 users around the world. For more than 20 years, we have been developing innovative, powerful and easy-to-use software for regulated content, data and process management.

EPISTA LIFE SCIENCE

Booth # 304

Website: https://www.epista.com/

LinkedIn: <u>https://www.linkedin.com/company/epista-life-</u>

science/?originalSubdomain=dk

Epista Life Science is a team of experts working at the intersection of business priorities and compliance requirements. We pioneer new methodologies and implement technologies to help companies balance risk and efficiency to achieve more.

When starting the company in 2009, founder Klavs Esbjerg wanted to make an impact on regulatory compliance in the entire Life Science industry. He envisioned Epista as an industry influencer, pioneering new compliance methodologies and technologies to eliminate compliance challenges for Epista's clients.



Website: https://extedo.com/

LinkedIn: <u>https://www.linkedin.com/company/extedo</u>

EXTEDO makes pharmaceutical compliance an effortless process. We provide solutions and expert knowledge that help life science organizations worldwide to reduce the time and effort required to create and submit regulatory applications for medicinal products and maintain them throughout their lifecycle.



booth # 317

Booth # 207

Website: https://www.fme-us.com/

LinkedIn: <u>https://www.linkedin.com/company/fme-us-llc/</u>

Digitalization enables new ways of dealing with existing businesses and creates totally new business models. We believe in the opportunities of digital transformation and love to help our clients worldwide maintain and create competitive businesses. Our devoted consultants optimize or challenge our clients' business models through existing and new technologies and advise them on the necessary cultural change in their company. Cloud, Business Intelligence, Social Business Collaboration and Enterprise Content Management technologies in combination with custom software development and the ability to operate our clients' systems 24×7 help us to add value to our clients' transformation process.

GENERIS

Booth # 104

Website: https://generis.com/

LinkedIn: https://www.linkedin.com/company/generis/

Generis is a team of experienced guides who walk with churches and ministries of all shapes, sizes, and personalities to develop a sustainable culture of generosity to fund their God-inspired vision.

Since 1989, we've partnered with churches and Kingdom focused non-profits in matters of stewardship, generosity and fundraising.

The Generis playbook is battle tested but not plug and play. We take biblical principles, best practices and over 30 years of experience and weave them together into a plan that will align beautifully with your unique culture and DNA.

Our make-it-last mindset ensures that everything we accomplish together outlives the length of any one campaign, project, or initiative and continues to fund your vision for years to come.





Website: https://www.genpact.com/

LinkedIn: <u>https://www.linkedin.com/company/genpact/</u>

Genpact (NYSE: G) is a global advanced technology services and solutions company that delivers unparalleled value for leading enterprises. Powered by our mix of deep business knowledge, operational excellence, and innovation, we help companies across industries reimagine finance and risk, supply chains, core industry operations such as regulatory affairs, and more. We use our innate curiosity and courage to relentlessly pursue a world that works better for people.

GLEMSER TECHNOLOGIES

Booth # 213

Website: https://glemser.com/

LinkedIn: https://www.linkedin.com/company/glemser-

technologies/

Glemser is a global leader in compliance and regulatory systems, empowering pharmaceutical companies to streamline regulatory submissions across global labeling, clinical labeling, and Chemistry, Manufacturing, and Controls (CMC). Its industry-proven platform, ComplianceAuthor® AI, supports faster time-to-market while ensuring rigorous compliance with evolving standards.

GLOBAL EXPONENTIAL TECHNOLOGIES, INC. (GXT)

Booth # 315

Website: https://www.globalxt.io

LinkedIn: https://www.linkedin.com/company/global-

exponential-technologies-gxt/

Team of regulatory compliance professionals, scientists, technical writers, designers, and software engineers dedicated to building Regulatory Technology. We provide regulatory affairs, clinical research, and quality-management professionals with next-generation software-based tools and services to improve the efficiency and quality of their work.

GLOBALVISION

Booth # 110

Website: https://www.globalvision.co/

LinkedIn:

https://www.linkedin.com/company/globalvision-co/

GlobalVision is the market leader in Al-powered, automated quality inspections and proofreading for regulated industries. Our solutions empower teams to deliver flawless packaging and digital content at scale.

i4i INC.

Website: https://www.i4i.com/

LinkedIn: <u>https://www.linkedin.com/company/i4i/</u>

<u>i4i</u> is a recognized world leader in providing services and technology for structuring regulated content to meet global regulatory authority submission requirements, with a focus on HL7 standards SPL, XML PM, and FHIR.

INTELINOTION LLC

Booth # 211

Website: https://intelinotion.com/

LinkedIn: https://www.linkedin.com/company/intelination/

InteliNotion is a next-generation Content Platform designed specifically for the Life Sciences industry. This cutting-edge Al-driven platform enables unprecedented levels of productivity and content quality for Medical and Regulatory Writers, fundamentally transforming the way content is created, re-used and managed.

InteliNotion revolutionizes Content Management with its modern, cloud-native Innovation Platform, enabling digital transformation for content-centric business applications in the Life Sciences industry. By addressing Information Management and Content Governance challenges, InteliNotion overcomes the limitations of traditional Document Management and empowers companies to innovate and thrive in today's fast-paced digital landscape.

IRISS FORUM

Booth # 202

Website: https://www.iriss-forum.org/

LinkedIn: https://www.linkedin.com/company/iriss-forum/

IRISS Forum is a global, open, multidisciplinary, non-profit networking organization for life science professionals by life science professionals, dedicated to advancing Implementation of Regulatory Information and Submission Standards for Life Sciences and Healthcare around the world. IRISS provides a unique inclusive forum for industry, vendors, government agencies, consultants, and others, to collaborate for the mutual benefit of industry, agencies and ultimately, public health.

KIVO, INC.

Booth # 201

Website: https://www.kivo.io/

LinkedIn: <u>https://www.linkedin.com/company/kivoio</u>

Kivo is the easiest-to-use document and regulatory management solution for life science companies. Kivo's platform includes DMS, RIM, QMS, eTMF and more. All features are included with your subscription - with no separate charges or hidden fees.





Booth # 300/302

Website: https://www.lorenz.cc/

LinkedIn: https://www.linkedin.com/company/lorenz-life-

sciences-ltd-/posts/?feedView=all

LORENZ Life Sciences Group (www.lorenz.cc) has been developing and marketing software solutions for the Life Sciences market for over 30 years. The LORENZ Regulatory Information Management solutions address industry, health authorities and academia to ensure compliance enforcement worldwide. LORENZ's proven portfolio offers:

- Product Registration/IDMP,
- Submission Assembly,
- · Validation and Management,
- Publishing/eCTD,
- Regulatory Planning and Tracking products and related

Interoperability between LORENZ products and third-party solutions, as well as the ability to automate processes, allow LORENZ customers to enhance operational efficiencies. LORENZ has a strong customer base worldwide, with over 1800 paid installations in 48 countries, including 15 agencies.



Booth # 313

Website: https://www.main5.de/de/unternehmen.html

MAIN5 is a premier consulting firm dedicated to the life sciences industry. We specialize in enhancing operational efficiency, ensuring regulatory compliance, and driving digital transformation. With deep expertise pharmaceuticals, biotechnology, medical devices, and healthcare technology, we offer tailored solutions across regulatory affairs, data governance, quality management, and systems validation. At MAIN5, we redefine consulting with a dynamic and forward-thinking approach: We stand for unparalleled expertise, tailor-made solutions and partnership-based collaboration. Our team of over 60 professionals, including regulatory experts, digital transformation specialists, and operational efficiency mavens, collaborates closely with clients to foster innovation and drive digital transformation. Choosing MAIN5 means embarking on a journey towards strategic operational excellence, and regulatory growth, compliance, guided by a partner renowned for its industry expertise, customized solutions, and proven success. With our unwavering commitment to the success of our clients, we guide Life Sciences organizations towards achieving their most ambitious goals. Together, let's drive digital transformation in Life Sciences.

MPILOTAI

Booth # 203

Website: https://mpilot.ai/

LinkedIn: https://www.linkedin.com/company/mpilotai/

We are proud to be at the forefront of innovation, revolutionizing the way clinical trials are conducted. Join leading researchers, pharmaceutical companies, and academic institutions who have embraced our service and experienced unparalleled results.

NNIT A/S

Booth # 205

Website: https://www.nnit.com/

LinkedIn: <u>https://www.linkedin.com/company/nnit/</u>

We strive to build unmatched excellence in the industries we serve, and we use our domain expertise to represent a business first approach - strongly supported by a selection of partner technologies, but always driven by business needs rather than technology.

NNIT consists of group company NNIT A/S and subsidiaries SCALES, Excellis Health Solutions and SL Controls. Together, these companies employ more than 1,700 people in Europe, Asia and USA.



Booth # 214

Website: https://rednucleus.com/

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

We are a global strategic partner with decades of experience across the entire life sciences product lifecycle. We excel in providing our clients with unique insights and efficiencies to support them in their journey to improve health outcomes and ultimately the quality of people's lives. By connecting our full suite of products and services from scientific and advisory services, market access, medical communications and learning and development, we are the "red thread" to lead our life sciences clients through transformational change to accelerate customer success.

SCHLAFENDER HASE

Booth # 311

Website: https://www.schlafenderhase.com/

LinkedIn: https://www.linkedin.com/company/schlafender-

hase

Schlafender Hase serves regulated industries across the globe. Clients include the world's leading pharmaceutical and medical device companies, as well as healthcare regulatory bodies. The continued success of Schlafender Hase is based on delivering quality products and a strong understanding of customer pain points. Easy to use, our products reduce proofreading workloads, assure the quality of printed and online materials, and mitigate the risk of costly errors.





SLICKBIT TECHNOLOGIES

Booth #310

Website: https://slickbit.ai/lifesciences/

LinkedIn: https://www.linkedin.com/company/slickbit-ai/

Your Al Innovation Partner for Life Sciences

We empower Pharma Regulatory, Clinical, Safety, and Commercial teams with cutting-edge AI solutions tailored to your needs.

- Rapid MVP Development: From concept to prototype,
- Custom Al solution Development: Custom solutions for specific needs.
- Al Integrations: Harness the power of Al with integrations.
- Al Chatbots: Deliver smarter, faster interactions.
- Al Document Processing: Transform complex workflows with intelligent automation.

Stop by our booth 310 to discover how we can accelerate your Al journey!



Booth # 212/212.5

Website: https://www.veeva.com/products/vault-rim/ LinkedIn:

https://www.linkedin.com/company/https://www.linkedi n.com/company/veeva-systems/

Veeva Vault RIM provides a single trusted platform for faster, real-time regulatory information management. The unified RIM platform increases visibility, cross-team collaboration, and data quality, reducing submission timelines. More than 400 companies are transforming regulatory operations with Veeva Vault RIM Platform applications to speed execution and keep pace with evolving health authority requirements.

WEAVE AI

Booth #100

Website: https://www.weave.ai/

LinkedIn: https://www.linkedin.com/company/weave-ai

Weave's Al-native platform simplifies regulatory workflows, from document creation to submission, tackling the industry's biggest challenges. By providing a single source of truth, Weave fosters seamless collaboration, ensures compliance, and accelerates therapeutic development timelines. Streamlining processes and creating a living record of therapeutic candidates. Weave empowers teams to focus on strategic decisions with confidence and clarity.



Booth # 215

Website: https://yseop.com/

LinkedIn: https://www.linkedin.com/company/yseop/

Yseop is the leader in GenAl for life science and pharmaceutical companies, changing the way content automation solutions are delivered with a human-centric, Al platform.

Yseop acts as a "Copilot" for medical writers, maximizing their efficiency and accuracy in generating reports and insights crucial to drug development and approval.

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Floor Plan

Exhibit Hall Hours

Monday, February 3 | 11:30AM - 6:30PM

Tuesday, February 4 | 7:45AM - 4:30PM

Wednesday, February 5 | 7:30AM - 11:20AM



Exhibiting Companies

100. Weave Al

102. Daelight Solutions

104. Generis

106. Celegence

110. Global Vision

112. Artos Al

114. ArisGlobal LLC

200. Court Square Group, Inc.

201. Kivo, Inc.

202. IRISS Forum

203. MPilotAI

204. Certara

205. NNIT

206. Ennov

207. EXTEDO Inc.

210. Docshifter

211. InteliNotion, LLC

212/212.5 Veeva Systems Inc 2

13. Glemser Technologies Corporation

214. Red Nucleus

215. Yseop

300/302. LORENZ Life Sciences Group

301. DNAnexus

303. LexisNexis Reed Tech

304. Epista Life Science

305. BIOVIA

306. Astrix

307. Docuvera

308. DACHS

310. Slickbit Technologies

311. Schlafender Hase

312. i4i

313. MAIN5 GmbH & Co. KGaA

314. Genpact UK Limited

315. Global Exponential Technologies

316. AlphaLife Sciences

317. fme US

318. DXC Technology Services, LLC

CASE STUDY SPOTLIGHTS





CASE STUDY HOSTED BY DNAnexus[®]

Fostering Dynamic Submission Management (DSM) Innovation through Trusted Regulatory Spaces (TRS)



CASE STUDY HOSTED BY



Evaluating Time Savings in Regulatory Writing: A Scientific Comparison of Human and Al Approaches



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Harnessing GenAl in a Global Biopharmaceuticals Company



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Optimizing Change Management for Collaborative Success

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