DIA

Regulatory Submissions, Information, and Document Management Forum

Primer: February 4 | Short Courses: February 5 | Conference: February 8-11 | Virtual

PROGRAM CO-CHAIRS

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Overview

Regulatory information is arguably the most valuable asset of a pharmaceutical, biotech, or medical device company. It includes data, meta-data, documents and other forms of information about regulatory and submission intelligence, regulatory authority submission and reporting requirements, submission plans for new products and life cycle management activities, as well as product registration information, labeling, CMC, safety submissions, communications from health authorities, and more.

How regulatory information is managed has a profound impact on operational efficiency across the whole organization, on data quality, and ultimately on the company's ability to meet the needs of patients. As global regulatory requirements, technology, data sources, and data standards evolve, the importance of sound regulatory information management becomes even greater.

The global COVID-19 pandemic has had shed light on the importance of operational efficiency of the management of regulatory information to ensure quality regulatory submission to health authorities. We have seen how the ability to perform at this level has allowed drug companies to bring therapeutics and vaccines to patients faster. At DIA's *Regulatory Submissions, Information, and Document Management (RSIDM) Forum*, we will hear from industry and regulatory stakeholders working across the scope of regulatory information to examine current and evolving data standards and requirements and effective regulatory information management approaches to align related systems. The Forum presents four tracks: Regulatory Informatics Business, Regulatory Informatics Technology, Electronic Document Management, and Electronic Regulatory Submissions. Cross-track sessions provide the opportunity to discuss key connection points across major components of regulatory information, and plenary sessions featuring regulatory intelligence updates by FDA and other regulatory authorities are offered each day.

This Forum provides multiple opportunities for networking, knowledge sharing, and education for business, technology, and regulatory-focused attendees.

Who Should Attend?

Professionals involved in:

- Regulatory Affairs and Operations
- Regulatory Information Management
- Regulatory Informatics
- Submissions and Global Submissions Management/Project Management
- Medical, Technical, and Regulatory Writers
- TMF and eTMF Management
- Informatics/Bioinformatics Professionals
- Clinical Data/Data Managers
- Information Technology and Support Personnel
- Document and Records Management/ Specialists
- Essential Document Process and Business System Owners
- Regulatory Standards Implementation Specialists and Associates
- Clinical Operations and Processes
- Quality Management
- Quality Assurance/Quality Control and Compliance Professionals
- Strategic Planning and Operations
- Contract Research and Service Support Providers
- Emerging Pharmaceutical/Biotech/ Device Professionals
- Outsourcing/Clinical Outsourcing
- Vendor Relationship Managers

Schedule-At-A-Glance

Track Key: **Track 1:** Regulatory Informatics – Business **Track 2:** Regulatory Informatics – Technology
Track 3: Electronic Document Management (EDM) **Track 4:** Electronic Regulatory Submissions (ERS)

PRIMER | THURSDAY, FEBRUARY 4

10:00AM-5:00PM	**Primer:** Regulatory Content and Submissions Primer: Content from Authoring Through Archive **Primer requires an additional registration fee. You do not need to be registered for the Forum to attend** **CE credit is available for this educational activity**

SHORT COURSE | FRIDAY, FEBRUARY 5

12:30-4:00PM	**Short Course 1:** Regulatory Considerations for Blockchain in Clinical Research and Drug Development **Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend** **CE credit is available for this educational activity**

DAY ONE | MONDAY, FEBRUARY 8

10:00-10:25AM	**Welcoming Remarks and Presentation of the Excellence in Service Award**
10:25-11:00AM	**Session 1: Keynote Address:** Featured Fireside Chat
11:00-11:30AM	BREAK/Visit the Virtual Exhibit Hall
11:00-11:30AM	Exhibit Event: Coffee Corner – hosted by Grant Thornton, LLP Leading the "People" Side of Change in Regulatory Innovation Efforts
11:30AM-12:30PM	**Session 2:** FDA Plenary – Driving Data and Information Technology
12:30-1:30PM	BREAK/Visit the Virtual Exhibit Hall
1:30-2:45PM	**Session 3:** BREAKOUT SESSIONS **Track 1:** Accelerating RIM Performance: Learning from Top Performers of the 2020 Industry World Class RIM Benchmark Survey **Track 4:** Be Prepared! Submission Management for Health Authority Filings *OR You can view from our On-Demand Library at any time throughout the forum!*
2:45-3:15PM	BREAK/Visit the Virtual Exhibit Hall
3:15-4:30PM	**Session 4:** BREAKOUT SESSIONS **Track 2:** Connecting Regulatory, Clinical, and Quality Information **Track 3:** eTMF Collaboration in Outsourced Studies *OR You can view from our On-Demand Library at any time throughout the forum!*
4:45-5:30PM	Exhibit Event: Happy Hour – hosted by Generis Managing Structured Content Authoring in Regulatory Affairs

DAY TWO | TUESDAY, FEBRUARY 9

10:00-11:15AM	**Session 5**: FDA Electronic Submissions
11:15-11:45AM	BREAK/Visit the Virtual Exhibit Hall
11:15-11:45AM	Exhibit Event: Coffee Corner hosted by Genpact Finding the Data Needle in the Document Haystack with AI

11:20-11:40AM	**Q&A Session**: International Regulatory Update
11:45AM-1:00PM	**Session 6:** BREAKOUT SESSIONS **Track 1:** The Crossroads Between Regulatory and Safety **Track 4**: Evolution from the "Global Dossier Concept" to Joint Dossier Co-Creation *OR You can view from our On-Demand Library at any time throughout the forum!*
1:00-1:30PM	BREAK/Visit the Virtual Exhibit Hall
1:30-2:45PM	**Session 7:** BREAKOUT SESSIONS **Track 2:** Emerging Technologies and Data Driven Initiatives within the Regulatory Environment **Track 3:** Merge and Go! Learning Opportunities from the AbbVie/Allergan Experience *OR You can view from our On-Demand Library at any time throughout the forum!*
2:45-3:15PM	BREAK/Visit the Virtual Exhibit Hall
3:15-4:30PM	**Session 8:** BREAKOUT SESSIONS **Track 1:** Three Perspectives on achieving Medicinal Product (Data) Quality **Track 4:** AdPromo eCTD, The Time is Now! *OR You can view from our On-Demand Library at any time throughout the forum!*

DAY THREE | WEDNESDAY, FEBRUARY 10

10:00-11:15AM	**Session 9:** BREAKOUT SESSIONS **Track 2:** Enabling Regulatory Strategy through Automation and Analytics **Track 3:** NextGEN TMF Management Panel– Data is the Key *OR You can view from our On-Demand Library at any time throughout the forum!*
11:15-11:45AM	BREAK/Visit the Virtual Exhibit Hall
11:20-11:40AM	**Q&A Session**: Global eCTD Specifications
11:45AM-1:00PM	**Session 10:** BREAKOUT SESSIONS **Track 2:** Introducing DIA RIM Reference Model 1.0 **Track 3:** From Question to Answer: How Automation can Improve Health Authority Communication *OR You can view from our On-Demand Library at any time throughout the forum!*
1:00-1:30PM	BREAK/Visit the Virtual Exhibit Hall
1:10-1:30PM	**Q&A Session:** IDMP - to Iteration 1 and Beyond
1:30-2:45PM	**Session 11:** Emerging Technologies Panel
2:50-3:10PM	**Q&A Session:** Outsource Partners - Selection Process, Best Practices, and Case Study
2:45-3:15PM	BREAK/Closing Mingle in the Exhibit Hall
3:15-4:15PM	**Session 12:** Ask the Regulators
4:15-4:30PM	Closing Remarks
4:30PM	Forum Adjourns

Track Descriptions

Track 1: Regulatory Informatics Business - This track addresses processes for obtaining and managing regulatory information, in the form of data through data management, governance, change control, organizational impact, standards, and key issues shaping the global regulatory and business environments.

Track 2: Regulatory Informatics Technology - This track focuses on technology and solutions for managing data, extrapolating, and developing analytics, and emerging technologies to support data control and enhancements.

Track 3: Electronic Document Management (EDM) - This track examines the processes, systems, and best practices for content management across the product lifecycle, including alignment with the RIM system for optimal use of regulatory information.

Track 4: Electronic Regulatory Submissions (ERS) - This track explores the submission process, regulatory requirements and new developments, best practices in regulatory submissions and industry adoption techniques.

Learning Objectives

At the conclusion of this forum, participants should be able to:

- Explain the regulatory electronic submission process from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team
- Discuss the agency target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications
- Describe the current required data standards for regulatory submissions and the status of ongoing data standards initiatives
- Describe organizational processes and governance to ensure integrity, quality, and security of regulatory information (data, documents, records)
- Examine the scope and assess the future of data standards, including IDMP, with respect to systems, processes, and master data
- Discuss ways data can be harmonized, integrated, and viewed to provide an end-to-end view of the regulatory information value chain
- Discuss organizational implications related to increasing electronic interactions with stakeholders and health authorities
- Explain ways to improve processes and communication of regulatory activities including communications, end-to-end processes, and integration of systems for document, submission, and records management
- Interpret global health authority regulations and guidance's for systems and business processes
- Identify ways in which the integration of data, documents, and knowledge can be leveraged to develop insights and enable better business decisions
- Identify changes in submission-related regulations impacting regulatory informatics business processes

Continuing Education Credit

ACPE credit and IACET CEUs will be offered if you attend the live virtual Primer and/or Short Course(s) on February 4-5, 2021. **Credit will not be awarded for attending the Forum sessions.**

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY MONDAY, MARCH 22, 2021

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 8.75* contact hours or .875* continuing education units (CEU's). Type of Activity: Knowledge

*ACPE credit only available for the Primer and Short Course(s).

February 4, 2021 – Primer: Regulatory Content and Submissions Primer: Content from Authoring Through Archive UAN: 0286-0000-21-008-L04-P; 5.5 Contact Hours; .55 CEUs

February 5, 2021 – Short Course 1: Regulatory Considerations for Blockchain in Clinical Research and Drug Development UAN: 0286-0000-21-009-L04-P; 3.25 Contact Hours; .325 CEUs

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity**. If ACPE credit is not requested by, **Monday March 22, 2021**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to **.9*** CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

***IACET CEUs are only available for the Primer and Short Course(s)**.

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual primer and/or short course, you must virtually attend the primer and/or short course(s), in their entirety, achieve a passing score of 80% or better on the post-assessment, and complete the program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, February 24, 2021.**

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose. To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**.

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Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

PRIMER | THURSDAY, FEBRUARY 4

10:00AM-5:00PM

Regulatory Content and Submissions Primer: Content from Authoring Through Archive

Primer requires an additional registration fee. You do not need to be registered for the Forum to attend

CE credit is available for this educational activity

These talks are designed to meet the needs of individuals who are either new to biopharmaceutical-based regulated document management, information management, and regulatory submission publishing for authorities or already experienced in one area looking to gain a broader understanding. This Primer will present the full spectrum of the regulatory submission, information and document management arena. Understanding the various steps throughout the life of document components from their authoring, publishing to PDF, assembling into a submission, delivery to regulatory agencies, and ultimately company archival will yield "aha" moments for the attendees of this offering from all functions along the life-span of regulatory content.

A Pandemic Impact Assessment (PIA) will be provided to identify high-level overall analysis and actual and potential risks will be identified in relevant sessions.

Virtual exercises will provide the attendees the ability to apply material as the day progresses. Participate in anonymous interactive polling to share your understanding of the material, your experiences and hear from your fellow attendees.

At the conclusion of this primer, participants should be able to:

- Describe the benefits of understanding the complete life phases of regulatory content and the impact that decisions in one place along the life path will have at other stages of the process
- Identify key drivers within each of the life phases and potential pros and cons associated with solution choices
- Recognize the needs of the other organizations involved within the lifespan of the regulatory content and fairly assess their concerns in process and procedure decision-making
- Comprehend the newly released regulations, guidelines, and industry best practices and gain an awareness of their impact

Betsy Fallen, RN, Consultant, BAFallen Consulting, LLC

Daniel Orfe, MS, President and CEO, Regulatory eSubmissions, LLC

SHORT COURSE | FRIDAY, FEBRUARY 5

12:30-4:00PM

Short Course 1: Regulatory Considerations for Blockchain in Clinical Research and Drug Development

Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend

CE credit is available for this educational activity

While 70% of life sciences organizations plan to implement blockchain in the near future, blockchain developers and operators are often unfamiliar with clinical research regulations and related data and technology standards. Health regulators may also be unfamiliar with this family of rapidly maturing technological tools and their potential impact on research regulations. In this course, we will provide an overview of this emerging technology: how it is being used in healthcare and life sciences, where it is being explored for future use, how it operates from a non-technical perspective, and the risks, benefits, and trade-offs of its use in the life sciences. No prior knowledge of blockchain technology is required for this short course, though existing knowledge of the technology will be enhanced.

At the conclusion of this session, participants should be able to:

- Describe what blockchain is, how it operates from a non-technical perspective, and how it is currently being used in life sciences research
- Study approaches that regulatory agencies have taken toward blockchain technologies in contract, drug, and device development
- Design documentation and testing strategies for IRB submissions, privacy laws, and electronic record/signature regulations

Agenda

1. Blockchain 101: Introduction to Blockchain
2. General Real World Uses
3. Research Data Applications
4. Pharmaceutical Industry Uses
   - Break -
5. Blockchain 201: Regulatory Considerations of Blockchain
6. Role Play Compliance Investigation
7. Future State

Wendy Charles, PhD, Chief Scientific Officer, Burstiq

Sean Manion, PhD, Chief Science Officer, ConsenSys Health

10:00-10:25AM

Welcoming Remarks and Presentation of the Excellence in Service Award

Robin Weinick, PhD, Senior Vice President and Managing Director, Americas and Global Program Officer, DIA

Brooke Casselberry, MS RAC, Senior Director, R&D Consulting, NNIT

Cindy Chiu, Director, Regulatory Affairs Operations & Quality Management, Merck & Co., Inc.

Peter Terbeek, MBA, Senior Director, Publishing and Submission, Astellas

Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

Excellence in Service Awardee
Michelle Charles, MPH, Director, Regulatory Affairs, Gene Therapy Program, University of Pennsylvania, Perelman School of Medicine

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10:25-11:00AM

Session 1: **Keynote Address:** Featured Fireside Chat

Ram Iyer, MS, Chief Data Officer, FDA

As the Chief Data Officer of the FDA, Ram C Iyer has the accountability to develop and execute an agency wide data modernization strategy, building robust central functions that can be leveraged by the centers and the agency for high value decisions. The scope spans the entire stack from data identification to actionable decision, including data policies and governance. Ram is an industry and peer recognized data and technology professional with experience in the Pharma, Consulting, Telecom and International Government organizations. His expertise includes Data and Decision Sciences, Digital and Technology Architecture, and Talent Development with a focus on building collaborative partnerships and Ecosystems.

Moderator
Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

11:00-11:30AM

BREAK/Visit the Virtual Exhibit Hall

11:00-11:30AM

Exhibit Event: Coffee Corner – Hosted by Grant Thornton, LLP

Leading the "People" Side of Change in Regulatory Innovation Efforts

Attendees for the Coffee Corner will receive a Starbucks gift card ($5). Must be a registered attendee for **DIA's Regulatory Submissions, Information, and Document Management Forum** to qualify.

Many Regulatory teams are investing in technology, but some fail to get the expected benefits when employees don't fully adopt the solution. Join us to discuss how to apply a successful change management strategy specifically for Regulatory initiatives. With coffee cup in hand, let's chat about tactics for regulatory leaders as change agents, the importance of a tailored approach, and the potential value unlocked when done right – from reduced disruption and risk to better outcomes and faster adoption.

CLICK HERE for more information or to RSVP.

BONUS! Grant Thornton, LLP is also giving the first 20 attendees to register, a special gift box to be mailed to your home. **Claim your gift now!!**

Presenters
Amy Flynn, National Life Sciences Leader, Grant Thornton LLP

Laura Robinson Campbell, VP Regulatory Affairs, Merck

Talia Ben David, Global Regulatory Collaboration & Service Center Lead, Bristol Myers Squibb

11:30AM-12:30PM

Session 2: FDA Plenary – Driving Data and Information Technology

Session Chair

Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

FDA is focused on a strategic approach not only to technology, but to data itself. Data is at the heart of FDA's work as a science-based Agency, and there is anticipation of ongoing, rapid increases in the amount and complexity of the data that will inform regulatory decision-making and its public health mission. Leaders from the FDA's Office of Information Management and Technology, CDER's Office of Strategic Programs, and CBER's Data Standards Branch, Office of the Director will discuss data topics, for instance, standards, RWD/RWE, quality, stewardship, access / exchange, analytics, cloud, and, artificial intelligence.

Speakers

Vid Desai, Chief Technology Officer, FDA

Mary Ann Slack, Director, Office of Strategic Programs, CDER, FDA

Virginia Hussong, Chief, Data Standards Program, CBER, FDA

12:30-1:30PM

BREAK/Visit the Virtual Exhibit Hall

1:30-2:45PM

Session 3: BREAKOUT SESSIONS

Track 1: Accelerating RIM Performance: Learning from Top Performers of the 2020 Industry World Class RIM Benchmark Survey

Session Chair

Sarah Powell, RAC, President, Powell Regulatory Services

This session will present the results from the Top Performer analysis of the 2020 RIM Survey. It will evaluate the differences from the top performer cohort in regard to data management, technology usage, process maturity and operational structure

Speakers

Steve Gens, MS, Managing Partner, Gens and Associates

Greg Brolund, MS, Consultant, Chicopee Falls Consulting, LLC

Kelly Hnat, Principal, K2 Consulting

Track 4: Be Prepared! Submission Management for Health Authority Filings

Session Chair

Kevin Tompkins, MBA, MS, Senior Director, Global Submission Management, Bristol-Myers Squibb

"By failing to prepare, you are preparing to fail."

Regulatory submissions are complicated. While trying to compile a high quality submission package to meet health authority requirements, you are working with multiple stakeholders and aggressive timelines within your organization. It can become overwhelming as the days pass and deadlines missed with the submission date fast approaching. Effective submission project management can help you mitigate those challenges and have a plan to meet your target submission date. This session will give suggestions and strategies to keep the project on track in order to deliver a high quality submission to health authorities.

Teamwork for Timelines; Our Regulatory Project Management and Publishing

Dom Moloney, Associate Director, Regulatory Submission Management, PRA Health Sciences

Submission Management: Who needs Project Management?

Patricia Oliva Millonig, Senior Director, Regulatory Operations and Compliance, Bluebird Bio

Supporting Cross-Functional Teams to Execute a Successful Global Filing

Sandra Krogulski, MA, Associate Director, Submission Management, Bristol-Myers Squibb

2:45-3:15PM **BREAK/Visit the Virtual Exhibit Hall**

3:15-4:30PM **Session 4:** BREAKOUT SESSIONS

Track 2: Connecting Regulatory, Clinical, and Quality Information

Session Chair
Danielle Beaulieu, PhD, Senior Director, Global Regulatory Business Capabilities, Bristol-Myers Squibb

Regulatory, clinical, and quality teams leverage hundreds of overlapping documents and data points, but this information often exists in disparate systems. This session will focus on strategies for connecting regulatory, clinical, and quality information to streamline complex processes. We'll hear from two innovation biopharma companies, Vertex and Urogen they faced with data model design and governance and what benefits they hope to achieve.

Regulatory, Quality and Clinical Data Connection Points: What Are the Possibilities and How Do We Prioritize?
Alison Marjanowski, Director, Vault RIM, Veeva Systems

Connecting Quality and Regulatory Information
Rebecca Smissen, Director, RIM Strategy, Vertex Pharmaceuticals

Connecting Clinical and Regulatory Information
Dominick Gagliostro, Senior Director, Project Management and Regulatory Operations, Urogen

Track 3: eTMF Collaboration in Outsourced Studies

Session Chair
Joanne Malia, MS, MSC, Director, Clinical Documentation Management, Regeneron Pharmaceuticals

Utilizing experiences and case studies from both the Sponsor and CRO side, we will outline typical operating models, and introduce potential new models for consideration, outlining the pros and cons of each, importantly, for both the Sponsor and CRO.

In deciding on an operating model, it is important to understand the total cost of ownership holistically, as well as the impact to Inspection Readiness, and the roles and responsibilities between CRO and Sponsor.

Managing Trial Master File and Regulatory documents in an outsourced model can be a stressful and challenging effort, if the operating model is not well thought out and planned for. In this session you will hear from both Sponsor and CRO experiences.

eTMF Collaboration – What are the Operating Models?
Jamie O'Keefe, Vice President, Business and Technology Consulting, Just In Time GCP

TMF Collaboration: Sponsor View
Mallorie Sayre, TMF Manager, Moderna

TMF Collaboration: CRO View
JP Miceli, Associate Director, Document Management, Advanced Clinical

4:45-5:30PM Exhibit Event: **Happy Hour:** Hosted by Generis

Managing Structured Content Authoring in Regulatory Affairs

Bonus: Attendees for the Happy Hour will receive a Visa gift card ($10) from DIA: (must be a registered attendee for **DIA's Regulatory Submissions, Information, and Document Management Forum** to qualify).

Life Sciences Organizations strive to bring more products to market in as little time as possible to help the population with unmet medical needs. Regulatory Affairs is a critical function in enabling cross-functional collaboration to put together submissions for new product approvals as well as life cycle management of marketed products in various markets. In order to accomplish this authoring, reviewing, publishing and compiling troves of documents is a tedious and time consuming process. Industry has been trying to adopt Structured Content Management to address this challenge, promote content reuse

and move towards a data-driven regulatory document management for over a decade. Now, Cognizant, Generis and Fonto have partnered and brought to life a platform that can support end-to-end structured content management. This can be extended to CMC, Clinical and Labeling documents that typically make up the eCTD submissions.

Featured topics to include:

- Understanding the challenges in managing regulatory affairs content
- Benefits of structured content management
- Strategy and Roadmap you can devise to adopting SCM in your organization
- Demonstration of next level platforms to realize structured content authoring strategy

CLICK HERE for more information or to RSVP

Presenters
James Kelleher, CEO, Generis

Venugopal Mallarapu, Director & Global Head, Regulatory Affairs Advisory Consulting, Cognizant

Jan Benedictus, CEO, Fonto

DAY TWO | TUESDAY, FEBRUARY 9

10:00-11:15AM — **Session 5:** FDA Electronic Submissions

Session Chair
Jonathan Resnick, PMP, Project Management Officer, OBI, OSP, CDER, FDA

During this session, FDA will provide a summary on electronic submissions. Studies started after December 17, 2016 are required to be submitted in standardized format when submitted to NDA, BLA, and ANDA (required for Commercial INDs if study start date is after December 17, 2017). FDA will discuss how eCTD validation is used to check a submission containing study data for conformance to the requirement. In addition, FDA will provide an update on submission metrics, processing challenges, and best practices for successful submission.

Electronic Submissions Update
Jonathan Resnick, PMP, Project Management Officer, OBI, OSP, CDER, FDA

Study Data Conformance: Technical Rejection Criteria for Study Data and Self Check Worksheet
Ethan Chen, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

11:15-11:45AM — **BREAK/Visit the Virtual Exhibit Hall**

11:15-11:45AM — **Exhibit Event:** Coffee Corner hosted by Genpact

Finding the Data Needle in the Document Haystack with AI

Access to accurate and structured regulatory data enables faster and more efficient decision-making. However, regulatory data is often scattered across multiple systems and documents. And for regulatory affairs, reviewing mountains of documents for data collection and extraction is manual and labor-intensive.

CLICK HERE for more information or to RSVP

Presenters
Padmanabham (Paddy) Navuluri, Head of growth and commercial solutions, Regulatory affairs, Genpact

Rajiv Naidu, Global Business Leader, Regulatory Affairs, Genpact

11:20-11:40AM — **Q&A Session:** International Regulatory Update

Session Chair
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

Have you watched the *International Regulatory Update* session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Jesper Kjær, Director of the Data Analytics Center, Danish Medicines Agency (DKMA)

Shannon Laforce, MBA, Executive Director, Transformation and Business Informatics, RMOD, HPFB, Health Canada

11:45AM-1:00PM

Session 6: BREAKOUT SESSIONS

Track 1: The Crossroads Between Regulatory and Safety

Session Chair
Brooke Casselberry, MS, RAC, Senior Director, R&D Consulting, NNIT

Pharmacovigilance and Regulatory are two functional areas that are directly impacted by each other and that has become more evident by the COVID-19 pandemic. Regulatory decisions impact preparation for case load peaks and safety reporting, and safety reporting drives regulatory strategy for risk mitigation and submission optimization. Additionally, managing Pharmacovigilance systems with the increase demands on data intake has created a thoughtful approach to technology and process. Join this session to hear experiences and case study approaches to the lifecycle of data across regulatory to safety and coping with large data loads in the year 2020.

Integrated RIM and Pharmacovigilance: Meeting the Evolving Challenges of Life Cycle Management
Kristen Mandello, DVM, Global PV, Signal Detection Manager, Zoetis

Seeking Synergy Between Regulatory & Safety
Mark Loudon, Advisory Director, NNIT

Strategic PV Technology Challenges in the era of COVID-19
Bill Ringbloom, MBA, PMP, IT Business Partner, Global Patient Safety, AstraZeneca

Track 4: Evolution from the "Global Dossier Concept" to Joint Dossier Co-Creation

There is an emerging need to accommodate global submission support for international countries covering both eCTD and non-eCTD requirements. This session features practical case study experience implementing the "Global Dossier Concept": a global collaborative operational model pilot to enable global co-creation methodology and successful same day filings across multiple countries. Hear perspectives from sponsor experts in both US and China Regulatory Submission Management, as well as from the application vendor partner.

Session Chair
Stacy Tegan, Program Manager, TransCelerate Biopharma, Inc.

Evolving the "Global Dossier Concept"
Teresa Martins, Senior Director, US Site Head Regulatory Submission Management, Bayer US, LLC

The "Co-Compilation" Journey
Nikki Qu, Associate Director, Regulatory Submission Management, Bayer Healthcare Company Limited

Challenges to Achieve Success with the Global Dossier Concept
Akira Yamaguchi, MBA, Chief Technology Officer, Lorenz Life Sciences

1:00-1:30PM

BREAK/Visit the Virtual Exhibit Hall

1:30-2:45PM

Session 7: BREAKOUT SESSIONS

Track 2: Emerging Technologies and Data Driven Initiatives within the Regulatory Environment

Session Chair
Jo English, Vice President, Regulatory Information Management, Calyx, United Kingdom

Health Authorities and industry recognize the benefits for more efficient and effective decision making, but can they keep pace with emerging technologies? This session will describe how data and technology modernization requires active collaboration with regulatory authorities and other stakeholders and will review the principles of informatics, data management and data governance as they apply to regulatory acceptability. A case study on Real World Data (RWD) and Real-World Evidence (RWE) will be presented to provide an example of how this is being applied. The session will present regulatory and scientific perspectives from regulators, industry, and life sciences data/tech sector on emerging technology and its application to regulatory initiatives to further advance public health.

Speakers
Vada Perkins, DrSc, MSc, Executive Director, Regulatory Policy and Intelligence, Bayer Pharmaceuticals

Mary Ann Slack, Director, Office of Strategic Programs, CDER, FDA

Hilmar Hamann, PhD, Head of Information Management Division, European Medicines Agency (EMA)

Taha Kass-Hout, MD, MS, Director, Machine Learning and Chief Medical Officer, Amazon

Track 3: Merge and Go! Learning Opportunities from the AbbVie/Allergan Experience

Session Chair
Cindy Chiu, Director, Regulatory Affairs Operations & Quality Management, Merck & Co., Inc.

The AbbVie/Allergan merger is one of the most recent for pharma. The intersection if Developmental and Regulatory Operation groups of two large organizations posed challenges for the systems, processes, and the people. We'll present plans designed for success, assess the progress and outline some case studies that will be sure to initiate conversations!

Mergers & Acquisitions: The Penthouse View
Betsy Fallen, RN, Consultant, BA Fallen Consulting, LLC

Maintaining Operational Momentum After A Merger
Caitlyn Flaherty, Associate Director, Regulatory Affairs, Abbvie, Inc.

2:45-3:15PM **BREAK/Visit the Virtual Exhibit Hall**

3:15-4:30PM **Session 8:** BREAKOUT SESSIONS

Track 1: Three Perspectives on achieving Medicinal Product (Data) Quality

Session Chair
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

All three presenters will share different perspectives on gaining better control over Medicinal Product Quality and associated information, utilizing the increasing amount of structured data available. What all three presentations have in common is anticipating on the global shift from primarily paper-based assessments to structured data. What is the impact of these changes on the organization of the regulatory affairs strategy, organization, and related processes? What framework and skills are required to effectively manage structured data quality during the product life cycle and what is the impact on the regulatory assessment procedures at the Health Authorities?

Building a Culture Around Data for Successful Registration Tracking; The Transformation of a Data Management Office
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

Should Publishers Become Ambassadors for Data Quality, What Might the Role of a Publisher Look Like, a Few Years from Now?
Jennie May, Director, Regulatory Informatics & Operations, Pharmalex, United Kingdom

An Industry Proposal for the Registration and Lifecycle Management of Manufacturing Models
Isabelle Lequeux, MSc, Facilitator, Biophorum

Track 4: AdPromo eCTD, The Time is Now!

Session Chair
Tom Noto, Senior Director, Regulatory Operations, Lexicon Pharmaceuticals

The FDA AdPromo eCTD Guidance was finalized in June 2019 and becomes mandatory in June of this year! In this session you will hear from speakers who have successfully implemented AdPro eCTD in their organizations and gain a greater understanding of how it can be done in yours. The focus will be on real world lessons-learned and practical tips for a smooth transition.

Ad Promo Submissions in eCTD: Are you Ready to be Compliant?
Allison Steffen, Manager, Regulatory Operations, WAYS Pharmaceutical Services

Implementing eCTD AdPromo Submissions Under a Critical Timeline
Tom Noto, Senior Director, Regulatory Operations, Lexicon Pharmaceuticals

Speaker
Melinee Wilson, Regulatory Submissions Associate Manager, Astellas Pharma Global Development, Inc.

DAY THREE | WEDNESDAY, FEBRUARY 10

10:00-11:15AM

Session 9: BREAKOUT SESSIONS

Track 2: Enabling Regulatory Strategy through Automation and Analytics

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Innovation

Several enabling technologies have evolved over the years to support the regulatory operations function but not too many to support Regulatory Strategists. It is time to look at how digital transformation can enable regulatory strategy and regulatory intelligence activities to drive decision making, to streamline analysis, and to improve global coordination. Effective decision making can be supported by the exploitation of information present in RIM systems which requires harnessing quality data and transforming data into intelligence using analytics. Better analytics is possible only through the integration of data across siloed systems and processes not only within Regulatory but also across adjoining functional areas such as Clinical, Safety, Manufacturing, Quality, etc. During this session, we will see presenters making the connection between digital transformation to enable regulatory strategy activities with quality data and analytics followed by a framework on how analytics can be accomplished using existing systems with appropriate examples.

Enabling Regulatory Strategy Teams through Technology and Automation
Brian Williams, Managing Director, Life Sciences, KPMG

Increase Regulatory Efficiencies through Analytics
Daniel Smith, Business Analyst, RIM, Calyx

An Architectural Framework for R&D Analytics and Impact Analysis
Ravi Krishnamurthy, MBA, Senior Vice President, Life Sciences, Orion Innovation

Track 3: NextGEN TMF Management Panel-Data is the Key

Session Chair
Karen McCarthy Schau, Director, Global Clinical Operations, Vertex Pharmaceuticals

Our panel of TMF experts share their vision of successfully managing your TMF in the age of data and what it takes to survive and thrive in an inspection. From hearing about how using a Risk-Based approach to efficiently manage your key content and minimize the inspection scramble, to using Machine Learning for document identification and filing, your TMF process will benefit from the hard-won knowledge and experience of the panel.

How Risk-Based Quality Control in a Trial Master File Improves Quality While Reducing Effort
Marion Mays, Vice President, Client Solutions & Quality Assurance, Phlexglobal Limited

Machine Learning and TMF Management: Evolving to Data-Driven Processes
Ken Keefer, MBA, PMP, Principle Consultant, Keefer Consulting, Inc.

Leveraging Technology for Preparing for and Surviving Remote TMF Inspections
Paul Fenton, MBA, CEO, Montrium

11:15-11:45AM **BREAK/Visit the Virtual Exhibit Hall**

11:20-11:40AM **Q&A Session:** Global eCTD Specifications

Peter Terbeek, MBA, Senior Director, Publishing and Submission

Have you watched the *Global eCTD Specifications* session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Panelists
Rob Labriola, MS, Senior. Director, Regulatory Services, Sychrogenix

Joel Finkle, Associate Director, Regulatory Information Management, Beigene

11:45AM-1:00PM **Session 10:** BREAKOUT SESSIONS

Track 2: Introducing DIA RIM Reference Model 1.0

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Innovation

Life Sciences companies continue to strive towards effective management of regulatory information. The industry has recognized the need for defining a baseline information model so everyone can embrace it, to develop RIM capabilities that improve efficiencies, ensure compliance and enable interoperability among systems. During RSIDM 2020, members of the DIA RIM Working Group provided an overview of the RIM Reference Model and sought broader industry engagement. The model has been developed further this year along with input from industry sponsors, product vendors, system integrators and consulting companies. During this session, we will be introducing Version 1.0 of the Reference Model, which includes high-level data specifications on key information constructs which form the foundation for RIM including data definitions, representative values, controlled vocabularies, sources of regulatory information, consumers of regulatory information and metrics for eight key regulatory processes.

The session is designed as a panel with subject matter experts from the RIM Reference Model Working Group presenting key deliverables (information flows, information objects and relationships) and discussing how the model can help companies achieve their RIM objectives and ultimately improve overall speed, efficiency and compliance.

Panelists
Pat Shafer, Managing Director, FTI Consulting

Vahe Ghahraman, Senior Director, Apellis Pharma

Vanessa Brewer-Yizar, Manager Regulatory Affairs, SG Research International LLC

Don Palmer, MA, Senior Regulatory Affairs Director; Business & Technology Transformation, IQVIA

Track 3: From Question to Answer: How Automation can Improve Health Authority Communication

Session Chair
Cindy Chiu, Director, Regulatory Affairs Operations & Quality Management, Merck & Co., Inc.

This session will focus on the innovations being made with technology to address the need for compliance, quality and efficiency when handling health authority questions and communication. From original receipt and handling to responding with consistent information quickly, companies such as Merck and Phlexglobal are improving the end-to-end process with intelligent technologies.

Biopharmaceutical Case Study: Automating Health Authority Communications with Machine Learning - Presentation
James Nichols, Chief Product Officer, Phlexglobal

Response to Health Authority Questions (RTQ)
Leslie Kitchen, BSN, RN, Director Innovation and Information Management, Merck & Co., Inc.

1:00-1:30PM **BREAK/Visit the Virtual Exhibit Hall**

1:10-1:30PM **Q&A Session:** IDMP – to Iteration 1 and Beyond

Session Chair
Jo English, Vice President, Regulatory Information Management, Calyx, United Kingdom

Have you watched the *IDMP – to Iteration 1 and Beyond* session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Panelists
Karen Harry, Director, Regulatory Information Management, Calyx, United Kingdom

Remco Munnik, Associate Director, Iperion, The Netherlands

Hans van Bruggen, MSc, CEO and Senior RA Consultant, Qdossier, The Netherlands

1:30-2:45PM **Session 11:** Emerging Technologies Panel

Session Chair
Jake Doran, Head of Global R&D IT, Bausch Health

In this session, attendees will hear from a panel of experts that specialize in development and application of emerging technologies. As the usage of these technologies further matures, this panel of experts will bring forward well-defined use cases and success stories that have been used in practice within Regulatory. Topics to be discussed will include: Artificial Intelligence, Machine Learning, Robotic Process Automation, Unstructured Content usage, and the broader application of digital transformation across the Regulatory space.

Panelists
Olaf Schoepke, PhD, Vice President, Regulatory Solutions, Samarind, Instem, United Kingdom

Chrystal Zhang, MSc, Senior Manager of Business Intelligence and Automation, Bayer Healthcare Co. Ltd., Beijing

Thomas Kivlehan, Chief Data Officer, Docxonomy

Daniel Chen, PhD, Principle Product Manager, Open Text, Canada

Susant Mallick, MBA, Director, Digital Transformation & Management, Amazon, The Netherlands

2:45-3:15PM **BREAK / Closing Mingle in the Exhibit Hall**

2:50-3:10PM

Q&A Session: Outsource Partners – Selection Process, Best Practices, and Case Study

Session Chair
Dan Orfe, MS, President & CEO, Regulatory eSubmissions, LLC

Have you watched the Outsource Partners – Selection Process, Best Practices, and Case Study session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Jillian Carinci, MS, MSc, Director, Submission Science, Biogen

Adam Bone, Senior Specialist, Regulatory Affairs, Merck & Co., Inc.

Efstathia Sergi, MS, PMP, Sr Manager Associate Director, Regulatory Project and Submission Management, PRA Health Sciences

3:15-4:15PM

Session 12: Ask the Regulators

Session Chair
Mark Gray, Senior Project Manager, BSS, CBER, FDA

This session provides attendees the opportunity to ask regulators questions. Submit your questions in advance in the Virtual Forum Platform by navigating to the session, clicking on "Polls" then enter your question for the speakers. You can also email **AsktheRegRSIDM@DIAglobal.org**. Please note: due to the high volume of questions, not all will be answered live at the forum

Panelists
Ethan Chen, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

Ron Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

Virginia Hussong, Chief, Data Standards Program, CBER, FDA

Jonathan Resnick, PMP, Project Management Officer, OBI, OSP, CDER, FDA

Mary Ann Slack, Director, Office of Strategic Programs, CDER, FDA

Norman Schmuff, PhD, Associate Director for Science, OPQ, OPF, CDER, FDA

4:15-4:30PM

Closing Remarks

4:30PM

Forum Adjourns

ON DEMAND SESSIONS

In order to remain flexible in this virtual environment, we have decided to pre-record a library of BRAND NEW sessions that you can view at a time that works for your schedule! If you are an early riser, a night owl, or joining us from a different time zone, our live sessions may not be convenient for you. Therefore, you can enjoy our On Demand Library at any time! We do encourage you to look through the agenda as there are some On Demand Session Speakers who will be participating in live Q&A throughout the forum. Enjoy!

On Demand 1 Track 1: IRISS Forum Hot Topics

Session Chair
Jake Doran, Head of Global R&D IT, Bausch Health

Since 2012, IRISS has taken a leadership position across the regulatory landscape and has grown to be a place where regulatory professionals come to not only learn, but also contribute to cultivating the future of the regulatory profession. In this session, topic leads from the following IRISS Topic Groups will share the latest developments and discussions from their respective IRISS communities: GSO, ePI, and digitalization in regulatory.

Electronic Product Information Topic Group Highlights
Tris Nockles, Labeling Nets Lead, Navitas Life Sciences

Global Submissions Operations Topic Group Highlights
David Ross, Director, Strategy and Change Management, Regulatory Affairs, AstraZeneca

Digitalization in Regulatory Topic Group Highlights
Cesar Vinces, Director, eSubmission Strategy & Innovation Lead, Pfizer, Inc.

On Demand 2 Track 1: IDMP – to Iteration 1 and Beyond

Session Chair
Jo English, Vice President, Regulatory Information Management, Calyx, United Kingdom

IDMP and other structured data initiatives continue to challenge organizations; There is a pressing need to be ready for the end of 2022, when Centralized products become mandatory alongside existing XEVMPD reporting. As well as data gathering, and data enrichment opportunities and strategies other process changes could bring efficiencies. The panel will describe different approaches for IDMP readiness and the emerging global picture for structured data acceptance.

Blue Sky IDMP-Compliant Process as Reference for Gap Analyses
Hans van Bruggen, MSc, CEO and Senior RA Consultant, Qdossier, The Netherlands

Implementing IDMP Strategies for Iteration 1
Karen Harry, Director, Regulatory Information Management, Calyx, United Kingdom

Implementation of Structured Data
Remco Munnik, Associate Director, Iperion, The Netherlands

On Demand 3 Track 2: Using Intelligent Automation and Advanced Technology to Enhance Regulatory Performance

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President, Life Sciences, Orion Innovation

Life Sciences companies continue to work towards more efficient and compliant regulatory business processes and effective management of regulatory information. With the advent of intelligent automation (IA) technologies such as robotic process automation and natural language processing, firms are looking for ways to take advantage of IA to make their processes more efficient and drive innovation. After the artificial intelligence (AI) panel session at last year's conference, the DIA RIM Reference Model Working Group decided there was enough momentum around AI in the industry to establish an AI topic team. In this session, we will share the work that this team has been doing to date and upcoming plans to increase awareness and understanding of the various IA technologies, key problems in regulatory that they can potentially solve, potential solutions and best practices.

In this session, we will provide a high-level overview of what the various IA technologies are and how each of them can best be used to benefit Regulatory, what some key regulatory problems or use cases are that they can solve and some thoughts on potential solutions. Additionally, we will share examples of how sponsors are beginning to adopt IA, provide an industry point of view on IA usage and an understanding of how these tools can be validated in your Regulatory ecosystem.

Speakers
Cary Smithson, MBA, Director, Digital Transformation Advisory, Grant Thornton LLP

Teresa Eastwood-Kiefer, Global Team Leader, F. Hoffman La Roche Ltd.

Karin Schneider, MS, Document Management Business Lead, Janssen Pharmaceuticals, Inc.

On Demand 4 Track 3: Transformation of the Documentation World: What's Here and What's to Come

Session Chair
Joanne Malia, MS, MSc, Director, Clinical Documentation Management, Regeneron Pharmaceuticals

In our first presentation, we will demonstrate how leveraging artificial intelligence and machine learning can rapidly decrease the duration of time it takes to complete the due diligence process by leveraging machines to enhance the process allowing humans to focus on the results.

Our second presentation will discuss the need as new solutions are introduced of providing our stakeholders with the opportunity to be part of this change, to be heard, and to leverage their knowledge to co-create a sustainable future. Thus, we have established a feedback and change control process to aid in the development of mature and robust content solutions and to harness the collective experience of our medical writing group to advance our content strategy.

Lastly, we will round out the session with our third presentation on a discussion involving the exploration of how metadata may assist the research process focusing on the use case of protocol amendments.

Leveraging Artificial Intelligence to Simplify Due Diligence During The Merger And Acquisition Process
Bryan Reynolds, CEO, Doxonomy

Content Management Transformation Journey - Preparing for Automation - Presentation
Deborah Card, PhD, Regulatory Content Transformation Lead, Roche

Protocol Amendment Metadata Landscape Exploration
Sharon McErlean, Clinical Development & Analytics Associate Director, Novartis

On Demand 5 Track 4: Global eCTD Specifications

Session Chair
Peter Terbeek, MBA, Senior Director, Publishing and Submission

This session will cover significant eCTD specification changes in several prominent countries/agencies. Health Canada is accepting Clinical Trial Applications in eCTD format via the Electronic Submissions Gateway and has announced it will accept eCTD submissions for other trial-related activities as well. In Russia there is a new EA EU submission format called R.022 which certainly resembles the eCTD and the Mutual Recognition Procedure but has its own nuances. And there have been notable changes to Module 1 specifications for FDA, EMA, SwissMedic and Health Canada. This session will bring you up to speed on all of these specifications and ensure you can remain compliant.

eCTD Module 1 Specifications Updates for AU, JO, EU, US, CH, and CA
Sujit Shetty, MBA, Manager, Regulatory Publishing, Quartesian

Everything Old is New Again – Health Canada CTAs in eCTD
Rob Labriola, MS, Senior Director, Regulatory Services, Sychrogenix

The Eurasian Economic Union Electronic Submission Format: It's not *not* an eCTD
Joel Finkle, Associate Director, Regulatory Information Management, Beigene

On Demand 6 Track 4: Outsource Partners – Selection Process, Best Practices, and Case Study

Session Chair
Dan Orfe, MS, President & CEO, Regulatory eSubmissions, LLC

This session will provide an exploration of outsource partner business practices. Best practices for the selection of an outsource partner that both meets the submission production needs as well as aligns with your organization culture will be examined. Methods for understanding and addressing the various unique considerations associated with particular outsource and insourced partners will be described. Lastly, the real-world submission production experiences of a service provider for a critical client submission will illustrate lessons learned, the sophistication of planning through experienced and dedicated project submission managers and best practices for submission production and partner interactions.

How do you choose the right one? Queries to help refine your choice in Outsourcing Partner
Jillian Carinci, MS, MSc, Director, Submission Science, Biogen

Merck and its Outsourced Partners
Adam Bone, Senior Specialist, Regulatory Affairs, Merck & Co., Inc.

Lessons Learned from Preparing and Submitting an IND Application for a COVID-19 Treatment Candidate
Efstathia Sergi, MS, PMP, Associate Director, Regulatory Project and Submission Management, PRA Health Sciences

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On Demand 7: International Regulatory Update

Session Chair
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

Receive the latest updates from International Regulators about recent and future developments related to data standards, analytics, electronic submissions, and Health Authority IT programs.

Speakers
Shannon Laforce, MBA, Executive Director, Transformation and Business Informatics, RMOD, HPFB, Health Canada

Jesper Kjær, MS, Director of the Data Analytics Center, Danish Medicines Agency (DKMA)

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There are several opportunities for you to win prizes while exploring the platform, getting to know our exhibitors, and meeting each other. ***The best part, you can keep the monetary prize or pay it forward!*** If you wish, we will donate to a registered U.S. Charity in your name. You can search **here** for eligible organizations.

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Download exhibitor/sponsor files	Every time	10 pts
Accept private meeting	Every time	10 pts
Request private meeting	Every time	10 pts
Post photo in forum	Only Once	10 pts
Send private message	Only Once	10 pts
Add profile photo	Only Once	10 pts
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If you have any questions, please contact **Patti Shaughnessy**.

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