"...These network program systems are deficient in that: The network program lacked adequate validation and/or documentation controls." — EXCERPT FROM A FDA WARNING LETTER DATED JULY 2000

Hurry! Special discounts expire soon! See page 7 for details.

NETWORK INFRASTRUCTURE QUALIFICATION

Strategies for Complying with 21 CFR Part 11

Two Day National Conference January 28 & 29, 2003

Conference Workshops January 27-28, 2003 • San Francisco, CA • The Sir Francis Drake Hotel

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Stephen C. Arnold, Ph.D.
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Process Manager
Computer Validation
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Anthony Fiorito
VP Engineering
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Quality Engineering Manager
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Deborah A. Fullam, M.S.
Manager, Computer & Automation Validation
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Madhavi Ganesan
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Kevin C. Martin
Director of Sales and Marketing
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Director, Analytical Chemistry
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- ✓ Apply 21 CFR Part 11 Guidelines to Your **Network Infrastructure**
- ✓ Develop Effective Documentation for Your **Infrastructure Requirements**
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- ✓ Implement a **Compliant IT Infrastructure** Roadmap
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NETWORK INFRASTRUCTURE QUALIFICATION

Dear Colleague:

Is your network infrastructure Part 11 compliant? Not sure?

If you attend only one conference this year, make sure it's CPT's **Network Infrastructure Qualification** event.

In today's highly regulated environment, how your company handles information material flow will have a huge impact on profitability and competitiveness. Your IT systems must be able to measure up to the FDA's strict standards. To make sure they do, the systems must be tested, sampled, and validated. And you need to know how to comply with the FDA's regulations and be prepared for inspections in order to remain competitive and focus on long-term growth. This conference will show you how to:

- Apply the FDA's Part 11 requirements to your network infrastructure
- Identify the components of your network that need to be qualified
- Recognize the value of network qualification, maintenance techniques, and documentation tools
- Strategically manage your laboratory and manufacturing network operations
- Define roles and responsibilities for your IT/QA team to prepare for FDA inspections
- Develop a strategy to qualify your networked systems efficiently and effectively

Network Infrastructure Qualification includes over **25 hours of detailed information** on the best ways to prepare your network infrastructure for Part 11 compliance. And more than just the speakers on the program — you'll also hear how your colleagues and peers are handling the same issues facing you!

Whether your company is at the assessment, remediation, or implementation phase of network qualification, you will gain valuable insight into today's major issues facing leading pharmaceutical/biotechnology companies through the hands-on experience of our speakers.

Don't wait for the feared warning letter to cross your desk before you start incorporating strategies for achieving compliance within your network infrastructure. Learn how pioneering companies have approached qualifying networked systems for Part 11 compliance **NOW**.

Sincerely,
Michelle A. Liu
Director of Pharmaceutical Conferences
mliu@pharmaceuticaltraining.us

P.S. Don't miss our interactive, in-depth workshops! Register today!

Who Will Attend

This conference is designed for executives in the Pharmaceutical, Biotechnology, Medical Device and Diagnostics industries who are involved with:

INFORMATION TECHNOLOGY (IT)
INFORMATION SERVICES (IS)
COMPUTER/SOFTWARE VALIDATION
QUALITY SYSTEMS ENGINEERING
QUALITY ASSURANCE/QUALITY CONTROL

TEAM DISCOUNTS

With all of the critical information that is going to be discussed during this two-day conference, you are going to want to make sure that all of your key team members are present. To encourage team participation in this event IQPC is pleased to offer you the following discounts:

Number of Attendees	*Cost Per Attendee*	*Savings Of:*
1	*$1,899*	-
2	*$1,709*	**10%**
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ABOUT THE EVENT ORGANIZER

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CPT is the world's premier training and development resource for drug and medical device development learning and performance. CPT provides objective information, research, analysis and practical information from market research, the knowledge and experience of its members, training courses, conferences, e-newsletters, and partnerships.

About the Venue

San Francisco — a city of unforgettable sights and exotic attractions, a city of culture, romance and history. Trends come and go. A true classic withstands the test of time. The Sir Francis Drake Hotel in downtown San Francisco has been in style since 1928. A mixture of timeless elegance and high style, the landmark San Francisco hotel offers historic accommodations in the heart of Union Square. The downtown Sir Francis Drake Hotel is a San Francisco legend, just steps from Moscone Convention Center, the Financial District, Nob Hill, Chinatown, SOMA, and the Theatre District. The Beefeater doorman, exquisite service, and offbeat style all create a unique hotel presence on vibrant Union Square, San Francisco.

"More than 40 non-compliance citations have been issued so far, primarily for deficiencies in security, audit trails, and data storage and retrieval." — **Gartner, Inc.**

A Note From CPT about Workshops… *Our workshops are short training courses attached to our conferences to give our participants real world, practical experience through exercises, discussions and case study analyses. CPT workshops are specially designed to optimize sharing of best practices and practical tips through an in-depth look at niched topics.*

A Pre-Conference Workshop • Monday, January 27th, 2003 • 9:00am - 12:00pm

Implementing a Compliant IT Infrastructure Roadmap

Although software may have the ability to be compliant with regulatory authorities, the environment under which it is used must also be capable of supporting it as well. This workshop provides a process model for implementing an appropriate IT Infrastructure (based on GAMP) for supporting compliant systems. The workshop will include Applicable regulatory predicate rules and provide an overview of Good Electronic Records Management practices. The described approach uses an actual case study from a major pharmaceutical company. This workshop:

- Provides a roadmap to be followed for implementing compliant IT practices
- Describes how the process model was developed
- Identifies the activities which must be in place to support a regulated system
- Examines the deliverables which result after implementing the infrastructure
- Standardizes compliance practices across departments
- Provides an understanding of applicable regulations that affect the IT activities

About your Workshop Leader:

Kevin C. Martin, Director of Sales & Marketing at **CimQuest**, has twenty-six years of pharmaceutical operating company Experience, which include stints at Wyeth Laboratories and McNeil Pharmaceutical. He is a former member of the PhRMA Computer Systems Validation Committee, was involved in the industry response to the Part 11 ANPR, and is a former chairperson for the Pharmaceutical SIG/GMP Computer Validation SubCommittee for the POMS User Group. He is a former chair of the ISPE Delaware Valley Chapter Computer System Validation Sub-Committee, a Core Team member for the PDA Part 11 Task Group, and the GAMP Americas Steering Committee. He received his Bachelors degree in Chemistry from Delaware Valley College of Science and Agriculture and his Master of Engineering in Manufacturing Systems from Penn State University.

B Pre-Conference Workshop • Monday, January 27th, 2003 • 1:30pm - 5:00pm

Qualifying Computer and Network Infrastructures (CNI's) for Regulatory Compliance

21 CFR Part 11 requires that your computer and network infrastructure (CNI) be qualified and that any qualification methodology produce a high degree of assurance that the (CNI) provides confidential, accurate, authentic, and reliable electronic records that can be used in drug submissions. This session describes how the qualification methods have been designed to support a (CNI) that is managed, maintained, and extended in real-time. This session begins with a discussion of the need for an infrastructure qualification methodology, and an overview of the requirements of such a methodology. This session will teach you how to qualify your computer and network infrastructure using a specific methodology, such as Concurrent Computer Configuration Qualification (C3Q) methodology, which focuses on the Computer and Network Infrastructure Qualification (CNIQ) standard practices. The discussion continues with how (CNIQ) methods ensure the confidentiality, integrity, and availability of systems and records via the six key concepts of:

- Atmosphere of Compliance
- Formal System Specifications
- Replication of Proven Arrangements
- Affirm Vendor Claim
- In-service Qualification
- Dynamic Configuration and Document Management

The speaker pays particular attention to the (CNIQ) techniques that enable "real time" qualification of an operating computer and network infrastructure (CNI). Particular focus is placed on the concepts of the arrangements, qualification plans, and history records.

About your Workshop Leader:

Anthony Fiorito, VP Engineering for **The Hollis Group,** has eighteen years of experience in the design and operation of computer systems in regulated industries. In his present capacity, he designs and manages qualified computer and network infrastructures (CNI) for both Hollis Group and client facilities. His expertise includes qualification of computer systems and infrastructure, information security (INFOSEC), and electronic archiving systems and technology. Mr. Fiorito graduated from Georgia Institute of Technology with a B.S. in Physics. He also holds a Master of Engineering Science from Penn State University.

C Pre-Conference Workshop • Monday, January 27th, 2003 • 5:30pm - 9:00pm

Evidence is the Best Answer: Preparing for Part 11 Compliance with a Simple, Cost-Effective Validation Program

The bottom line on CFR 21 Part 11 is that eventually, a compliance officer is going to come knocking with questions about your infrastructure. And all answers are subject to proof. Who built that server? When? What methodology was employed? When was it last validated? Answer with evidence and the officer goes away. This workshop will examine cost-effective strategies for initiating ongoing compliance programs, including the establishment of baseline configurations, change tracking, and audit trail maintenance which will give you the implacable proof that all is as you say in your IT infrastructure. The workshop, led by Part 11 engineering consultant Dave Wilson, includes case studies presented by major pharmaceutical company representatives on how they compile and manage evidence to prove Part 11 compliance. This will be a lively session with no-nonsense advice on how Part 11 will confront your organization, and how managers can best prepare for compliance, so CEOs avoid the 483 warning letter from the FDA and the possible fines!

This workshop will enable you to:

- Outline the evidence you will need to prove Part 11 compliance
- Evaluate manual and automated processes for gathering compliance data
- Establish workable approaches for initiating ongoing systems validation and compliance monitoring
- Examine the types of questions compliance officers will ask, and how to answer each with implacable evidence

About your Workshop Leader:

David Wilson is a renowned validation engineering expert and project manager who has consulted on Part 11 compliance and systems validation for such companies as Pfizer Central Research, and has managed numerous infrastructure management and IT security projects for commercial and government installations in the United Kingdom.

DAY 1 Tuesday, January 28th, 2003

8:00 Registration and Continental Breakfast

8:45 Chairperson's Welcome and Opening Remarks

9:00 Case Study: Pharmacia's Path to Network Qualification

Computer validation principles and requirements have become well-defined over the past decade. In recent years, there has been increased emphasis on network qualification throughout the pharmaceutical industry and FDA. The application of computer validation principles to the qualification of networks requires an acute appreciation for the nature of infrastructure operations. In July of 2000, Pharmacia received an FDA 483 citing them for not "validating" their network. In response, Pharmacia embarked on a corporate-wide program to qualify crucial site networks (LANs). In this presentation, you will see how Pharmacia applied computer validation principles to define network qualification and how the program was structured, executed, and verified.

- Gaining an overview of responding to an FDA 483
- Discovering how Pharmacia approached the re-evaluation of their network infrastructure
- Understanding "state of control" and good network management practices to qualify networks
- Learning about Pharmacia's Site Network Qualification Program

Bob Herr
Senior Manager, IT Quality Assurance
PHARMACIA

10:00 Interpreting 21 CFR Part 11 Guidelines for Networked Systems

Establishing the appropriate criteria for FDA-audit readiness for your networked systems is the first step to achieve compliance. In this session, you will learn what the FDA is looking for and what areas need to be covered.

- Evaluating the impact of 21 CFR Part 11 to your networked systems
- Learning what the FDA expects
- Reviewing recent observations and citations for non-compliance
- Assessing major challenges associated with Part 11 interpretation

Madhavi Ganesan
Manager of Corporate Computer Validation
WATSON LABORATORIES

10:45 Morning Refreshment Break

11:00 Developing a Network Strategy that Meets Regulatory Compliance

This session will explore and discuss regulatory expectations related to Network and Computing environments. A comprehensive and effective methodology will be suggested. Actual experiences from industry will be presented.

- Defining the OSI Model
- Evaluating applicable US FDA regulations, including 21 CFR Part 11
- Identifying security issues and challenges
- Examining the major validation elements, strategy, and approach for your network infrastructure

Orlando Lopez
Executive Consultant, CSV
NETWORK AND COMPUTING SERVICES, A J&J COMPANY

11:45 Luncheon for Speakers and Delegates
Sponsored by **NuGenesis Technologies**

1:15 Defining the Essential Components for your Network Infrastructure

This presentation examines the validation process applicable to infrastructures and supporting systems to keep the networks and infrastructures within the expectations of regulatory compliance. This session will cover network and computing hardware (i.e. servers, WAN/LAN components, and routers) and software related tools (system-level software, monitoring tools, scripts, middleware, and layered products).

- Defining the scope of the validation process
- Gaining an overview of the network, computing hardware, and tools validation process
- Determining the appropriate documentation requirements and standard operating procedures

Orlando Lopez
Executive Consultant
NETWORK AND COMPUTING SERVICES, A J&J COMPANY

2:00 Tracking Audit Trails: Implement Ways to Handle Audit Trails Effectively

Audit trails are a necessary component of records management for ensuring data security and integrity within your network infrastructure. In this session, you will learn the specifics of audit trail compliance for Part 11 compliance and strategies for effectively managing your audit trail. A case study using NuGenesis Scientific Data Management (SDMS) and its ability to generate accurate complete copies of records and the implementation of computer generated, time-stamped audit trails will also be presented. Topics include:

- Understanding data management essentials — unlocking potential, data handoff and data security
- Meeting audit trail requirements within your networked systems
- Evaluating current approaches for design and implementation

Victoria V. Lander
Development Manager
NUGENESIS TECHNOLOGIES

2:45 Afternoon Refreshment Break

3:00 Paper Trail: Developing Effective Documentation for Your Infrastructure Requirements

Developing and maintaining documentation is critical to installing and supporting a compliant network infrastructure. Documentation must be specific enough to identify the complete network configuration. This presentation describes the types of documentation that should be required and how engineering change controls should be used to maintain that documentation. Topics addressed include:

- Understanding the applicable types of drawings and other engineering documentation
- Defining the level of detail included in key documentation
- Developing appropriate document change control in the engineering environment
- Identifying when engineering change control should and should not apply

Joshua Froimson
Quality Engineering Manager
ABBOTT BIORESEARCH CENTER

3:45 Outsourcing Network Infrastructure Qualification

Selecting a vendor to qualify your network infrastructure is one of the most critical decisions you will make. In addition to the main task of qualifying your network infrastructure, you will need to evaluate proposals, determine roles and responsibilities, coordinate the project schedule, stay within your budget, and develop a plan for turnover. You must also provide documentation that is easily updated and will satisfy regulatory requirements. Topics addressed include:

- Understanding the Request For Quote (RFQ) process
- Defining project coordination, oversight, and documentation requirements
- Examining the process of interviewing and deciding between vendors
- Managing your network once the vendor is no longer on-site

Deborah A. Fullam, M.S. Computer Science
Manager, Computer & Automation Validation
SCHERING-PLOUGH

4:30 Panel Discussion: Understanding the Critical Issues of Achieving Regulatory Compliance Within Your Network Infrastructure

In this expert panel discussion, the participants address your major concerns with first hand knowledge and experience. Issues discussed include but are not limited to:

- Interpreting 21 CFR Part 11 guidelines for networked systems
- Examining the critical issues associated with achieving compliance
- Discussing strategies to qualify networked systems efficiently and effectively

Moderator:
Bob Herr
Senior Manager, IT Quality Assurance
PHARMACIA

Panelists:
Joshua Froimson
Quality Engineering Manager
ABBOTT BIORESEARCH CENTER

Deborah A. Fullam, M.S. Computer Science
Manager, Computer & Automation Validation
SCHERING-PLOUGH

Madhavi Ganesan
Manager of Corporate Computer Validation
WATSON LABORATORIES

Orlando Lopez
Executive Consultant, CSV
NETWORK AND COMPUTING SERVICES, A J&J COMPANY

5:15 Chairperson's Day One Closing Remarks

D Conference Workshop • Tuesday, January 28th, 2003 • 5:30pm - 9:00pm

Pragmatic, Effective Security for Web-Enabled, ePharma Systems

This workshop is designed to give senior managers and steering team members the technical background needed to evaluate, manage, and oversee the security risks associated with ePharma projects. The first half of the workshop is a security technology overview that focuses on the key technologies of:

- Authentication & Digital Signatures
- Digital Certificates and Identity Assurance
- Encryption and Intellectual Property Protection
- Virtual Private Networks for Secure Communications

The second half of the workshop is a case study of a fictitious company that is developing a follow-on therapy that promises to dramatically improve the quality of life in certain patient groups. The company initiates a web-based project to recruit study participants, research physicians, and clinics. The company wrestles with the difficult challenges of guarding participant privacy, assuring accurate and timely information dissemination, and protecting their intellectual property. The discussion focuses on the pragmatic, compliant application of INFOSEC technology to solve business and clinical research problems.

About your Workshop Leader:

Anthony Fiorito, VP Engineering for **The Hollis Group,** has eighteen years of experience in the design and operation of computer systems in regulated industries. In his present capacity, he designs and manages qualified computer and network infrastructures (CNI) for both Hollis Group and client facilities. His expertise includes qualification of computer systems and infrastructure, information security (INFOSEC), and electronic archiving systems and technology. Mr. Fiorito graduated from Georgia Institute of Technology with a B.S. in Physics. He also holds a Master of Engineering Science from Penn State University.

DAY 2 Wednesday, January 29th, 2003

8:00 Continental Breakfast

8:45 Chairperson's Day Two Opening Remarks

9:00 Information Technology and 21 CFR Part 11 Compliance — A Comprehensive Approach to IT's New Quality/ Compliance Responsibilities

IT Professionals have a new found compliance responsibility since the enactment of 21 CFR Part 11 regulations. In this presentation, you will hear actual case studies that address the systemic issues underlying implementation of Part 11 and the roles and responsibilities of IT professionals, for both network and PC based applications. The audience will learn an effective, yet simple roadmap to develop an IT Quality/Compliance Program.

- IT Professionals and 21 CFR Part 11 Implementation — Myths and Realities
- Gaining an overview of how Part 11 Compliance affects the roles and responsibilities for IT professionals
- Developing an IT/Quality Compliance Program and System Development Life Cycle Model
- Evaluating documentation issues addressing procedures and protocols
- Understanding QA/Compliance System Training Issues associated with IT professionals

Shahid T. Dara, BPharm, MS (Medicinal Chemistry), MPharm (Industrial Pharmacy)
Process Manager Computer Validation
ASTRAZENECA — WILMINGTON, DELAWARE

9:45 Case Study: Maintaining Change Control of 21 CFR Part 11 — Compliant Systems

Genentech has been implementing and maintaining 21 CFR Part 11 compliant Enterprise applications since 1998. Concurrent with these deployments, the company has developed a comprehensive Change Control system to ensure all changes are assessed for impact to regulatory expectations, lot release, validation, and QC Test Methods and Stability. In this presentation, you will gain an overview of Genentech's Change Control system and how the company assures changes to validated systems while maintaining Part 11 Compliance.

- Developing a Change Control philosophy
- Implementing a comprehensive Change Control system
- Making signatures meaningful and reducing the number of approvals on changes
- Improving change request turnaround times using business process automation
- Taking the Quality Systems approach to your Change Control system

Peter W. Bland
Senior Manager, QA Change Control
GENENTECH, INC.

10:30 Morning Refreshment Break

11:00 Evaluating Critical Issues for a Compliant Network Infrastructure in a Manufacturing Environment

Establishing and managing an effective network infrastructure for Part 11 Compliance represents a major challenge for pharmaceutical/biotechnology companies. In this presentation, you learn to identify what components of your network need to be qualified and how to address these issues systematically and specifically for a manufacturing setting. Topics addressed include:

- Addressing physical and logical security for networked systems
- Determining levels of criticality
- Developing strategies for audit trails, backup and disaster recovery
- Managing change control within a manufacturing setting

Michael N. Blackton
Associate Director of Validation Services
MILLENNIUM PHARMACEUTICALS, INC.

11:45 Case Study: Qualifying on a Budget — Establishing a Risk-Based Approach to Achieve Network Infrastructure Compliance

This presentation provides an in-depth case study on how Inhale Therapeutic Systems, Inc. developed a network infrastructure to minimize cost and maximize efficiency. In this session, you will how to qualify networked systems using a risk-based approach and evaluate the considerations that are needed to reduce the impact on your company's bottom line. Topics to be included in this discussion are:

- Identifying the major considerations and common issues from an IT perspective
- Learning the reasoning behind Inhale's decisions
- Understanding the criteria that can affect your company's cost and efficiency

Michael Lamb
Director of Network and Operations
INHALE THERAPEUTIC SYSTEMS, INC.

12:30 Luncheon for Speakers & Delegates

2:00 Case Study: Designing and Validating a Laboratory Data System

This case study will describe how the system design impacts the scope of validation and maintenance of a computerized system. In this session, you learn how Gilead approached network and computer system design issues to allow rapid implementation, validation, and manageable change control documentation. Specific design considerations to be discussed include: security, disaster recovery, and ease of maintenance. Additional topics that will be discussed include network qualification vs. Computer System Validation and Part 11 issues.

- How IT professionals can make their lives easier in a GMP environment and provide a more robust system
- How QA or Validation professionals can reduce change control documentation
- How design can allow you to install the servers, configure the application, and validate the system in less than four months

Thomas R. Weber, Ph.D.
Director, Analytical Chemistry
GILEAD SCIENCES

2:45 Implementing the Appropriate Computer Technologies to Meet your Long-Term Archiving Needs

This presentation highlights how computer technologies and procedures for use of these technologies can meet the FDA 21 CFR Part 11 electronic record archiving guidance document. The presentation will be organized based on what aspect of the guidance document can be met by what technologies and procedures. It addresses what information about the records need to be gathered in order to meet this guidance and what areas of computer expertise are needed to implement and operate the appropriate technology.

- Understanding how long-term archiving within Part 11 regulations can be addressed by different computer technologies
- Knowing the questions that need to be asked about records in order to archive them on computer

- Acquiring a laymen's description of the technologies involved in archiving electronic records
- Identifying areas of computer expertise that can help implement and operate these technologies

Stephen C. Arnold, Ph.D.
Software Quality Engineer
CHIRON CORPORATION

3:30 Afternoon Refreshment Break

4:00 Round Table Discussion: Network Infrastructure Qualification — Past, Present, Future

This round table panel provides insight into how the process of qualifying networked systems has evolved since the inception of 21 CFR Part 11. Hear perspectives about the lessons learned from the past, the current state of the industry, and the challenges of network infrastructure qualification for the future.

Moderator:
Bob Herr
Senior Manager, IT Quality Assurance
PHARMACIA

Panelists:
Michael N. Blackton
Associate Director of Validation Services
MILLENNIUM PHARMACEUTICALS, INC.

Peter W. Bland
Senior Manager, QA Change Control
GENENTECH, INC.

Shahid T. Dara
Process Manager Computer Validation
ASTRAZENECA

Michael Lamb
Director of Network and Operations
INHALE THERAPEUTIC SYSTEMS, INC

Thomas R. Weber, Ph.D.
Director, Analytical Chemistry
GILEAD SCIENCES

4:45 Chairperson's Closing Remarks & End of Conference

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Scholarships & Discounts Available
Center for Pharmaceutical Training sets aside a limited number of scholarships that may be applied to its conferences for delegates from the non-profit sector, government, military organizations and academia. For more information about scholarships to this event, please call Michelle A. Liu at (212) 885-2747.

Lodging Information: Sessions for the Conference & Workshops will be held at:

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