Regulatory Submissions Primer:
Tracking Content from Conception to Interment

Agenda

10:00-5:00 Regulatory Submissions Primer: Tracking Content from Conception to Interment

Session Instructors: Betsy Fallen, Consultant, BAFallen Consulting, LLC

Dan Orfe, President, Regulatory eSubmissions, LLC

This activity is designed to meet the needs of individuals who are either new to biopharmaceutical-based document management, Information Management, and regulatory submission publishing for authorities or already experienced in one area looking gain a broader understanding of the full spectrum of the Regulatory Submission, Information and Document Management arena. Understanding the various steps throughout the life of document components from their conception, publishing into a submission, delivery to regulatory agencies and ultimate company archival will yield “aha” moments for the attendees of this offering from all function along the life-span of content.

Learning Objectives:

At the conclusion of this activity, 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 life span 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.

10:00-10:30 Welcome and Introductions

10:30-11:00 Session 1: Part 1

Documents: What are they good for?

Clinical trials are a critical element of drug development. Introducing the investigational products to consenting subjects under Good Clinical Practices (GCPs) and using the resulting data to support the marketing of a trial are critical to an investigational products successful use by patients. The documentation directly related to a clinical trial must be recognized and appropriately handled. The trial could result in a Clinical Study Report published into an eCTD (electronic Common Technical Document) with many other documents. For human protection, this content is regulated. We will review regulations, guidelines, standards and best practices for good document management.

11:00-11:15 Refreshment Break

11:15-11:45 Session 1: Part 2

Site & Sponsor Essential Documents

The Trial Master File (TMF) is comprised of Essential Documents that drive the conduct of a clinical trial and validate compliance by all stakeholders. We will discuss the content of the TMF as defined by standards and best practices and describe the roles of all involved in their creation, management, and retention. Partnerships including CROs and functional sourced roles will be considered.

11:45-12:45 Luncheon (attendees dine on their own)

12:45-1:15 Session 2

Regulatory Information Management

Regulatory Information Management (RIM) encompasses the business practices in the pharmaceutical industry involved in the development, capture, dissemination, control and management of regulatory-focused content, throughout the product lifecycle stages. We will assess the business processes and the technology tools, products and service platforms that assure compliance and efficiency. Regulatory influences driving the increasing amount of data to be collected and provided to the regulatory authorities, and standards like XEVMDP or IDMP will be discussed.

1:15-1:45 Session 3: Part 1

EDMS & eCTD: How these are connected

There is a potential for synergy between the EDMS and eCTD. Organizations that make the best use of industry/agency standards, requirements and best practices stand to benefit the most from these tools. The best of these provide for a clear channel for their staff, processes, technology and policies to interact and align. Documents stored within an EDMS with appropriate meta-data applied by the author/contributor can smoothly move through review cycles and onto the publishing organization for production into an eCTD sequence deliverable.

We will touch on the industry standards, regulatory requirements and best practices associated with “making the connection”.

1:45-2:15 Session 3: Part 2

eCTD: A 50 thousand foot eCTD overview

What it is and why it matters. The eCTD has been in place since 2000. By March of 2018 the FDA will require nearly all regulatory deliverables to CDER and CBER by in eCTD format (NDA, BLA, ANDA, IND, DMF). The eCTD is based upon the Common Technical Document (CTD), which provided for the “harmonization” of scientific content to the signatures (US, EU, Japan) of the International Conference on Harmonization (ICH) and other observer regulatory agencies. The eCTD is comprised of Module 1 Regional Specific Admin & Label, Module 2 Summaries, Module 3 Chemistry Manufacturer Controls, Module 4 Safety-Animal Studies and Module 5 Clinical-Human Studies.

We will provide a brief overview of the eCTD construct, document level publishing and submission level publishing. Additionally, we will touch on company options for eCTD production; examine considerations associated with “on premise publishing tools” versus “cloud publishing tools” versus “outsource publishing”.

2:15-2:45 Session 3: Part 3

EDMS: A 50 thousand foot EDMS overview

Electronic Document Management Systems (EDMS) have been used for well over a decade. These have provided significant benefit for the biopharmaceutical industry but not without some challenges driven by significant resource investment. EDMS have been primarily leveraged by large organizations for the benefit of their research and development activities; this limited adoption has been due to the substantial expertise and financial investment. This is changing with the advent of “cloud-based” EDMS providers with standards and industry best practice based systems which has expanded the obtainability of EDMS to the entire Biopharmaceutical community; covering the full range of company scale from small emerging biopharmaceuticals through the largest of biopharmaceutical enterprises.

We will discuss a high level overview of EDMS their use, benefit and best practices. Additionally, we will provide an overview of the changes to systems driving broader adoption including “on-premise” versus “cloud” and own versus lease options.

2:45-3:00 Refreshment Break

3:00-3:30 Session 4: Part 1

Regulatory Archive – Overview of the Why, What and How

The ability to produce evidence of the conduct of a clinical trial or research and development program is critical to the product’s value. Whether the records and documentation is maintained and accessible within minutes or days, stakeholders from regulators to legal representatives to potential future owners of the product must be assured that the integrity of the documentation is assured.

We will share opportunities and best practices for processes, both legacy and forward looking.

3:30-4:00 Session 4: Part 2

Regulatory Inspection - Overview of the Why, What and How

The event of a regulatory inspection is pivotal in the life cycle of an investigational product. We will explore various models of inspections at Sponsors, CROs, and Clinical Sites from both clinical and regulatory perspectives. In this global regulated industry, there are widely varying regional focuses. There is one absolute in this equation, the Sponsor is ultimately responsible.

4:00-4:30	Session 5: Looking Forward: What regulations are expected? Standards? There are a number of recently released and upcoming regulations, regulatory guidelines and standards. We will briefly outline these and what their impact has been and could be going forward.
4:30- 5:00	Q&A
5:00	Conclusion