



in collaboration
with



eDrug Listing and Establishment Registration FDA & Industry: Overview and Lessons Learned on SPL

August 11-12, 2009 | The Westin Philadelphia Hotel, Philadelphia, PA, USA

PROGRAM CHAIRPERSONS

THERESA BRUNONE, MS

Assistant Director, Global Regulatory Operations
GlaxoSmithKline

MICHAEL FAHMY, MS

Manager, Global Dossier Management
Bristol-Myers Squibb

VIRGINIA M. HOGAN

Associate Director, Labeling and Package Control
TEVA Pharmaceuticals

PROGRAM COMMITTEE

CAROL L. GARCIA

Manager Global Labeling, Alpharma Inc.

ALAN GOLDHAMMER, PhD

Vice President, Scientific and Regulatory Affairs,
PhRMA

MARCIA D. HOWARD, PhD

Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

GORDON JOHNSTON, MS, RPh

Vice President, Regulatory Sciences
Generic Pharmaceutical Association (GPhA)

GARY SANER

JOHN LORENC

Life Sciences Services, Reed Technology

CRAIG S. TRAUTMAN

CEO, Intagras

KEITH THOMAS

Product Strategist, Infrastructures For Information Inc.

A Prime Opportunity to Hear Industry and FDA Discuss Best Practices for Electronic Establishment Registration and Product Listing.

The FDA Amendments Act (FDAAA) mandated the requirements for electronic drug establishment registration and drug product listing. FDA has adopted the use of extensible markup language (XML) files in a standard structured product labeling format as the standard format for the exchange of drug establishment registration and drug product listing information.

FEATURED TOPICS

- Lessons learned from the electronic registration/drug product listing pilot
- Validation rules applied by FDA
- Nuances of SPL lifecycle management, including findings from the electronic listing pilot and early production submissions.
- SPL Release 4 terminology
- Product listing and establishment registration of various and complex scenarios (e.g., export only products, product kits, etc.)
- Much more!

TARGET AUDIENCE This program will benefit individuals involved in:

INDUSTRY

- ▶ Pharmaceuticals
 - Brand
 - Generics
 - Over-the-counter
- ▶ Biotechnology
- ▶ Vaccines
- ▶ Active pharmaceutical ingredient suppliers
- ▶ Veterinary medicine

JOB FUNCTION

- ▶ Regulatory Affairs
- ▶ Research & development/Strategic issues
- ▶ Manufacturing: drug substance, drug product, packaging
- ▶ Document management
- ▶ Information management
- ▶ Information technology
- ▶ Dictionaries/Data standards

LEARNING OBJECTIVES – DAY ONE – AUGUST 11 At the conclusion of this meeting, participants should be able to:

- ▶ Identify information to be included in electronic drug establishment registration and drug product listing submissions and understand validation rules applied by FDA
- ▶ Explain SPL Release 4 terminology and process

LEARNING OBJECTIVES – DAY TWO – AUGUST 12 At the conclusion of this meeting, participants should be able to:

- ▶ Discuss findings from the electronic listing pilot and early production submissions
- ▶ Discuss nuances of SPL lifecycle management

2 Registration Options!

OPTION 1: 2-day Registration includes:

August 11

SPL 101

Lonnie Smith, Project Manager
SPL Team, CDER, FDA

SPL VENDOR SHOWCASE

1:30-5:00 PM

NETWORKING RECEPTION

5:00-6:30 PM Network with participating vendors.

August 12

DAY 2 CONFERENCE

OPTION 2: 1-1/2-day Registration includes:

August 11

(SPL 101 not included)

SPL VENDOR SHOWCASE

1:30-5:00 PM

NETWORKING RECEPTION

5:00-6:30 PM Network with participating vendors.

August 12

DAY 2 CONFERENCE

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

• BASEL, SWITZERLAND • TOKYO, JAPAN • MUMBAI, INDIA • BEIJING, CHINA



SPECIAL SPL VENDOR SHOWCASE

The SPL Vendor Showcase provides a fantastic opportunity for attendees to evaluate a number of currently available services and tools as they are used to produce an equivalent final product. During this session, participating vendors will demonstrate their services and/or tools and present their results.

CONTACT INFORMATION

Conference: Ben Zaitz, Phone +1-215-293-5803/email Benjamin.Zaitz@diahome.org

Exhibits: Jeff Korn, Phone +1-215-442-6184/email Jeff.Korn@diahome.org

Accreditation and Credit Designation



The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. DIA is authorized by IACET to offer 1.1 CEUs for this program.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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

- ▶ Identify information to be included in electronic drug establishment registration and drug product listing submissions and understand validation rules applied by FDA
- ▶ Explain SPL Release 4 terminology and process
- ▶ Discuss findings from the electronic listing pilot and early production submissions
- ▶ Discuss nuances of SPL lifecycle management

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

MONDAY • AUGUST 10

6:00-8:00 PM REGISTRATION

TUESDAY • AUGUST 11

8:00-9:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

9:00-10:30 AM SESSION 1

SPL 101 "THE BASICS" (PART 1 OF 2)

SPEAKER

Lonnie Smith

Project Manager, Structured Product Labeling & eList Team,
Medical Informatics Staff & FDA Data Standards Council, FDA

This presentation spanning Sessions 1 and 2 provides an overview of the electronic Drug Establishment Registration and Drug Product Listing (eDRL) submission process using SPL format that replaces the previous Form 2656, 2657, and 2658 submission process. The topics include SPL definition, Terminology, NDC Labeler Code Request, Establishment Registration (domestic and foreign), Drug Listing, Content of Labeling (CoL), and the Electronic Submission Gateway (ESG).

10:30-11:00 AM REFRESHMENT BREAK

11:00-12:30 PM SESSION 2 (continuation of Session 1)

SPL 101 "THE BASICS" (PART 2 OF 2)

12:30-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 3

SPL VENDOR SHOWCASE (PART 1 OF 2)

MODERATOR

Michael Fahmy

Manager, Global Dossier Management
Bristol-Myers Squibb

The SPL Vendor Showcase provides a fantastic opportunity for attendees to evaluate a number of currently available services and tools as they are used to produce an equivalent final product. During this session, a number of participating vendors will be allocated time to demonstrate their services or tool and present their results.

1:30-2:00 PM

VENDOR 1: REED TECHNOLOGY

Gary Saner

Senior Manager, Information Solutions Life Sciences, Reed Technology

Vendor Description:

www.ReedTech.com

Reed Technology is the leading provider of SPL conversion, life cycle management and publication composition services for Human Health, Animal Health, OTC, and Biologic/Vaccine labeling. Using our in-depth knowledge of the FDA's SPL R4/eDRL regulations, we have successfully converted more than 4,500 drug labels for over 130 life sciences companies.

2:00-2:30 PM

VENDOR 2: i4i INC.

Greg Heater

Senior Business Development Executive, i4i Inc.

Vendor Description:

www.i4i.com

Through our innovative solutions and expertise i4i can simplify your SPL R4 Labeling requirements allowing for easy eDrug Listing and Establishment Registration. With over 50+ pharma clients, i4i is the industry leader in SPL structured authoring and collaborative content management with our Word-based XML authoring and 21CFR11 document management tools.

2:30-3:00 PM

VENDOR 3: Virtify, Inc.

Ikram Baig

Chief Technology Officer, Virtify, Inc.

Vendor Description:

www.virtify.com

Virtify is the market leader in Enterprise Content Compliance solutions for life sciences. Virtify's Virtx Software Suite automates a variety of paper-based processes and is pre-configured to comply with different global standards and regulatory mandates such as Clinical Trial Disclosure, eCTD, SPL/PLR, and other electronic submissions standards.

3:00-3:30 PM

REFRESHMENT BREAK

3:30-5:00 PM

SESSION 4 (continuation of Session 3)

SPL VENDOR SHOWCASE (PART 2 OF 2)

3:30-4:00 PM

VENDOR 4: Intagras, Inc.

Craig Trautman

Chief Executive Officer, Intagras, Inc.

Vendor Description:

www.intagras.com and www.splportal.com

Intagras is a Tampa-based consulting firm that focuses on the specific IT needs of companies within the Life Sciences industry as well as providing custom application development services across industries.

4:00-4:30 PM

VENDOR 5: Quark, Inc.

Richard Brandt

Vice President, Life Sciences, Quark, Inc.

Vendor Description:

http://dynamicpublishing.quark.com/xml_author/spl_accelerator_spl_authoring.html

Quark is a leader in SPL compliance solutions. Quark SPL Accelerator for Quark XML Author is an out-of-the-box solution that lets anyone produce SPL submissions using Microsoft® Word, requires little training and no knowledge of XML. Our customers include Pfizer, Wyeth, Par Pharmaceuticals, and A&Z Pharmaceuticals, among others.

4:30-5:00 PM

VENDOR 6: Data Conversion Laboratory, Inc.

Don Bridges

Life Sciences Manager, Data Conversion Laboratory, Inc.

Vendor Description:

www.dclab.com

DCL provides conversion services and software to major industries, converting and organizing content to create electronic documents, populate databases and publish on the web. A leader in SPL submissions, DCL has converted thousands of labels for more than 150 pharmaceutical companies and guarantees your data will conform to FDA SPL XML requirements.

5:00-6:30 PM

NETWORKING RECEPTION

Opportunity to visit participating vendor exhibits



WEDNESDAY • AUGUST 12

7:15-8:15 AM

REGISTRATION AND CONTINENTAL BREAKFAST

8:30 AM

WELCOME AND OPENING REMARKS

Theresa Brunone

Assistant Director, Global Regulatory Operations
GlaxoSmithKline

8:35-10:00 AM

SESSION 5

SPL UPDATE AND LESSONS LEARNED

SPEAKER

Lonnie Smith

Project Manager, Structured Product Labeling & eList Team,
Medical Informatics Staff & FDA Data Standards Council, FDA

The session includes various topics related to the current SPL submission process, such as:

- Current FDA SPL reference documents emphasizing the specification changes found in the final versions
- Establishment Registration scenarios (API, International Products, etc.)
- Drug Listing scenarios in SPL (kits, combo products, private labeling/labelers, etc.)
- Experiences from the eDRL Pilot Program and recent SPL production submissions, including validation issues and errors

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 6

INDUSTRY SPL EXPERIENCE

Theresa Brunone, MS

Assistant Director, Global Regulatory Operations
GlaxoSmithKline

PRESENTER

Dragan Obradovich

Regulatory Project Manager
Abbott Quality and Regulatory (AQR), Abbott

PANELISTS

Theresa Brunone, MS

Assistant Director, Global Regulatory Operations
GlaxoSmithKline

Michael Fahmy

Manager, Global Dossier Management, Bristol-Myers Squibb

Carol L. Garcia

Manager Global Labeling, Alpharma Inc.

Virginia M. Hogan

Associate Director, Labeling and Package Control
TEVA Pharmaceuticals

Paula Markert

Regulatory Associate
GlaxoSmithKline Consumer Healthcare R&D

Devon Morgan

Regulatory Affairs Manager, Perrigo Company

In this session industry representatives will discuss representative experiences setting up, preparing and submitting SPL R4 documents for Labeler Code Request, Establishment Registration and Product Listing/Labeling.

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 7

SPL Q&A LIVE

MODERATOR

Virginia Hogan

Associate Director, Labeling and Package Control
Teva Pharmaceuticals USA

Previously submitted questions and live questions from the audience are discussed by FDA representatives. Questions can be related to electronic establishment registration and product listing regulatory content, SPL technical content, or the ESG submission process.

PANELISTS

Lonnie Smith

Project Manager, Structured Product Labeling & eList Team,
Medical Informatics Staff & FDA Data Standards Council, FDA

David E. Mazyck

Project Manager, eDRLS Operations, Office of Compliance,
CDER, FDA

CDR Vada Perkins, BSN, MSc, RN

Regulatory Program Management Officer, Office of the
Director, CBER, FDA

Michael Blanchard Fauntleroy

Program Manager, CBER, FDA

Charise Kasser, BPharm

Consumer Safety Officer, Office of Surveillance and
Compliance, Center for Veterinary Medicine, FDA

3:00-3:10 PM

CLOSING REMARKS

Michael Fahmy

Manager, Global Dossier Management
Bristol-Myers Squibb

Note: Vendor exhibits open until 3:45

3:45 PM

CONFERENCE ADJOURNED

TRAVEL AND HOTEL

The most convenient airport is Philadelphia International Airport and attendees should make airline reservations as early as possible to ensure availability. The Westin Philadelphia is holding a block of rooms at the reduced rate below until July 31, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$179 Double \$179

Please contact The Westin Philadelphia by telephone at +1-215-563-1600 and mention the DIA event. The hotel is located at 99 South 17th Street, Philadelphia, PA 19103, USA.

GROUP DISCOUNTS*

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

- To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

MEMBER EARLY BIRD

Register by July 31, 2009

SAVE \$190

eDrug Listing and Establishment Registration FDA & Industry: Overview and Lessons Learned on SPL

Event ID #09015

The Westin Philadelphia Hotel, Philadelphia, PA, USA

AUGUST 11-12, 2009

AUGUST
11

SPECIAL SPL VENDOR SHOWCASE

See page 1 for details!

Also, 2 Registration Options.

Details on page 1.

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and during receptions (if applicable).

Event information: Contact Ben Zaitz at the DIA office by telephone +1-215-293-5803, fax +1-215-442-6199 or email Benjamin.Zaitz@diahome.org.

Tabletop exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For tabletop exhibit space, please check the box below.

☐ To receive a tabletop exhibit application, please check.

GROUP DISCOUNTS (not available online or on already discounted fees)

Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. See page 3 for complete details.

Registration Fees If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only.

	On or before JULY 31, 2009	After JULY 31, 2009
Member Fee on 2-day conference	US \$1260 <input type="checkbox"/>	US \$1450 <input type="checkbox"/>
		MEMBERSHIP
		US \$ 140 <input type="checkbox"/>

Join DIA now to qualify for the early-bird member fee! Go to www.diahome.org and click on Membership + Communities.

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee on 2-day conference

US \$1590 ☐

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ☐ I do NOT want to be a DIA member ☐

Special 1-1/2 day Rate!

MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only.

	On or before JULY 31, 2009	After JULY 31, 2009
Member Fee on 1-1/2-day conference	US \$ 965 <input type="checkbox"/>	US \$1100 <input type="checkbox"/>
Nonmember Fee on 1-1/2-day conference	US \$1240 <input type="checkbox"/>	

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ☐ I do NOT want to be a DIA member ☐

Discount Fees on 2-day or 1-1/2 day conference

MEMBER

NONMEMBER*

Government (Full-time) US \$ 365 ☐ US \$ 505 ☐

Charitable Nonprofit/Academia (Full-time) US \$ 730 ☐ US \$ 870 ☐

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

CANCELLATION POLICY: On or before AUGUST 4, 2009

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

Government or Academia or Nonprofit (Member or Nonmember) = \$100

Tutorial (if applicable) = \$50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

DRUG INFORMATION ASSOCIATION

800 Enterprise Road, Suite 200
Horsham, PA 19044-3595 USA

REGISTRATION FORM

Do not remove mailing label. Please return this entire page.

09015

PLEASE CONSIDER THIS FORM AN INVOICE

Please check the applicable category:

☐ Academia ☐ Government ☐ Industry ☐ CSO ☐ Student (Call for registration information)

Last Name ☐ Check if part of group registration First Name M.I.

Degrees ☐ Dr. ☐ Mr. ☐ Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

PAYMENT OPTIONS

Register online at www.diahome.org or check payment method

☐ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX Exp Date

Card #

Name (printed)

Signature

☐ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

☐ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.