How the RSIDM Forum will Address Key Regulatory Changes

eSubmissions

As of May 5, 2017, all NDAs, ANDAs, and BLAs were required to be submitted using the eCTD format. As of May 5, 2018, INDs and Drug Master Files (DMFs) must be submitted using the eCTD format. FDA will share what to know and do to get all Master File submissions into compliance.

PDUFA VI

PDUFA VI was effective as of September 30, 2017. FDA will discuss their goals and implementation road map for improving the predictability and consistency of PDUFA electronic submission processes and continued enhancement of data standards. Get your company ready to provide input at the March 2018 Public Meeting on these topics.

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11

This Draft Guidance addresses the applicability of CFR Part 11 requirements for electronic systems used in clinical investigations, covering electronic systems and software (off the shelf, customized, or created), outsourced electronic services, electronic systems used for medical care, mobile technology, and telecommunication systems. Dialog with FDA on their interpretation of the applicability of Part 11 which will have important impacts on the management of these systems and tools and the data they generate.

IDMP

Though the implementation of IDMP (Identification of Medicinal Products) will be delayed in the EU due to the publishing delay for the EU Implementation Guides, the Organization data and Referential data (OMS and RMS) are available for use starting the last quarter of 2017. Companies will need to develop a strategy on how to consume and use the data, including the type of data alignment that will need to happen. Take away approaches to evaluate organizational and functional needs related to RIM to get ahead of the coming crush of IDMP implementation.

Why Attend DIA's *Regulatory Submissions, Information, and Document Management Forum*?

Comprehensive approach to content and regulatory information management and submissions

RSIDM is the only forum that covers end-to-end management of content, data, and regulatory information, addressing the integration of the systems and processes that generate and use the information. Bringing these elements together into one forum provides valuable insights for company teams as they work to integrate siloed systems and streamline processes to optimize the use of their content.

Breadth and Depth of Knowledge: Takeaways that can be applied to challenges at home

The knowledge shared at the Forum is relevant to all of the information/data the biopharmaceutical company is responsible for, including Drug Master Files, Biologic Master Files, and Trial Master Files across all lifecycle events (INDs, NDAs/BLAs/ANDAs, Supplemental Applications, and other Post-Market documents).

Regulatory Authority participation

Regulatory Authorities such as the FDA, Health Canada, PMDA, and EU Health Authorities provide the regulatory context for compliance with existing regulations, standards, and guidances; they will also discuss new developments that are expected to have an impact on data or processes related to regulatory submissions.

Four tracks covering emerging operational standards, best practices and the processes for submission, creation, and maximum use of regulatory information

RIM Business track; RIM Technology track; Electronic Regulatory Submissions (ERS) track, and Electronic Document Management (EDM) track.

Preconference Primer for those new-to-the-field, looking to expand their scope, or those needing a refresher

A full-day primer on regulatory content and submissions provides a solid foundation in the concepts and requirements for regulatory submission, information, and document management. The primer course is designed to enable those new-to-the-field or who wish to expand beyond their area of current specialization to better assimilate the intermediate-level content of the full forum.

Two Preconference Short Courses

Two trainings to choose from covering both applied principles and practical compliance for IDMP, and the important regulatory and clinical guidance documents for submission needs.

Regulatory Submissions, Information, and Document Management Forum

February 5-7 | North Bethesda, MD

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