Digital Exhibitor Directory

Regulatory Submissions, Information, and Document Management Forum 2016

DIA DEVELOP INNOVATE ADVANCE

arivis, inc.

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Email: gerard.bradley@arivis.com
Contact Person: Gerard Bradley | Director of Sales

arivis is a leading provider of integrated clinical and regulatory software solutions (Clireo) serving the emerging life science markets. Our solutions are easy to implement, cloud based and 21 CFR Part 11 compliant. The Professional Services Group at arivis provides premier strategic and tactical services to fit a client's specific regulatory needs with individual attention to detail. Emerging entities use our Clireo suite to improve efficiencies in their workflows, simplify collaboration with external partners, mitigate compliance risk with federal agencies, and accelerate the drug approval process.

Who we are

arivis started with the first ever eDMS system that integrated Business Process Management (BPM). We enhanced these tools with the addition of eCTD Regulatory Submission Management along with full Virtual Data Room capabilities. Later we introduced more regulatory submission management capabilities with support for 510k, PMA, and custom submission types. This enables us to support any and all output required by global Biotech, Pharmaceutical, Diagnostic and Medical Device companies. Now arivis Clireo provides the only Azure based eTMF with full eDMS capabilities. And Clireo eMPM supports end-to-end Promotional Materials Management for Medical, Legal, and Regulatory review and approval. Combined with Clireo Submissions and the new Module 1 for the FDA eCTD, Clireo creates the industries only integrated Promotional Materials Management system with integrated eSubmissions capabilities.

CSC

3170 Fairview Park Drive
Falls Church, VA 22042
Phone: +1.703.876.1000
Website: www.csc.com/life_sciences
Email: CSC_Life_Sciences@csc.com
Contact Person: John J. Bell | Industry General Manager - Life Sciences, Americas

Working with over 300 life science companies across the globe, CSC is committed to the digital transformation of the industry's value chain for enabling companies to execute on strategies that deliver better health outcomes through innovation.

At CSC, we understand shifting healthcare profit pools complicate the industry's future and is driving a new basis for competition. A focus on health outcomes, scientific and technology breakthroughs and an emerging digital healthcare ecosystem that includes a more engaged patient are driving the need for new industry strategies, business models and processes.

With over 6000 healthcare and life science technology professionals across the globe and the experience in managing 100 million patient records, installing 5000 clinical systems and enabling regulatory approval for over 15,000 life science products, we recognize the disruptive potential of digital and next generation technologies for the life sciences industry.

Leveraging our IP and next generation technologies in cloud, mobility, advanced analytics and digital services we are leading the Life Science industry's digital transformation in the following areas: Regulatory Affairs and Operations, Supply Chain Flexibility and Responsiveness, Commercial Acceleration, R&D Productivity, Operating Model Agility and Risk Management & Security.

We are a committed partner to helping the Life Sciences industry navigate the digital revolution in healthcare to deliver value to their healthcare customers and shareholders.

Learn more at csc.com/life_sciences

DIA

DIA Global Center
21 Dupont Circle NW, Suite 300
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Contact Person: Courtney Ingram | Associate Director, Strategic Communications

For over 50 years, DIA has served as a global platform for more than 30,000 health care product development professionals, researchers, regulators, clinicians, academics and patient advocates to collaborate to improve health globally through the advancement of lifesaving medicines and technologies. As the premier professional community for the health care product development ecosystem, DIA (the Drug Information Association) provides global players a neutral and transparent forum for the exchange of ideas and collaboration. By offering access to tools, resources, and networking opportunities, DIA provides its members and international participants objective opportunities for extending debate and discussion to advance scientific and medical innovation.

DIA is an independent, global nonprofit organization based in Washington, DC, USA, with regional offices representing the Americas (Horsham, PA, USA); Europe, Africa and the Middle East (Basel, Switzerland); and Asia (Beijing, China; Mumbai, India; and, Tokyo, Japan). For more information, visit our website at www.DIAgobal.org or contact us via Twitter @DrugInfoAssn, LinkedIn, or on Facebook.

EMC Corporation

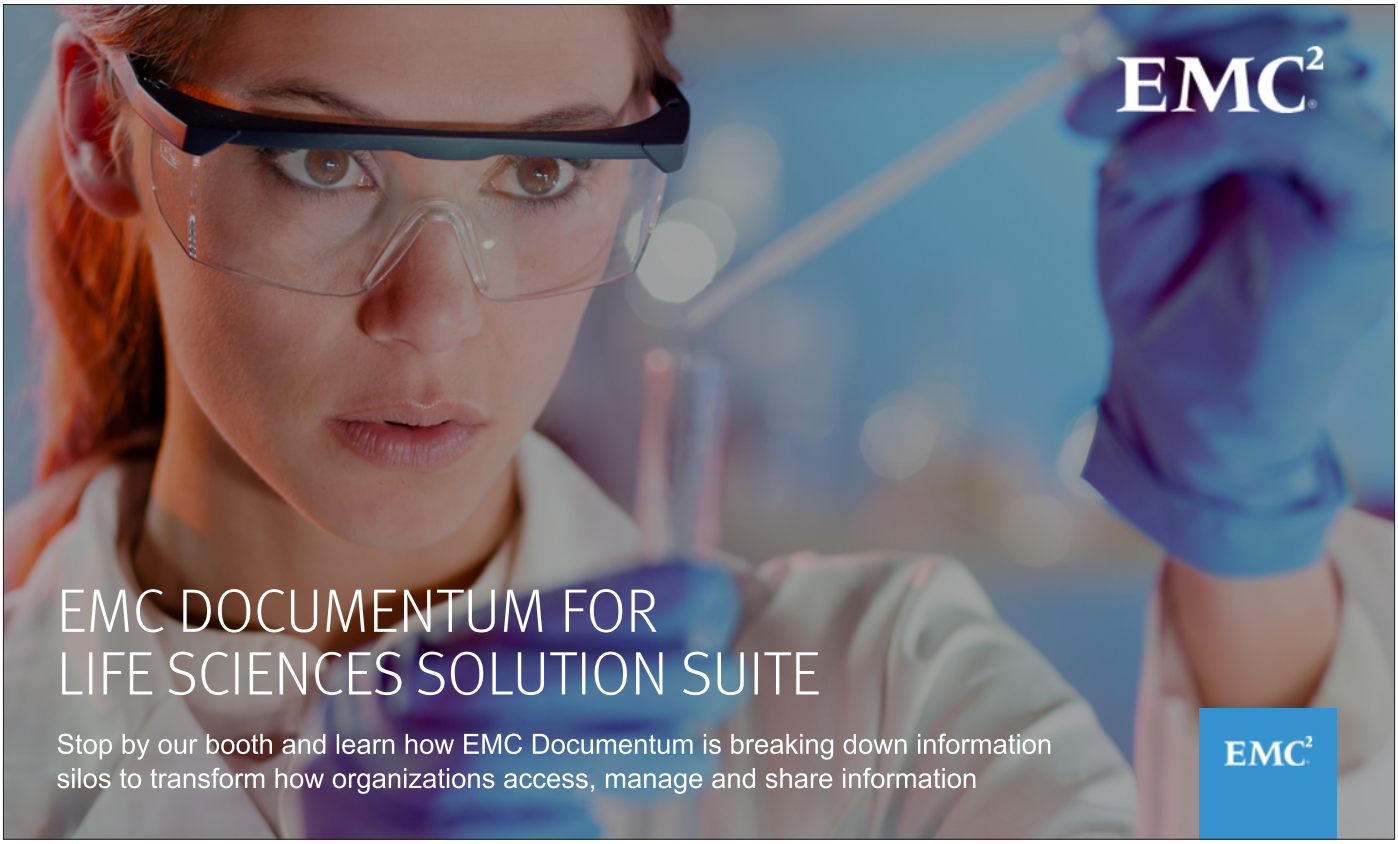
Enterprise Content Division
6801 Koll Center Parkway
Pleasanton, CA 94566-7047

Phone: +1.925.600.6800
Website: www.emc.com/documentumforlifesciences
Email: lori.mckellar@emc.com
Contact Person: Lori McKellar | Director, Global Life Sciences Marketing

EMC Corporation is a global leader in enabling businesses and service providers to transform their operations and deliver IT as a service. For over 20 years, EMC's Enterprise Content Division has been an industry leader in regulated content management for Life Sciences. Using its experience and expertise, EMC is helping to transform Life Sciences organizations to drive efficiency, productivity and value across the extended enterprise.

The EMC Documentum for Life Sciences solution suite, available on premise or in the cloud, breaks down information silos to transform how organizations access, manage and share information ensuring a single authoritative source for regulated content. Doing so, helps bring high quality, safe drugs to market faster to improve health and well-being at a lower cost. The fully integrated suite of purpose-built, configurable solutions span the clinical, regulatory and quality domains.

Additional information can be found at www.emc.com/documentumforlifesciences



HighPoint Solutions

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East Norriton, PA 19401
Phone: +1.610.233.2700
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Contact Person: Danielle McDowell | Events and Communications Coordinator

HighPoint Solutions is a premier, global provider of specialized IT services with vertically-focused business consulting, system integration, professional service, and managed hosting solutions for life sciences and healthcare companies. Since 2000, our 650+ consultants have provided business consulting and technology solutions that continue to deliver business value and competitive advantage to more than 170 clients globally.

LORENZ Life Sciences Group

1515 Market Street, Suite 1200
Philadelphia, PA 19102
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Website: www.lorenz.cc
Email: www.lorenz.cc/email
Contact Person: Yaprak Eisinger | Director North America

LORENZ Life Sciences Group has been developing and marketing software solutions for the Life Sciences market since 1989, and is the most established provider of e-regulatory software and services in the world focusing on submission management, labelling and tracking. LORENZ ensures proven performance to all sizes of businesses and global health authorities across the globe.

NNIT Inc.

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Contact Person: Jan Weber | General Manager

IT for life sciences

NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality. We apply the latest advances in technology to make our clients' software, business processes and communication more effective.

Greater agility for regulatory affairs

To successfully adapt to the rapid pace of change in the pharmaceutical industry, regulatory affairs needs agile IT solutions to support business processes and ensure compliance with regulations.

NNIT provides consultancy and IT solutions for regulated business processes—from drug development and regulatory submissions to post-marketing. We help you adapt to the regulatory constraints and requirements by ensuring that you can manage data and your entire document and process value chain.

NNIT uses established methods to analyze your business processes and IT systems so you can achieve your performance goals.

The time to get ready for ISO IDMP is now

Pharmaceutical companies will soon be required to submit data in accordance to the ISO IDMP standard. The new standards will impact the preparation and planning of submissions and maintenance of data that is company-wide: from manufacturing data, and structured substance information to registration information. NNIT's approach consists of five phases to help you become compliant:

- Impact Assessment
- Software & Vendor selection
- Hosting & Support
- Business Preparation
- Application Setup & Interfacing

Paragon Solutions

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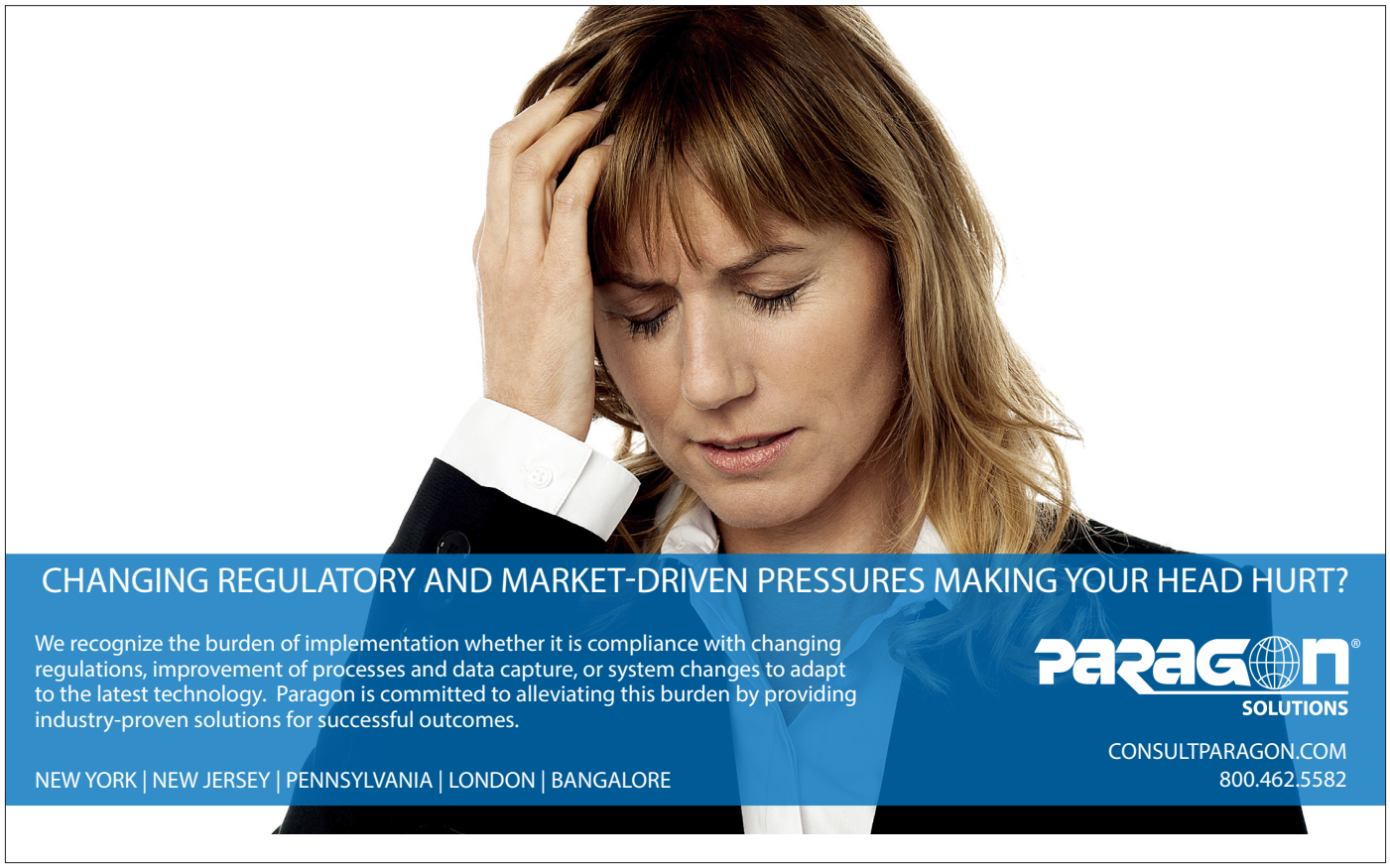
Contact Person: Che Dildy| Marketing Lead

Paragon Solutions is an advisory consulting and systems integration firm specializing in enterprise information management for life sciences.



Veeva Systems

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Contact Person: John Lawrie | Director, Vault RIM

Veeva Vault RIM is a suite of applications providing fully integrated regulatory information management (RIM) capabilities on a single cloud-based platform including submission document management, product registration management, health authority correspondence and commitments, and submission archiving.

The visibility that results from a unified solution will streamline global processes and improve data quality, helping life sciences companies respond faster to business changes, and health authority requests.

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 375 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America.

Exhibitor Directory

Regulatory Submissions, Information, and Document Management Forum

February 8-10 | North Bethesda, MD

DIA DEVELOP INNOVATE ADVANCE

ACUTA LLC — Booth 201

Contact: Shylendra Kumar
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ACUTA was founded in November 2012 to assist life science companies comply with ever-changing regulatory requirements that guide product approval and maintenance. ACUTA's founder Shylendra Kumar, and his team members are well known in the industry, with over 20 years of experience. Our Mantra: Find a better way to do it!.

AMPLEXOR — Booth 308

Contact: Maja Judez
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Maja.judez@amplexor.com
www.amplexor.com/lifesciences

AMPLEXOR Life Sciences helps pharmaceutical, medical device and biotechnology organizations launch products and break new markets quickly. Its services include technology consultancy, implementation and management services, as well as technical writing, medical translation and linguistic validation services, and the creation and management of marketing assets.

arivis — Booth 203

Contact: Gerard Bradley
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Arivis provides integrated, cloud based technology & consulting services to help life science companies work smarter. The Clireo platform includes modules for each phase of development:

- eTMF and eISF for clinical
- eDMS for nonclinical, CMC, regulatory
- eCTD for regulatory submissions
- eQMS for quality assurance
- eMPM for promotional materials

Cardinal Health Regulatory Sciences — Booth 301

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regulatoryscience@cardinalhealth.com
www.cardinalhealth.com/regulatorysciences

Founded in 1976, Cardinal Health Regulatory Sciences partners with pharma, biotech and medical device companies at all phases of development to provide regulatory and product development consulting services. Our strategies are designed to help companies achieve regulatory approval, as well as keep products on the market after approval.

CSC — Booth 100

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Working with over 300 life science companies across the globe, CSC is committed to the digital transformation of the life sciences industry's value chain for enabling companies to execute on strategies that deliver better health outcomes through innovation. We provide unique best-in-class technology, consulting services, and insights for life sciences companies worldwide. More at csc.com/life_sciences

DIA — Booth 402

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www.DIAglobal.org

As the premier professional community for the health care product development ecosystem, DIA provides global players a neutral and transparent forum for the exchange of ideas and collaboration by offering access to tools, resources, and networking opportunities for extending debate and discussion to advance scientific and medical innovation.

DITA Exchange — Booth 309

Contact: Christine Myers
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www.ditaexchange.com

DitaExchange is committed to simplifying the way regulated organizations create, manage, deliver and re-use important content through structured content management solutions that are built to run on the SharePoint platform.

Drug Lifecycle Tracking Application (DLTA) by Aurotech — Booth 408

Contact: Matt Mitchell
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info@druglifecycle.com
www.druglifecycle.com

Our purpose is to improve the quality of life of everyone we come in contact with. Our customers see this shift first in the quality of work life of their employees, resulting in a higher quality of work. DLTA simplifies the work you do, so you can more effectively bring life changing products to market.

EMC Corporation — Booth 101

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www.emc.com/documentumforlifesciences

EMC Corporation is a global leader in enabling businesses and service providers to transform their operations and deliver IT as a service. The EMC Documentum for Life Sciences solution suite, available on premise or in the cloud, breaks down information silos to transform how organizations access, manage and share information ensuring a single authoritative source for regulated content.

EXTEDO GmbH — Booth 300

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EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management (RIM) including: product registration planning & tracking (IDMP), submission publishing & lifecycle management and pharmacovigilance. EXTEDO serves over 700 customers in 60 countries, including the EMA and 35 regulatory authorities worldwide..

GlobalSubmit — Booth 107

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GlobalSubmit offers software solutions and regulatory publishing services to facilitate the delivery of high-quality, compliant regulatory submissions to health agencies around the world. We are introducing products for life sciences document management and regulatory information management in 2016. Headquartered in Philadelphia, we have regional offices in Boston and Research Triangle Park, NC.

HighPoint Solutions — Booth 108

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www.highpointsolutions.com

HighPoint Solutions is a premier provider of specialized IT services with vertically-focused business consulting, system integration, professional service, and managed hosting solutions for life sciences and healthcare companies. Since 2000, our 650+ consultants have provided business consulting and technology solutions that deliver value and competitive advantage to more than 170 clients globally.

i4i — Booth 302

Contact: Karen Heater
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info@i4i.com
www.i4i.com

i4i is a world leader in the development of structured content applications. i4i has brought its innovative technology and regulatory expertise to the Life Sciences industry with solutions that enhance compliance by delivering intelligent content reuse, repurposing and tracking across your organization as products and regulations evolve.

LORENZ Life Sciences — Booth 200

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LORENZ Life Sciences Group has been developing and marketing software solutions for the Life Sciences market since 1989, and is the most established provider of e-regulatory software and services in the world focusing on submission management, labelling and tracking. LORENZ ensures proven performance to all sizes of businesses and global health authorities across the globe.

MakroCare Ltd — Booth 409

Contact: Mahesh Malneedi or Subrata Biswas
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www.makrocare.com

MakroCare is an international Drug/Device development and consulting services firm operating since 1996. MakroCare has successfully helped many Pharma, Biotech and Device companies right from designing their Regulatory Strategy to getting product approvals globally. Our functional services include Reg Intel, Affiliate support, RIM Operations, CMC Authoring, LCM, Labeling & Submission Management.

Microsystems — Booth 109

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Microsystems provides cutting-edge document technology solutions. Our products enhance the submission process and document production lifecycles by providing automation to improve efficiency and content accuracy, reduce document rework, and ensure compliance with agency and regulatory guidelines.

NNIT Inc. — Booth 400

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NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality.

Paragon Solutions, Inc. — Booth 207

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Paragon Solutions is an advisory consulting and systems integration firm that specializes in enterprise information management to help life sciences organizations leverage information assets for better business results. Paragons specialized competencies help companies achieve operational efficiency, business scalability and regulatory compliance.

PAREXEL — Booth 403

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PAREXEL provides comprehensive drug development capabilities to help clients get their new and innovative drug treatments into the hands that need them most. We simplify the journey to market through our global regulatory expertise, Phase I-IV clinical research services, integrated eClinical technologies, and commercialization services.

PleaseTech Ltd. — Booth 208

Contact: David Cornwell
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info@pleasetech.com
www.pleasetech.com

PleaseTech specializes in document co-authoring and review. Our flagship product, PleaseReview, is a unique collaborative review and co-authoring solution for Microsoft Word and other document types. Used extensively by Life Sciences organizations, it facilitates controlled, simultaneous and secure collaboration for document review and editing.

RegCheck™ — Booth 209

Contact: Zina Suriano
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zsuriano@myregcheck.com
myregcheck.com

RegCheck™ utilizes Hurley Consulting's proprietary methodology developed by its expert team of regulatory professionals. Now this proven process has been captured in RegCheck. An easy-to-use program that simplifies and shortens the regulatory submission process. From pre-IND to IND, this new software identifies potential development issues.

Schlafender Hase — Booth 306

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www.text-verification.com

Schlafender Hase® is the global leader in computer-driven proofreading. Our Text Verification Tool® (TVT) is the international benchmark for accurate text and graphic verification. TVT is used by the world's leading pharmaceutical and medical device companies as well as numerous regulatory bodies to ensure compliant, error-free packaging.

Schulman IRB — Booth 307

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Schulman IRB provides high quality, rigorous IRB reviews for all research phases in North America via streamlined processes, customized technology and responsive customer service. We offer dedicated, AAHRPP-accredited IRB services for sponsors, CROs, sites and institutions and also offer CQA and HRP consulting via our partner Provision Research Compliance Services.

Synchrogenix, A Certara Company — Booth 206

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www.Synchrogenix.com

Synchrogenix is a global regulatory and medical writing consultancy providing strategic solutions to address the industry's greatest regulatory challenges. We offer cross-functional expertise; nonclinical, clinical, CMC, and drug safety; and the only Artificial Intelligence-enabled solutions to meet transparency and disclosure requirements.

Veeva Systems — Booth 401

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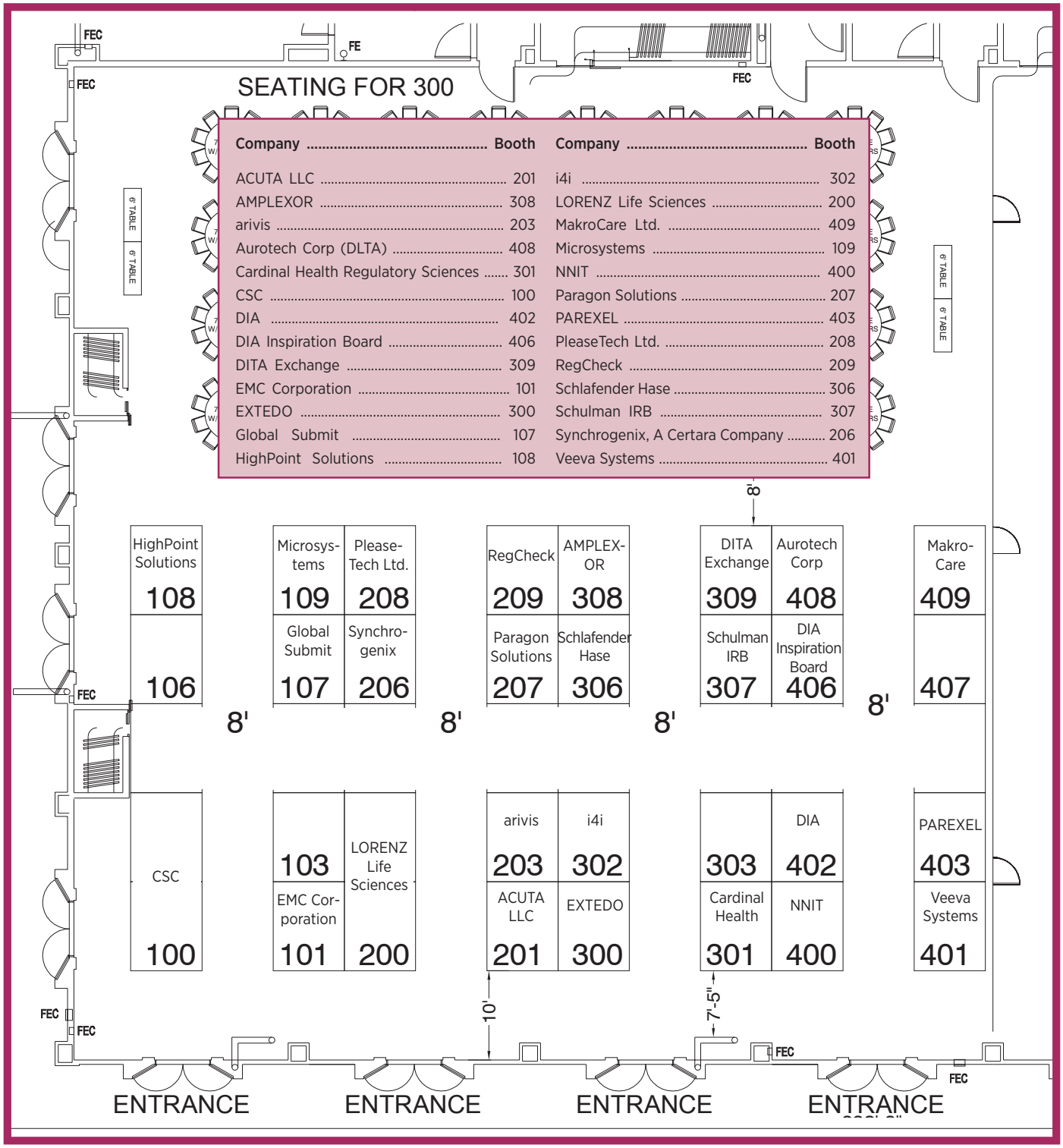
Veeva Vault RIM is a suite of applications providing fully integrated regulatory information management (RIM) capabilities on a single cloud-based platform including submission document management, product registration management, health authority correspondence and commitments, and submission archiving.

Floor Plan

Regulatory Submissions, Information, and Document Management Forum

DIA DEVELOP INNOVATE ADVANCE



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