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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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.

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LinkedIn: *https://www.linkedin.com/showcase/iqvia-global-compliance*
Twitter: *https://twitter.com/EnnovGroup*
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

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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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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

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.

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.

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 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.

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.

NNIT

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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.

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.

Red Nucleus

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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.

Veeva Systems, Inc.

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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

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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.

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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

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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 — Booth 109

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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 — Booth 112

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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 — Booth 101

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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!

fme US — Booth 202

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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

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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.

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.

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

Gens & Associates, Inc. — Booth 209

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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.

inSeption Group, LLC — Booth 208

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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 — Booth 211

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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 — 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.

KPMG — Booth 012

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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 — 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.

MMS Holdings — Booth 010

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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

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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.

OpenText — Booth 110

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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

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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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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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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.

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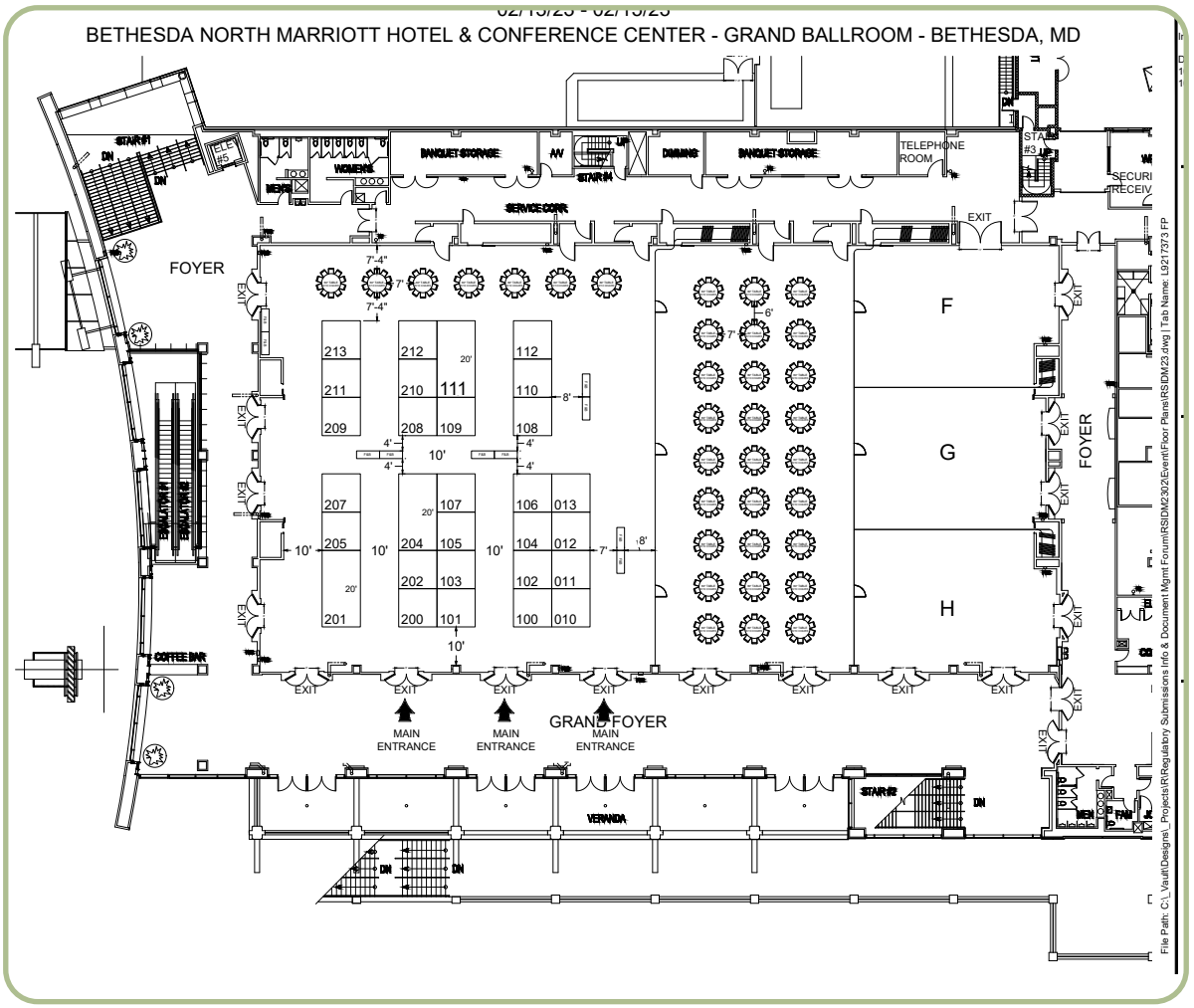
Floorplan



Exhibiting Companies

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AADE Evaluation / Drug Safety Assessment

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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

Veeva 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

Veeva 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

Veeva 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

Veeva 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

Veeva 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

Licensing / Acquisitions

Genpact Booth 108
IQVIA Booth 204

Medical Communications

Certara Booth 011

Medical Devices / Combination Products

DDi LLC Booth 210
PharmaLex GmbH Booth 207

Medical Writing

Certara Booth 011
DDi LLC Booth 210
inSeption Group, LLC Booth 208
Kivo Booth 200
MMS Holdings Booth 010
Qdossier – a Celegence company Booth 102

Pharmacokinetic / Pharmacodynamic Modeling

Certara Booth 011

Pharmacovigilance

ArisGlobal, LLC Booth 105
Ennov Booth 101
FTI Consulting Booth 212
Generis Booth 013
MMS Holdings Booth 010
NNIT Booth 107
PharmaLex GmbH Booth 207

Preclinical Development Services

IQVIA Booth 204

Process Validation

AMPLEXOR LIFE SCIENCES Booth 205
LORENZ Life Sciences Group Booth 201
Veeva Systems, Inc. Booth 111

Programming (Database, SAS, etc)

AMPLEXOR LIFE SCIENCES Booth 205
Docxonomy Booth 112
MMS Holdings Booth 010

Project Management

AMPLEXOR LIFE SCIENCES Booth 205
ArisGlobal, LLC Booth 105
DDi LLC Booth 210
FTI Consulting Booth 212
inSeption Group, LLC Booth 208
Kivo Booth 200
KPMG Booth 012
NNIT Booth 107

Quality Assurance / Control

AMPLEXOR LIFE SCIENCES Booth 205
ArisGlobal, LLC Booth 105
fme US Booth 202
FTI Consulting Booth 212
Generis Booth 013
inSeption Group, LLC Booth 208
Kivo Booth 200
OpenText Booth 110
PharmaLex GmbH Booth 207
Veeva Systems, Inc. Booth 111

Registries

Red Nucleus Booth 106

Regulatory Affairs / Regulatory Strategy

AMPLEXOR LIFE SCIENCES Booth 205
ArisGlobal, LLC Booth 105
Certara Booth 011
DDi LLC Booth 210
Docxonomy Booth 112
EXTEDO Booth 213
fme US Booth 202
FTI Consulting Booth 212
Genpact Booth 108
inSeption Group, LLC Booth 208
IQVIA Booth 204
Kivo Booth 200
KPMG Booth 012
MMS Holdings Booth 010
PharmaLex GmbH Booth 207
Qdossier – a Celegence company Booth 102
Red Nucleus Booth 106
Veeva Systems, Inc. Booth 111

Regulatory Document Preparation

AMPLEXOR LIFE SCIENCES Booth 205
ArisGlobal, LLC Booth 105
Certara Booth 011
Court Square Group, Inc. Booth 100
DDi LLC Booth 210
DocShifter Booth 109
Docxonomy Booth 112
EXTEDO Booth 213
fme US Booth 202
Generis Booth 013
Genpact Booth 108
IQVIA Booth 204
Kivo Booth 200
LORENZ Life Sciences Group Booth 201
OpenText Booth 110
PharmaLex GmbH Booth 207
Qdossier – a Celegence company Booth 102
Red Nucleus Booth 106
Veeva Systems, Inc. Booth 111

Rx to OTC Switch

DDi LLC Booth 210

Software Development & Evaluation

AMPLEXOR LIFE SCIENCES Booth 205
DDi LLC Booth 210
DocShifter Booth 109
LORENZ Life Sciences Group Booth 201

Standard Operating Procedures

DocShifter Booth 109
Generis Booth 013
OpenText Booth 110
Red Nucleus Booth 106

Statistical Services / Meta Analysis

DDi LLC Booth 210
MMS Holdings Booth 010
PharmaLex GmbH Booth 207

Strategic Planning and Implementation

AMPLEXOR LIFE SCIENCES Booth 205
Certara Booth 011
DocShifter Booth 109
fme US Booth 202
IQVIA Booth 204
KPMG Booth 012
NNIT Booth 107
PharmaLex GmbH Booth 207
Red Nucleus Booth 106
Veeva Systems, Inc. Booth 111

Technology Assessment

AMPLEXOR LIFE SCIENCES Booth 205
Court Square Group, Inc. Booth 100
DocShifter Booth 109
Gens & Associates, Inc. Booth 209

KPMG Booth 012

Telephone Support

LORENZ Life Sciences Group Booth 201

Training

EXTEDO Booth 213
KPMG Booth 012
LORENZ Life Sciences Group Booth 201

Translations

Docxonomy Booth 112

Trial Management

Ennov Booth 101

Workflow Assessment / Re-engineering

ArisGlobal, LLC Booth 105
fme US Booth 202
FTI Consulting Booth 212
KPMG Booth 012