## INSIDER UPDATE

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

Tutorials: October 15 | Conference: October 15-17

Town and Country Resort and Convention Center | San Diego, CA







## Insider Update

This edition of *Insider Update* provides insights from key industry thought leaders about important topics facing professionals involved in Electronic Document Management (EDM), Electronic Regulatory Submissions (ERS), and Regulatory Information Management (RIM).

All of the experts interviewed will speak at this year's <u>EDM and ERS/eCTD</u>: <u>Impact of e-Initiatives on Content and Context</u> conference in San Diego.

"To keep up with the changes in technology, submissions professionals need to possess qualities like adaptability and business management skills as well as a high aptitude for learning multiple IT systems and vendor management.

"The Cloud allows you to remove barriers."

"Technology solutions must be in place in order to decrease cost, increase efficiency, and provide maximum value to the global effort of regulatory content alignment."

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DIA Insider Update





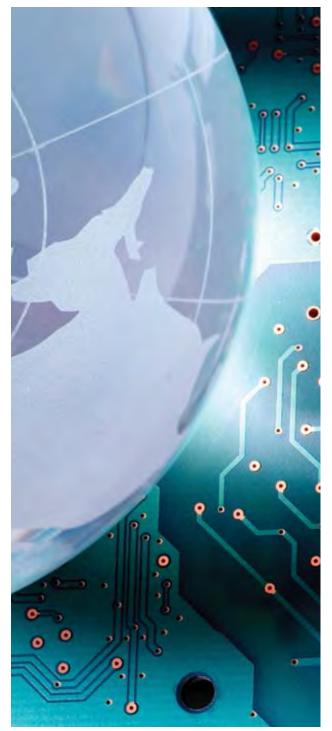
#1
Christian A. Buckley, MBA
Associate Director, Regulatory Operations
Astellas Pharma Global Development, Inc.

Q: How has the role of submissions support changed in the last fifteen years to keep pace with evolving drug development processes and technology?

A: "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. The public pressures for agencies and drug development sponsors to reduce time to market and speed up review have increased the need for efficient processes and to leverage technology.

When I started my first submissions support job in the mid 1990's, paper submissions were required by regulatory agencies. I was fortunate to join a very dynamic team that piloted electronic submissions in the form of Computer Aided New Drug Applications (CANDAs). It has been a fun ride through the years of evolving technologies like hybrid e-submissions through the adoption of Structured Product Labeling (SPL) and the electronic Common Technical Document (eCTD). Each advancement in technology has furthered information exchange and standards. The final deliverable that was once shipped as hundreds of boxes of paper by truck can now be submitted electronically through the Gateway in a fraction of the previous time. To navigate these newer technical hurdles, there are more open channels of communication between submissions professionals directly with the health authorities.

To keep up with the changes in technology, advanced skill sets have become increasingly critical for personnel in the regulatory submissions space. Submissions professionals need to possess qualities like adaptability and business management skills as well as a high aptitude for learning multiple Information Technology (IT) systems and vendor management. To be successful in this fast-paced environment, it is critical to embrace change management and focus on continual improvement in both processes and professional development."





#2
Dan Glass
Vice President, eContent Management
Y-Prime

**Q:** What are some pros and cons to leveraging the cloud within an organization?

At "I think cloud allows you to remove barriers. Personally speaking, I can get to anything I create from all my devices virtually anywhere. That kind of access allows you to be productive in nearly any situation. However, from a customer to vendor point of view, I think it's important to take "Due Diligence" very seriously and make sure you're comfortable both that the vendor you're leveraging is trustworthy enough to house your data, but also that you're willing to accept the risk that will come with putting your information in the cloud. That's not to say there's no risk when your information is contained within your own on premise systems (there certainly is), but there's an obvious difference between that and handing your critical information to a cloud vendor."

Q: In addition to the terminology around cloud computing, what are some other pieces of information that are important about the different types of offerings?

**A:** "In interactions with my clients, the number one difference I end up explaining is the difference between cloud and hosting. While you can be hosted in the cloud, in essence hosting can simply be taking the burden of supporting your own hardware/software and handing that off to another vendor. While there are certainly advantages to this approach, you may still have to deal with some of the same issues (upgrades, parts failures, etc) that you would deal with in an on premise scenario. So I think it's important to educate yourself on hosting, virtualization, multi-tenant, etc before making the leap to a "cloud" approach and understand what each of your options truly mean."





#3
Sarah Powell
Executive Director, Regulatory Affairs and Writing Services
LIQUENT, A PAREXEL Company

Q: What are some of the challenges organizations have faced with data governance and quality as it relates to RIM?

**A:** "Data Governance must be part of the corporate philosophy. 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.

To be successful, it's critical to establish rules for governing data and information before embarking on implementation so that all areas impacted by the data asset understand how it is used and where it is needed. These discussions help align the business with respect to understanding the standards, business processes, data modeling, business rules, security, compliance, stewardship, etc.

It's important to understand that data governance and data quality not the same thing, but they are related. 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.

Come learn more about some of the specific challenges organizations have faced and approaches to overcoming these challenges at the Importance of Data Integrity for RIM Systems panel discussion on Wednesday afternoon."





#4

Mauricha Marcussen, MBA

Program Manager, Global Label Alignment, Regulatory Affairs,
Global Labeling, Ad Promo, Operations and Compliance, AbbVie, Inc.

Q: What are some ways a company can manage global compliance for critical safety information within regulatory content while ensuring that labeling data is consistent and accurate across regions and sustainable over time?

**A:** "Our singular, shared vision across the industry is to improve global patient safety. The global alignment and harmonization of safety data in product labeling, among other business areas, is an important stepping stone to improving the accuracy of data that is provided to the patient, while reducing the risks of compliance-related issues for the sponsor.

The program tasks of managing – and maintaining – this global content, while ensuring accuracy of critical safety information, can be achieved with a planned, pro-active regulatory approach combined with an innovative technology solution.

The six steps to a successful baseline content alignment program for regulated data are:

- 1. Compare the master document (i.e. Company Core Data Sheet) to the source document (i.e. USPI, SPC)
  - Define the sections, regions, and products for inclusion
- 2. Identify, manage, prioritize and track gaps
  - Categorize, score, and report gaps by safety severity level
- 3. Adjudicate findings
  - Utilize existing documents, newly created documents, and historical data
- 4. Develop and execute a remediation plan
  - Communicate with stakeholders and identify gaps that necessitate a regulatory filing
- 5. Confirm Health Authority updates and responses
  - Consider filing strategies, audit commitments, and agency-specific requirements
- 6. Revise master document and local source documents
  - Integrate into current business workflow processes





## #4, continued

#### Mauricha Marcussen, MBA

Program Manager, Global Label Alignment, Regulatory Affairs, Global Labeling, Ad Promo, Operations and Compliance, AbbVie, Inc.

"The subsequent compliance maintenance program is vital, and, along with repeating the six steps above, must also consider the following:

- 1. Who should maintain the data?
- 2. What types of reporting mechanisms are the most advantageous?
- 3. Where should audit checks be deployed?
- 4. When should maintenance updates be implemented?
- 5. Why would an organization assume risk by not maintaining accuracy in safety data?
- 6. How do we best use technology to pro-actively support a long-term maintenance strategy?

Finally, a technology solution must be in place in order to decrease cost, increase efficiency, and provide maximum value to the global effort of regulatory content alignment. The technology solution must encompass the six steps above and be deployed globally to sustain the long-term maintenance program dynamically and intelligently, with flexibility into multiple content areas.

In summary, a sustainable compliance program can be established and extendable across the portfolio, across the world, and over time. Industry trends are evolving towards outsourcing these types of programs, which is a viable option with the collaboration of qualified regulatory and technology partners."





#5
Mollie Shields-Uehling
President & CEO
SAFE Bio-Pharma Association

**Q:** Why is standardized identity management essential to effective pharmaceutical and healthcare collaboration?

**A:** "Internet communications have helped the pharmaceutical industry achieve new levels of globalization and collaboration. However, this operating environment creates trust issues in the identities of those both inside and outside of the firewall to whom we provide access to valuable intellectual property and other information assets.

The SAFE-BioPharma standard was established by a group of major pharmaceutical companies with the participation of the EMA and the US FDA. It was conceived to help companies engaged in life sciences and healthcare make their business processes fully electronic.

The SAFE-BioPharma standard comprises business rules and technical specifications covering all aspects of identity management. A distinguishing characteristic of the standard requires each digital identity to be closely bound to its user's proven identity. This provides a high level of trust in the identity of its user and is the basis for its interoperability – SAFE-BioPharma identity credentials are trusted by US Government agencies (e.g. FDA, NIH, VA) and other systems that are directly or indirectly cross-certified with SAFE-BioPharma. The user only needs a single credential for use across many enterprises.

Digital identities based on the SAFE-BioPharma standard are in use globally. They are used to authenticate into portals and to gain access to valuable intellectual property and to EHRs. They also are used to sign electronic laboratory notebooks, regulatory submissions, contracts, ePrescriptions, and other electronic documents. Recently, EMA announced it accepts eSubmissions with SAFE-BioPharma digital signatures."



### Are YOU Eager to Know More?

- What are the challenges for ensuring compliance to meet regional requirements?
- In what ways can companies best optimize business processes when collaborating with CROs and Cloud computing across the life cycle continuum?
- What is the importance of maximizing content reuse, metadata, aligning standards, and technology in processes?
- What are some organizational processes and governance to ensure integrity, quality, and security of records?
- What are the current global regulatory agency requirements and future initiatives?

Where can you get answers to these questions and more?

#### **REGISTRATION FEES:**

Member: Charitable Nonprofit/Academia Government Industry Standard	\$615
Nonmember: Charitable Nonprofit/Academia Government Industry Standard	\$790
Tutorials	. \$405

Group discounts available: Register three, get the fourth free!

## You're Invited to this Year's EDM & ERS/eCTD Conference

We would like to invite you to this year's **EDM and ERS/eCTD: Impact of e-Initiatives on Content and Context** conference, being held October **15-17** in **San Diego, CA,** where you'll get the answers to all your questions.

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

#### **Plenary Session Topics:**

- FDA Update/eCTD Progress Report
  - eCTD Update
  - Quality and Product Data Standards
  - Study Data Standards Update
  - Top Ten Issues with Data
- Other Regions Update
- "Ask the Regulators"
  - Discuss hot topics with the Regulators and ask the panelists questions regarding FDA submission standards, processes, regulations, guidance, or initiatives

#### **Breakout Session Topics:**

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

#### **Tutorial Topics:**

- Tutorial 1: eCSRs
- Tutorial 2: Get Ready for Global ISO IDMP, Including Lessons Learned from the EU XEVMPD



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#### **Networking & Exhibits:**

- Networking Reception: October 15 | 5:00-6:00PM
- Exhibit Hall: October 15-17

#### Who Should Attend?

- Regulatory Affairs and Operations Professionals
- Global Submission Managers/Project Managers
- Regulatory, Medical and Technical Writers
- Data Managers
- Information Technology and Support Personnel
- Document and eRecords Managers
- Regulatory Standards Implementation Specialists and Associates
- Clinical Operations Representatives
- Quality Assurance and Compliance Professionals
- Contract Researchers and Service Support Providers
- Emerging Pharmaceutical/Biotechnology/Device Professional



#### **Interested in Exhibiting?**

Showcase your products and services to key decision makers in the EDM and ERS communities. <u>Submit</u> your application to <u>exhibits@diahome.org</u> today!

We look forward to seeing you in San Diego, CA!

REGISTER ONLINE



## You Might Also be Interested in:

#### Featured Offerings Training Course:

**Electronic Submissions: The Next Era of Electronic Submissions** 

November 11 | Horsham, PA | Enter coupon code EUBS25 at checkout and Save 25%.

This hands-on course will bring professionals with no experience up to date on all aspects of electronic submission and will address US specific requirements as well as the status in the rest of the world and the future of eCTD.

#### Faculty:

• Nancy P. Smerkanich, Educational Liaison/Regulatory Science Doctoral Candidate University of Southern California

#### Webinar:

<u>Electronic Submissions 101 – Essential MS Word and Adobe Acrobat Tools/Skills and Current IT Options</u>
December 4 | 11:00AM-12:30PM ET

This webinar will focus on the myriad skills and tools needed to prepare e-submission-ready documents, and will conclude with discussions on the various IT options for electronic submissions and the various deployment approaches including a full license, pay-per-submision models, and cloud environments.

#### **Training Courses:**

- Regulatory Affairs: The IND, NDA, and Postmarketing
- Global Considerations for Regulatory Strategy Development
- Preparing for a US FDA Advisory Committee Meeting

#### Meeting:

• <u>Regulatory Information Management 2014</u> | February 25-26 Call for Abstracts Now Open. Deadline: October 11, 2013

### DIA recommends the following Communities (formerly SIACs) which contributed to the development of this program:

- Document and Records Management
- Electronic Regulatory Submissions



- DrugInfoAssn
- © DrugInfoAssn, #DIAEDM13
- Drug Information Association (DIA)
- DrugInfoAssn DIA
- DrugInfoAssn