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

Save $300
When you Register by July 11th!

CPT's 2nd

IT Infrastructure Qualification

Summit 2003

Best Practices for Computer and Network Infrastructure Qualification

Two Day National Conference September 23 & 24, 2003

Conference Workshops September 22, 2003 • Doubletree Hotel—Philadelphia, PA

Featuring an Unparalleled Speaker Faculty that Highlights Case Studies, Practical Strategies, and Do's and Don'ts for Complying with FDA Regulations. Highlighting Real-World Examples From:

Michael N. Blackton
Associate Director of Validation Services
MILLENNIUM PHARMACEUTICALS

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

Joshua Froimson
Quality Engineering Manager
ABBOTT BIORESEARCH CENTER

Michael L. Rutherford
Manager, Corporate Computer Systems QA
ELI LILLY AND COMPANY

Madhavi Ganesan
Manager, Corporate Computer Validation
AVENTIS-BEHRING

Steve Coates
Associate Director, Computer Validation
WYETH

Ralph L. May
Associate Director, Systems Integration
NOVARTIS PHARMACEUTICALS CORPORATION

Michael Lamb
Director of Network and Operations
NEKTAR THERAPEUTICS

William Devorick
Manager, MIS Compliance
WEST PHARMACEUTICAL SERVICES

Debbie Everidge
Director, IT Infrastructure
SOLVAY PHARMACEUTICALS

David Harrison
Sr. Director, IT Global Infrastructure
ELAN PHARMACEUTICALS

Randy Slain
Network Support Manager
PFIZER

AND MUCH MORE...

- 4 In-Depth Workshops
- 2 Interactive Panels
- 1 Valuable Conference

Featuring How to:

- ✓ **Qualify Your Computer and Network Infrastructure**
- ✓ **Prepare for FDA Inspections Through Real-Life Experiences**
- ✓ **Design An Infrastructure Qualification Master Plan**
- ✓ **Analyze Informative Case Studies from Leading Pharmaceutical/ Biotechnology Companies**

Presented by CPT Center for Pharmaceutical Training

A division of IQPC sharing business solutions

Media Partners: Bio-IT World Technology for the Life Sciences; Pharmaceutical Technology North America; Validation Times

Current Exhibitors: GE Life Sciences; PC

Register Today! Call 1-800-882-8684, ext. 5158 or 973-812-5158 or Visit: www.CPTPharma.org Keyword: IT Infrastructure

IT Infrastructure Qualification

Summit 2003

Top 23 Reasons on Why You Should Attend IT Infrastructure Qualification Summit 2003

1. Qualify A Computer And Network Infrastructure System From The Initial To Final Stages
2. Establish Effective Tools And Practical Guidelines While Qualifying The Data Center And The Environment In Which The Servers Reside
3. Qualify Data Center Environment And Generate Appropriate Documentation
4. Write Test Scripts And Developing The Test / Design / Requirements Matrix
5. 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
6. Develop An IT/Quality Compliance Program And System Development Life Cycle Model
7. Develop And Maintain Documentation Is Critical To Installing And Supporting A Compliant Network Infrastructure
8. Identifying When Engineering Change Control Should And Should Not Apply
9. Achieve A Documented State Of Control For Information Technology Infrastructure
10. Establish The Role Of Quality And Compliance In Infrastructure Activities
11. Develop And Execute A GXP Compliant Infrastructure Qualification Plan
12. Assess The Data Necessary To Complete The Qualification And Whether The Data, As It Exists In Your Organization, Meets The GXP Standards Required To Be Included In Your Report
13. Comprehend At A Higher Level How To Do Risk Assessment After The First Qualification To Determine When It Is Necessary To Completely Re-Qualify Vs. Partial Retesting
14. Establish The Essential Components Of Your Workstation As An Integral Part Of The Overall Qualification Process
15. Define Your Hardware, Operating System And Validated Applications
16. Differentiate Between "Validation" Vs. "Qualification"
17. Create An Effective Template For IQ/OQ/PQ
18. Utilize An Effective CSV Audit As A Risk Analysis Tool
19. Redesign The Change Control Process Into An Integrated Quality Systems Approach
20. Incorporate Security Measures To Infrastructure Qualification Plan
21. Qualify On A Budget: Establishing A Risk-Based Approach To Achieve Infrastructure Compliance
22. Qualify Networked Systems, Workstations, And Servers Using A Risk-Based Approach: How To Identify The Major Considerations And Common Issues From An IT Perspective
23. Apply Prevention Techniques, Recovery Techniques, And Recovery Plans While Balancing Business Recovery Priorities

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)**
- **Network and Data Center Operations**
- **Computer/Software Validation**
- **Quality Systems Engineering**
- **Quality Assurance/Quality Control**

If You Attend Only One Conference This Year, Make Sure it's CPT's IT Infrastructure Qualification Summit.

It does not matter whether your company is at the assessment, remediation, or implementation phase of infrastructure qualification, you gain valuable insight into today's major issues facing leading pharmaceutical/biotechnology companies through the hands-on experience of our speakers. Don't take our word for it — hear what past attendees have said about our event:

"Since I come from an operations background, I've grappled with the traditional CSV approach, the Hollis Group's CNI approach, and the conference clarified the differences for me. As a result of attending the conference, I was able to give a talk to Genentech validation engineers on the topic of Infrastructure Qualification."

—Roy Takai, CIT Validation Manager, GENENTECH

"This conference exceeded my expectations…it was not a vendor show — with it, I was able to do 'benchmarking' and obtain knowledge about what's happening in the industry."

—Jorge Sosa, Sr. Technical Analyst, BAXTER HEALTHCARE CORP.

"I liked the broad variety of topics – from integrating 'pure' technology to sharing organizational procedures…I got much more than I expected!"

—Tanya Cherkov, Project Manager, AMGEN, INC.

Register Today! Call 1-800-882-8684 or Visit: www.CPTPharma.org Keyword: IT Infrastructure

A Note From CPT about Workshops... CPT workshops are short, interactive 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 practice tips through an in-depth look at niched topics. These vital sessions are designed to give you an "A to Z" roadmap approach for tackling common challenges.

A Interactive Morning Workshop • Monday, September 22nd, 2003 • 8:30am—11:30am

HOW TO ESTABLISH PROCEDURAL CONTROLS AND QUALIFY YOUR DATA CENTER

Managing your server and data center requirements is an integral part of your infrastructure qualification plan. The process that must be employed to formalize minimum specifications and functional standards involves generating copious amounts of supporting documentation and data. Establishing effective tools and practical guidelines include qualifying the data center and the environment in which the servers reside.

In this workshop, attendees create tolerance levels for their data center environment and server functionality and gain an understanding of the various challenges associated with qualifying your data center. This interactive session covers what you must know regarding the topology of the networks, wiring, temperature monitoring, and HVAC systems. Practical guidelines are illustrated through case study examples and workshop discussion. Topics include how to:

- Formalize minimum specifications for your server
- Qualify data center environment and generating appropriate documentation
- Establish specs for data center functions and tolerance levels
- Identify the activities which must be in place to support a regulated system
- Provide an understanding of applicable regulations that affect the IT activities

About your Workshop Leader:

Steve Coates, Associate Director of Computer Validation, at **Wyeth** has 27 years experience in Pharmaceutical Industry Quality Assurance with 13 years of laboratory management and the past 14 years with responsibilities for the compliance of GMP impacted computer systems. He is a Certified Software Quality Engineer (American Society for Quality) and a core team member of the PDA Good Electronic Records Management (GERM) guidance. Other professional affiliations include the International Society for Pharmaceutical Engineering (ISPE) and the Information Systems Security Association (ISSA).

B Interactive Luncheon Workshop • Monday, September 22nd, 2003 • 1:30pm—4:30pm

VERIFICATION, VALIDATION, AND QUALIFICATION OF A PAPERLESS SYSTEM

In this case study-based workshop, attendees gain a unique opportunity to witness the process of qualifying a computer and network infrastructure system from the initial to final stages. Find answers to questions regarding IT/QA interactions, managing relationships with an outside consultant/vendor, and understanding software and system lead roles in your organization. This session includes a description of the systems integration quality assurance methods used to design and build a paperless Clinical Trial Material System (CTMS) at the start-up company ACCULOGIX. The lead instructor presents the overall Verification, Validation, and Qualification (VV&Q) strategy for the project, the methodological basis for that strategy, and the major project milestones and deliverables for the CTMS. Several individual area leads present the particular methods and tactics used to (VV&Q) the system.

As of the writing of this abstract, the design / build / deploy team is approximately halfway through the test phase of the project. "Go-live will occur well before the conference. Thus, the tutorial presents the latest information available from this very "real world" case study. All of the discussion leaders are the individuals who worked on the project and "got the job done." Questions and discussions are encouraged throughout the session.

About your Workshop Leaders:

AccuLogix provides clinical supply logistic support to Pharmaceutical, Biopharmaceutical, and Medical Device companies. Their professional pharmacy services include packaging, labeling, storage and distribution. Ecologic has invested in "best in class" people and facilities to support traditional and VRS-based trials with 100% accurate, "Smart Label" fulfillment systems. They have also made the commitment to develop and operate 100% compliant, paperless systems to manage automated, temperature-controlled, humidity-controlled, and vaulted secure environments.

SUBJECT / VV&Q AREA	PRESENTER	TITLE
Compliance as a Business Objective	Chuck Gettis	Bus. Dev. Manager
Requirements, Design, and Test as a Coordinated Development Effort	Phil Conner	Software Project Lead
Writing Test Scripts and Developing the Test / Design / Requirements Matrix	Barbara Meserve	System Test Lead
Qualifying a Computer and Network Infrastructure for a "Regulated" CTMS	Jim Mancini	Director, IT
Tracking, Controlling, and Documenting Changes Throughout Development	Frank Keyack	Director, QA
Estimating, Justifying, and Tracking the Cost of Integrated System VV&Q	Tim Brewer	General Manager
Moderator	Thomas Quinn	President, The Hollis Group, Inc.

C Interactive Afternoon Workshop • Monday, September 22th, 2003 • 5:00pm - 8:00pm

FDA AUDIT PREPARATION: ENSURING COMPLIANCE FOR YOUR NETWORK INFRASTRUCTURE

As the backbone for every computer system, your network infrastructure is an integral part of your organization's functionality – moreover, the FDA is watching. Can you prove to the FDA that you are in control? Network infrastructure qualification was once all but overlooked but the spotlight has been pointed at what may have become an ugly beast of tangled wires and mysterious connections driven by ad hoc emergency reconfigurations and the need to add capacity yesterday.

This session addresses the issues associated with Infrastructure and Network Qualification and defines critical considerations you must know when planning your route to a solid baseline. Highlights include a first-hand account from a network manager that felt the ramifications of the audit process and rallied a team to respond to a 483 warning letter. This workshop presents real-life issues and sparks interactive discussions with some of today's industry leaders, who are ready to share their experiences and perspectives with you. Topics addressed include:

- Qualification versus Validation–how are they different?
- Examining common FDA reasons for the 483
- Conducting a risk-based assessment of your computer and network infrastructure
- Preparing for an FDA audit – what you must know
- Remediation tactics and strategies for your network infrastructure qualification
- Establishing a baseline through the qualification process
- Selecting an effective and efficient approach
- Assessing key components of your validation plan
- Preparing the organization to maintain a qualified state

About your Workshop Leaders:

Randy Slain, Network Support Manager, at **Pfizer** has 27 years of information technology experience. As part of the core response team to an FDA 483 letter, Randy has written the Standard Operating Procedures and rolled out the supporting programs to qualify Pharmacia's most critical and complex sites. His experience spans the pharmaceutical and banking industries and involves compliance and validation assurance for numerous federal guidelines and regulatory reporting requirements.

Glenn Howes, IT Project Manager, at **Technology Professionals Corporation** has with 14 years of experience in Information Technology, has specialized in global network infrastructure implementations. His most recent concentration has been in the area of network infrastructure qualification and validation for 21 CFR Part 11 compliance. Glenn has managed extensive projects on an international scale for the pharmaceutical, manufacturing, and professional services industries.

John Pataky, IT Project Manager, at **Technology Professionals Corporation** has over 20 years of Computer System and telecommunications experience in the pharmaceutical, healthcare and banking industries. As a project manager for major Infrastructure and Network Qualification projects, John has worked extensively on the methodology and approach to the qualification process and mitigating risks associated with government regulatory issues including 21 CFR Part 11.

D Interactive Dinner Workshop • Tuesday, September 23, 2003 • 5:30pm—8:30pm

ADVANCING COMPLIANCE, QUALITY & COMPETITIVE ADVANTAGE IN A PAPERLESS ENVIRONMENT

While automation, advanced computing and software solutions have helped make many aspects of pharmaceutical manufacturing safer and more efficient, one process which has remained largely unchanged, has been the creation, review and retention of regulatory paperwork. The regulatory and business risks of inaction are mounting and a tremendous opportunity exists for companies who are aggressive in their Part 11 and FDA compliance strategies and are moving toward a fully paperless environment. In this workshop, guidelines focusing on how to ensure data integrity through a successful implementation of audit trails and security measures utilizing expert software solutions are examined.

Attendees gain insight to technologies that are critical to eliminating paper from the pharmaceutical manufacturing process—such as electronic work instructions, point verification and security standards—and how they can be applied towards a paperless environment. A case study regarding how one major pharmaceutical manufacturer has been able to achieve measurable business and regulatory benefits from the implementation of paperless batch records and electronic record keeping is presented.

About your Workshop Leader:

Keith Chambers, Senior Product Evangelist, at **GE Fanuc Intellution** has over 20 years experience in the application development and marketing of automation software. He has extensive experience in the specification and delivery of these systems into the regulated industries both in the US and internationally. Keith has spent the last 2 years developing and presenting information on 21 CFR Part 11 and how it relates to plant floor systems, to forums and manufacturers around the world. He holds a bachelors degree in electrical engineering, and is GE Fanuc's representative on the ISA S88, S95 and S99 standards committees.

DAY 1 TUESDAY, SEPTEMBER 23, 2003

8:00 Registration and Continental Breakfast

8:45 Chairperson's Welcome and Opening Remarks

9:00 Establishing Best Practices for Network Qualification at Solvay Pharmaceuticals, Inc.

Establishing and maintaining a qualified infrastructure environment is an integral part of supporting business requirements. In this presentation, Solvay Pharmaceuticals, Inc. share how they performed network qualification, maintained acceptance throughout the company, and managed that level of commitment throughout the lifecycle of their infrastructure. Attendees gain an overview of Solvay Pharmaceuticals' understanding and interpretation for network qualification. Topics include, but are not limited to:

- Creating an effective qualification plan
- Executing and preparing qualification documents
- Examining the audit of vendors
- Obtaining viewpoints from resources both in IT and QA around the topic of network qualification
- Implementing change management and change control
- Reviewing the qualification audit process

Debbie Everidge, Director, IT Infrastructure
Raha Alavi, Manager, Quality Assurance Validation
SOLVAY PHARMACEUTICALS, INC.

10:00 Assessing IT/QA Requirements for Infrastructure Qualification

IT Professionals have a new found compliance responsibility since the enactment of Part 11 and various infrastructure requirements and standards. In this presentation, you 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 learns an effective, yet simple roadmap to develop an IT Quality/Compliance Program. Topics include how to:

- Assess IT Professionals and 21 CFR Part 11 Implementation – Myths and Realities
- Gain an overview of how Part 11 Compliance affects the roles and responsibilities for IT professionals
- Develop an IT/Quality Compliance Program and System Development Life Cycle Model
- Evaluate documentation issues addressing procedures and protocols
- Understand QA/Compliance System Training Issues associated with IT professionals

Michael L. Rutherford
Manager, Corporate Computer Systems QA
ELI LILLY AND COMPANY

10:45 Morning Refreshment Break

11:00 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

11:45 Achieving a Documented State of Control for Information Technology Infrastructure

Achieving a documented state of control poses a challenge to the IT organization. This problem is amplified by the requirement to deliver projects while simultaneously responding to the 'crisis of the day'. This presentation provides some real world practices aimed at making a successful transition to a more mature organization. The following topics are discussed:

- Linking IT documentation activities to the value proposition
- Establishing the role of Quality and Compliance in infrastructure activities
- Leveraging existing practices for maximum value
- Maintaining control over the documented state

William D. Devorick, MS, MBA, ASQ CSQE
Manager, MIS Compliance
WEST PHARMACEUTICAL SERVICES

12:30 Luncheon for Speakers and Delegates

2:00 Developing and Executing a GXP Compliant Infrastructure Qualification Plan

Developing a qualification plan that meets GXP standards can be challenging for the first time quality manager. It is a detailed process that can create anxiety and frustration because it is often not clear what is needed until it has traveled the reviewing circuit a few times. This presentation provides a practical guide to creating a draft plan that includes the necessary steps to execute the plan and advises you on the foundation information, when available, that makes the process easier. Topics addressed include:

- How to draft a Quality Plan that 'generally' meets the needs of your site quality group
- Assessing the data necessary to complete the qualification and whether the data, as it exists in your organization, meets the GXP standards required to be included in your report
- Comprehending at a higher level how to do risk assessment after the first qualification to determine when it is necessary to completely re-qualify vs. partial retesting
- How it is possible to qualify an infrastructure that deviates from full GXP compliance

Ralph May
Associate Director, Systems Integration
NOVARTIS PHARMACEUTICALS

3:00 Afternoon Refreshment Break

3:15 How to Qualify Workstations to Run Validated Applications

Establishing the essential components of your workstation is an integral part of the overall qualification process. What areas must be examined? What requirements do I need to follow in order to maintain compliance? Where do I begin.? Topics addressed include:

- How to define your hardware, operating system and validated applications
- How do you secure your workstation?
- Designating procedural controls for your workstation
- Connecting from workstation to instruments and automated tools
- Evaluating pros and cons of various implementation strategies

Madhavi Ganesan
Manager, Corporate Computer Validation
AVENTIS-BEHRING

4:00 Panel Discussion: Developing Strategies to Achieve Regulatory Compliance Within Your 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:

- Interpret regulatory guidelines for your data centers, servers and routers
- Examine the critical issues associated with achieving compliance
- Discuss strategies to qualify your computer and network infrastructure efficiently and effectively

Debbie Everidge
SOLVAY PHARMACEUTICALS, INC.

Raha Alavi
SOLVAY PHARMACEUTICALS, INC.

Michael L. Rutherford
ELI LILLY AND COMPANY

Joshua Froimson
ABBOTT BIORESEARCH CENTER

William D. Devorick, MS, MBA
WEST PHARMACEUTICAL SERVICES

Ralph May
NOVARTIS PHARMACEUTICALS

Madhavi Ganesan
AVENTIS-BEHRING

5:00 Chairperson's Day One Closing Remarks

DAY 2 WEDNESDAY, SEPTEMBER 24, 2003

8:00 Continental Breakfast

8:45 Chairperson's Day Two Opening Remarks

9:00 Designing an Infrastructure Qualification Master Plan

Managing an effective infrastructure for compliance represents a major challenge for pharmaceutical/biotechnology companies. In this presentation you identify what components of your infrastructure must be qualified in order to validate equipment, facilities, systems and processes. Topics addressed include, but are not limited to:

- Differentiating between "validation" vs. "qualification"
- Creating an effective template for IQ/OQ/PQ
- How to draft your validation master plan
- Utilizing an effective CSV audit as a risk analysis tool

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

9:45 Lessons Learned: Elan Pharmaceuticals' Path to Infrastructure Qualification

In this presentation, Elan's approach to qualifying their network infrastructure is examined. Important steps included understanding the reason for qualification and validation and implementing an appropriate amount of infrastructure qualification in order to meet FDA regulations and compliance standards. Topics include:

- Developing an effective test plan for routers, switches, vpn concentrators and firewalls
- Planning and stepping through the network infrastructure qualification on a global level
- Addressing infrastructure qualification challenges associated with business condition changes and joint-venture qualifications
- Merging network qualification with existing Quality Management System initiatives

David Harrison
Sr. Director, IT Global Infrastructure
ELAN PHARMACEUTICALS

Case Study

10:30 Morning Refreshment Break and Hotel Check-out

10:45 Maintaining Change Control of Part 11 Compliant Systems—A Quality Systems Approach

Genentech implemented it's first computer system intended to comply with 21CRF Part 11 in April, 1998, and has been maintaining change control over multiple systems since. This presentation will review the evolution of the Change Control system at Genentech, starting with the implementation of the Master Change Control concept in the mid-1990's up to the present goal of complying with the FDA's Quality Systems and Risk-Based approach to inspections. Topics addressed include how to:

- Develop a reliable change review process for assessing the cGMP impact of change
- Ensure the change control system maintains Part 11 compliance
- Streamline EDMS workflows and shortening the approval cycle
- Redesign the Change Control process into an integrated Quality Systems approach
- Manage change across multiple sites, contract manufacturers and collaborators

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

Case Study

11:30 Qualifying on a Budget: Establishing a Risk-Based Approach to Achieve Infrastructure Compliance

This presentation provides an in-depth case study on how Nektar Therapeutic developed a network infrastructure to minimize cost and maximize efficiency. In this session, the method how to qualify networked systems, workstations, and servers using a risk-based approach and evaluate the considerations that are needed to reduce the impact on your company's bottom line. Topics include:

- How to identify the major considerations and common issues from an IT perspective
- Learning the reasoning behind Nektar's decisions
- Assessing the criteria that can affect your company's cost and efficiency

Michael Lamb
Director of Network and Operations
NEKTAR THERAPEUTICS, INC.

Case Study

12:15 Interactive Luncheon for Speakers & Delegates

1:45 Minimizing Downtime in a Worst-Case Scenario: Develop an Effective Disaster Recovery Plan

This presentation describes approaches and methods for formulating a Disaster Recovery Architecture and Plan. This information assists you in determining when to apply prevention techniques, recovery techniques, and recovery plans while balancing business recovery priorities. In this session, you identify how Nektar approaches disaster recovery to provide the necessary protection while keeping costs and complacency in mind. Topics to be addressed include:

- Recognizing the difference between prevention, recovery and continuity and determining which one should apply
- Establishing techniques for identifying, planning, and testing
- How to ensure the organization is prepared

Michael Lamb
Director of Network and Operations
NEKTAR THERAPEUTICS, INC.

2:30 Assessing Corporate IT Services and Their Impact On Local Computer and Network Qualification

This session includes a discussion of how the interaction with corporate IT groups affects the qualification of a Computer and Network Infrastructure (CNI) that is under control of a local IT organization. Many sites, especially regulated distribution, manufacturing, and laboratory operations within very large organizations, receive support and services from a corporate IT function. This presentation demonstrates how, by treating corporate IT as a vendor, regulated sites can add corporate IT support and services into compliant CNI qualification plans. Specific topics include:

- Analyzing corporate IT functions and the local site
- Considering corporate IT as a CNI Vendor
- A.F.R.A.I.D. – Affirming Qualified Vendor Claims
- Dealing with corporate standard desktop images
- Qualifying wide-area network connectivity services

Anthony Fiorito
VP, Engineering
THE HOLLIS GROUP, INC.

3:15 Afternoon Refreshment Break

3:30 Panel Discussion: Infrastructure Qualification—Past, Present, Future

This round table panel provides insight into how the process of qualifying networked systems has evolved over the years. How much validation/qualification is enough? When will you know if you've achieved your goal? Hear perspectives about the lessons learned from the past, the current state of the industry, and the challenges of infrastructure qualification for the future.

Michael N. Blackton
MILLENNIUM PHARMACEUTICALS, INC.

Peter W. Bland
GENENTECH, INC.

David Harrison
ELAN PHARMACEUTICALS

Michael Lamb
NEKTAR THERAPEUTICS, INC.

Anthony Fiorito
THE HOLLIS GROUP, INC.

4:30 Chairperson's Closing Remarks & End of Conference

SPONSORSHIP and EXHIBITION OPPORTUNITIES

WHY SPONSOR OR EXHIBIT AT CPT'S IT INFRASTRUCTURE QUALIFICATION

CPT Sponsorships and Exhibits are an excellent opportunity for your company to showcase its products and services to a highly targeted, senior-level audience. CPT helps companies achieve sales, marketing and branding objectives by setting aside a limited number of event sponsorships and exhibit places — all of which are custom-tailored to help your company create a platform that will maximize its exposure at the event and reach key decision makers.

WHAT TYPE OF EXPOSURE CAN MY COMPANY HAVE AT CPT EVENTS

IT Infrastructure Qualification conference is an excellent opportunity to market your company's products or services to executive-level decision makers. This is your chance to provide our attendees with the solutions they are looking for.

Breaks Luncheons Welcome Packs CD ROMS Networking Receptions Showcase Exhibits

PREVIOUS SPONSORS AND EXHIBITORS AT CPT EVENTS

When you decide to sponsor and/or exhibit an CPT event you'll be in good company. Here are just a few of the many companies that have showcased products and services at CPT events:

CimQuest, Applied Biosystems, Ecora Software, Coda Corp USA, NetRegulus, Emerson Process Management

EXHIBITION BOOTHS

Exhibit booth location is based on two factors — the type of sponsorship package your organization chooses and the date of sponsorship/exhibit registration. Reserve your space today to ensure you get the booth location of your choice.

For more detailed information on these sponsorship and exhibition opportunities, please call Zachary Bayer at 212-885-2773 or zbayer@cptpharma.org.

Current Exhibitors: GE Life Sciences TPC

About the Event Organizer

CPT
Center for Pharmaceutical Training

Center for Pharmaceutical Training (CPT)
A division of IQPC

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.

Center for Pharmaceutical Training's mission is to:

- Enhance skills and competencies through quality compliance-related courses and conferences
- Link training, learning, performance and productivity for the pharmaceutical industry
- Evaluate and measure training and performance
- Clarify regulatory guidelines, guidances and best industry practices
- Distribute best industry practices, case studies and real-world experiences through conferences

Specifically, CPT's objectives are:

- Enhancing Drug Discovery
- Speeding Clinical Trials
- Meeting Regulatory Compliance Issues
- Validation of Processes and Equipment
- Complying with Good Manufacturing Practices
- Speeding Development of Automated Processes

Media Partners

Pharmaceutical Technology NORTH AMERICA

Celebrating 25 years serving the pharmaceutical/biopharmaceutical industry, 1977-2002. ***Pharmaceutical Technology*** provides authoritative and timely information covering all aspects of pharmaceutical/biopharmaceutical manufacturing including: drug delivery, applied research and development, solid dosage, manufacturing machinery and equipment, information technologies, contract services, biotechnology trends and regulatory issues. Published monthly, *Pharmaceutical Technology* has a BPA audited circulation of over 33,000. For more information contact, Paul Milazzo at 732-346-3027 or visit www.pharmtech.com.

VALIDATION TIMES

Monthly analysis of GMP validation issues, plus weekly FDA compliance and en-forcement news updates. For questions, contact Washington Information Source Co., (800) 776-5105 or (301) 770-5553 ... WIS@FDAINFO.COM

Bio·IT World TECHNOLOGY FOR THE LIFE SCIENCES

Bio-IT World — a new magazine focused on Technology for the Life Sciences. Packed with insight, best practices, and expert reviews of systems, products and services for specific LS applications. Go to www.bio-itworld.com for more information.

Register Today! Call 1-800-882-8684 or Visit: www.CPTPharma.org Keyword: IT Infrastructure

CPT Conferences Available on CD Rom!

Can't attend the conference? While there's no substitute for being onsite, you can now benefit from all of the presentations, exhibitor information and other key strategies and insights passed along at the event by purchasing a specially prepared *IT Infrastructure Qualification*

The CD Rom is a permanent reminder of the conference and contains all of the detailed PowerPoint™ presentations that were prepared by the speaker faculty and presented at the event; a full color conference brochure; detailed information about the event sponsors and exhibitors along with information about how your company can get involved in future events; and upcoming CPT events! The cost of the CD Rom is only $499 — a mere fraction of the registration price! To reserve your CD Rom call CPT's Customer Service Department at **800-882-8684.**

Are You Already Registered For Another Event But Would Rather Attend This CPT Event?

DON'T WORRY! If you have already registered for an alternative event but would rather attend **IT Infrastructure Qualification , CPT will reimburse the cost of your cancellation fee (up to $200).**

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 CPT is pleased to offer you the following discounts:

Number of Attendees	*Cost Per Attendee*	*Savings of:*
1	*$1,899*	-
2	*$1,709*	**10%**
3+	*$1,614*	**15%**

For personalized help (logistics, discounts, etc.) in choosing the right program for you and your staff, simply call Richard Clark at 212-885-2760 or email rclark@cptpharma.org now.

Register by Phone, Fax, E-Mail or Online

Call: **1-800-882-8684**

Fax: **973-256-0205 24 Hours A Day**

Mail: **CTP c/o IQPC**
150 Clove Road
Little Falls, NJ 17424-2157

E-Mail: **info@cptpharma.org**

Web site: **www.cptpharma.org**

Important! To speed registration, provide the product code located on the back page —even if it is not addressed to you!

REGISTRATION OPTIONS	Conference Plus 4 Workshops	Conference Plus 3 Workshops	Conference Plus 2 Workshops	Conference Plus 1 Workshop	Conference Only
Early Pre-Registration 1 Register by July 7, 2003	**$3199**	**$2999**	**$2599**	**$2099**	**$1599**
Early Pre-Registration 2 Register Between July 8 and July 28	$3299	$3099	$2699	$2199	$1699
Early Pre-Registration 3 Register Between July 29 and August 25	$3399	$3199	$2799	$2299	$1799
Standard Registration Register Between August 26 and September 22	$3499	$3299	$2899	$2399	$1899

MAKE CHECKS PAYABLE IN U.S. DOLLARS TO: CPT
* CT residents or people employed in the state of CT must add 6% sales tax.

Details for making payment via EFT or wire transfer:

Greater Community Bank, 150 Clove Road, Little Falls, NJ 07424-2157
Phone 973-890-5444

ABA/Routing #:021206566 Account Name: CPT
Account #: 21104450 Federal Tax ID #:13 3839754

Reference: Please include the name of the attendee(s) and the event number 1877.02

Payment Policy: Payment is due in full at the time of registration and includes lunches, refreshments and detailed conference materials. Your registration will not be confirmed until payment is received and may be subject to cancellation.

CPT Cancellation, Postponement and Substitution Policy:
You may substitute delegates at any time. CPT does not provide refunds for cancellations. For cancellations received in writing more than seven (7) days prior to the conference you will receive a 100% credit to be used at another CPT conference for up to one year from the date of issuance. For cancellations received less than seven (7) days prior to the event no credits will be issued. In the event that CPT cancels an event, delegate payments at the date of cancellation will be credited to a future CPT event. This credit will be available for up to one year from the date of issuance. In the event that CPT postpones an event, delegate payments at the postponement date will be credited towards the rescheduled date. If the delegate is unable to attend the rescheduled event, the delegate will receive a 100% credit representing payments made towards a future CPT event. This credit will be available for up to one year from the date of issuance. No refunds will be available for cancellations or postponements. CPT is not responsible for any loss or damage as a result of a substitution, alteration or cancellation/postponement of an event. CPT shall assume no liability whatsoever in the event this conference is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this conference impracticable or impossible. For purposes of this clause, a fortuitous event shall include, but not be limited to: war, fire, labor strike, extreme weather or other emergency.

Please note that speakers and topics were confirmed at the time of publishing, however, circumstances beyond the control of the organizers may necessitate substitutions, alterations or cancellations of the speakers and/or topics. As such, CPT reserves the right to alter or modify the advertised speakers and/or topics if necessary. Any substitutions or alterations will be updated on our web page as soon as possible.

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 and academia. For more information about scholarships to this event, please call Michelle Liu at 212-885-2747.

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

Doubletree Hotel
237 South Broad Street, Philadelphia, PA 19107
Phone: 215-893-1600 Fax: 215-893-1663
www.doubletree.com

To secure reduced rates, please call the hotel at least 4 weeks prior to the conference and be sure to mention our conference name. Note: call hotel for directions or transportation suggestions.

Making Travel Plans: For discounted Flight reservations on most major carriers, make sure you or your Corporate Travel Department contacts CPT's Official Travel Planner, Candy Eardley of Travel Forum, toll-free at 1-877-852-4135 or locally at 973-942-0100. Candy can also be reached via email at candy@travelforuminc.com.

REGISTRATION CARD

- ❑ **GOLD PACKAGE: Conference plus ALL FOUR Workshops**
- ❑ Conference plus THREE Workshops (Choose 3): ❑ A ❑ B ❑ C ❑ D
- ❑ Conference plus TWO Workshops (Choose 2): ❑ A ❑ B ❑ C ❑ D
- ❑ Conference plus ONE Workshop (Choose 1): ❑ A ❑ B ❑ C ❑ D
- ❑ Conference ONLY

If you would like to register for workshops individually please indicate:
Individual Workshops: ❑ A ❑ B ❑ C ❑ D

- ❑ I qualify for a Early Bird discount... see page 7 for details
- ❑ I qualify for the Team discount... see page 7 for details

Your product code is:

C*99

When registering by phone, please provide the product code above.

Name _____

Title _____

Approving Manager Name/Title _____

Organization _____

Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____

E-Mail _____

❑ Please keep me informed via email about this and other related events.

❑ Check enclosed for $_____(Payable to IQPC)

❑ Charge ❑ AMEX ❑ Visa ❑ Master Card ❑ Diners Club

Card #_____ Exp Date:____/____

❑ CD Rom Orders: Send me _____ sets of CD Roms

$499 + $15 shipping/ handling in the U.S.; $20 to Canada; $55 to all other countries.
Payment must accompany your order.

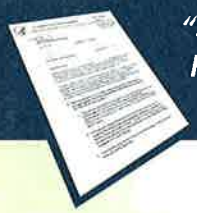
❑ I cannot attend, but please keep me informed of all future events.

International Quality & Productivity Center
150 Clove Road
PO Box 401
Little Falls, NJ 07424-2157

If addressee is no longer with the company, please deliver to Director, IT/IS

Phone: 1-800-882-8684
Fax: 973-256-0205
E-Mail: info@cptpharma.org
Web: www.cptpharma.org

1877.02/D/DS



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

Save $300
When you Register by July 11th!

CPT's 2nd

IT Infrastructure Qualification

Best Practices for Computer and Network Infrastructure Qualification

Summit 2003

Two Day National Conference September 23 & 24, 2003

Conference Workshops September 22, 2003 • Doubletree Hotel—Philadelphia, PA

Featuring an Unparalleled Speaker Faculty that Highlights Case Studies, Practical Strategies, and Do's and Don'ts for Complying with FDA Regulations. Highlighting Real-World Examples From:

- MILLENNIUM PHARMACEUTICALS
- GENENTECH, INC.
- ELAN PHARMACEUTICALS
- PFIZER
- ABBOTT BIORESEARCH CENTER
- ELI LILLY AND COMPANY
- AVENTIS-BEHRING
- WYETH
- NOVARTIS PHARMACEUTICALS CORPORATION
- NEKTAR THERAPEUTICS
- WEST PHARMACEUTICAL SERVICES
- SOLVAY PHARMACEUTICALS
- AND MUCH MORE...