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# 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

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PhRMA

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Consumer Healthcare Products Association

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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**

AUGUST  
11

## 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@diahomes.org](mailto:Benjamin.Zaitz@diahomes.org)

**Exhibits:** Jeff Korn, Phone +1-215-442-6184/email [Jeff.Korn@diahomes.org](mailto:Jeff.Korn@diahomes.org)

**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@diahomes.org](mailto:dia@diahomes.org)

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

## 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](http://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](http://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](http://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](http://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](http://www.intagras.com) and [www.splportal.com](http://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](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](http://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.

**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.

**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, eDRRLS 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**

**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.

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Register by July 31, 2009

SAVE \$190

## eDrug Listing and Establishment Registration

## FDA &amp; 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 &amp; 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.

Member Fee on 2-day conference

On or before	After
JULY 31, 2009	JULY 31, 2009

US \$1260

US \$1450

MEMBERSHIP

US \$ 140

► Join DIA now to qualify for the early-bird member fee! Go to [www.diahome.org](http://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.

Member Fee on 1-1/2-day conference

On or before	After
JULY 31, 2009	JULY 31, 2009

US \$ 965

US \$1100

MEMBERSHIP

US \$1240

*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.*

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## ► 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](http://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.