

May 1-3, 2006

Risk-Based Approach to Computer Validation

Realize the Value in Your Computer Validation Efforts



Joseph Schenk, CEO, QA Edge, Inc. - *Instructor*

The Warren V. Musser Auditorium

Penn State-Great Valley Campus
Malvern, PA

May 1-3, 2006
8:30 a.m.—4:00 p.m.

Discussions Include:

- Common problems and greatest issues of system risk
- Identifying and prioritizing risk
- How risk classifications impact Computer Validation
- Selecting the appropriate risk mitigation strategy
- Speeding up test script writing
- Managing change control
- The scope and latest status of 21 CFR Part 11
- System specifications
- Risk-based approach industry standards
- Writing clearer requirements
- Effective system testing
- Writing a validation report
- Risk assessment and management

Professionals whom you will meet:

Quality Assurance Professionals
Quality Control Specialists
Regulatory Personnel
Electronic Records Managers
Validation Supervisors
Regulatory/Compliance Consultants
Manufacturing Supervisors
Technical Support Personnel
IS/IT Project Managers
Software Development Engineers
Internal Auditing Specialists
Document Management Managers

See Page 5 for
**EARLY-BIRD
DISCOUNTS!**

Presented by:



QA Edge, Inc.
3515 Silverside Road
Suite 205
Wilmington, DE 19810

AGENDA

Risk-Based Approach To Computer Validation

May 1-3 - Malvern, PA
800.459.3363, Ext. 28

DAY ONE

8:30-8:45 – Introductions: Joseph Schenk, QA Edge, Inc.
8:45-9:45 – Guest Speaker: Garo Yepremian, the Pro-Football Hall of Fame's choice of "Kicker of the Decade" from 1970-1980
9:45-10:05 – Break
10:05-11:45 – Joseph Schenk, QA Edge
11:45-1:00 – Luncheon Break (provided on-site)
1:00-2:30 – Joseph Schenk, QA Edge
2:30-2:50 – Break
2:50-4:00 – Joseph Schenk, QA Edge

- Regulatory Background & Predicate Rules
- Scope and Latest Status of 21 CFR Part 11
- Overview of Computer Validation
 - Lifecycle Requirements
 - Regulatory Expectations/Inspections
- Applying a Risk-Based Approach
 - Industry Standards for Risk Analysis
 - Safety, Regulatory, Complexity, Project

DAY TWO

8:30-8:45 – Review/Introductions; Joseph Schenk, QA Edge, Inc.
8:45-9:45 – Dyadem Corporation: Best Practices for Performing FMEAs in a Regulated Environment
9:45-10:05 – Break
10:05-11:45 – Joseph Schenk, QA Edge
11:45-1:00 – Luncheon Break (provided on-site)
1:00-2:30 – Joseph Schenk, QA Edge
2:30-2:50 – Break
2:50-4:00 – Joseph Schenk, QA Edge

- Writing Better User Requirement Specifications (URS)
 - URS Process
 - Requirements Management
 - Generic User Requirements for Part 11 Technical Controls
- Effective System Testing
 - Test Planning & Management
 - Test Case Development for System Acceptance, IQ/OQ
 - An Effective Approach to Testing Complex Algorithms
 - Use of Testing Tools
 - Classic Testing Mistakes
 - Generic Test Scripts for Part 11 Technical Controls

DAY THREE

8:30-8:45 – Review/Introductions: Joseph Schenk, QA Edge, Inc.
8:45-9:45 – Hewlett Packard, Subrato Majumdar: The Key to Sustained Infrastructure Compliance
9:45-10:05 – Break
10:05-11:45 – Joseph Schenk, QA Edge
11:45-1:00 – Luncheon Break (provided on-site)
1:00-2:30 – Joseph Schenk, QA Edge
2:30-2:50 – Break
2:50-4:00 – Joseph Schenk, QA Edge

- Writing Production Control SOPs Appropriate for Risk
- Infrastructure Risk Mitigation
- Validation Completion
- Change Control & Re-Validation
- Risk-Based Approach for Legacy System Compliance Remediation
 - A Unique Efficient Method Using the "Fit for Purpose™" Approach
- Summary Q&A

YOUR INSTRUCTOR

Joseph Schenk is the CEO of QA Edge, Inc. Established in 1995, this 48-person consulting firm provides real-world strategies to avoid costly mistakes through a diverse range of Computer Validation and Part 11 training and services.

Joe has been involved in Computer Validation and software development since 1981. Since 1995, his efforts have been focused on leading a nationally-recognized, Computer Validation and 21 CFR Part 11 consulting firm. He has trained thousands of Pharmaceutical personnel in Part 11 assessment, Computer Validation, and testing. He also participates in regular meetings with the FDA to discuss advanced computing technologies and their input on validation.

REGISTER AND SAVE

**Risk-Based Approach
To Computer Validation**
May 1-3 - Malvern, PA
800.459.3363, Ext. 28

What a great value - for only \$995, you'll benefit from three, information-packed days. This targeted conference is hosted by QA Edge, Inc., a trusted advisor in supplying Computer Validation and Part 11 solutions to leaders within the pharmaceutical, biotech and medical device industries.

There are various discounts available! Register by **March 15** and take advantage of a **\$195** discount. Register three individuals from the same firm and receive a complimentary pass for the fourth attendee! All four individuals must register and prepay at the same time.

Registration fees include daily continental breakfasts, warm lunches and refreshment breaks throughout the day.

Unprecedented Conference Guarantee

If you are not fully satisfied with the contents of this information-packed conference, you will receive a full refund. NO QUESTIONS ASKED!

Your registration may be transferred to any other member of your organization at any time. Requests for cancellations (accepted by mail or fax only) must be received by April 24. No cancellations will be accepted after that date. All cancellations are subject to a \$35 processing fee.

Conference coordinators reserve the right to cancel the event. They will not be held responsible for airfare, hotel or other costs incurred by registrants.

FIVE EASY WAYS TO REGISTER

CALL

us at 800.459.3363, Ext. 28 or
302-230-5000, Ext. 28 (International)

E-MAIL

all the required information from the
registration form to
Conference.Registration@QAedge.com

MAIL

the completed registration form to
QA Edge, Inc.
3515 Silverside Road
Suite 205
Wilmington, DE 19810
C/O Conference Registration

FAX

the completed registration form
to 302.230.5151, attention
Conference Registration

ONLINE

[Click here for online registration](#)

HOTELS

A block of rooms has been reserved at the Homewood Suites Hotel Philadelphia/Great Valley. Mention the ***Risk-Based Approach to Computer Validation*** conference when registering and receive a discounted rate of \$129/night, **a \$50/night savings!**

Both hotels provide free shuttle service to the conference.

Homewood Suites Hotel Philadelphia/Great Valley

12 East Swedesford Road
Malvern, PA 19355
800.225.5466—610.296.3500

The Desmond Great Valley Hotel and Conference Center

One Liberty Boulevard
Malvern, PA 19355
800.575.1776—610.296.9800

DIRECTIONS

**Risk-Based Approach
To Computer Validation**
May 1-3 - Malvern, PA
800.459.3363, Ext. 28

From New Jersey and East:

1. Take the Pennsylvania Turnpike to Exit 326 at Valley Forge.
2. Follow signs for Route 202 South/West Chester Exit 328. Continue on Route 202 South to the Great Valley Exit (Route 29 North).
3. At the first traffic light, turn left onto Swedesford Road. Then take the first left turn into Penn State Great Valley.
4. As you enter the driveway into the Campus, the Main Building is on the right and the Safeguard Scientifics Building is on the left. The Warren Musser Auditorium is located in the Scientifics Building.

From Reading and West:

1. Take the Pennsylvania Turnpike eastbound to Exit 326 at Valley Forge.
2. Follow signs for Route 202 South/West Chester, Exit 328. Continue on Route 202 South to the Great Valley Exit (Route 29 North).
3. At the first traffic light, turn left onto Swedesford Road. Then take the first left turn into Penn State Great Valley.
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From West Chester, Delaware, and South:

1. Take Route 202 North to the Great Valley Exit (Route 29 North).
2. Turn right at the end of the ramp and turn right again at the light onto Route 29 North.
3. Continue to the next traffic light and turn right onto Swedesford Road.
4. Continue approximately 2/10s of a mile to Penn State Great Valley on the right.
5. As you enter the driveway into the Campus, the Main Building is on the right and the Safeguard Scientifics Building is on the left. The Warren Musser Auditorium is located in the Scientifics Building.

From Philadelphia:

1. Follow the Schuylkill Expressway (Route 76 West) to Valley Forge.
2. Then follow signs for Route 202 South/West Chester Exit 328 (old Exit 26B).
3. Take Route 202 South to the Great Valley Exit (Route 29 North).
4. At the first light, turn left onto Swedesford Road. Then take the first left turn into Penn State Great Valley.
5. As you enter the driveway into the Campus, the Main Building is on the right, and the Safeguard Scientifics Building is on the left. The Warren Musser Auditorium is located in the Scientifics Building.

From King of Prussia, Norristown:

1. Follow Route 202 South to the Great Valley Exit (Route 29 North).
2. At the first traffic light, turn left onto Swedesford Road. Then take the first left turn into Penn State Great Valley.
3. As you enter the driveway into the Campus, the Main Building is on the right and the Safeguard Scientifics Building is on the left. The Warren Musser Auditorium is located in the Scientifics Building.

From the Philadelphia Airport :

1. Exit the Airport and follow the signs for I-95 South toward Delaware. Travel on I-95 South approximately five miles.
2. Take I-476 North (Exit 7) toward Plymouth Meeting. Travel on I-476 North approximately 15 miles.
3. Follow Route 202 South to the Great Valley Exit (Route 29 North).
4. Take I-76 West — Exit No. 16B — towards Valley Forge. Travel on I-76 West approximately 4 miles.
5. Take US 202 South — Exit No. 328B — towards West Chester. Travel on US 202 South approximately 7 miles. You will see an exit information sign for Penn State Great Valley.
6. Take the exit marked PA 29 North - Great Valley. Proceed along exit ramp to the traffic light at the end of the exit ramp.
7. At this traffic light, make a left turn onto Swedesford Road.
8. Make first left turn into Penn State Great Valley.
9. As you enter the driveway into the Penn State Great Valley Campus, the Main Building is on the right, and the Safeguard Scientifics Building is on the left. The Warren Musser Auditorium is located in the Scientifics Building.

REGISTRATION

**EARLY-BIRD
DISCOUNTS**
Register Today!

Take \$195 off the standard
\$995 registration fee if you
register by March 15.
You pay only \$800
for this three-day event!

Conference Attendee: _____

Title: _____

Company: _____

Business Address 1: _____

Business Address 2: _____

City: _____ State: _____ Zip: _____

Business Telephone: _____

E-Mail Address: _____

Participation subject to approval.

Special Lunch Requirement - Vegetarian

Cancellations/Substitutions:

Your registration may be transferred to another member of your organization at any time, requests for cancellation (by mail or fax only) must be received by April 24. Cancellations will not be accepted after that date. All cancellations are subject to a \$35 processing fee. Conference coordinators reserve the right to cancel the event. Conference coordinators are not responsible for airfare, hotel or other costs incurred by registrants.

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NO QUESTIONS ASKED!

Want To Take A Test Drive?

We invite you to kick our tires and take a test drive of this inclusive seminar. After joining us for this three-day session, if you feel a similar, customized session would benefit your firm's compliance team, we'll apply your registration fee to the total cost of your on-site session. Contact us for details, 800.459.3363, Ext. 28.

800.459.3363, Ext. 28 - U.S.
302.230.5000, Ext. 28 - International
www.QAedge.com

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Campus, Malvern, PA

Group Discounts Available:

Register three (3) individuals from the same company to the *Risk-Based Approach to Computer Validation* conference, and receive one complimentary registration for your fourth attendee. All four individuals must register and prepay at the same time.

Please list below the attendees' names that are part of the group discount.

1. _____
2. _____
3. _____

Payment Methods

1. Credit Card:

- Visa Master Card
 American Express

Card # _____

Expiration Date _____

Name _____

Card Verification Code _____

(3-4 digit code on the card face/back)

2. Fax Credit Card Information to:

302-230-5151

C/O Conference Registration

3. Check drawn on US Bank payable and mailed to:

QA Edge, Inc.

3515 Silverside Road

Suite 205

Wilmington, DE 19810

C/O Conference Registration



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