DIA

Regulatory Submissions, Information, and Document Management Forum

Primer: February 4 | Short Courses: February 5 | Forum: February 5-7
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

Schedule At-A-Glance

Track 1: RIM Business **Track 2:** RIM Technology **Track 3:** EDM **Track 4:** ERS

PRIMER | SUNDAY, FEBRUARY 4	
9:30-10:30AM	Primer Registration
10:00AM-5:00PM	**Regulatory Content and Submissions Primer:** Tracking Content from Conception to Interment
DAY ONE | MONDAY, FEBRUARY 5	
7:30AM-5:00PM	Registration
8:30AM-12:00PM	**Short Course 1:** Global Identification of Medicinal Products: Applied Principles and Practical Benefits from Compliance and Beyond
8:30AM-12:00PM	**Short Course 2:** Submission Survival Kit
1:00-1:30PM	**Welcoming Remarks and Presentation of the Volunteer Award**
1:30-2:00PM	**Session 1:** Keynote Address: Introduction to Blockchain: Distributed Ledger Technology for Regulation and Supply Chain Security
2:00-2:30PM	Refreshments, Exhibits, and Networking Break
2:30-3:45PM	**Session 2:** FDA Opening Plenary Panel: PDUFA VI Informatics
3:45-5:00PM	**Session 3:** Other Regions Update
5:00-6:00PM	Networking Reception in the Exhibit Hall
DAY TWO | TUESDAY, FEBRUARY 6	
7:30AM-4:00PM	Registration
7:30-8:30AM	Networking Breakfast in the Exhibit Hall
8:30-9:45AM	**Session 4:** New FDA Draft Guidance on Part 11 in Clinical Investigations and Mobile Technologies in Clinical Investigations
9:45-10:30AM	**Session 5:** FDA Ask the Regulators: Part 1
10:30-11:00AM	Refreshment, Exhibits, and Networking Break

DIA

Regulatory Submissions, Information, and Document Management Forum

Primer: February 4 | Short Courses: February 5 | Forum: February 5-7
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

Schedule At-A-Glance

Track 1: RIM Business **Track 2:** RIM Technology **Track 3:** EDM **Track 4:** ERS

DAY TWO | TUESDAY, FEBRUARY 6

11:00AM-12:15PM	**Session 6:** Breakout Sessions **Track 1:** HeRO Forum Benchmarking: Global Regulatory Sourcing Strategies for Evolving Regulatory and Industry Solution **Track 2:** The Increasingly Critical Roles of RIM Systems and Their Expanding Number of Use Cases Beyond Regulatory Affairs **Track 3:** Strategies for Ensuring Part 11/Annex 11 Compliance of eTMFs at Research Sites **Track 4:** Ad Promo
12:15-1:45PM	Networking Luncheon in the Exhibit Hall
1:45-3:00PM	**Session 7:** Breakout Sessions **Track 1:** Paradigm Shift in Data Management and How to Enrich Business Intelligence to Benefit the Industry **Track 2:** TBD **Track 3:** Understanding ICH E6 R2 and the Impact to Clinical Trial Documentation and the Trial Master File **Track 4:** Keeping up with Trends in eCTD: Submitting in US Module 1 Specification
3:00-3:30PM	Refreshment, Exhibits, and Networking Break
3:30-4:45PM	**Session 8:** Breakout Sessions **Track 1:** Processes - Don't Make Them an Afterthought **Track 2:** Transforming Regulatory Information Management Through Innovation **Track 3:** Creating and Streamlining Regulatory Dossier Management **Track 4:** Using Submission Management to Enable Streamlined Regulatory Planning
5:30PM	Dinner on the Town

DAY THREE | WEDNESDAY, FEBRUARY 7

7:30AM-2:00PM	Registration
7:30-8:30AM	Networking Breakfast in the Exhibit Hall
8:30-9:45AM	**Session 9:** Breakout Sessions **Track 1:** Critical Success Factors for Implementation of Regulatory Information Management Capabilitiest **Track 2:** Digital Innovation in Regulatory Technology **Track 3:** How to Utilize Systems and Technology as Document Enablers **Track 4:** Regulatory Sourcing: Regulatory Sourcing - Who is Doing What and Some Real-World Industry Experiences
9:45-10:15AM	Refreshment, Exhibits, and Networking Break
10:15-11:30AM	**Session 10:** Breakout Sessions **Track 1:** RIM 2020: Connecting to Other Functional Processest **Track 2:** Artificial Intelligence (AI): The Next Frontier **Track 3:** Panel Discussion: Managing Partnerships **Track 4:** TransCelerate, FDA, and NIH: The Evolution of a Common Protocol Template
11:30AM-1:00PM	Networking Luncheon in the Exhibit Hall
1:00-1:45PM	**Session 11:** FDA Ask the Regulators: Part II
1:45-2:00PM	**Closing Remarks**
2:00PM	**Forum Adjourns**