DIA Regulatory Submissions Information, and Document Management Forum

Hear from the Foremost Authorities.

Access key regulators from FDA and regulatory agencies worldwide. Don't miss the Keynote Address, *Perspective on PDUFA VI, and the Strategic Vision for CDER Going into the Next PDUFA Cycle*, from Dr. Theresa Mullin, Director, Office of Strategic Programs, CDER, FDA.

Knowledge is Power. Increase your confidence of submissions through our new FDA Track. With cross-functional sessions from FDA, you will learn the latest information in data standards and compliance, electronic submissions, and PDUFA updates. There will also be an opportunity to secure answers in the "Ask the Regulators Session." Learn how others in your industry are implementing and harnessing the power of technology to propel regulatory information, documentation, and submissions across the globe.

Engage. In addition to exchanges throughout the Forum sessions, you will have a myriad of opportunities to network: meet your company's next vendor through the RSIDM Exhibit Program; laugh and learn with your peers at the all new *Regulatory War Stories* Dinner on the Town; and wind down with colleagues during our evening Networking Reception.

New to the Industry or looking to branch out?

Don't miss the Regulatory Content and Submissions Primer on February 5. This course is designed for individuals new to the space or experienced professionals in one area looking gain a broader understanding of the full spectrum of the regulatory arena. Benefit from expert insights and explore various steps from all functions along the lifespan of documented content from conception, submission, delivery to regulatory agencies, and ultimate company archival.

Explore Further. Attend one of three half day Short Courses covering IDMP, TMF Metrics, and Outsourcing. Review these topics in-depth with your peers and expert instructors.

#RSIDM17

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Primer and Short Courses

Regulatory Content and Submissions Primer

New to the regulatory space or experienced professionals will gain a broader understanding of the various steps throughout the lifespan of **Document Components** to yield **AHA** moments.

SHORT COURSE 1

For those charged with staying on top of issues in **Regulatory Information Management,** you can't miss the course on **IDMP.**

SHORT COURSE 2

Professionals responsible for **Data Management** will gain a better understanding of how to implement quality and time metrics and how to monitor the health of the Trial Master File. Register for the short course, **TMF Metrics: Measuring Regulated Content.**

SHORT COURSE 3

Focused on Regulatory Submissions? Hear from your colleagues about best practices and lessons learned in **Outsourcing.**

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