

Exhibitor Directory

Regulatory Submissions, Information, and Document Management Forum

February 13-15, 2023

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



Booth 105

3119 Ponce de Leon Blvd.
Coral Gables, FL 33134

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ArisGlobal is transforming the way today's most successful Life Sciences companies develop breakthroughs and bring new products to market. Designed with deep expertise and a long-term perspective that spans more than 30 years, LifeSphere® Regulatory is a simple, unified platform that boosts efficiency, ensures compliance, delivers actionable insights, and lowers total cost of ownership through multi-tenant SaaS architecture.



The advertisement features a dark blue background with yellow and white geometric line art in the corners. The LifeSphere logo, consisting of a white circle with a dot inside, is positioned to the left of the text "LifeSphere". Below this, the main text reads: "The name you trust in safety, serving you with *industry-recognized* regulatory solutions." At the bottom center, the ArisGlobal logo is displayed. A light blue footer bar contains the text "Recognized by:" followed by the logos for GENS (GENS REGULATORY), FROST & SULLIVAN, and SULLIVAN.

Ennov

Booth 101

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LinkedIn: <https://www.linkedin.com/showcase/iqvia-global-compliance>

Twitter: <https://twitter.com/EnnovGroup>

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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.

The graphic features the Ennov logo at the top left. Below it is a circular diagram with segments for 'Regulatory', 'IDMP', 'RIM', 'Dossier Publishing', 'Regulatory Documents', 'Quality Documents', and 'Unified Repository'. To the right, the text reads: 'Ennov Regulatory Suite Simplify compliance with a unified regulatory information management solution'. Below this text is a paragraph: 'The Ennov Regulatory software suite combines the power and flexibility of Ennov Doc, Ennov Dossier, and Ennov RIM to support the entire regulatory lifecycle from the early planning of registration targets through product retirement.' There are four icons: a folder with a checkmark, a document with a checkmark, a globe with a checkmark, and a document with a checkmark. A QR code is located at the bottom right, with the URL 'ennov.com' below it.

EXTEDO

Booth 213

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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!

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.

With our end-2-end platform EXTEDOpulse, we offer a complete RIM solution, including

- Planning & Tracking
- Document Management
- Product Registration
- Submission Publishing & Lifecycle Management, and
- Safety Management.

If you want to know what your organization's future in RIM can look like, secure a time slot with us at our booth #213.

Tell us about your individual challenge – we will answer all your questions.

www.extedo.com info@extedo.com +1 (855) 328-3500



Generis

Booth 013

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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.

cara
LIFE SCIENCES PLATFORM

Regulatory Information Management on the CARA Life Sciences Platform provides a powerful foundation for managing data to make it easy to identify and re-use efficiently across the organisation with our enterprise-wide information lake.

generis

Events, Activities & Commitments
Understand what is used, submitted, approved and required in every market. Eliminate double-work, create and manage while submissions, not just documents.

Product Management
Meet the latest industry requirements including SPOR, IDMP, XEVMPD, reduce time managing data standards, replace biological data entry and user experiences, and improve enterprise access to consistent data.

Applications and registrations
Leverage an interconnected web of documents and data with complete traceability. Save time searching and connecting with CARA's "Where Used" functionality.

Submission Planning & Tracking
CARA provides the tools to create consistent and repeatable global submission processes, as well as the flexibility to tackle ad-hoc submissions and agency interactions.

Correspondence
Process communications more quickly and consistently with automations to ingest and manage correspondence.

Labelling
CARA enables automatic translations, artwork management, and submission of labels in line with various industry formats such as Structured Product Labelling (SPL).

Structured information lake

Simplicity of users working within their own area - but with access to enterprise information.

Genpact

Booth 108

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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



**Transforming regulatory affairs
for a world that works
better for people**



inSeption Group, LLC

Booth 208

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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.



The advertisement features a black background. On the left is a photograph of two young girls; one is wearing a white lace dress and a pink headscarf, and the other is behind her. On the right is the inSeption GROUP logo in white and red. Below the logo is the tagline 'Inspired by Excellence Empowered by People' in a gold-colored font, followed by a QR code. At the bottom, there is a white text block that reads: 'Founded on the principle of changing an industry stifled by faceless, profit-driven and high-volume outsourcing solutions... ...motivated by hope and accountability for the well-being of the people within our patient communities.'

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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.

RIM Smart:

A single solution, optimized for both pharmaceutical and MedTech

RIM Smart offers an integrated, automated and intelligent way of managing the complete regulatory lifecycle of pharmaceutical, medical device and combination products.

- Improved decision-making and compliance
- Increased productivity and speed
- Real-time global transparency
- Reduced cycle times

Ready to learn more?
Come see us at booth 204
www.IQVIA.com/RIMSmart

Kivo

Booth 200

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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.



RIM: RIMAGINGED

Regulatory platform built for how you work

[kivo.io](https://www.kivo.io)

Regulatory. Clinical. Quality

LORENZ Life Sciences Group

Booth 201

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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.

Ask us about flexible RIM



Visit us at booth 201/203

DIA RSIDM Forum
February 13 - 15, 2023

www.lorenz.cc



NNIT

Booth 107

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NNIT
We make a mark

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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.

NNIT

Empower those who change lives

Leading System Implementation Provider.
Regulations, Business Processes and Systems.

- Digital Transformation
- Data Quality
- Migration
- Life Sciences Accelerator



OpenText

Booth 110

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opentext™

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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.

The graphic features the OpenText logo on the left, followed by the text 'Content Cloud™ for Life Sciences'. To the right is a QR code and the text 'Booth 110'. Below this is a list of GxP capabilities, and at the bottom, a laptop displaying the OpenText Documentum interface. The interface shows a 'My Collections' section with a table of items, including columns for 'Name', 'Status', 'Version', 'Created', and 'Modified'. The table lists several 'Study Report Assembly' items. At the bottom of the graphic, the text 'COMPLIANCE ♦ CONVENIENCE ♦ CONFIDENCE' is displayed.

opentext™ | Content Cloud™
for Life Sciences

Booth 110

GxP capabilities of OpenText™ Documentum™ for Life Sciences combined with cloud efficiencies

- Fully managed cloud service
- Hyperscaler choices
- Flexible configurations and integrations
- Personalized upgrade schedule

COMPLIANCE ♦ CONVENIENCE ♦ CONFIDENCE

Red Nucleus

Booth 106

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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.

A promotional banner for Red Nucleus. The background is dark with a glowing, purple and blue molecular structure. In the top left corner is the Red Nucleus logo. The main text reads: "Trusted guidance and long-term partnerships to solve *strategic* and *operational* challenges." Below this is the website "rednucleus.com" and social media handles "@rednucleushq" with icons for LinkedIn, Instagram, Twitter, and YouTube. On the right side, a man and a woman are looking at a tablet together. The man is holding the tablet, and the woman is pointing at the screen. The tablet has the Red Nucleus logo on it.

red nucleus

Trusted guidance and
long-term partnerships
to solve *strategic* and
operational challenges.

rednucleus.com

@rednucleushq |

Veeva Systems, Inc.

Booth 111

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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.

Streamline Regulatory Processes with One Unified Platform



End-to-end
Submissions
Publishing



Active
Dossier



Vault RIM for
Small Pharma
& Biotech



Vault
Connections



New Submissions
Archive User
Experience



Events /
Activities



Email to
RIM



Collaborative
Authoring



IDMP DADI
Report



Labeling



Report-level
Content Plans

Veeva Vault RIM

Stop by **Booth #111** to see a live demo and meet with our experts

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.



ZS R&D Excellence is harnessing the power of data and technology to unlock the future of life sciences innovation

Bringing skills and expertise to address
clients' regulatory affair challenges

Visit ZS at exhibit 104

Regulatory Submissions, Information, and Document Management Forum

Exhibitor Directory

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AMPLEXOR LIFE SCIENCES

Booth 205

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Amplexor Life Sciences is a global provider of regulatory, quality and safety software solutions, serving and trusted by pharmaceutical, biotechnology and medical device companies for over 25 years. Its holistic Life Sciences Suite of solutions helps life sciences organizations to be efficient with launching products and breaking into new markets quickly while ensuring quality, efficacy and safety through end-to-end support to product lifecycle processes, data and content management.

ArisGlobal, LLC

Booth 105

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Calyx

Booth 103

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Certara

Booth 110

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

Court Square Group, Inc.

Booth 100

Contact: Keith Parent
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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

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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

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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

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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

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Facebook: <https://www.facebook.com/profile.php?id=100063464291433>

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Booth 109

EXTEDO

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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!

Booth 112

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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.

Booth 101

FTI Consulting

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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.

Booth 213

Booth 202

Booth 212

Generis

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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

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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.

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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.

Booth 013

inSeption Group, LLC

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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.

Booth 108

IQVIA

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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

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

Kivo

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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

Booth 208

Booth 204

Booth 211

Booth 200

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

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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

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Website: <http://www.lorenz.cc>
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

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Website: <https://www.mmsholdings.com/>
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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

Contact: Toni Lakin-Ritter
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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

Contact: Robin Gellerman
Phone: 760.331.3545
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

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

Booth 107

Booth 012

Booth 110

Booth 201

Booth 207

Booth 010

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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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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Twitter: <https://twitter.com/rednucleushq>
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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LinkedIn: <https://www.linkedin.com/company/veeva-systems/>

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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LinkedIn: <https://www.linkedin.com/company/zs-associates>

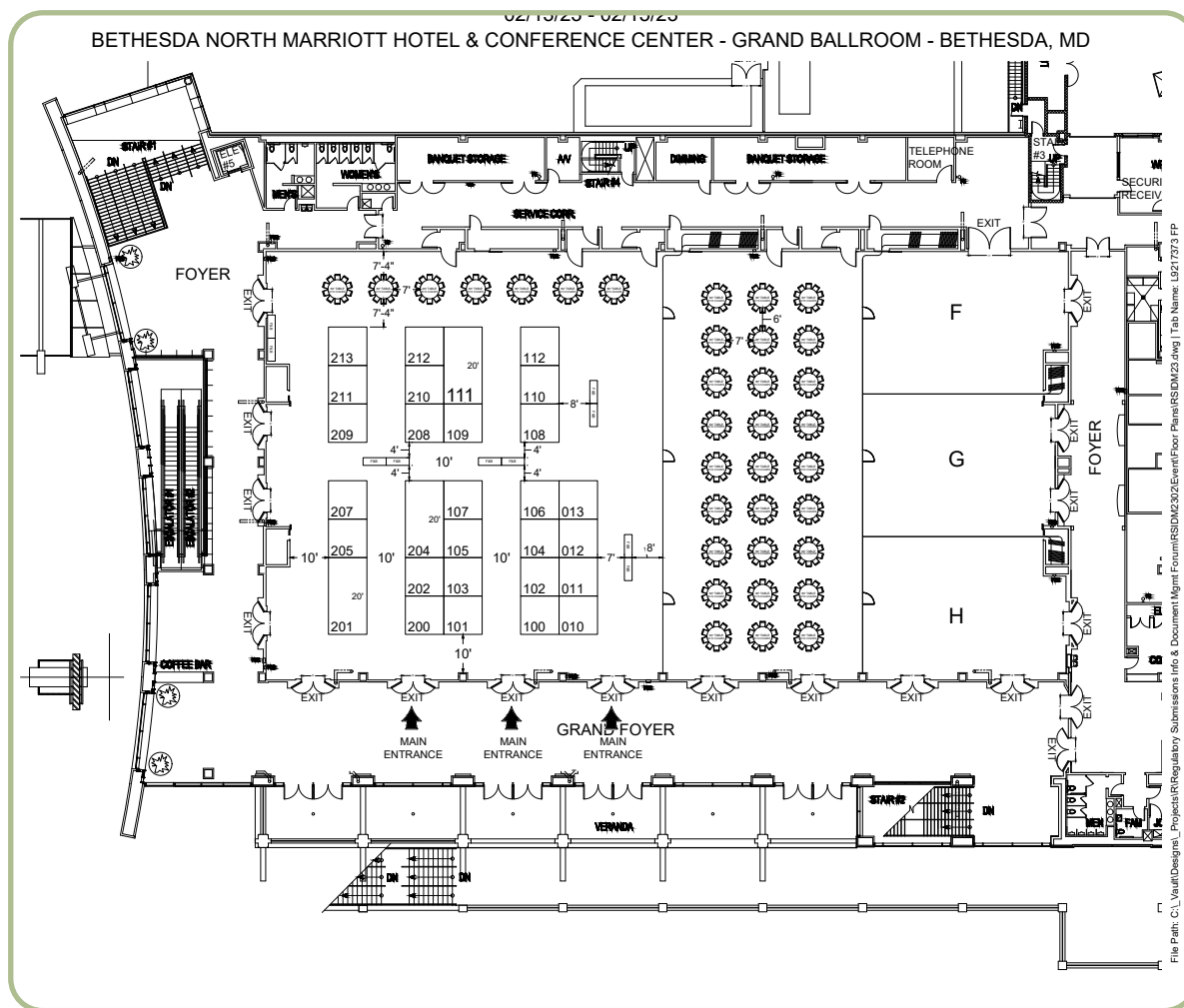
ZS is a management consulting and technology firm focused on transforming global healthcare and beyond. We leverage our leading-edge analytics, plus the power of data, science and products, to help our clients make more intelligent decisions, deliver innovative solutions and improve outcomes for all. 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.

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 | 109 | DocShifter NV | 211 | IRISS Forum |
| 011 | Certara | 110 | OpenText | 212 | FTI Consulting |
| 012 | KPMG | 111 | Veeva Systems, Inc. | 213 | EXTEDO |
| 013 | Generis Enterprise Technology Ltd | 112 | Docxonomy | | |
| 100 | Court Square Group, Inc / RegDocs365 | 200 | Kivo, Inc. | | |
| 101 | Ennov | 201 | LORENZ Life Sciences Group | | |
| 102 | Celegence | 204 | IQVIA / IQVIA Technologies | | |
| 103 | Calyx | 202 | fme US | | |
| 104 | ZS | 205 | Amplexor Adriatic D.O.O. | | |
| 105 | ArisGlobal | 207 | PharmaLex GmbH | | |
| 106 | Red Nucleus | 208 | inSeption Group | | |
| 107 | NNIT | 209 | Gens & Associates, Inc. | | |
| 108 | Genpact UK Limited | 210 | DDi LLC | | |

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

ArisGlobal, LLC Booth 105

DocShifter Booth 109

Change Management / Implementation

EXTEDO Booth 213

FTI Consulting Booth 212

Generis Booth 013

Genpact Booth 108

KPMG Booth 012

NNIT Booth 107

Vevea Systems, Inc. Booth 111

Chemistry / Manufacturing / Controls

FTI Consulting Booth 212

Genpact Booth 108

Clinical R&D

DocShifter Booth 109

fme US Booth 202

Generis Booth 013

Kivo Booth 200

NNIT Booth 107

Clinical Study Reports

Certara Booth 011

DocShifter Booth 109

inSeption Group, LLC Booth 208

Kivo Booth 200

Clinical Trial Design

MMS Holdings Booth 010

Clinical Trial Monitoring

Ennov Booth 101

inSeption Group, LLC Booth 208

Kivo Booth 200

Red Nucleus Booth 106

Comprehensive Drug and Biologic Development

IQVIA Booth 204

Computer System Validation

Court Square Group, Inc. Booth 100

fme US Booth 202

FTI Consulting Booth 212

KPMG Booth 012

NNIT Booth 107

Consulting

Certara Booth 011

EXTEDO Booth 213

fme US Booth 202

FTI Consulting Booth 212

Genpact Booth 108

Gens & Associates, Inc. Booth 209

KPMG Booth 012

LORENZ Life Sciences Group Booth 201

NNIT Booth 107

PharmaLex GmbH Booth 207

Qdossier – a Celegence company Booth 102

Red Nucleus Booth 106

ZS Booth 104

Data Management

Court Square Group, Inc. Booth 100

DDi LLC Booth 210

Docxonomy Booth 112

Ennov Booth 101

EXTEDO Booth 213

Generis Booth 013

Genpact Booth 108

Gens & Associates, Inc. Booth 209

KPMG Booth 012

LORENZ Life Sciences Group Booth 201

MMS Holdings Booth 010

NNIT Booth 107

PharmaLex GmbH Booth 207

Vevea Systems, Inc. Booth 111

Data Safety Monitoring Board Services

inSeption Group, LLC Booth 208

MMS Holdings Booth 010

Data Validation

Court Square Group, Inc. Booth 100

EXTEDO Booth 213

Genpact Booth 108

LORENZ Life Sciences Group Booth 201

NNIT Booth 107

Database Conversions

Docxonomy Booth 112

Document Management

ArisGlobal, LLC Booth 105

Certara Booth 011

Court Square Group, Inc. Booth 100

DocShifter Booth 109

Ennov Booth 101

EXTEDO Booth 213

fme US Booth 202

Generis Booth 013

Genpact Booth 108

inSeption Group, LLC Booth 208

Kivo Booth 200

LORENZ Life Sciences Group Booth 201

NNIT Booth 107

OpenText Booth 110

Qdossier – a Celegence company Booth 102

Vevea Systems, Inc. Booth 111

Drug Master File Dossiers

EXTEDO Booth 213

IQVIA Booth 204

OpenText Booth 110

Electronic Data Capture

ArisGlobal, LLC Booth 105

Court Square Group, Inc. Booth 100

Docxonomy Booth 112

Ennov Booth 101

Vevea Systems, Inc. Booth 111

Electronic Submissions

AMPLEXOR LIFE SCIENCES Booth 205

Certara Booth 011

Court Square Group, Inc. Booth 100

DDi LLC Booth 210

DocShifter Booth 109

Ennov Booth 101

EXTEDO Booth 213

fme US Booth 202

Genpact Booth 108

Gens & Associates, Inc. Booth 209

inSeption Group, LLC Booth 208

LORENZ Life Sciences Group Booth 201

MMS Holdings Booth 010

PharmaLex GmbH Booth 207

Qdossier – a Celegence company Booth 102

Red Nucleus Booth 106

Vevea Systems, Inc. Booth 111

Expert Reports

Docxonomy Booth 112

GCP Compliance

Ennov Booth 101

inSeption Group, LLC Booth 208

Kivo Booth 200

GLP Compliance

Ennov Booth 101

GMP Compliance

Ennov Booth 101

FTI Consulting Booth 212

OpenText Booth 110

Imaging

Docxonomy	Booth 112	FTI Consulting	Booth 212	DDi LLC	Booth 210
Licensing / Acquisitions		Generis	Booth 013	Software Development & Evaluation	
Genpact	Booth 108	inSeption Group, LLC	Booth 208	AMPLEXOR LIFE SCIENCES	Booth 205
IQVIA	Booth 204	Kivo	Booth 200	DDi LLC	Booth 210
Medical Communications		OpenText	Booth 110	DocShifter	Booth 109
Certara	Booth 011	PharmaLex GmbH	Booth 207	LORENZ Life Sciences Group	Booth 201
Medical Devices / Combination Products		Veeva Systems, Inc.	Booth 111	Standard Operating Procedures	
DDi LLC	Booth 210	Registries		DocShifter	Booth 109
PharmaLex GmbH	Booth 207	Red Nucleus	Booth 106	Generis	Booth 013
Medical Writing		Regulatory Affairs / Regulatory Strategy		OpenText	Booth 110
Certara	Booth 011	AMPLEXOR LIFE SCIENCES	Booth 205	Red Nucleus	Booth 106
DDi LLC	Booth 210	ArisGlobal, LLC	Booth 105	Statistical Services / Meta Analysis	
inSeption Group, LLC	Booth 208	Certara	Booth 011	DDi LLC	Booth 210
Kivo	Booth 200	DDi LLC	Booth 210	MMS Holdings	Booth 010
MMS Holdings	Booth 010	Docxonomy	Booth 112	PharmaLex GmbH	Booth 207
Qdossier – a Celegence company	Booth 102	EXTEDO	Booth 213	Strategic Planning and Implementation	
Pharmacokinetic / Pharmacodynamic Modeling		fme US	Booth 202	AMPLEXOR LIFE SCIENCES	Booth 205
Certara	Booth 011	FTI Consulting	Booth 212	Certara	Booth 011
Pharmacovigilance		Genpact	Booth 108	DocShifter	Booth 109
ArisGlobal, LLC	Booth 105	inSeption Group, LLC	Booth 208	fme US	Booth 202
Ennov	Booth 101	IQVIA	Booth 204	IQVIA	Booth 204
FTI Consulting	Booth 212	Kivo	Booth 200	KPMG	Booth 012
Generis	Booth 013	KPMG	Booth 012	NNIT	Booth 107
MMS Holdings	Booth 010	MMS Holdings	Booth 010	PharmaLex GmbH	Booth 207
NNIT	Booth 107	PharmaLex GmbH	Booth 207	Red Nucleus	Booth 106
PharmaLex GmbH	Booth 207	Qdossier – a Celegence company	Booth 102	Veeva Systems, Inc.	Booth 111
Preclinical Development Services		Red Nucleus	Booth 106	Technology Assessment	
IQVIA	Booth 204	Veeva Systems, Inc.	Booth 111	AMPLEXOR LIFE SCIENCES	Booth 205
Process Validation		Regulatory Document Preparation		Court Square Group, Inc.	Booth 100
AMPLEXOR LIFE SCIENCES	Booth 205	AMPLEXOR LIFE SCIENCES	Booth 205	DocShifter	Booth 109
LORENZ Life Sciences Group	Booth 201	ArisGlobal, LLC	Booth 105	Gens & Associates, Inc.	Booth 209
Veeva Systems, Inc.	Booth 111	Certara	Booth 011		
Programming (Database, SAS, etc)		Court Square Group, Inc.	Booth 100	KPMG	Booth 012
AMPLEXOR LIFE SCIENCES	Booth 205	DDi LLC	Booth 210	Telephone Support	
Docxonomy	Booth 112	DocShifter	Booth 109	LORENZ Life Sciences Group	Booth 201
MMS Holdings	Booth 010	Docxonomy	Booth 112	Training	
Project Management		EXTEDO	Booth 213	EXTEDO	Booth 213
AMPLEXOR LIFE SCIENCES	Booth 205	fme US	Booth 202	KPMG	Booth 012
ArisGlobal, LLC	Booth 105	Generis	Booth 013	LORENZ Life Sciences Group	Booth 201
DDi LLC	Booth 210	Genpact	Booth 108	Translations	
FTI Consulting	Booth 212	IQVIA	Booth 204	Docxonomy	Booth 112
inSeption Group, LLC	Booth 208	Kivo	Booth 200	Trial Management	
Kivo	Booth 200	LORENZ Life Sciences Group	Booth 201	Ennov	Booth 101
KPMG	Booth 012	OpenText	Booth 110	Workflow Assessment / Re-engineering	
NNIT	Booth 107	PharmaLex GmbH	Booth 207	ArisGlobal, LLC	Booth 105
Quality Assurance / Control		Qdossier – a Celegence company	Booth 102	fme US	Booth 202
AMPLEXOR LIFE SCIENCES	Booth 205	Red Nucleus	Booth 106	FTI Consulting	Booth 212
ArisGlobal, LLC	Booth 105	Veeva Systems, Inc.	Booth 111	KPMG	Booth 012
fme US	Booth 202	Rx to OTC Switch			