# Digital Exhibitor Directory

## Regulatory Submissions, Information, and Document Management

February 6-8, 2017 | North Bethesda, MD
Bethesda North Marriott Hotel and Conference Center

DIA DEVELOP INNOVATE ADVANCE

# ACUTA LLC

225 Cedar Hill Street, Suite 200
Marlborough, MA 01752

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Phone: +1.240.457.0644
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Website: www.acutallc.com
Twitter Handle: @AcutaLLC
LinkedIn: www.linkedin.com/company-beta/2934853

ACUTA
SOLUTIONS FOR LIFE SCIENCES

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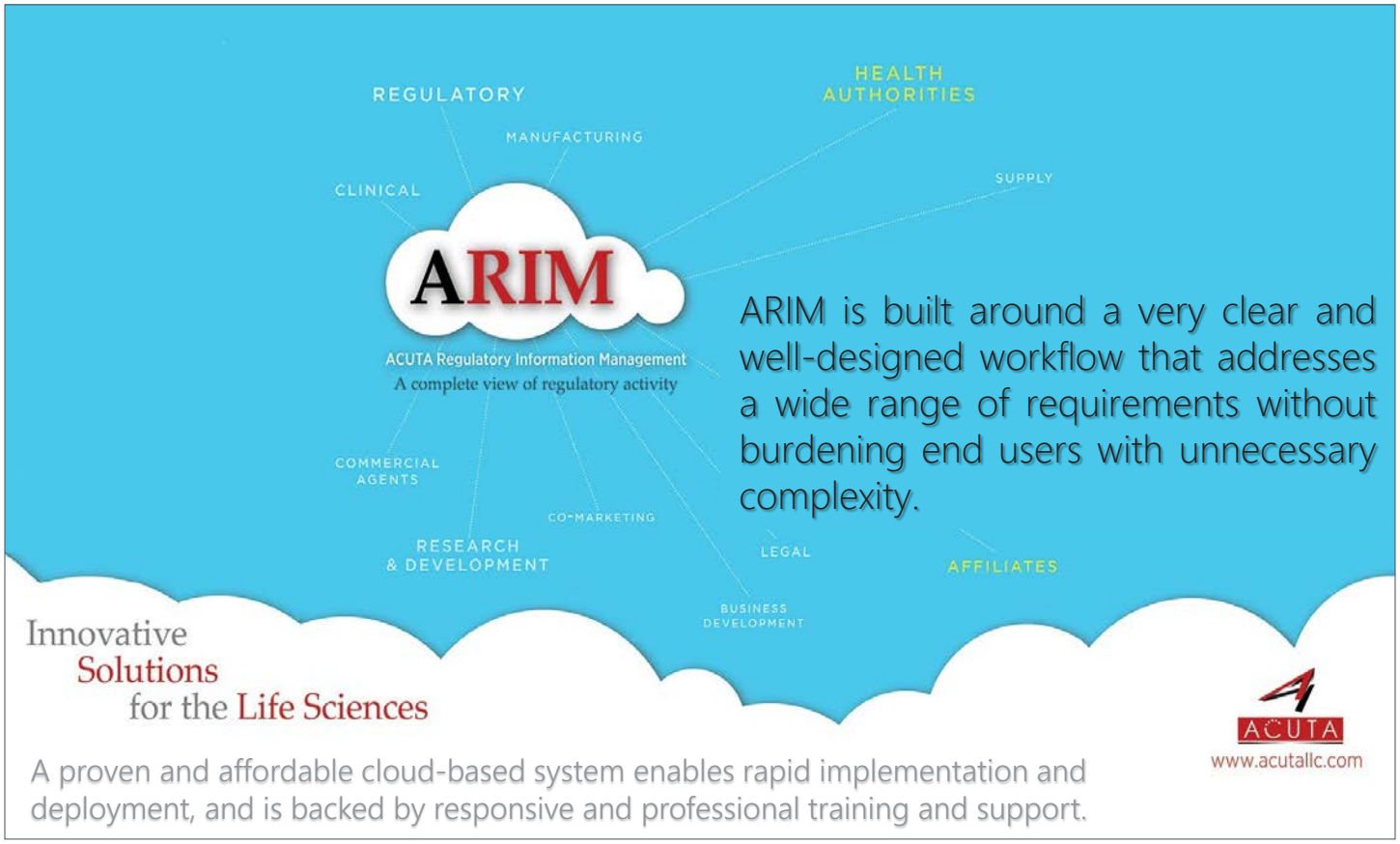
Our mission is to be the partner of choice for the life sciences and related industries by helping you to collect, manage and share regulatory information through innovative, reliable and cost-effective technical and software solutions.



# AMPLEXOR Life Sciences

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Roseland, NJ 07068

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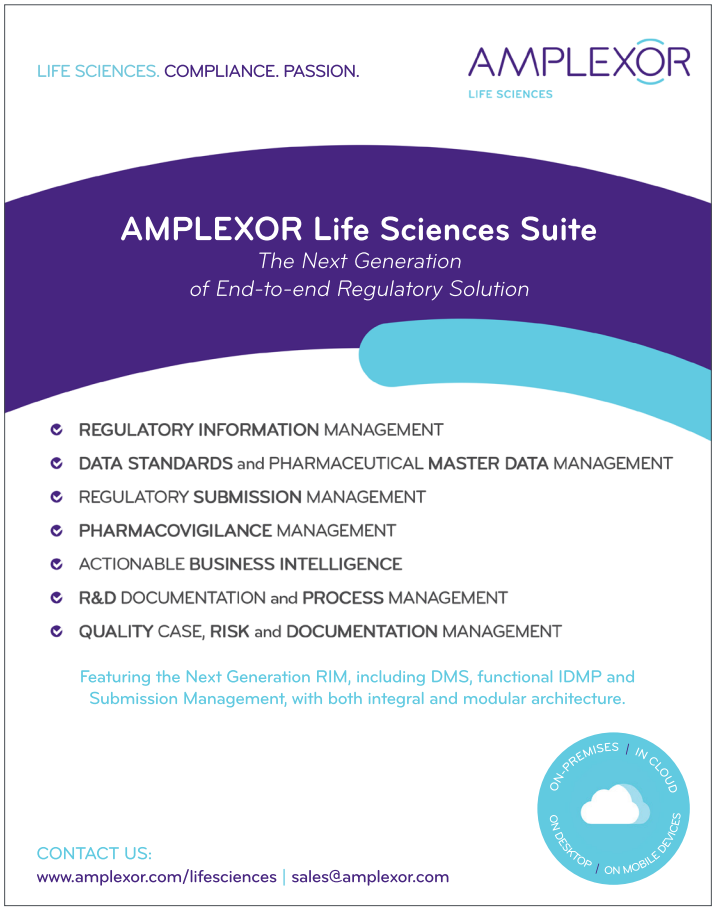
AMPLEXOR Life Sciences helps pharmaceutical, medical device and biotechnology organizations launch products and break new markets quickly. Its solutions and services globally expedite the creation and delivery of consistent, compliant, and high-quality global content and data convergence – both physical and digital. Its services include technology consultancy, implementation and management services, as well as technical writing, medical translation, and linguistic validation services.

AMPLEXOR is the market leader in medicinal product information. Its AMPLEXOR Life Sciences Suite™ is the only next-generation solution available that is Integral by Design, Modular by Implementation™, that provides a single, authoritative source of "product truth" across an organization.

The AMPLEXOR Life Sciences Suite™ is a unique and innovative Integral by Design, Modular by Implementation™ solution which is fully and easily configurable.

This integral approach is the DNA of the solution, a true holistic solution, unlike integrating multiple components into an imperfect whole. With our integral methodology, life sciences organizations can benefit from one universal object model, one single user interface philosophy with process specific applications and an integral Quality Management System, to manage product data holistically.

With the combination of data model and process-centric and role-based workspaces, AMPLEXOR Life Sciences´ unique user interface enables a user-friendly way to manage data complexity. Combined with other powerful functionalities such as Change Control to manage the entity lifecycle, it offers the next generation of applications in this area.



## arivis

2198 East Camelback Road, Suite 205
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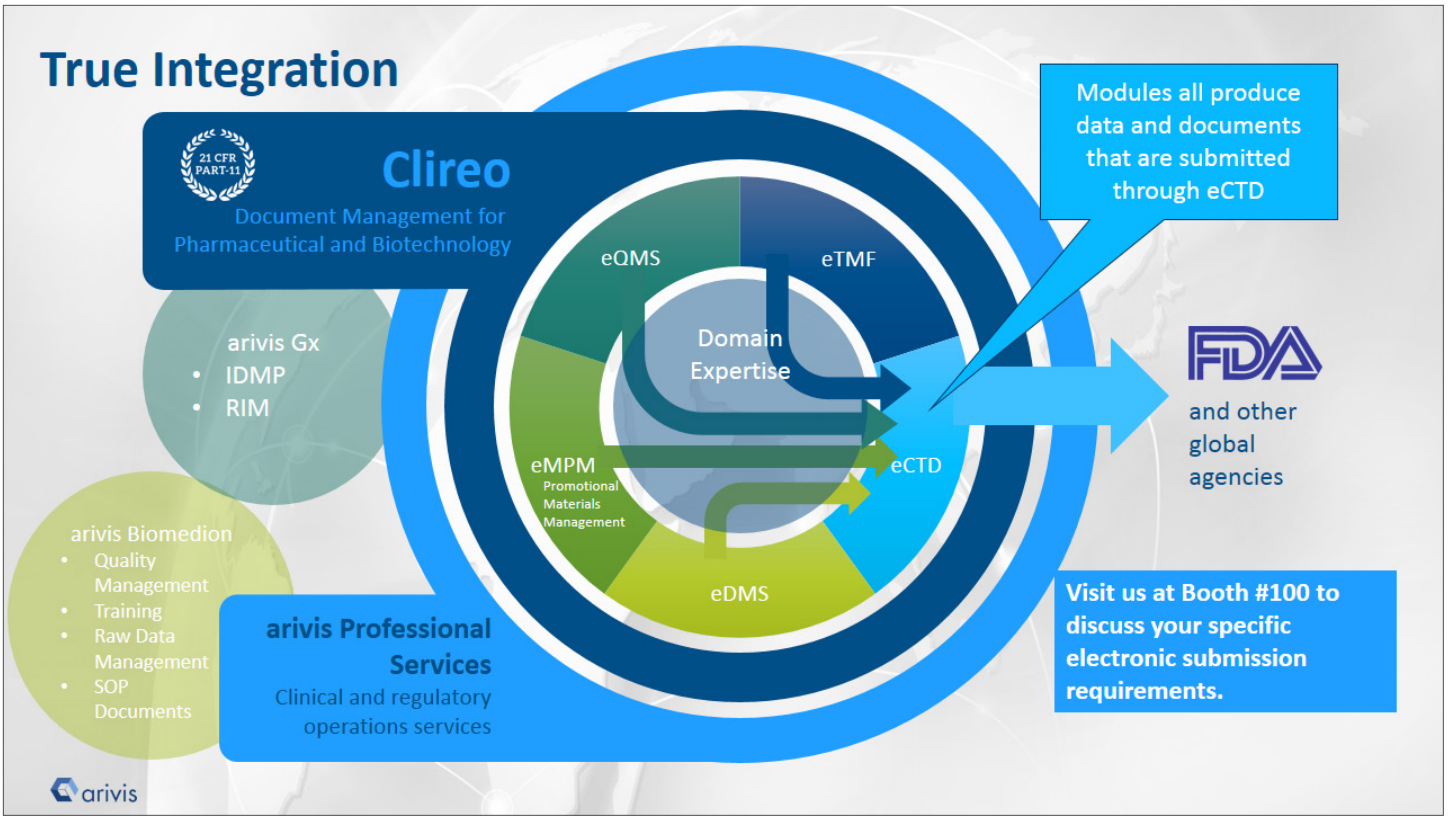
arivis award winning Clireo suite (eDMS, eQMS, eTMF, eCTD, and eMPM) consists of integrated modules delivered via the Microsoft Azure cloud. We are committed to delivering quality software that is easy to implement and use. Our Professional Services Group of industry experts provides unparalleled support for all FDA electronic submissions.



# Cardinal Health Regulatory Sciences

7400 West 110th Street, Suite 300
Overland Park, KS 66210

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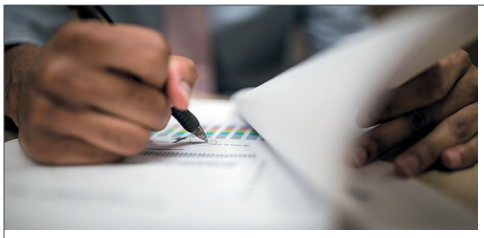
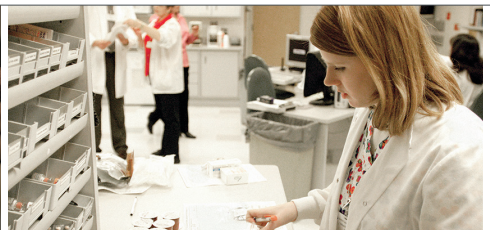
Cardinal Health Regulatory Sciences delivers proven regulatory consulting expertise to help you obtain global product approval and maintain filings throughout the entire product lifecycle. For 40 years, our more than 150 industry-and FDA-trained regulatory consultants have provided expertise and guidance to help pharmaceutical, biotechnology and medical device companies get their products to market quickly. Our regulatory and product development strategies are designed to reduce the risk of failure and increase financial returns on research investments. Our strategies have proven successful for more than 100 New Drug Application (NDA), Biologic License Application (BLA) and Abbreviated New Drug Application (ANDA) approvals. We've provided drug development services for new drugs in all major therapeutic areas.


**Cardinal Health Regulatory Sciences**

Accurate. Accelerated. **Approved.**

## For 40 years,

our team of experts has delivered proven regulatory consulting expertise to help you obtain global product approval and maintain filings throughout the entire product lifecycle.



## Booth 202

Our regulatory experts understand that each product is unique. Come meet us to learn how we can create opportunities for your product development program.

Learn more at:
**cardinalhealth.com/regulatorysciences**
Email us at:
regulatoryscience@cardinalhealth.com

CardinalHealth
*Essential to care™*

## Cunesoft GmbH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Cunesoft provides a sophisticated and integrated regulatory operations solution that unifies DMS, eCTD, IDMP and RIM capabilities as well as its innovative document data mining solution purpose built for IDMP readiness. For more information, please visit www.cunesoft.com.

# The IRISS Forum

Contact Person: James Nichols | President and CEO
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The IRISS (Implementation of Regulatory Information Submission Standards) Forum was created to address the need for a single central forum for open, and broad stakeholder discussions of evolving standards, user requirements and practical, global implementation issues of these standards for the mutual benefit of both industry, government agencies and ultimately, public health.

# LORENZ Life Sciences Group

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Philadelphia, PA 19102

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LinkedIn: www.linkedin.com/company/478461

LORENZ Life Sciences Group (www.lorenz.cc) 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 which enable enforcing compliance globally. LORENZ's 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. With over 600 paid installations in over 30 countries and an average customer growth of 10 new customers per month in 2016, LORENZ has a strong worldwide customer base.

# Microsystems

3025 Highland Parkway, Suite 450
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Microsystems is the leading provider of innovative document technology solutions and cutting-edge software worldwide.

In a highly competitive world restricted by limited resources and tight deadlines, Microsystems delivers patented technology that empowers professionals to focus on content, instead of worrying about formatting, style and semantics. The software works seamlessly in the background to analyze and correct language and formatting.

Five core products optimize all stages of the document production life cycle, improving content quality and formatting, identifying errors and inconsistencies, mitigating risk, and enhancing document production efficiency for the legal, professional services and life sciences industries.

Microsystems Artificial Document Intelligence averts costly errors and preserves professional reputations. Backing all of their client solutions, Microsystems delivers a level of service and support that have consistently earned the firm superior customer service ratings. Clients not only receive extensive customer support, training and education, but they are also invited to influence the product evolution. This practice has earned Microsystems unparalleled customer loyalty and a 98% retention rate. The end result is bullet-proof documents, delivered effortlessly, every time.

Microsystems supports more than 650 document-intensive organizations across the globe, helping them satisfy the complex demands of clients and regulators. For more information, please visit microsystems.com.

## OpenText

275 Frank Tompa Drive
Waterloo, ON N2L 0A1
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Twitter Handle: @OpentextDCTM
LinkedIn: www.linkedin.com/company-beta/2709?pathWildcard=2709

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OpenText is a global leader in Enterprise Information Management (EIM), enabling the digital world by creating a better way for organizations to work with information and achieve actionable results. With OpenText's recent acquisition of Documentum, the combined organization is using its experience and expertise to transform Life Sciences organizations to drive efficiency, productivity and value across the extended enterprise.

Our Life Sciences solutions support critical documents and processes where global regulatory compliance management and shortening product development cycles are essential -- from informal research collaborations to formal procedures like SOP review and approval to coordinating and managing clinical trials and regulatory submissions.

Additional information can be found at:

documentum.opentext.com/industries/life-sciences

and

www.opentext.com/what-we-do/industries/life-sciences

## Schlafender Hase

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Twitter Handle: @SchlafenderHase
Facebook: www.facebook.com/SchlafenderHase
LinkedIn: www.linkedin.com/company/schlafender-hase

Schlafender Hase®

Schlafender Hase® is the global leader in computer-driven proofreading. Our Text Verification Tool® (TVT) is the international benchmark for accurate and user friendly text and graphic verification. TVT is currently used by the world's leading pharmaceutical and medical device companies as well as numerous regulatory bodies to ensure compliant, error-free and consistent packaging. TVT allows users to compare text and graphics with one solution. It is ISO 9001:2008 certified, 21 CFR Part 11 and Annex 11 compliant.

## Veeva Systems

4280 Hacienda Drive
Pleasanton, CA 94588

Contact Person: Lisa Ghatala | Senior Marketing Manager
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Email: lisa.ghatala@veeva.com
Website: veeva.com

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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 450 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. For more information, visit http://www.veeva.com.

# DIA

# Regulatory Submissions, Information, and Document Management Forum 2017

## Exhibitor Directory

February 6-8, 2017 | Bethesda North Marriott Hotel & Conference Center
North Bethesda, MD

### ACUTA — Booth 201

**Contact:** Shylendra Kumar **Phone:** +1.508.466.7799
**Email:** info@acutallc.com
**Website:** www.acutallc.com

Our mission is to be the partner of choice for the life sciences and related industries by helping you to collect, manage and share regulatory information through innovative, reliable and cost-effective technical and software solutions.

### AMPLEXOR — Booth 101

**Contact:** Eric Haase **Phone:** +1.585.880.2590
**Email:** eric.haase@amplexor.com
**Website:** www.amplexor.com/lifesciences

AMPLEXOR Life Sciences helps pharmaceutical, medical device and biotechnology organizations launch products and break new markets quickly. Its solutions and services globally expedite the creation and delivery of consistent, compliant and high-quality global content and data convergence – both physical and digital.

### ArisGlobal LLC — Booth 102

**Contact:** Alexandra Lowe **Phone:** +1.609.360.4052
**Email:** alowe@arisglobal.com
**Website:** www.arisglobal.com

ArisGlobal is the leading provider of integrated solutions for pharmacovigilance & safety, regulatory affairs, clinical development and medical communications. Regulatory Affairs is cloud-based, IDMP-compliant Lifesphere Regulatory Information Management System helps ensure compliance and enables end-to-end management of regulatory affairs activities

### arivis — Booth 100

**Contact:** Gerard Bradley **Phone:** +1.480.269.8124
**Email:** gerard.bradley@arivis.com
**Website:** www.arivis.com

arivis award winning Clireo suite (eDMS, eQMS, eTMF, eCTD, and eMPM) consists of integrated modules delivered via the Microsoft Azure cloud. We are committed to delivering quality software that is easy to implement and use. Our Professional Services Group of industry experts provides unparalleled support for all FDA electronic submissions.

### Cabeus, Inc. — Booth 405

**Contact:** V. Balasubramanian **Phone:** +1.609.423.1889
**Email:** balasubv@cabeus.com
**Website:** www.cabeus.com

Cabeus is a niche products, solutions and services firm enabling Life Sciences clients to unearth the full potential of their IT investments in Enterprise Transformation, Regulatory Information Management (RIM) Solutions, Pharmacovigilance Solutions, Quality Management Solutions and Enterprise Collaboration and Content Management (ECCM) solutions.

### Cardinal Health Regulatory Sciences — Booth 202

**Contact:** Chris Kavlick **Phone:** +1.913.661.3835
**Email:** chris.kavlick@cardinalhealth.com
**Website:** www.cardinalhealth.com/regulatorysciences

Cardinal Health Regulatory Sciences delivers proven regulatory consulting expertise to help you obtain global product approval and maintain filings throughout the entire product lifecycle. Our regulatory and product development strategies are designed to reduce the risk of failure and increase financial returns on research investments.

### Cunesoft GmbH — Booth 209

**Contact:** Rainer Schwarz **Phone:** +1.508.466.7799
**Email:** info@acutallc.com
**Website:** cunesoft.com/en/products/idmp

Cunesoft provides a sophisticated and integrated regulatory operations solution that unifies DMS, eCTD, IDMP and RIM capabilities as well as its innovative document data mining solution purpose built for IDMP readiness.
For more information, please visit www.cunesoft.com.

### DDi — Booth 305

**Contact:** Mahesh Malneedi **Phone:** 1.888.931.0060
**Email:** info@ddismart.com
**Website:** www.ddismart.com

DDi provides smarter technology for Regulatory areas with key focus on Automation utilizing AI/NLP. In addition, DDi has next generation tools like VISU (RIMS), MPDsmart, cmcXtract, smpXtract and LabOps (for Labeling). DDi is a Makro company with HQ in NJ (USA) and other offices in London, Singapore and India.

## ENNOV — Booth 302

**Contact:** Jim Wade **Phone:** +1.336.613.4887
**Email:** contact-us@ennov.com
**Website:** en.ennov.com

With over 15 years' experience and 500 clients worldwide, Ennov makes the most integrated, cost-effective and user-friendly software for Life Sciences. Our 4 mobile solutions: Quality, Regulatory, Clinical and Pharmaco-vigilance integrate with your workflow to help you reach your compliance and productivity goals faster, with no IT skills required.

## EXTEDO, Inc. — Booth 400

**Contact:** Thomas Kessler **Phone:** +1.855.328.3500
**Email:** info@extedo.com
**Website:** www.extedo.com

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. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

## Generis Knowledge Management — Booth 407

**Contact:** Max Kelleher **Phone:** 1.877.244.2022
**Email:** info@generiscorp.com
**Website:** www.generiscorp.com

Generis is a leader in content and information management systems, specializing in proven solutions for regulated industries. Our mission is to provide fast and intuitive implementations to bring our customers an enjoyable and efficient experience, offer unprecedented customer care, and drive the future of information management.

## Genpact Pharmalink — Booth 107

**Contact:** Matt Pitters **Phone:** 1.800.434.5808
**Email:** matt.pitters@genpact.com
**Website:** www.genpact.com/what-we-do/industries/regulatory-affairs

Genpact Pharmalink combines Pharmalink's domain expertise in Regulatory Affairs with Genpact's process, technology, and analytics offerings for the global life sciences market. We deliver custom regulatory affairs projects at any scale, across the globe, providing custom, cost-effective regulatory solutions in over 166 regulated markets.

## Global Vision — Booth 104

**Contact:** Christine Vannelli **Phone:** +1.514.624.4422
**Email:** cvannelli@globalvisioninc.com
**Website:** www.globalvisioninc.com

GlobalVision is the world leader in the design of innovative proofreading technologies. With over 25 years of experience, we've helped customers increase proofreading accuracy, efficiency, and speed. Our solutions have been integrated into the packaging workflows of leading consumer packaged goods companies, printing firms and over 70% of the top pharmaceutical companies worldwide.

## GlobalSubmit, Inc. — Booth 403

**Contact:** Brandon Underwood
**Email:** brandon.underwood@globalsubmit.com
**Website:** www.globalsubmit.com

GlobalSubmit is an industry leader in regulatory technology solutions and services to support global life sciences submissions. We offer Regulatory Publishing Services, eCTD Submissions Management Software, Regulatory Information Management Software and COLLABORATE, an electronic document management system. All software solutions are Cloud hosted.

## HighPoint Solutions — Booth 103

**Contact:** Danielle McDowell **Phone:** +1.610.233.2700
**Email:** danielle.mcdowell@highpointsolutions.com
**Website:** www.highpointsolutions.com

HighPoint Solutions provides specialized IT services with vertically-focused business consulting, system integration, professional service, and managed hosting solutions for life sciences and healthcare companies globally. Our 850+ consultants deliver business consulting and technology solutions that deliver to 170+ clients.

## i4i Inc. — Booth 207

**Contact:** Ruth Wylie
**Email:** rwylie@i4i.com
**Website:** i4i.com

i4i is a world leader in the development of structured content applications. i4i's innovative technology, regulatory and standards expertise enhance compliance through solutions that deliver intelligent content reuse, data identification, tracking and lifecycle management of key Corporate, Clinical, CMC, Safety and Labelling documents.

## Intagras, Inc. — Booth 205

**Contact:** Craig Trautman **Phone:** +1.813.226.1860
**Email:** ctrautman@intagras.com
**Website:** www.intagras.com

Intagras is a leading global provider of pharmaceutical regulatory software solutions. Our applications help clients bring products to market safely and efficiently. Intagras' software provides centralized and consolidated tracking, data entry, and regulatory reporting for pharmaceutical companies to manage the global labeling process.

## InteliNotion, LLC — Booth 303

**Contact:** Andrea Vajtay **Phone:** 1.800.750.4182
**Email:** info@intelinotion.com
**Website:** www.intelinotion.com

InteliNotion is a revolutionary, Cloud based, highly secure and scalable, modern platform built on the latest Web technologies that delivers a new generation of ground-breaking solutions to enable our customers to meet their Compliance, Structured Content Authoring, Component Content Management and Regulatory Information Management requirements.

## The IRISS Forum — Booth 308

**Contact:** Jim Nichols **Phone:** +1.302.310.7138
**Email:** jim.nichols@cunesoft.com
**Website:** www.iriss-forum.org

The IRISS (Implementation of Regulatory Information Submission Standards) Forum was created to address the need for a single central forum for open, and broad stakeholder discussions of evolving standards, user requirements and practical, global implementation issues of these standards for the mutual benefit of both industry, government agencies and ultimately, public health.

## Lionbridge — Booth 406

**Contact:** Jennifer Chan **Phone:** +1.978.964.1435
**Email:** jennifer.chan@lionbridge.com
**Website:** www.lionbridge.com

Lionbridge Life Sciences is the leading provider of language services for pharmaceutical companies, CROs, and medical device manufacturers. Our expert network of medically trained linguists specialize in translation, linguistic validation, and interpretation services in 250+ languages and operate in over 40 solution centers across 27 countries.

## LORENZ Life Sciences Group — Booth 304

**Contact:** Maria DeRose **Phone:** 1.866.956.7369
**Email:** mderose@lorenz.cc
**Website:** www.lorenz.cc

LORENZ Life Sciences Group has an array of RIM solutions geared towards industry, health authorities and academia which enable enforcing compliance globally. LORENZ's tried and tested portfolio offers Product Registration/ IDMP, Submission Assembly, Validation and Management, Regulatory Planning and Tracking products and related services.

## Microsystems — Booth 301

**Contact:** Maribeth Torbik **Phone:** +1.630.310.5957
**Email:** MattG@microsystems.com
**Website:** Microsystems.com

Microsystems is the leading provider of innovative document technology solutions and cutting-edge software worldwide. Microsystems supports more than 650 document-intensive organizations across the globe, helping them satisfy the complex demands of clients and regulators. For more information, please visit microsystems.com.

## Montrium, Inc. — Booth 106

**Contact:** Oliver Pearce **Phone:** +1.514.229.9153
**Email:** info@montrium.com
**Website:** www.montrium.com

Montrium is a Global Leader in Cloud-based Document and Quality Management Solutions and GxP Consulting Services for the Life Sciences. Through our industry leading SharePoint solution, Montrium Connect, we offer a truly collaborative and compliant document and quality management environment on the cloud or on-premise.

## Navitas Inc. — Booth 200

**Contact:** Patrick Mullen **Phone:** +1.609.454.7753
**Email:** Patrick.mullen@navitas.net
**Website:** www.navitas.net

We offer document, report and submission level publishing for simple/complex submission applications including life cycle management by providing subject matter expertise in evolving eSubmissions standards, health authority guidelines and processes. We have extensive eSubmissions experience gained from serving life sciences companies across the globe.

## NNIT — Booth 408

**Email:** nnitcontact@nnit.com
**Website:** www.nnit.com

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..

## OpenText — Booth 105

**Contact:** Lori McKellar **Phone:** +1.519.888.7111
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OpenText is a global leader in Enterprise Information Management (EIM), enabling the digital world by creating a better way for organizations to work with information and achieve actionable results. With OpenText's recent acquisition of Documentum, the combined organization is using its experience and expertise to transform Life Sciences organizations to drive efficiency, productivity and value across the extended enterprise.

## Paragon Solutions — Booth 307

**Contact:** Dineka Robbins **Phone:** +1.610.832.8110 x3078
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Paragon Solutions is an advisory consulting and systems integration firm that works with life sciences organizations to help our clients achieve operational efficiency, business scalability and regulatory compliance.

## PAREXEL International — Booth 204

**Contact:** Chris Braun **Phone:** +1.978.436.1627
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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.

## Pharmaceutical eConsulting — Booth 409

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Pharmaceutical eConsulting (PeC) is the emerging leader in electronic submissions services for the global life sciences industry. Our premier expertise has been utiliized by small to large pharmaceutical companies to emerging bio-tech. Headquartered in Copenhagen, we have offices in Boston and London. Please visit us www.pec-services.com

## Planet Pharma Solutions — Booth 206

**Contact:** Hidemichi Fukasawa **Phone:** +81 359800721
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Planet Pharma Solutions Inc. provides efficient tools and support for Pharmaceutical companies to produce high-quality regulatory documents for eCTD submission. Our products help to accelerate your regulatory submissions by improving leaf file quality, from the rendition phase to the final verification of the documents.

## PleaseTech Ltd. — Booth 208

**Contact:** David Cornwell **Phone:** 1.877.205.4940 or
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PleaseTech's flagship product, PleaseReview, is a unique collaborative review and co-authoring solution for Microsoft Word, PDF and other document types. Used extensively by Life Sciences organizations, it facilitates controlled simultaneous and secure collaboration for document review, editing and redaction.

## QuintilesIMS — Booth 409

**Contact:** Michael Lough **Phone:** +1.919.998.2451
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**Website:** www.quintilesims.com

QuintilesIMS helps companies drive healthcare forward by creating novel solutions from the industry's leading data, technology, healthcare and therapeutic expertise. To learn more, visit www.QuintilesIMS.com.

## RegCheck — Booth 109

**Contact:** Zina Suriano **Phone:** +1.908.273.8637
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**Website:** 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 309

**Contact:** Peter Muller **Phone:** +1.617.607.4900
**Email:** us@sh-p.com
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Schlafender Hase® is the global leader in computer-driven proofreading. Our Text Verification Tool® (TVT) is currently used by the world's leading pharma and med device companies as well as numerous regulatory bodies to ensure compliant, error-free packaging. TVT allows users to compare text and graphics with one solution and generate one report.

## ShareVault — Booth 402

**Contact:** Michael Liccardo **Phone:** +1.650.269.0463
**Email:** mliccardo@sharevault.com
**Website:** sharevault.com

Secure document sharing for life science companies. Applications are CRO/CMO collaboration, trial master file storage/preparation, regulatory eCTD submission storage/review, partnering. eCTD submission inter document links supported. Integrated secure eCTD viewer using the Rosetta Phoenix eCTD Viewer ShareVault Edition to streamline sharing/review.

## Sylogent — Booth 300

**Contact:** Jack Yeager **Phone:** +1.215.504.7000
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Sylogent develops software for the life science industry that automates repetitive information intensive processes. From regulatory submissions and clinical data disclosure to medical information, publication planning and resource documentation; our tools improve compliance and productivity while reducing operational costs.

## Synchrogenix, a Certara company — Booth 401

**Contact:** Kirra Sponenberg **Phone:** +1.302.892.4800
**Email:** kirra.sponenberg@synchrogenix.com
**Website:** 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 108

**Contact:** Lisa Ghatala **Phone:** +1.925.452.6500
**Email:** lisa.ghatala@veeva.com
**Website:** veeva.com

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 450 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.

# DIA

# Regulatory Submissions, Information, and Document Management Forum 2017

## Floor Plan

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North Bethesda, MD