Network Quality Package Contents

1. **Manual:** over 140 pages

2. **SOPs:**
   - Training for GxP, 21 CFR Part 11, and Computer Validation
   - Risk Assessment for Systems Used in GxP Environments
   - 21 CFR Part 11 – Scope and Controls
   - Development and Maintenance of Test Scripts for Equipment Hardware, Software and Systems
   - Testing File Integrity of E-Mail Attachments
   - Validation of Commercial Off-the-Shelf (COTS) Computer Systems
   - Auditing Computer Systems
   - Change Control for Networks and Systems – Planned Changes
   - Change Control for Networks and Systems – Unplanned Changes
   - Risk-Based Qualification of Network Infrastructure
   - Handling Security Patches
   - Qualification of Client PCs
   - Qualification of Data Centers

3. **Gap Analysis/Checklists:**
   - Qualification of Networks and Validation of Networked Systems
   - Using Computers in FDA-Regulated Environments
   - 21 CFR Part 11: Electronic Records & Signatures
   - Cross Check Your Network Documentation with the OSI-Layer Approach

4. **Templates/Examples:**
   - Network Infrastructure and System Identification
   - Test Protocol – Authorized System Access
   - Complete Validation Example: Win MD5 Software
   - Network Qualification Project Schedule
   - Requirement Specifications Data Systems

5. **US FDA Regulations**
   - **Food**
     - ✓ 21 CFR 106
       Infant Formula Quality Control Procedures
       Revised as of April 1, 2001

     - ✓ 21 CFR 107
       Infant Formula
       Revised as of April 1, 2001

- ✓ 21 CFR 110
  Current Good Manufacturing Practice in Manufacturing
  Packing and Holding Human Food
  Revised as of April 1, 2001

- ✓ 21 CFR 113
  Thermally Processed Low Acid Foods Packaged in Hermetically
  Sealed Containers
  Revised as of April 1, 2001

- ✓ 21CFR 114
  Acidified Foods
  Revised as of April 1, 2001

- ✓ 21 CFR 123
  Fish and Fishery Products
  Revised as of April 1, 2001

- ✓ 21 CFR 129
  Bottled Drinking Water
  Revised as of April 1, 2001

- **Good Laboratory Practice**
  - ✓ 21 CFR 58
    Good Laboratory Practice for No Clinical Laboratory Studies
    Revised as of April 1, 2001

- **Good Manufacturing Practice**
  - ✓ 21 CFR 210
    Current Good Manufacturing Practice in Manufacturing
    Processing, Packaging or Holding of Drugs
    Revised as of April 1, 2000

  - ✓ 21 CFR 211
    Current Good Manufacturing Practice for Finished
    Pharmaceuticals
    Revised as of April 1, 2000

- **Good Clinical Practices**
  - ✓ 21 CFR 50
    Protection of Human Subjects
    Revised as of April 1, 2001

- **Medical Device**
  - ✓ 21 CFR 803
    Medical Device Reporting
    Revised as of April 1, 2002

  - ✓ 21 CFR 806
    Medical Devices – Reports of Corrections and Removals
    Revised as of April 1, 2002

  - ✓ 21 CFR 808
    Exemptions from Federal Preemption of State and Local Medical Device Requirements
    Revised as of April 1, 2002

  - ✓ 21 CFR 814
    Premarket Approval for Medical Devices
    Revised as of April 1, 2001

  - ✓ 21 CFR 820
    Quality System Regulation
    Revised as of April 1, 2001

- **Electronic Records & Signatures (Part 11)**
  - ✓ 21 CFR 11
    Electronic Records – Electronic Signatures
    1997

- **New Drugs**
  - ✓ 21 CFR 310
    New Drugs

  - ✓ 21 CFR 312
    Investigational New Drug Application

  - ✓ 21 CFR 314
    Applications for FDA Approval to Market a New Drug

- **Animal Drugs**
  - ✓ 21 CFR 510
    New Animal Drugs

  - ✓ 21 CFR 511
    New Animal Drugs for Investigational Use

  - ✓ 21 CFR 514
    New Animal Drug Applications

- **Other US FDA Regulations**
  - ✓ 21 CFR 1
    Exports: Notification and Recordkeeping Requirements

  - ✓ 21 CFR 56
    Institutional Review Boards – Table of Contents

6. US FDA Guidelines

- **Related to Computer Validation and Part 11**
  - ✓ Computer and Software Validation
  - ✓ 21 CFR Part 11
  - ✓ Policy/Inspection Guides Computer Systems

- **Computer and Software Validation**
  - ✓ Guidance for Industry
    General Principles of Software Validation
    January 2002

  - ✓ Guidance for Industry
    Computerized Systems Used in Clinical Trials
    September 2004

  - ✓ Reference Material for Inspectors
    Glossary of Computerized System and
    Software Development Technology

  - ✓ FDA Guidance

  - ✓ Cyber Security for Networked Medical Devices Containing Off-the-Shelf (OTS)

- **E-Records/Signatures 21 CFR Part 11**
  - ✓ Guidance for Industry
    21 CFR Part 11: Electronic Records; Electronic Signatures, Scope and Applications
    September 2003 (final)

  - ✓ Compliance Policy Guide
    Enforcement Policy: Electronics Records; Electronic Signature – Compliance Policy Guide; Guidance for FDA Personnel
    Compliance Policy Guide (CPG) Section 160.850
    1999 (withdrawn)

- ✓ Guidance for Industry
  21CFR Part 11; Electronic Records; Electronic Signatures
  Glossary of Terms
  August 200 (draft) (withdrawn)

- ✓ Guidance for Industry
  21 CFR Part 11; Electronic Records; Electronic Signatures,
  Time Stamps
  March 2002 (draft) (withdrawn)

- ✓ Guidance for Industry
  21 CFR Part 11; Electronic Records; Electronic Signatures;
  Maintenance of Electronic Records
  July 2002 (draft) (withdrawn)

- ✓ Guidance for Industry
  21 CFR Part 11: Electronic Records; Electronics Signatures,
  Electronic Copies of Electronic Records
  July 2001 (draft) (withdrawn)

- **Compliance Policy & Inspection Guides Computer Systems**
  - ✓ Compliance Program Guidance Manual, Attachments A
    Good Laboratory Practice – Bioresearch Monitoring
    Computerized Systems
    February 2001

7. Other Regulations, Standards and Private Publications

- **US Laws/Regulations**
  - ✓ ESIGN Act

  - ✓ Sarbanes Oxley

  - ✓ Federal Food, Drug, and Cosmetic Act
    (As amended through P.L. 106-540, December 8, 2000)

  - ✓ US Environmental Protection Agency (EPA)
    Cross-Media Electronic Reporting and Recordkeeping Rule
    (CROMERRR)
    Establishment of Electronic Reporting; Electronic Records
    Proposed Rule, 2000

  - ✓ 45 CFR 142
    HIPAA – 1996

- ✓ 45 CFR 160 and 164
  Standards for Privacy of Individually Identifiable Health Information
  Security Standards for the Protection of Electronic Protested Health Information

- **European and International Regulations/Guidelines**
  - ✓ Annex 11 of EU GMP
    Computerized Systems
    Requirements are somewhat similar as 21 CFR Part 11

  - ✓ AVP Interpretation of EU GMP Annex 11
    Annex 11 of EU GMP Interpretation
    Annex 11 of the EU GMP directive specifies requirements for computer use in GMP regulated environments. The International Association for Pharmaceutical Technology (AVP) has developed this 27 page interpretation guide for easier implementation

- **NIST**
  - ✓ Risk Management Guide for Information Technology Systems
  - ✓ Guidelines on Electronic Mail Security
  - ✓ Contingency Planning Guide for Information Technology Systems
  - ✓ Procedures for Handling Security Patches
  - ✓ Guidelines on Firewalls and Firewall Policy
  - ✓ Wireless Network Security: 802.11, Bluetooth, and Handheld Devices
  - ✓ Guideline on Network Security Testing

- **Industry Standards**
  - ✓ IVT Proposed Standard

- **Private Publications**
  - ✓ Qualification of Network Components and Validation of Networked Systems

8. **Warning Letters/483s**

9. **Video – Qualification and Validation of Databases and Networked Systems**

10. **Audio Seminar: Network Infrastructure Qualification**

11. On-line Updates (need ID & password and must be on-line)

12. Validation Master Plan: Equipment and Computers