EDM and ERS/eCTD: Impact of e-Initiatives on Content and Context

Tutorials: October 15 | Conference: October 15-17
San Diego, CA

PROGRAM CO-CHAIRS:

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Deputy Director, Office of Business Informatics
CDER, FDA

Laura J. Sherman, MBA
Training Partner, Clinical Business Operations
Vertex Pharmaceuticals

Betsy Fallen
Lead, Global Essential Document and
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Integrating eDM, eSubs, and RIM

OVERVIEW:

This year's combined EDM and ERS/eCTD conference continues to explore information generated along the drug development continuum life cycle and alignment to ever evolving regulatory and electronic standards. The pace of global electronic initiatives necessitates industry to continually assess internal processes to maximize content reuse and streamline efforts by pushing submission-ready and data standards farther upstream.

As technologies and standards progress along with the real-time increasing volume of information generation, the complexities and challenges of data sharing and data protection are becoming ever more apparent. Advances in technology, standards, and evolving regulations impact documents along their life cycle. Managing the associated risk, transparency, reliability, and accessible document storage are essential elements for ensuring your organization's compliance to current and emerging regulatory requirements.

This conference will serve as a forum for the discussion of emerging standards and the processes for submission creation and maximum use of regulatory information.

FEATURED TOPICS:

- eTMF
- Global Labeling
- Career in Submission Production and Support
- Outsourcing
- Managing Advertisement & Promotional Materials for eCTDs
- eCTD v4.0, HL7, ICH, RPS
- Cloud Content Management

LEARNING OBJECTIVES:

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

- Discuss challenges for ensuring compliance to meet regional requirements
- Examine process optimization when collaborating with CROs and Cloud computing across the lifecycle continuum
- Outline the importance of maximizing content reuse, metadata, aligning standards, and technology with the process
- Describe organizational processes and governance to ensure integrity, quality, and security of records
- Explain current global regulatory agency requirements and future initiatives

This program has been developed by the Document and Records Management and Electronic Regulatory Submissions Communities.

Register at **diahome.org/EDM2013**

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Tutorial 1: eCSRs: .3 IACET CEUs
Tutorial 2: Get Ready for Global ISO IDMP, Including Lessons Learned From the EU XEVMPD: .3 IACET CEUs
Conference: EDM and ERS/eCTD: Impact of e-Initiatives on Content and Context: 1.3 IACET CEUs

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TUESDAY, OCTOBER 15

7:30 AM-6:00 PM REGISTRATION

8:00-11:30 AM TUTORIALS

Tutorial #1 – eCSRs

Tutorial Instructors:

Nancy Smerkanich
Educational Liaison/Regulatory Science Doctoral Candidate
University of Southern California

This tutorial will examine the myriad of issues around the authoring and publishing of clinical study reports and their related components for electronic submissions. This includes but is not limited to document granularity, hyperlinking and bookmarking best practices for US and EU, as well as the relationship between tables, figures and listings and the data that is submitted to the FDA. A member of the eDATA team from the Center for Drug Evaluation and Research FDA will provide insight into how the data from study reports are utilized by the agency during the course of application assessments.

Learning Objectives:

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

- Recognize and utilize granular CSRs for submissions
- Determine best practices for publishing standards for clinical reports
- Incorporate the agency and reviewer's needs into standards and processes for clinical submissions

Target Audience:

Regulatory Affairs/Operations, Medical Writers and Data/Project Managers who wish to gain a better understanding of the challenges of authoring and compiling clinical study reports and the supportive documentation and data that are used to evaluate them.

Tutorial #2 – Get Ready for Global ISO IDMP, Including Lessons Learned From the EU XEVMPD

Tutorial Instructors:

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

Michiel Stam
Manager, Regulatory Operations
Qdossier B.V.

The tower of Babel was never finished, because the builders did not speak the same language anymore; in other words they used different vocabularies. Within the pharmaceutical industry we also apply multiple vocabularies across the various disciplines. Across industries; regulatory bodies and health care professionals we use even more vocabularies. This negatively impacts the transparency of information related to an efficient production, risk-benefit evaluation and safe usage of medicinal products. Improved transparency will achieve better medicine and better usage of medicines. ISO established ways to identify medicinal products using standard terms; ISO IDMP. This is one of the ways to achieve a common vocabulary.

Learning Objectives

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

- Describe why ISO IDMP impacts all R&D, RA and manufacturing departments within a pharmaceutical company; to obtain a common vocabulary
- Discuss what documents and databases from those departments are impacted
- Explain that companies need to start ASAP with setting up a common vocabulary
- Identify external sources that can be used as a reference for setting up a common vocabulary

Please note that lunch is not served on tutorial day

1:00-1:30 PM WELCOME AND OPENING REMARKS

Program Co-Chairs:

Laura J. Sherman, MBA
Training Partner, Clinical Business Operations
Vertex Pharmaceuticals, Inc.

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

1:30-3:00 PM PLENARY SESSION 1

Collaborative Session: FDA Topics of Interest

FACILITATOR

Nancy Smerkanich
Educational Liaison/Regulatory Science Doctoral Candidate
University of Southern California

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM PLENARY SESSION 2

Other Regions Update

SESSION CHAIR

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

Health Canada Update

Irena Pastorekova
Unit Head\e-Review
Office of Submissions and Intellectual Property (OSIP)
Health Canada

EU Update

Mickel Hedemand
Internal Adviser
Danish Health and Medicines Authority
Medicines Regulation & MAs

5:00-6:00 PM NETWORKING RECEPTION

WEDNESDAY, OCTOBER 16

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30–10:00 AM SESSION 1

TRACK 1

EVMPD, IDMP, UDI and Managing Metadata in Regulatory Information Management Systems

Session Chair:

Joel Finkle
Senior Strategist Global
Professional Services
CSC Life Sciences

Trust and transparency are important keywords in 2013. These are particularly relevant when it concerns regulatory information. What product has been registered where? Since when? What manufacturers in the supply chain are registered? Do we have valid GMP certificates for them? Where have we registered the product with corn-starch and where with potato starch? Which countries where supplied by products using raw materials from a particular supplier? What storage conditions and shelf life is applicable where? Etc. This is just a small example of questions raised frequently by various disciplines world-wide. This session will touch upon regular questions and how principles of IDMP and UDI can be applied to create common vocabularies to build reliable data sources for queries, reports and specific analyses.

Futureproofing for IDMP with RIM

Joel Finkle
Senior Strategist Global
Professional Services
CSC Life Sciences

Introduction to UDI; Tracking of Regulatory Information on Medical Devices

Michiel Stam
Manager, Regulatory Operations
Qdossier B.V.

GS1 Standards and UDI

MJ Wylie
Senior Director, Healthcare
GS1 US

TRACK 2

Using Performance Metrics to Drive Efficiency in Regulatory Information Management

Session Chair:

Christian A. Buckley, MBA, RAC
Associate Director, Regulatory Affairs Submissions
Astellas Pharma Global Development, Inc.

Regulatory Information Management business processes need to be updated and improved to meet the demands of a changing regulatory environment. It often falls on change agents and middle managers to gather, analyze and persuade stakeholders and upper management to approve budgets in order to implement solutions and determine ROI. This session explores the types of metrics that can be used as persuasive business tools to influence business decisions to improve regulatory information management.

If You Can't Always Get What You Want, Try Using Metrics to Get What You Need

Christian A. Buckley, MBA, RAC
Associate Director,
Regulatory Affairs Submissions
Astellas Pharma Global Development, Inc.

Utilizing Metrics to Determine ROI of a RIM System

Adair Turner, MSc, RAC
Director of Professional Services
Mission3, Inc.

Industry Status: Demonstrating Value with Performance Metrics and Continuous Improvement

Steve Gens, MSOD
Managing Partner
Gens and Associates

TRACK 3

Document Preparation Across and Within Disciplines

Session Chair:

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

Within the pharmaceutical industry many disciplines contribute to the documentation to justify the quality, safety and efficacy of drugs. Not uncommon is the need to collaborate with CROs which might or might not have access to the same systems. Multiple individuals are involved in the authoring, review, QC and approval process. Processes can run in sequence or in parallel. Sometimes the process loops back to make corrections. All companies struggle with finding the balance between automated workflows, shared infrastructure, permissions, flexibility, transparency and above all; time constraints. This session will elaborate on case studies (lessons learned) and future directions.

Realize the Power of Document Collaboration and Ease the Pain of Regulatory Submissions

Dave Sheppard
Business Development Manager
PleaseTech Ltd

Across the Divide: Key Messages Not To Miss!

Nancy Smerkanich
Educational Liaison/Regulatory Science
Doctoral Candidate
University of Southern California

The Power of Content Reuse within Clinical and Labeling Documentation

Shailesh Shah
Solutions Architect
ArborSys Group

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM–12:00 PM SESSION 2

TRACK 1

Implementation of Regulatory Information Submission Standards (IRISS)

Session Chair:

Lenore Palma
Senior Principal Consultant
Pharmaceutical eConsulting

Implementation...where the rubber meets the road. Members of the IRISS Forum discuss using a global sounding board of expert advice and experience from peer-based IRISS topic groups to achieve successful regulatory submissions and to proactively address implementation issues.

The Devil's in the Data – Using IDMP to Drive Data Quality in ICSRs

Susan Metz
Director, Product Management
LIQUENT – A PAREXEL® Company

eCTD Strategies for Global Submissions

Olga Alfieri, MBA, RAC
Associate Director
Global Submissions Management (US)
Eisai Co., Ltd.

Migrating eCTD Submissions between Publishing Platforms and Viewing Tools

Gina A. Ross
Director, Quality Document Systems Management
Regulatory Publishing Services
Scientific and Regulatory Consulting (Beckloff Associates)
Cardinal Health Specialty Solutions

TRACK 2

Managing Global Labeling Content Alignment

Session Chair:

Laura J. Sherman, MBA
Training Partner, Clinical Business Operations
Vertex Pharmaceuticals, Inc.

Managing global accuracy for critical safety information for regulatory content is a challenging process that traditionally spans different organizations, functions, regions, languages and systems. Each of these areas adds a layer of complexity and a potential for positive integration and new approaches within the global process.

This session will focus on a case study which examines regulatory audit requests, insights to the extensiveness of this issue across the industry, and complexities to address, as well as share the process developed, implemented, and maintaining a label alignment program for Company Core Data Sheets (CCDS) prescribing and patient Information to ensure that labeling data is consistent, accurate, and sustainable across regions. Creative technology methods which encapsulated the entire process in a cloud-based environment allow regulatory contributors to use information earlier in the work stream.

Developing a Sustainable Labeling Global Alignment Program

Tracy D. Rockney, JD
Vice President, Regulatory Affairs
Global Labeling, Advertising & Promotion, Regulatory Policy & Intelligence
AbbVie

Mauricha F. Marcussen, MBA
Program Manager, Regulatory Affairs
Global Labeling, Advertising & Promotion, Compliance and Operations
AbbVie

Jeff Elderton
CEO
Pivotstream

TRACK 3

The Continuous Journey into eTMF

Session Chair:

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

As for any interesting journey, the path to the optimal TMF has its challenges and rewards. We will bring the expertise of those who are at different stages of the journey to a panel discussion. They will share their experiences and answer your questions. Technology, business processes and the cultures that we work impact how the journey proceeds. Anticipate to hear the lessons learned as these sponsors share their insight.

Panel Facilitator:

Nancy Smerkanich
Educational Liaison, International Center for Regulatory Science
University of Southern California

Panelists:

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

Andrew Waite, MBA
Director, Records and Information Management
Amgen, Inc.

Keith Davis, MBA
Global Director & Head, R&D Records Management
Biogen IDEC

12:00-1:30 PM LUNCH

1:30–3:00 PM SESSION 3

TRACK 1

A Career in Submission Production and Support

Session Chair:

Christian A. Buckley, MBA, RAC
Associate Director,
Regulatory Affairs Submissions
Astellas Pharma Global Development, Inc.

The dynamics of regulatory submissions has grown from basic paper processing to requiring a diverse set of technical and business skills to be successful. As a result, the regulatory operations space has evolved into a respected professional career and function critical to product registrations. This session will explore the career experiences from different perspectives of professionals who are passionate about the topic. The discussion includes tools for boosting professional development as well as management tools to inspire team growth.

Submission Professionals: Finding the Intersection of Three Circles

Christian A. Buckley, MBA, RAC
Associate Director, Regulatory Affairs Submissions
Astellas Pharma Global Development, Inc.

Navigating to Success in Regulatory Operations: The View from the Vendor Path

Stacy Tegan
Senior Consultant, Strategic Consulting
Accenture

A Career in Regulatory Operations: What You Will Need, To Start and To Flourish

Joseph R. Baldari
Manager, Regulatory Publishing Systems
CSL Behring

TRACK 2

Managing Advertisement & Promotional Materials for eCTDs

Session Chair:

Laura J. Sherman, MBA
Training Partner, Clinical Business Operations
Vertex Pharmaceuticals, Inc.

This session will share best practices in preparing for the current and future changes to the OPDP for managing and submitting electronically advertisement and promotional materials to the FDA. Topics include the OPDP mandate, how to address the various types of materials and associated complexities. Managing materials globally is challenging as well as internally developing a streamlined approach for the process while ensuring compliance.

End-to-end Promotional Materials Management for Biotech and Pharmaceutical Companies

Dirk Beth
CEO
Mission3, Inc

Beginning with the End in Mind: Paving the Path from Paper to Electronic

Barb Daanen
Associate Director Pharmaceutical Regulatory Affairs, Ad/Promo
AbbVie

TRACK 3

The Complexity of the TMF in the 21st Century: Technologically Modern and Intuitive and Stuck in 20th Century Business Processes

Session Chair:

Lisa Mulcahy
Owner and Principal Consultant
Mulcahy Consulting, LLC

Electronic TMF systems are changing the way that trials are planned, conducted, and inspected; from driving business decisions to the assessments of quality and inspection-ready; from working with partners to the conduct of health authority inspections. This change is a direct result of the TMF content being created and managed electronically with the corresponding metadata, and the TMF being stored in multiple electronic content management solutions that might be managed in the cloud and not solely in company-located servers. Employees, partners, company leadership, and health authorities are all expecting direct access to all of the TMF and real-time metrics reporting and dashboards from the systems that hold it. Join this session to hear how our industry is moving quickly to design and utilize the electronic TMF technology and the benefit for its maintenance in “the cloud” technology and why our business processes have to be updated to achieve its full advantage. This session will contain some case study content.

Leveraging the Cloud to Achieve Audit-Readiness

Michael Burton
Director, Product Strategy, eTMF
Veeva Systems, Inc

Marcus Thornton
Senior Director, CTMS
Medidata Solutions

Considerations for Providing DIRECT Access to the eTMF (and other content repositories) for Health Authority Inspections

Lisa Mulcahy
Owner and Principal Consultant
Mulcahy Consulting, LLC

Empowering the TMF for the 21st century

Paul Fenton, MBA, MS
President and CEO
Montrium Inc.

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4

TRACK 1

Industry Roundtable: Importance of Data Integrity for RIM Systems

Session Chair:

Sarah Powell
Executive Director, Regulatory Affairs and Writing Services
LIQUENT, A PAREXEL Company

Data governance and data quality are critical to success of any life sciences business. Data governance deals with coordinating the people, processes, standards, and technologies, in order to optimize outcomes related to enterprise data assets. This may include the broader cross-functional oversight of standards, architecture, business processes, business integration, and risk and compliance. In other words, it includes anything that can impact the integrity, quality, and security of company information.

While data governance focuses primarily at a data element layer where technologies, best practices, and standards are applied in order to understand, analyze, monitor, fix, and report that specific data. Data quality focuses on a single source or use of a specific data piece related and is related to a specific project.

This panel with discuss the importance of data governance and quality as it relates to RIM systems, some of the challenges organizations have faced and approaches to overcoming the challenges.

Panelists:

Jake Doran
IT Director, Global Regulatory Affairs and Quality Assurance
Janssen Pharmaceuticals, a division of Johnson & Johnson

Meredith Sewell
Director
Global Regulatory Publishing
Allergan, Inc.

Dominique E. Lagrave, MSc, PharmD
Principal Consultant
Parexel International

TRACK 2

eCTD v4.0, HL7, ICH, RPS

Session Chair:

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

The eCTD was officially released by the ICH in 2003. Over the past years, we have appreciated the beneficial principles of eCTD and the vast majority does not want to return to paper. Nevertheless, some further areas for improvement have been identified. Many of the improvements have been captured in the Regulated Product Submissions (RPS) standard being developed by the Standard Development Organization HL7. This standard might be adopted by the ICH as basis for eCTD specification v4.0. What does that mean from the perspectives of a software vendor, agency (FDA) and industry? Should we be worried? How can we benefit from the principles yet, even before eCTD v4.0 will be made mandatory?

eCTD4 and RPS – Vendor Perspective

Joel Finkle
Senior Strategist
Global Professional Services
CSC Life Sciences

eCTD v4.0 / RPS – Agency Perspective

Presented by:

Joseph A. Cipollina
Director
Global Dossier Management eStrategy
Bristol-Myers Squibb Company

eCTD v4.0 / RPS – Industry Perspective

Joseph A. Cipollina
Director
Global Dossier Management eStrategy
Bristol-Myers Squibb Company

TRACK 3

CLOUD – It's a Solid Opportunity

Session Chair:

Betsy Fallen, RN
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

This session will bring a fresh approach to the overview of CLOUD services. The attendee will learn the terminology around cloud computing. Multi-tenancy, Private, Public, etc, are all terms used to describe cloud based software and services. There are pros and cons of each. The objective is to arm attendees with knowledge of what these terms mean and educate them on which might be better, based on their situation. Also presented will be an expert overview on the selection and implementation of the offerings to optimize your business processes. A case study from a sponsor will be shared which will give the audience insight and dispel the mystery of hosting services in the CLOUD.

Cloud Defined … Whether it's about Weather or Whether it's not … Clearly Clearing up Cloud Confusion

Dan Glass
MedComms Product Specialist
Veeva Systems, Inc.

Selection and Implementation of Cloud-Based Offerings, Some Real World Pointers

Jonathan Burd
Product Director and Principal Consultant
GXPi

Case Study of a CLOUD-Based Implementation: "Here Comes the Sun"

Melissa Hirschberg, RN
Clinical Research Associate
Arthrex, Inc.

THURSDAY, OCTOBER 17

8:30–10:00 AM SESSION 5

TRACK 1

Global Submission Management

Session Chair:

Daniel F. Orfe
President
Regulatory eSubmissions, LLC

The global nature of submission production requires a unique perspective and creative strategies to address the goals of trans-global enterprises. This session will explore various approaches taken to address this mission critical business concern. The goals of maximizing reuse of information and minimizing business risk at the same time will be explored.

Global Publishing – National Submission Uniqueness

Vincent Peszek
Global Publishing Lead
Pfizer, Inc.

Lessons Learned: Implementing Project Management Strategies to Coordinate Successful Global Submissions

Carrie A. Mazzrillo, MBA
Manager
Regulatory Submission Management
Eisai Inc.

Global Submission Management – A Service Providers Perspective

Yolanda F. Hall, MS
Vice President, Services
Pharmaceutical eConsulting Inc.

TRACK 2

Creation and Management of Content: Driving Value Through New Business Models

Session Chair:

Ken VanLuvanee
President/CEO
Virtual Regulatory Solutions, Inc.

How the life sciences industry creates and manages content is on the precipice of revolution. Many of the mainstays of this part of our business are now getting a fresh look at what value they really deliver to the business. With more and more companies either seriously looking at hosted environments or at applying new technologies for creation and management of content in new ways, it's worth a look at some of these new approaches and their impact.

This session will look at examples of hosted document management and its implications for smaller biopharma organizations, as well as how one larger biopharma organization has delivered new benefit via electronic content creation tools.

Using a Cloud-Based DMS to Enable the Virtual Organization

Jason Rock
Chief Technology Officer
GlobalSubmit, Inc.

Realizing Improved Compliance with Authoring Standards as part of Microsoft Office Upgrade

Joel Finkle
Senior Strategist
Global Professional Services
CSC Life Sciences

Do We Manage Documents, Content, Both or Neither?

Ken VanLuvanee
President/CEO
Virtual Regulatory Solutions, Inc.

TRACK 3

Digital Signatures, Introduction & Presentation of Identity Management Standards

Session Chair:

Shari Perlstein, PMP, MBA
Director, Enterprise Records & Information Management
Pfizer, Inc.

In this session you will learn about some of the concerns that should be addressed before implementing digital signatures. It will also explain why standardized identity management is essential to effective pharmaceutical and health care collaboration and can provide access to protected information assets.

Points to Consider When Using Digital Signatures in GxP Environments

Patricia Miller, PMP, MBA
Quality Assurance Director
Cempra Pharmaceuticals

The Role of Standardized High-Assurance Identity Trust in Biopharmaceutical and Health Care Internet Transactions

Mollie Shields-Uehling
President & CEO
SAFE Bio-Pharma Association

10:00–10:30 AM BREAK

10:30 AM–12:00 PM SESSION 6

TRACK 1

When Worlds Collide — Information Management Challenges in 21st Century Mergers, Acquisitions and Partnerships

Session Chair:

Joseph A. Cipollina
Director, Global Dossier Management
eStrategy
Bristol-Myers Squibb Company

This session will explore various aspects of managing the exchange, sharing and consolidation of information between companies prior to, during and after mergers & acquisitions as well as in support of development partnerships. This will include proposals for developing processes that promote successful cross-company interactions and ways to address the challenges of controlling access to data at various stages of engagement and consolidating information across companies.

Due Diligence: Facilitating a Winning Opportunity

Donna Yosua
President
PRIMA Solutions, Inc.

Mergers, Acquisitions and Big Pharma: How to Stay Efficient and Compliant

Bryan Reynolds
Life Sciences Practice Leader
Information Intelligence Group
EMC Corporation

Working Strategically with Partners in the Age of Electronic Data & Submissions

Rachel Harrington
Regulatory Affairs Submissions
Associate Manager
Astellas Pharma Global Development, Inc

TRACK 2

EU Particulars

Session Chair:

Mickel Hedemand
Internal Adviser
Danish Health and Medicines Authority
Medicines Regulation & MAs

EU Roadmap

Mickel Hedemand
Internal Adviser
Danish Health and Medicines Authority
Medicines Regulation & MAs

eCTD exchange and Validation Issues

Hans van Bruggen, MSc
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

TRACK 3

Leveraging Outsourcing for Submission Production. Three Organizations Experiences with Outsource Partnering for Submission Production

Session Chair:

Daniel F. Orfe
President
Regulatory eSubmissions, LLC

The Life Science industry is turning to specialized resources to meet the business needs of their organizations. A key area for the use of skilled partners is in the compilation of regulatory documents into electronic submissions assembled for delivery to regulatory authorities worldwide. This session will discuss opportunities for leveraging outsource partners from the perspectives of three pharmaceutical/biotechnology companies.

Submission Outsourcing: Stop Working For it, Make it Work For You

Karen Towns
Senior Director and Global Head,
Publishing & Product License Support
Pfizer, Inc.

Partnering with a Vendor to Create a Strategic Productivity Center

Monica Kennedy, MS, RAC
Senior Manager, GRAAS Operations
& Quality Management
Amgen, Inc.

Experiences of an Emerging Pharma Company with Submission Outsourcing

Monte Levinson
President
Aerie Canal Consulting, LLC

12:00-12:30 PM Q&A AND CLOSING REMARKS

Program Co-Chairs:

Laura J. Sherman, MBA
Training Partner, Clinical Business Operations
Vertex Pharmaceuticals, Inc.

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

12:30-1:30 PM LUNCH

This is your final chance to visit booths in the Exhibit Hall, speak with Exhibitors about their products and services and get your card signed for the drawing!

1:30 PM CONFERENCE ADJOURNED