Gain insight into the basics of computer validation, regulations applicable to computer system validation, how to plan computer system validation for the system’s lifecycle, and developing your own system vs. purchasing a system.

### Featured Topics

#### Part 1 – Monday, May 9
**What is CSV?**
- Computer Systems Validation
  - History
  - Process Validation
  - Computer Systems Validation
  - Quality/Quality Management

#### Part 2 – Wednesday, May 11
**The Systems Life Cycle – More Parts of the Life Cycle**
- More on the SLC
- Qualification
- Risk Management
- Regulations

#### Part 3 – Friday, May 13
**Computer Systems Validation – Some Other Variations and Special Cases**
- Purchased Systems
- Large Systems/Small Systems
- Other Special Cases
  - SAS, Excel, Instrumentation
  - Prototyping
  - Infrastructure/Qualification
  - Outsourcing
  - GAMP

#### Part 4 – Monday, May 16
**Computer Systems Validation – Where Most of the Effort Goes**
- Validation Plans
- Good User Requirements
- Testing (Mostly UAT)
- Change Control

#### Part 5 – Wednesday, May 18
**The Role of Auditing in CSV**
- The Basic Audit Process
- Standard Operating Procedures
- Part 11 – What to Look for
- Predicate Rules – Importance
- Computer Systems Validation – the CSV Matrix

For information about this online training series, please contact Colleen Buckley at +1.215.442.6108 or Colleen.Buckley@diahome.org

---

**STANDARD MEMBER $1095**
**GROUP SITE $2750***

*Receive a 15% discount when you register for more than one group site at the same time.
Valid only when group sites are purchased online for this training series.

Visit [www.diahome.org](http://www.diahome.org) and enter keyword 11462.

**COURSE INSTRUCTOR**

RICHARD CHAMBERLAIN, PhD
President
ECS, Inc.

**WHAT YOU WILL LEARN**

- Basics of computer validation
- Regulations applicable to computer system validation
- How to plan computer systems validation for the system’s lifecycle
- Developing your own system vs. purchasing a system
- Differences in internal vs. vendor audits

**WHO SHOULD ATTEND**

- Computer system users
- Auditors
- Quality assurance professionals
- Regulatory affairs professionals
- Information technology professionals

See page 2 for Technical Requirements and Continuing Education Credit information.
CONTINUING EDUCATION

Drug Information Association 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; (703) 506-3275.

Drug Information Association is authorized by IACET to offer .8 CEUs for this program.

If you would like to receive a statement of credit, you must participate in each offering of the live online course, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Continuing education credits are available to learners who participate in each session of the live online course.

Continuing education credits are not available for the archived sessions of the online course.

Disclosure Policy

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

LEARNING OBJECTIVES

At the conclusion of this online training series, participants should be able to:

- Validate a computer system
- Manage a computer systems validation project
- Use computer systems validation procedures within your organization
- Implement quality and risk procedures into computer systems used in your organization

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 training material information in any type of media, is prohibited without prior written consent from DIA.

Technical Requirements for Audience Members

<table>
<thead>
<tr>
<th>WebEx OS and Browser Support</th>
<th>Windows</th>
<th>Mac OS X</th>
<th>Linux</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum System Requirements</td>
<td>Intel or AMD</td>
<td>PowerPC or Intel</td>
<td>Intel or AMD</td>
</tr>
<tr>
<td>Processor</td>
<td>JavaScript and cookies enabled</td>
<td>JavaScript and cookies enabled</td>
<td>JavaScript and cookies enabled</td>
</tr>
<tr>
<td>JavaScript</td>
<td>Active X enabled (unblocked for IE is recommended)</td>
<td>Apple Java 5 or above</td>
<td>“Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system”</td>
</tr>
<tr>
<td>Other</td>
<td>Browsers (Recommended browsers are shown in bold)</td>
<td>Internet Explorer</td>
<td>Mozilla</td>
</tr>
<tr>
<td>Internet Explorer</td>
<td>6, 7, 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mozilla</td>
<td></td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Firefox</td>
<td>2/3/3.5</td>
<td>2/3/3.5</td>
<td>2/3/3.5</td>
</tr>
<tr>
<td>Safari</td>
<td>4-Mar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chrome</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Internet Connection Speed 56k or faster  
Display 800x600 pixel resolution or greater (1024x768 pixels recommended)

To test your system compatibility, click on the link below.  
https://diahome.webex.com/ecO6OSi/eventcenter/support/eventManager.do?siteurl=diahome
**INDIVIDUAL REGISTRATION FEES**

- Standard Member: US $1095
- Standard Nonmember: US $1150

**Discounted Fees**

- Government/Academia Member (Full-time): US $550
- Government/Academia Nonmember (Full-time): US $600

**GROUP SITE REGISTRATION FEE**

US $2750

Receive a 15% discount when you register for more than one group site attending this online training series. All groups must register at the same time to receive the 15% discount. This discount is valid only for online purchases.

**PAYMENT**

Please check the applicable category below:

- Academia  
- Government  
- Industry  
- CSO  
- Student

Please check payment method:

- CREDIT CARD number may be faxed to: +1.215.442.6199. Non-U.S. credit card payments will be subject to the currency conversion rate at the time of the charge.

Visa  
MC  
AMEX  
Exp Date ___________________________

# ____________________________________________________________________

Signature __________________________________________________________

**Join DIA now to qualify for the member fee and to receive all the benefits of membership for a full year!**

Membership

US $140 □

Go to http://www.diahome.org/membership

**Please complete the information below and fax this entire page to DIA +1.215.442.6199.**

**Last Name**

**First Name**

**Middle Initial**

- Dr.  
- Mr.  
- Ms.

**Degrees**

**Job Title**

**Affiliation (Company)**

**Address**

**City**

(please write your address in the format required for delivery to your country.)

**State**

**Zip**

**Country**

**Email** (Required for confirmation.)

**Telephone Number**

**Fax Number** (Required for confirmation.)

Registered attendees will receive a confirmation letter with access instructions one week prior to the Online Training Series.