



# DIGITAL SIGNATURES: Practical Strategies for Life Science Organizations

May 13, 2008 | Sheraton National Hotel, Arlington, VA, USA

#### PROGRAM CHAIRS

##### **RODD SCHLERF**

Life Science Practice Manager  
ARX, Inc.

##### **TAM WOODRUM**

Vice President, Worldwide Technical  
QA and Compliance  
Pfizer Inc

#### WHO SHOULD ATTEND

This program will benefit professionals involved in

- ▶ Clinical Operations
- ▶ Information Security
- ▶ Document Management
- ▶ Records and Archiving
- ▶ Technical Operations
- ▶ Quality and Compliance Management
- ▶ Project Management
- ▶ Regulatory Affairs

#### CONTACT INFORMATION

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#### TABLETOP EXHIBITS

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### *Achieve Fully Electronic Business-to-regulator and Business-to-business Processes*

Standards-based electronic signatures (Digital Signatures) are essential to electronic submissions in compliance with FDA 21 CFR Part 11. However, for the biopharmaceutical industry, the benefits of digital signatures extend beyond compliance requirements to accelerated decision making, approval processes, cost reductions, and more efficient and paperless operations.

#### HIGHLIGHTS

- Strategies to facilitate the adoption of digital signatures for organizations of every size,
- Case studies from organizations that have successfully implemented digital signature applications for processes, including:
  - Internal quality and clinical operations
  - Large web-based business-to-business portals
  - Cross-organizational workflows
- Presentations and discussion by industry thought leaders from biopharmaceutical companies, CROs, and technology providers.

#### LEARNING OBJECTIVES

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

- ▶ Explain the industry's need to meet compliance requirements with electronic signatures,
- ▶ Outline how digital signatures contribute to FDA initiatives for fully electronic transactions, and
- ▶ Discuss the value of electronic signatures.



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 5.75 contact hours or .575 continuing education units (CEU's). 286-000-08-022-L04.



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 .6 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.

## TUESDAY • MAY 13, 2008

**7:15-8:15 AM** REGISTRATION AND CONTINENTAL BREAKFAST

**8:15-8:30 AM** WELCOME AND OPENING REMARKS

**8:30-9:00 AM** **KEYNOTE SPEAKER**  
**Randy V. Sabett**  
 Co-chair of the Information Security Committee of the Section of Science and Technology Law of the American Bar Association

**9:00-10:30 AM** **SESSION 1**  
**THE STATE OF DIGITAL SIGNATURES**

CHAIRPERSON  
**Russ Housley**  
 Founder  
 Vigil Security, LLC

New advances in digital signature standards and technology solutions, alone with consideration of related topics such as identity proofing and credentialing are discussed by industry experts along with a case study from an organization that embraced digital signatures as a core strategy in a highly regulated, web-based, B2B business model.

**PLANNING/CHOOSING/IMPLEMENTING DIGITAL SIGNATURE FOR MISSION-CRITICAL, WEB-BASED B2B/C BUSINESSES**  
**Kevin Maher**  
 CEO  
 Global Vet Link (GVL), Inc.

**DIRECTORY ENABLED CREDENTIALING AND CENTRALIZED KEY MANAGEMENT**  
**Gadi Aharoni**  
 CEO  
 Algorithmic Research (ARX), Inc.

**DIGITAL SIGNATURE SUPPORT/SECURITY IN PDF AND COMMON APPLICATIONS**  
**John Landwehr**  
 Director of Security Solutions and Strategy  
 Adobe Systems, Inc.

**IDENTITY PROOFING AND CREDENTIALING CONSIDERATION**  
**Speaker has been invited**

Q&A PERIOD

**10:40-11:00 AM** **REFRESHMENT BREAK**

**11:00 AM-12:45 PM** **SESSION 2**  
**DIGITAL SIGNATURE IN INTERNAL AND QUALITY APPLICATIONS**

CHAIRPERSON  
**Earl Hulihan, MEd**  
 Corporate Compliance Officer,  
 Vice President, Global RA and QA  
 Medidata Solutions Worldwide

Case studies from organizations that have deployed digital signature systems for internal applications in areas such as QA and audits both as a stand-alone solution and as an integrated solution with document management and workflow systems.

**ECM AND DIGITAL SIGNATURE DEPLOYMENT**  
**Glenn Watt**  
 Corporate Security Office  
 Vice President, Global Information Security and Privacy  
 Medidata Solutions Worldwide

**DIGITAL SIGNATURE DEPLOYMENT WITHOUT ECM**  
**Fraser Simms**  
 Quality Assurance Director  
 ClinPhone

**MICROSOFT SHAREPOINT AND DIGITAL SIGNATURE DEPLOYMENTS VIA NEXTDOCS**  
**Zikria Syed**  
 CEO  
 NextDocs Corporation

**DIGITAL SIGNATURE IN NON-REGULATED APPLICATIONS**  
**Ryan Crum**  
 Project Manager  
 Pfizer (Capsugel subsidiary)

Q&A PERIOD

**12:50-1:45 PM LUNCHEON**

**1:45-3:30 PM SESSION 3**

**DIGITAL SIGNATURE IN EXTERNAL AND CROSS-ORGANIZATIONAL APPLICATIONS**

CHAIRPERSON

**Tam Woodrum**

Vice President, Worldwide Technical QA and Compliance  
 Pfizer Inc

Case studies from organizations that have deployed digital signature systems for external-facing applications in areas such as research, clinical development and manufacturing applications where signing and verification crosses organizational boundaries.

**DIGITAL SIGNATURES IN ELECTRONIC LAB NOTEBOOKS**  
**George Rathbun**  
 Senior Director  
 Worldwide Technology Quality and Compliance  
 Pfizer Inc

**DIGITAL SIGNATURES IN CLINICAL TRIAL MANAGEMENT SYSTEMS**  
**Jagath Wanninayake**  
 President, Clarix Informatics

**DIGITAL SIGNATURE FOR MEDICAL DEVICE FIELD SERVICE REPORTS**  
**Angela Gasper**  
 IT Project Manager  
 MEDRAD (Bayer-Schering Pharma AG)

**SAFE IMPLEMENTATION IN MANUFACTURING? CLINICAL? Speaker has been invited**

Q&A PERIOD

**3:35 PM MEETING ADJOURNED**

**TRAVEL AND HOTEL**

The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Sheraton National Hotel is holding a block of rooms at the reduced rate below until April 21, 2008, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

**Single \$251 / Double \$251**

Please contact the Sheraton National Hotel by telephone at +1-703-521-1900 or by fax at +1-703-271-6626 and mention the DIA event. The hotel is located at 900 South Orme Street, Arlington, VA 22204, 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.**

*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 information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.*

**CANCELLATION POLICY: On or before MAY 6, 2008**

Administrative fee that will be withheld from refund amount:

- Member/Nonmember = \$200
- Government/Academia/Nonprofit (Member/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.

**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.

**PLEASE CONSIDER THIS FORM AN INVOICE**

Digital Signatures: Practical Strategies for Life Science Organizations

Meeting I.D. # 08018 – May 13, 2008  
Arlington, VA, USA

**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 and will be accepted by mail, fax, or online.

<b>MEMBER EARLY-BIRD OPPORTUNITY</b> <i>Available on nondiscount member fee only.</i>	<b>On or before</b>	<b>After</b>
	<b>APRIL 22, 2008</b>	<b>APRIL 22, 2008</b>
<b>Member Fee</b>	US \$720 <input type="checkbox"/>	US \$800 <input type="checkbox"/>
<b>Join DIA now to qualify for the early-bird member fee!</b> <a href="http://www.diahome.org/en/Membership/AboutMembership/AboutMembership">www.diahome.org/en/Membership/AboutMembership/AboutMembership</a>		<b>MEMBERSHIP</b> US \$ 130 <input type="checkbox"/>

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.

<b>Nonmember Fee</b>	US \$930 <input type="checkbox"/>
<i>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>	
I want to be a DIA member <input type="checkbox"/>	I do NOT want to be a DIA member <input type="checkbox"/>

<b>Discount Fees</b>	<b>MEMBER</b>	<b>NONMEMBER*</b>
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Charitable Nonprofit/Academia (Full-time)	US \$ 525 <input type="checkbox"/>	US \$ 655 <input type="checkbox"/>

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**PAYMENT REGISTER ONLINE AT [www.diahome.org](http://www.diahome.org) or please check payment method:**

**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.

**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 Expiration Date \_\_\_\_\_

Card # \_\_\_\_\_

Signature \_\_\_\_\_

**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.

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Please indicate that this form is part of a group registration by checking this box.

Please list below the names of the other three registrants from your company.

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

**Please complete the information below.**

Please check the applicable category:  Academia  Government  Industry  CSO  Student (Call for registration information)

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ M.I. \_\_\_\_\_ Degrees \_\_\_\_\_  Dr.  Mr.  Ms.

Job Title \_\_\_\_\_ Affiliation (Company) \_\_\_\_\_

Address (Please write your address in the format required for delivery to your country.) \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Country \_\_\_\_\_

email (Required for confirmation.) \_\_\_\_\_ Telephone Number \_\_\_\_\_ Fax Number (Required for confirmation.) \_\_\_\_\_

I cannot attend but please keep me informed of DIA's future events.