Computer System Validation - Reduce Costs and Avoid 483s

Description: This Computer System Validation Training course will explore proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. Today, the FDA performs both GxP and Part 11 inspections, the Europeans have released an updated Annex 11 regulation that expands Part 11 requirements and companies must update their systems and processes to maintain compliance.

Many companies outsource IT resources and are involved in Software as a Service (SaaS) and cloud computing. These vendors are not regulated, and therefore, regulated companies must ensure compliance for both infrastructure qualification and computer system validation to avoid FDA form 483s and Warning Letters.

This Computer System Validation Training course is intended for these regulated companies, software vendors, and SaaS/cloud providers.

The seminar instructor will:

- Address the latest computer system industry standards for data security, data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.
- Help participants understand the specific requirements associated with local and SaaS/cloud hosting solutions.
- Illustrate the importance of validating the quality process and every computerized system used in laboratory, clinical, and manufacturing settings.
- Demonstrate how to decrease software implementation times and lower costs using a 10-step risk-based approach to computer system validation.
- Review recent FDA inspection trends and discuss how to streamline document authoring, revision, review, and approval.

Learning Objective:

- Understand what is expected in Part 11 and Annex 11 inspections
- Avoid 483s and Warning Letters
- Learn how to buy COTS software and qualify vendors
- Implement a computer system using risk-based validation to gain maximum productivity and reduce cost by as much as two thirds
- Requirements for local, SaaS, and cloud hosting
- How to select resources and manage validation projects
- "Right size" change control methods that allows quick and safe system evolution
- Minimize the validation documentation to reduce costs without increasing regulatory or business risk
- Write test cases that trace to elements of risk management
- Protect intellectual property and keep electronic records safe

Ordering:

Order Online - http://www.researchandmarkets.com/reports/4085026/

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct.

Product Name: Computer System Validation - Reduce Costs and Avoid 483s
Web Address: http://www.researchandmarkets.com/reports/4085026/
Office Code: SC

Product Format
Please select the product format and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1 + Day 2</td>
<td>USD 1999</td>
</tr>
<tr>
<td>Single User</td>
<td>USD 1999</td>
</tr>
</tbody>
</table>

*The price quoted above is only valid for 30 days. Please submit your order within that time frame to avail of this price as all prices are subject to change.

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: [ ] Mr  [ ] Mrs  [ ] Dr  [ ] Miss  [ ] Ms  [ ] Prof
First Name: ___________________________ Last Name: ___________________________
Email Address: * ___________________________
Job Title: ___________________________
Organisation: ___________________________
Address: ___________________________
City: ___________________________
Postal / Zip Code: ___________________________
Country: ___________________________
Phone Number: ___________________________
Fax Number: ___________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

If you have a Marketing Code please enter it below:

Marketing Code: __________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World