ACHIEVE QUALITY

Auditing, Consulting, and Training

CURRICULUM VITAE

NAME: **Terri P. Kelly, RN, MSQA, CCRA, CQA**

PRESENT ADDRESS: **Achieve Quality, Inc.**
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RN LICENSURE: Florida, RN1146842, active since 1979

EDUCATION:
Master of Science in Quality Assurance, Almeda University, 2006
Bachelor of Science in Health Administration, Trinity University, 1997
Associate of Science in Nursing, Florida College, 1979

HONORS:
Chairman, Global QA Forum, ACRP, 2006 to present
Preceptor, RN to BSN Program, St. Petersburg College, 2010-2013
Who's Who of Executives, Professionals & Entrepreneurs, 2009/2010
Who's Who of Nursing Professionals, 2005/2006
Who's Who of Professionals 1996/1997 and 1998/1999
Volunteer of the Year, American Lung Association of SC, 1990

PROFESSIONAL EXPERIENCE:

Jan. 1991 to present **President and Independent Principal Consultant**
International GCP Compliance Auditor and Trainer

- **GCP Compliance Auditor**
  - Mock Regulatory/Competent Authority Inspections, including preparation and facilitation
  - Internal Sponsor Program and Protocol Feasibility Assessments and Salvage
  - Pharmaceutical, Biotechnology and Device audits conducted on Sponsor Departments and Processes (Pharmacovigilance, Project Management, Clinical Operations, Monitoring, Study Start-Up, Regulatory Affairs, Data Management/EDC, Biostatistics, Quality Systems and Computer Systems), Trial Master Files, Reports, Investigator sites, IRBs, CROs, Vendors and Clinical Laboratories to ensure compliance with GCPs, FDA regulations (including 21 CFR Part 11), EU regulations, ICH Guidelines, ISO standards, SOPs and local requirements
  - International audits conducted according to applicable local regulations
- **GCP training of Sponsor, CRO, Vendor, IRB and Investigator Site personnel**
- **Consultant with FDA Office of Criminal Investigation (2008-current)**
- **Expert Witness to Office of US Attorney General (2010-current)**
- **FDA or other Regulatory Agency Inspection Preparation of Sponsors, Sites or IRBs**
- **FDA or other Regulatory Authority Inspection On-Site Facilitator**
- **System and Process evaluations of Sponsors, CROs, IRBs and Investigator sites**
- **Develop/Review SOPs for Sponsors, CROs, Investigator sites and IRBs**

PROFESSIONAL EXPERIENCE (cont.)

1990 to 1999 **Independent Consultant; Project Manager; Lead CRA**

- **Management of multicenter national research projects and Lead CRA, to include;** Investigator selection/evaluation, regulatory submission/management, CRA and site supervision, issue escalation and budget negotiation/management.

1989 to 1990 **Clinical Specialist Consultant**
Support Systems International
Charleston, SC

- **Consultant:** Clinical advice for design and development of experimental and prototype equipment, product evaluation and consumer preference trials.
- **CRA** monitoring of clinical trials

1986 to 1990 **Pulmonary Nurse Specialist/Supervisor/Research Director**
Pulmonary/Critical Care Medicine
Medical University of SC
171 Ashley Avenue
Charleston, SC 29425

- **Clinical Research Director/Subinvestigator/Coordinator**
  - Protocol design and writing, IRB submissions and reviews,
  - Budget negotiations, Patient recruitment, and Investigator-initiated clinical/device research
- **Auditor, MUSC IRB Continuing Reviews**
- **Supervisor, all professional and nonprofessional employees;**
  Application interviews, Staff meetings, Department SOP development, review and approval
- **Supervisor of** Medical ICU, Pulmonary Function Laboratory, Pulmonary Exercise Laboratory, Endoscopy Laboratory, Pulmonary Clinic and Sleep Disorders Laboratory.
- **Coordinator, Pulmonary Rehabilitation Clinic**
  Marketing, organization, patient education, and supervision of all personnel.
- **Consultant** Pulmonary/Critical Care Trauma Nurse Specialist, Cardiopulmonary Exercise testing, Pulmonary Function testing, patient and Nursing education, and Smoking Cessation
- **Executive Coordinator, Annual MUSC Lung Run**
  Meetings Chairperson, Fund raising, Public Relations with Press and Guest celebrities

1986 **ICU and ER Charge and Staff positions**
Stanton's Nursing Personnel Agency
Palm Harbor, FL

1982 to 1985 **Head Nurse, Intensive Care Unit**
Doctor's General Hospital
Plantation, FL

- Supervised all nursing staff assigned to ICU, including evaluations, staff scheduling, disciplinary conferences, application interviews, and coordination of ICU Nurses Continuing Education
- Quality Assurance development and direction.
- Developed Critical Care Policy and Procedure Manual.
- BCLS Instructor; ACLS Provider; CCRN # 44307

PROFESSIONAL EXPERIENCE (cont.)

1982 to 1982 **Critical Care Education Consultant**
Dunoon Hospital
Dunoon, Scotland, UK

- Developed and implemented Critical Care Course for ICU and ER nurses.
- Consulted with Critical Care nurses regarding specific patient problems and nursing education.

1981 to 1982 **Charge Nurse, Surgery and Recovery Room**
Bayside General Hospital
Virginia Beach, VA

1979 to 1981 **Emergency/Trauma Department Supervisor**
Methodist Hospital
Jacksonville, FL

CERTIFICATIONS and SIGNIFICANT COURSES:

FDA Annual BIMO Inspection Review, 2014
FDA Transferring Clinical Investigation Oversight to Another IRB, 2013
EMA and MHRA Advanced Inspection Readiness, 2011
SUSAR Reporting Requirements in EU, Asia, India and Australia, 2011
FDA's New Process Validation Guidance, 2011
FDA Exception from Informed Consent for Emergency Research, 2011
FDA's New 510(k) Action Plan: Changes for 2011
Reporting Potential Fraud and Scientific Misconduct to FDA, 2010
FDA's Updated Process for Issuing Warning Letters, 2010
Dr. Mengele's Human Experimentation Atrocities in Auschwitz, 2009
Detecting Scientific Fraud & Misconduct in Clinical trials, 2008
European Filing & Registration Procedures, 2007
European Regulatory Inspections, 2007
FDA Expectations re: Investigator Supervisory Responsibilities, 2007
Update on European Clinical Trial Directive, 2006
Standardized MedDRA Queries (SMQs), 2006
Advanced System-Based Evaluations, 2006
New FDA Guidances; Risk Assessment & Minimization, 2005
HIPAA Security Regulations, 2005
European Privacy Directive, 2004
ISO versus ICH in Good Clinical Practice, 2004
Update on Health Canada Drug and Device Regulations, 2004
ASQ Quality Lead Auditor Certification, 2003
HIPAA in International Trials, 2003
European Clinical Trials Directive, 2003
FDA Workshop on Quality Systems Inspections, 2003
FDA Safety Reporting Requirements, 2003
How HIPAA will affect the Investigator and IRB, 2002, 2003
Pediatric Assent, 2002
SQA Good Laboratory Practices Training, 2001
Advanced FDA Inspection Procedures, 2000
Introduction to Pharmacovigilance, 2000
GCP Audits of Sponsors & CROs, 2000
Comparison of ICH and FDA Regulations, 1999
FDA Handwriting Analysis: Detecting Fraud, 1999
Auditing Medical Device Trials, 1998
Investigating Scientific Misconduct, 1998
Advanced FDA BIMO Inspections, 1997
Advanced QA Auditing Procedures1996
ACRP Certified Clinical Research Associate (CCRA), 1995

PRESENTATIONS:

'Monitoring v. Auditing v. Inspections' Univ. of South Florida Moffitt Cancer Center, 15May2014

'A Comparison of FDA vs. European Regulations' Internal CRO Training, April 2014

'Monitoring v. Auditing v. Inspections: Aren't They All the Same?" ACRP Global Conference, San Antonio, TX, April 2014

'GCP: Beyond the Basics: Interpretation, Application, and Lessons Learned' Internal Pharmaceutical Company Training, 10Feb2014

'Advanced GCP Training' Internal Pharmaceutical Company Training, 16Jan2014

Internal Monitoring Training for Major Cancer Center CRAs, Sep2013

'Advanced Good Clinical Practices: Sponsor Responsibilities' Internal Pharmaceutical Company Training, 04Jun2013

'Monitor Like an Auditor: What are They Looking At?' Tampa Bay ACRP Chapter, 12Dec2012

'What a Different World We Live in: Investigator Responsibilities in Observational vs. Interventional Research' Univ. of South Florida Moffitt Cancer Center Clinical Research Conference, 19Jul2012

'Clinical SOPs: Hard to Write and Tougher to Teach — Benchmarks on What's Working and What's Not" Sixth Annual FDA Inspections Summit, Bethesda, MD, October 2011

Keynote Address "*Keeping Current with Good Clinical Practices*" Univ. of South Florida Moffitt Cancer Center 3rd Annual Clinical Research Conference, Tampa, FL, March 2011

"*Communication Dilemmas among Clinical Sites, Sponsors, and Institutional Review Boards (IRBs): A Case of Regulatory Confusion or Confused Interpretations? How do IRBs Assess Investigator Qualifications and Compliance?*" Drug Information Association 46th Annual Meeting, Washington, DC June 2010

"*Site Monitoring with an Auditor's Eye*" MAGI Clinical Research Conference, Boston, MA, May 2010

"*Good Clinical Practice Essentials: What You Won't Learn from the Regulations!*" University of Saskatchewan Clinical Trial Workshop and Symposium, April 2010

"*Who's Watching Who? Investigator and IRB Compliance*" ACRP Global Conference, Tampa, FL, April 2010

Keynote Address "*Roles and Responsibilities in Clinical Research*" USF Moffitt Cancer Center Oncology 2nd Annual Clinical Research Conference, June 2009

"*Concerns with Central vs. Local/Institutional IRBs*" USF Moffitt Cancer Center Oncology 2nd Annual Clinical Research Conference, June 2009

"*Good Clinical Practice: What You Won't Learn from the Regulations*" MAGI Clinical Research Conference, Miami, FL, May2009

"*Development of an Investigator Site QA System*" ACRP Global Conference, Boston, MA, April 2008

"*Developing SOPs for the Investigator Site*" Univ. of South Florida/Moffitt Cancer Center, Feb2008

"*Ethics in Clinical Research*" University of South Florida/Moffitt Cancer Center, February 2008

"*Regulatory Documents: A to Z*" ACRP Weekend Workshop, Baltimore, MD, October 2007

"*FDA Device Regulations*" Major Cardiovascular Device Company requested training provided to In-house and contracted CRO personnel, June 2007

"*Tales from the Auditing Crypt*" Annual ACRP Conference, Seattle, WA, April 2007

"*Regulatory Documents: A to Z*" Annual ACRP Conference, Seattle, WA, April 2007

"*Comparing ISO 14155 to FDA Device Regulatory Requirements*" Major Pharmaceutical and Medical Device company requested presentation, March 2007

"*How to Get a Nightmare Site Back on Track*" Annual ACRP Conference, Phoenix, May 2006

"*CRAs: Audit Your Sites*" ACRP International Audioconference, October 2005

"*How ISO Requirements Will Affect GCPs as We Know Them*" ACRP Conference, Orlando, FL, April 2005

"*HIPAA Privacy & Security Rules*" Annual ACRP Conference, Orlando, FL April 2005

"*HIPAA Requirements for the Investigator Site*", Suncoast Chapter of ACRP, Clearwater, FL 2004

"*The Impact of HIPAA Regulations: An Auditor's Perspective*" ACRP Conference San Diego, CA May 2004

Combination CRA/CRC GCP 6-Week Training Course; Barnett International & Univ of South Florida, Fall 2003

"*GCP Training for the Investigator Site*", Suncoast Chapter of ACRP, Clearwater, FL 2003

"*Investigator Sites and CRAs: Audit Thyself*", Annual ACRP Conference Pennsylvania 2003

"*Historical Overview of Research regulations, FDA and ICH*", 2003, 2004

"*Sponsor/CRO Requirements Regarding HIPAA*", 2003, 2004

"*How HIPAA Regulations will Affect the Research Site"*, 2002, 2003
"*Sponsor and CRA GCP Training*", 2001 - current
"*Differences Between FDA and ICH Requirements*", 1999, 2000, 2001
"*Preparing For the FDA Inspection*", 1996, 1997, 1998, 1999, 2001, 2002, 2003, 2004, 2008
"*How to be an Effective Project Manager*", 1994, 1997
"*Clinical Investigator GCP Training*", 1994 - current
"*Clinical Research Coordinator Training*", 1993 - 2007
"*Preparing For a GCP Audit*", 1993, 1994, 1996, 1997, 1999, 2000, 2001, 2002, 2003, 2004, 2006
"*What Does that CRA Want From Me?"* 1992
"*Basic Monitoring Techniques*", 1991

PUBLICATIONS:

- Kelly, Terri. "Who's Watching Whom? Investigator and IRB Compliance." The Monitor; The Global Voice of Clinical Research Professionals. June 2010, pp 11-14.
- Kelly Terri. "QA Q&A Corner." The Monitor; The Global Voice of Clinical Research Professionals. ongoing bi-monthly column; 2007 - current
- Sahn SA, Heffner JE. Critical Care Pearls. Philadelphia: Hanley-Belfus, 1989.
- Sahn SA, Heffner JE. Pulmonary Pearls. Philadelphia: Hanley-Belfus, 1988.

PROFESSIONAL ORGANIZATIONS:

- American Society for Quality; since 2002 (Certified Quality Auditor since 2003)
- Associates of Clinical Research Professionals; since 1988
  QA Forum since 1996, QA Forum Steering Committee 2001, QA Forum Chairperson 2006 to present
- Drug Information Association; since 2000
- Regulatory Affairs Professionals Society, since 2005
- Society of Quality Assurance, since 2001

RESEARCH EXPERIENCE as Study Coordinator and/or Subinvestigator:
(as Medical University of South Carolina employee)

1986-1988	Percutaneous Needle Aspiration versus Bronchoscopy in the Diagnosis of Sputum Negative **Tuberculosis**
1987-1989	Atrovent Solution in **COPD** Patients Who are on Concurrent Alupent Therapy
1987-1989	Alveolitis Uniformity in **Scleroderma** as Assessed by Bilobar Bronchoalveolar Lavage, Gallium 67 Scans, and Fibronectin Production
1988-1990	Characterization of Factors Limiting Exercise in **Scleroderma**
1988-1990	Comparative Study of Suprax and Ceftin in the Treatment of **Acute Lower Respiratory Tract Infections**
1988-1989	Comparative Study of Cefpirome Versus Ceftazidime in the Treatment of **Pneumonia**
1988-1989	Cough Suppression with Lidocaine during **Bronchoscopy**
1989-1990	Ipratropium/Albuterol Combination in the Treatment of **COPD**

1989-1990	Albuterol/Atrovent Combination in the Treatment of **Asthma**
1989-1990	Effect of Inhaled Ipratropium and Albuterol on Airway Obstruction in Adults with **Sarcoidosis**
1990	Comparison of Inhaled Fluticasone versus Theophylline versus Placebo in Treatment of **Asthma**
1990	Use of Restcue Bed in Prevention of **Nosocomial Pneumonias**

CONSULTANT RESEARCH ACTIVITIES:

1989-1990	Development of the **Restcue Lateral Rotation Therapy Bed System**
1991-1993	**CRA:** Therapy in the Prevention of **MAC Bacterium in AIDS** Patients
1991	**GCP Team Audit** - Study in the Treatment of **Hypertension**
1991-1993	**CRA:** Multi-Regimen in the Treatment of **MAC Bacterium in AIDS** Patients
1991-1992	**CRA: Antihypertensive** Study of Patients over 50 years of age
1991-1992	**CRA: Antihypertensive** Study of Patients 21 - 75 years of age
1991-1992	Use of Tetracycline Fibers in Treatment of **Periodontitis**
1991	**GCP Team Audits** - Comparative Trial of IV Compounds in the Treatment of **Nosocomial pneumonia** at **three** Investigator sites
1991	**CRA:** Effectiveness of Injections in Reducing **Osteoarthritis** Patient's Need for Nonsteroidal Anti-Inflammatory Drugs
1991	**GCP Team Audit** of facility **IRB**
1991-1992	**CRA:** Placebo Controlled Use of Compound Following Reductive Laparoscopy Surgery in Patients with **Endometriosis**
1991	**Lead CRA:** Comparative Study in the Treatment of Female Patients with **Acute Pelvic Infections**
1991-1992	**CRA:** Efficacy and Tolerability in Adult Patients with Mild to Moderate Essential **Hypertension**
1991-1992	**Project Manager** - Efficacy and Safety of Oral versus IV compounds in the Treatment of **Serious Skin and Deep Tissue Infections**
1992	**GCP Audits** - Comparative Study in the Treatment of **Rheumatoid Arthritis** at **two** Investigator sites
1992-1993	**Lead CRA:** Study of Patients with Signs and Symptoms of **BPH**
1993	**Lead CRA:** Dose Comparison Study in the Treatment of Female Patients with **Metastatic Adenocarcinoma of the Breast**
1993-1997	**CRA:** Compound, Clarithromycin and Ethambutol Regimen in the Treatment of **MAC Bacteremia in AIDS** Patients

1993-1995	**Project Manager** - Effect of Compound on **HIV Load in AIDS** Patients
1993	**Lead CRA:** Comparison Study of Compound in Treatment of **BPH** by Urological Flow
1993-1994	**Lead CRA:** Long Term Study of Patients with Signs and Symptoms of **BPH**
1993-1994	**Project Manager** - Long Term Trial of Patients with **COPD**
1993-1994	**Lead CRA:** Open Label Study of Patients with Signs and Symptoms of **BPH**
1993-1994	**Lead CRA:** Dose Response and Safety of Patients with **Hypertension**
1993	**CRA:** Compassionate Use Trial in Patients with **Parkinson's Disease**
1994	**GCP Audits** - Comparison Study in Treatment of Acute Exacerbations of **Asthma** at **three** Investigator sites
1993-1994	**Lead CRA:** Dose Ranging Study of Inhalation Capsules in **COPD** Patients
1994	**Lead CRA:** Comparison Study in Patients with **COPD**
1994	**GCP Audit** of facility **IRB**
1994-1996	**Lead CRA:** Activity of Compound on **Asymptomatic HIV** Infected Patients
1994	**Lead CRA:** Long-Term Efficacy of Patients with Chronic Stable **Angina**
1994	**GCP Audits** - Use of Compound in the Treatment of **COPD** at **three** Investigator sites in US and Canada
1994	**GCP Pharmaceutical and Device Audits** - Comparison of Continuous Low Dose Vaginal Ring vs. Vaginal Cream in the Treatment of **Urogenital Atrophy** in Post-Menopausal Women, to include audit of IND and PMA Submissions at CRO and three US investigator site audits
1994	**CRA:** Comparison Trial in Patients with **Acute Brainstem Injury**
1994	**GCP Audits** - Use of Compound in the Treatment of **Hypertension** at **two** US Investigator sites
1994-1995	**Lead CRA:** Dose Confirmation Study in Adult Patients with **COPD**
1994-1995	**Project Manager** - Dose Ranging Trial in Patients with **Chronic Bronchitis**
1995-1996	**Lead CRA:** Comparison Trial for Treatment of **Acute Hemorrhagic Stroke**
1995	**CRA:** Prophylactic Administration in **Cadaveric Renal Transplantation**
1995	**GCP Audits** - Comparative Trial in the Treatment of **Acute Angina** at **three** US Investigator sites
1995-1997	**CRA:** Preventative Therapy of **Latent Tuberculosis in HIV +** Individuals
1995	**GCP Audits** - Comparison Trial in Patients with **Community Acquired Pneumonia** at **two** US Investigator sites

1995-1997	**Lead CRA:** Multiple Protocols Studying Optional Propellants in Bronchodilators for Patients with **COPD**
1995	**Lead CRA:** Comparison Trial in Patients with **Asthma**
1995-1997	**CRA:** Multiple Comparison and Dose Combination Trials in Patients with **Hypertension**
1995-1998	**Lead CRA:** Long Term Comparative Trial in Patients with **Hypertension**
1996	**Project Manager** - Study of Patients with **Isolated Systolic Hypertension**
1996-1997	**CRA:** Comparison Trial in Patients with **Severe Hypertension**
1996	**GCP Audits** - Comparison Trial in Patients with **Upper Respiratory Infection** at **three** Investigator sites in US and Canada
1996-1997	**CRA:** Comparison of Compounds in Treatment of **Kaposi's Sarcoma**
1996-1998	**Lead CRA:** Long Term Dose Comparison Trial in Patients with **COPD**
1996	**GCP Device Audit** - 510K Application and Safety Process Audit at CRO of Device Trial in **Intermittent Claudication** trial
1996	**GCP Audit** of facility **IRB**
1997-1998	**Project Manager** - Dose Ranging Study of Patients with **Asthma**
1997-1998	**Lead CRA:** Comparison Trial of Compound & Placebo Administered within Six Hours of the Onset of Stroke Symptoms, for Treatment of **Acute Ischemic Stroke**
1997-1999	**Lead CRA:** Comparison of Compounds on **Left Ventricular Hypertrophy** as Assessed by echocardiography and Nuclear Magnetic Resonance Imaging
1997-1999	**CRA:** Dose Response in Patients with **Intermittent Claudication**
1998	**GCP Audits** - Pre-FDA QA/QC audits on multiple **Hypertension** Protocols at **ten** US sites nationwide
1998	**GLP Team Audit** - Animal rodent facilities and process audit
1998	**GCP Audit** - Central **Laboratory** Audit
1998-1999	**Lead CRA:** Phase IV Open-label Study of Patients with **BPH**
1998-1999	**Lead CRA:** Phase IV Comparative Trial of Patients with **BPH**
1998-1999	**CRA:** Open-Label Comparison Trial of Patients with **HTN using ABPM** monitoring
1998-1999	**CRA:** Open-Label Comparison Trial in a Managed Care Setting of Patients with **Osteoarthritis of the Hip, Spine, Hand or Knee**
1999-2000	**GCP Audits** - Multiple QA/QC audits at **four** investigative sites in Us and Canada conducting a **Pelvic Inflammatory Disease** protocol
1999	**Lead CRA:** Dose Ranging, Comparative Trial of Inhaled Corticosteroid Dependent Moderate to Severe **Asthmatic Children**

1999	**GCP IRB Audits** - Institutional **IRB** Audits at **three** IRBs
1999-2000	**GCP Audits –** Lead Auditor of **Twelve** Multiple Team Audits Sponsor (Data Management and Drug Safety Department Systems), CRO, Laboratory and **nine** investigator Sites of Phase III Chemotherapy Adjuvant to Radiation Therapy in Patients with **Head and Neck Cancer**
1999	**GLP Team Audit** - Animal rabbit and rodent facilities and process audit
1999-2000	**GCP Audits** - **Opioid-Induced Constipation in Patients with Chronic Pain** - **two** concurrent protocols at **eight** Investigator sites in US
1999-2000	**Project Manager** - Chemotherapy Product Used as an Adjuvant to Radiation Therapy in Patients with Inoperable **Head and Neck Cancer**
1999-2000	**Project Manager** - Chemotherapy Product Used as an Adjuvant to Radiation Therapy in Post Radical Neck Surgery Patients with **Head and Neck Cancer**
2000	**CRO Audit** - Multiple EKG and Holter-monitor protocols
2000	**GLP Audit** - Animal monkey facility systems and process Audit
2000	**GCP Audit** - Audit of Institutional **IRB**
2000	**GCP Audits** - Randomized Study of Chemotherapy product versus Gemcitabine in **Chemonaive Pancreatic Cancer** Patients at **three** Investigator sites in US and Canada
2000	**GCP Audits** - Randomized Study of Chemotherapy Product versus 5-Flouracil in **Pancreatic Cancer** Patients that have Progressive Disease Following Gemcitabine Treatment at **two** US Investigator sites
2000	**GCP Audits** - Chemotherapy Product versus Most Appropriate Therapy in **Refractory Pancreatic Cancer** Patients at **three** US Investigator sites
2000	**Pharmacovigilance System Audit** Safety and Efficacy of Thrombolytic Regimens in Patients with **Acute Myocardial Infarction**
2000	**GCP Audits** - Randomized Study Comparing Combination Therapy Used with Two Nucleoside Reverse Transcriptase Inhibitors in Single Protease Inhibitor Experienced **HIV-1** Patients at **five** Investigator sites in Canada
2000	**GCP IRB Audit** - Institutional **IRB** Audit
2000	**GCP Audit** - Safety and Efficacy Comparison of HFA Inhalation Aerosol to CFC Inhalation Aerosol in **COPD** Patients at a US Investigator site
2000-2001	**GCP Audits** - Safety and Efficacy Comparison Study in the Treatment of **Community-Acquired Pneumonia** at **four** US Investigator sites
2001	**GCP Audits** - Safety and Efficacy in Subjects with **Irritable Bowel Syndrome** with Potential **Ophthalmic** Adverse Reactions at **two** Investigator sites in US and Canada
2001	**GCP Audits** - Comparative Trial in **Children with Attention Deficit Hyperactivity Disorder** at **three** US Investigator sites
2001	**GCP Audits** - Withdrawal of Therapy Trial in **Children with Attention Deficit Hyperactivity Disorder** at **three** US Investigator sites

2001	**GCP Audits** - Comparison Trial in Subjects with **Advanced Parkinson's Disease** with Motor Fluctuations at **four** US Investigator sites
2001	**GCP Audits** - Phase II Dose Adjustment Trial of Subjects with **Major Depressive Disorder** with Potential **Ophthalmic** Adverse Reactions at **two** Investigator sites in US and **Canada**
2001	**GCP Device CRO Audit** - Phase II Device Trial for PMA Submission in the Prevention of **Post Cardiopulmonary Bypass Syndromes in Infants Undergoing Surgery for Congenital Heart Defects**
2001	**GCP IRB Audit** - Audit of **Institutional IRB**
2001	**Analytical GLP Audit** - S100β assay system and process audit
2001	**GCP Audits** - Safety and Efficacy Trial in the **Prevention of Post Cardiopulmonary Bypass Syndrome** in Adults at **five** Investigator sites
2001	**International GCP Audits** - Phase IV Study on Healing and Symptom Relief in Subjects with **Erosive Esophagitis** at **four** Investigator sites
2001	**GCP Audits** - Open-Label Long-Term Safety Study in Patients with **Gout** at **three** Investigator sites in US and Canada
2001	**Vendor Audit** - Electronic Data Submission of **Bone Density** Exams
2001	**GCP Audits** - Safety and Efficacy Study of Patients with **Endometriosis** at **three** Investigator sites in US and Canada
2001	**GCP Audit** - Institutional **Clinical Laboratory** audit
2001	**CRO Audit** - Two **Myocardial Infarction Anti-thrombolytic Therapy** protocols Database and Pharmacovigilance system audit
2001	**Internal System Audit** - Pharmaceutical Company Internal System Audit of **Regulatory Affairs** and **Pharmacovigilance**
2001	**Multiple GCP Audits** - Phase II Study to Evaluate Subjects with **Uterine Leiomyomata** at **three** Investigator sites in US and Canada
2001	**International CRO Audit** - to include Investigator audit, CRO Drug Safety and Project Management process audit, and Clinical Laboratory audit
2001	**GLP Audit** - Animal (dog) facility and process audit
2001	**Internal Process Audit** - For a Pharmaceutical Company Clinical Team and Drug Safety Department
2001	**Phase I Unit Audits** - Evaluation of **three** Phase I units in US
2001	**Pre-FDA GCP Audits** - At **five** investigator sites for a **Testicular Oncology** trial in US and Canada
2002	**GCP Device Audits** - **Male Erectile Dysfunction** trial at **four** Investigator sites for a device trial with 510(k) Submission
2002	**GCP Audits** - At **four** Investigator sites for a Third Line Treatment for **Metastatic Colorectal Carcinoma** trial in US and Canada
2001	**Pre-FDA Inspection Preparation** - at **two** sites for **three COPD** trials, to include GCP audit, QC of remedial measures and training of site staff

2002 **CRO Audit** - Major CRO to include **IVRS** validation, Data Management, **Part 11** review, Drug Safety and Clinical Operations Systems review

2002 **Three CRO Audits** - **Three** interrelated CROs to include **IVRS** software development, IVRS management, **Part 11** compliance and electronic data capture system

2002 **NDA Report Audit** - Internal system review in **Pharmacovigilance** and NDA report submission review at major pharmaceutical company

2002 **Central IRB Audit** - System and specific clinical trial records review

2002 **GCP Compliance Audits** - at **four** Investigator sites for two concurrent clinical trials for **Metastatic Breast Carcinoma** in US and Canada

2002 **NDA Report Audit** - NDA report submission review for major pharmaceutical company (Include correlation of Drug Safety Data)

2002 **GCP Compliance Audits** - at **three** Investigator sites for two pivotal trials of **Advanced Non-Small Cell Lung Cancer**

2002 **GCP Compliance Audits** - at **four** Investigator sites for two pivotal trials of **Metastatic Colorectal Cancer** in US and Canada

2002 **GCP Compliance Audits** - at **four** US Investigator sites for a **GERD Related Heartburn** clinical trial

2002 **Phase I Unit Comparative Evaluation** - at **three** Phase I units

2002 **International ICH GCP Compliance Audit** - of a site in **Birmingham, UK** of subjects with **PSVT Undergoing Electrophysiologic Study**

2002 **GCP Compliance Audits** - at **three** US Investigator sites for an **Intravitreal Implant in Patients with Non-Infectious Uveitis** clinical trial

2002 **University IRB Audit** - SOPs, Training, FDA and ICH Compliance

2002 **GCP Compliance / CRO Comparative Evaluation** - comparing **five central ECG Laboratories** for GCP, Part 11 and sponsor SOP compliance

2002 **GCP Compliance Audits / FDA preparation and Facilitation** - at **three** Investigator sites in US and Canada conducting a **Multiple Antiretroviral Drug-Experienced HIV Positive Subjects** clinical trial

2002 **International IVRS CRO Audit** - **IVRS** Laboratory in **Nottingham, England, UK** to assess ICH GCP, FDA 21 CFR Part 11 and sponsor SOP compliance

2002 **International ICH GCP Compliance Audits** - at an Investigator site in **Singapore** for an **Intravitreal Implant in Patients with Non-Infectious Uveitis** clinical trial

2002 **GCP Compliance Audits** - at **three** Investigator sites for a **Seasonal Allergic Rhinitis** clinical trial in US and Canada

2002 **Central IRB Audit** - SOPs, Training, FDA and ICH Compliance

2002 **CRO Evaluation** - of Monitoring, Project Management, Clinical Laboratory, Data Management, Device Safety and IP shipment services

2002 **GCP Compliance Audits** - at **two** US Investigator sites for a **Gout** trial

2002 **CRO Evaluation** - of a **Pediatric Specialty CRO** for their Monitoring and Project Management services

2002 **GCP Compliance Audits** - at **two** US Investigator sites for a **Gout** trial

2003 **University IRB Audit** - for a **Hepatic Oncology** trial to Assess SOPs, Training, Processes, Documentation and Compliance with regulations

2003 **GCP Compliance Audit** - at a US Investigator site for a clinical trial evaluating the **Treatment of Hot Flashes Following Surgical or Chemical Castration of Prostate Cancer Subjects**

2003 **Phase I Unit Evaluation** - Follow-up audit of a **University Phase I unit** with a Cautious evaluation during a prior audit

2003 **International ICH GCP Compliance Audits** - of **five** Investigator sites in **Hong Kong, Singapore, Manila and Hyderabad, and New Delhi, India** for an **Intravitreal Implant in Patients with Non-Infectious Uveitis** clinical trial

2003 **CRO Device Audit** - to include **Project Management, Monitoring, Data Mgt and IDE/PMA report/submission** of a **Contact Lens** device trial

2003 **International GCP Compliance Audit** - at **three** Investigator sites in US and Canada for a **Metastatic Pancreatic Cancer** trial

2003 **International CRO Audit** - to assess **Pharmacovigilance, Data Management** and **Part 11** compliance for a **Diabetes Mellitus** trial

2003 **International CRO Device Audits** - to assess **project management, monitoring, IDE/PMA report compilation and device accountability** in **two optical implant** trials

2003 **Internal Process Audit** - at **Pharmaceutical Company** to assess **Safety Reporting Process** across Departments, including Safety Database records review

2003 **Central International IEC Audit** - to assess compliance with ICH and FDA **IRB** requirements for **NDA submission**

2003 **GCP Investigator Site Audits** - at **three** Investigator Sites for an **Intravitreal Implant** trial for **Posterior Uveitis (Combination product)**

2003 **International CRO Audits** - at a CRO in **Munich** and **Brussels**, to assess **Project Management, Monitoring, Training, Drug Safety, Masterfile documentation and SOPs** in two **Endometriosis** trials for NDA submission

2003 **Investigator GCP Audits** - **Three** Investigator site audits in US and Canada for an Oncology Trial in Men with **Prostate Cancer**

2003 **Japanese Inspection Preparation** of **two** Investigator Sites for **COPD** and **Asthma** clinical trials

2003 **International Investigator Audits** - **Two** Investigator Site Audits in **India** of a **Uveitis** clinical trial **(Combination Product)**

2003	**International CRO Audit** - in **India** to include **Monitoring, Project Management, IP, PV and Masterfile Management**
2003	**Investigator GCP Site Audits** - at **three** Investigator Sites for a **Gout** trial
2003	**Investigator GCP Site Audits** - at **two** Investigator Sites in US and Canada for a **Uterine Leiomyomata** clinical trial
2003	**Hospital IRB Audit** – IRB processes, documentation and SOPs
2003	**Investigator GCP Site Audits** - at **five** Investigator sites in US and Canada for an **Intravitreal Implant** trial for **Posterior Uveitis (Combination Product)**
2003	**CRO Audit** - To include **Project Management, Monitoring, Masterfiles, SOPs, and Device Safety, Training documentation** of a **Device** trial
2003	**Internal Device Sponsor Audit** - To include **Project Management, Monitoring, SOPs, Training, Safety Systems and Processes**
2003	**Investigator GCP Site Audits** - at **two** Investigator sites in US and Canada for a **Uterine Fibroid** study
2003	**IRB Audit** - of a **Central IRB** processes and documentation
2003	**Investigator GCP Site Audits** - at **two** Investigator sites for an **HIV** trial
2003	**CRO Audit** - To include **Project Management, Monitoring, Masterfiles, SOPs, and Training documentation** of a **Device** clinical trial
2003	**CRO Audit** - To include **Data Management, Protocol Writing Process, Safety Database, FDA NDA Report and Writing Process, SOPs, and Training documentation** of an **Optical Multi-Vitamin** clinical trial
2003	**International CRO Audit** - To include **Project Management, Monitoring, Masterfiles, Pharmacovigilance, SOPs, and Training documentation** of a **Device** trial and a **Pharmaceutical** clinical trial conducted in **India**
2003	**CRO System and Process Evaluation** – To include **SOPs** revision and development, **staff**, **training**, **regulatory review** and **site management**
2003	**Data Management Vendor Audit** - of **three** protocols
2003	**Canadian Research Ethics Board Audit** - of **two Device** protocols
2004	**Investigator GCP Site Audits** - at **two** Investigator sites in the U.S. and Canada for a **Posterior Uveitis** clinical trial
2003	**Investigator GCP Site Audits** - at **seven** Investigator sites in US and Canada for an **HIV** trial prior to **NDA submission (Four For-cause investigations)**
2004	**International Investigator GCP Site Audits** – at **two** Investigator sites in **Mexico** for an **HIV** trial according to **ICH** and **Mexican regulatory standards**, as well as an **FDA Gap Analysis**
2004	**International Internal Sponsor Audit** – at **Mexican Local Operating Unit** of Major Pharmaceutical Company and **Mexican CRO** for **Project Management, Monitoring, Safety Management, SOPs, Organization and Training, TMF** and **Investigational Product Management**

2004	**International IRB GCP Compliance Audits** at **two Mexican** hospital **IRBs** for **Membership, SOPs, Processes** and **Documentation**
2004	**CRO System and Process Pre-Study Evaluation** – to include **Organization and Staffing**, **Training, SOPs, Regulatory Review, Masterfile, Safety Management, Outsourcing, Records Archival, Monitoring** and **Project Management**
2004	**SOP Review and Development** for a Central ECG Laboratory; to include training and implementation assistance; GCP Consultant
2004	**Japanese Pharmaceutical company** remote evaluation of systems and processes
2004-2006	**Audit Reports Review and Closure** – working with the Sponsor and audited entity to assist and evaluate closure of multiple Sponsor, CRO and Investigator site audit reports
2004	**CRO System and Process Pre- and Post-Study Evaluation** – to include **Organization and Staffing**, **Training, SOPs, Regulatory Review, Safety Reporting, Masterfile Management, Outsourcing, Records Archival, Monitoring** and **Project Management Systems & Processes**
2004-2005	**Investigator Site GCP Audits** – at **five** investigator sites in the U.S. for a **Postmenopausal Symptomology** clinical trial, to include working with sites to complete all **corrective action** to close audit report
2004-2006	**GCP Consultant to Pharmaceutical company** to include managing Auditing team, updating QA SOPs, GCP review of documents, and conducting audits, as needed
2004	**GLP Audit** - Animal facilities system and process audit
2004	**Process Audit** at **three** locations of a **Central Clinical Laboratory** for **GCP, GLP** and **Part 11** compliance, **SOPs, training** and **raw data comparison to electronic database**
2005	**Device Audits** of **eight** US Investigator sites and **Sponsor SOPs, CTMF,** and **Project Management, Monitoring and Safety Reporting** of **Spinal Implant trial**
2005-2007	**Interim QA Manager** for Medical Device company, to include management of QA efforts and Auditors
2005-2006	**NDA Submission to FDA** – Review and revise **final Clinical Study report** for Sponsor to include process, Safety Database content and accuracy, as well as **regulatory advice on meeting with the FDA**
2005	**INH Grant Application Composition and Compilation** for an FDA-exempt **medical device**
2005	**Evaluation and Training of CRAs** at multiple U.S. sites for an Inpatient Orthopedic Trial of **DVT Prophylaxis** in Total Hip Replacement Surgery
2006	**International FDA/ICH Compliance Audits and Inspection Preparation** at one site in **Italy** and two sites in **Germany** for a **BPH** clinical trial
2006	**Medical Device Audits** at **five** Investigator sites for an **Orthopedic** trial

2006	**GLP Audit** - Animal facilities system and process audit
2006	**CRO Capability Audit** at an International CRO to evaluate **Drug Safety, Project Management, Monitoring, Data Entry, Data Management, CTMF, Coding and SOPs**
2006	**FDA Prep Prior to and Interaction During Inspections** at **two** US Investigator Sites and **Sponsor** facility for NDA submission/approval of a **Parkinson's Disease** trial
2006	**FDA / ICH GAP Analysis of Current SOPs** for a Pharmaceutical company, including revision of current SOPs and generation of new SOPs
2006	**Sponsor System Audit of Medical Device Company** to include evaluation of **SOPs**, **Regulatory submissions, CTMF, Safety, Project Management** and **Monitoring**
2006	**Regulatory submission management** for a multicenter clinical trial, including review and revision of the protocol, IB, IND Safety Reports and CRF to comply with applicable regulations
2006	**FDA Inspection Facilitator** during FDA inspection of **six** Investigator sites in US and Canada for NDA submission for **ALS** trial
2006	**FDA / ICH GAP Analysis of Current SOPs** for a Pharmaceutical company, including revision of current SOPs and generation of new SOPs
2006	**Protocol and CRF Writing** and **Project Management** of protocol for a **Medical Device** company
2006	**GCP Audits of Five Investigator Sites** in US and Canada for a Phase II **Poorly Controlled Hypertension** clinical trial (Two For-Cause audits)
2006	**Pharmacovigilance Pre-Qualification Vendor Audit** of Global CRO
2006	**GCP Comparison Audits/Evaluations** of **five Phase I facilities**
2006-2008	**Management Review of GCP Audit Reports** written by other Auditors for Pharmaceutical and Device company audits
2006-2007	**Comparison Evaluation** of **five Phase I Units** for a Pharmaceutical Sponsor company
2007	**Lead Auditor** of 7-Auditor team for In-house 3-week **Database** Audit
2007	**GCP Audits of Two Investigator Sites** in US and Canada for a Phase III **Oncology** trial in **Leukemia** Subjects
2007	**Pharmacovigilance System Audit** at Major Global CRO, including Safety Database and records comparison and reconciliation
2007	**GLP Audit** - Animal facilities system and process audit
2007	**Pharmacovigilance Vendor Comparison Pre-Qualification Evaluation** of **three** Vendors for Pharmaceutical Sponsor
2007-2009	**Long-Term Audit Manager** including audit coordination, sponsor point of contact interaction and audit report review of proprietary **EDC** system

2007	**Full Service CRO Comparison Audits – Lead Auditor, Coordinator,** Sponsor point of contact interaction and audit report review of **six** CRO Pre-Qualification audits for transfer of **all Sponsor services/obligations**.
2007	**Investigator Device Audits** at **two** Investigator sites in **India** for a **Cardiovascular Stent** clinical trial
2007	**Investigator Audit** to include investigation and verification of alleged questionable data and scientific misconduct with subsequent FDA Inspection Facilitator for a Phase III **Sickle-Cell Anemia** clinical trial
2007	**Central ECG Vendor** Interim Study Audit
2007	**Lead Auditor** of **GCP Team Audits at Five Investigator Sites** in US and Canada for a Phase III **Breast Implant** clinical trial
2007	**GLP Audit** - Animal facilities system and process audit
2007	**Audit Project Lead** of **Ten Vendor Audits** and **Fourteen Investigator Audits** for two pivotal **interventional drug eluting coronary stent clinical device** trials
2007	**Mock FDA Full-Service Inspection** of **CRO** for **Combination product**
2007	**Ten Investigator Device Team Audits** and **FDA CDRH BIMO Inspection preparation** of Investigator sites for two **Coronary Stent** trials
2008	**Three Investigator Audits** of a Phase III trial in **Cystic Fibrosis** in **Adult** and **Pediatric** populations
2008	**Sponsor System and Process Audit; Mock FDA Inspection**
2008	**Audit Project Lead** for twelve US Investigator Audits; including FDA preparation and FDA BIMO Inspections facilitation for a **MS** trial
2008	**Consultant to Clinical Investigator** for Administrative Hold placed by Sponsor and subsequent Enrollment Suspension of all active trials by IRB, including training, review and revision of SOPs and assistance with Appeal process
2008	**GLP Audit** - Animal facilities system and process audit
2008	**FDA BIMO Inspection preparation** of Clinical Investigator site for two pivotal trials
2008	**Lead Auditor** of **five International and Domestic team data integrity and GCP compliance** audits related to **FDA concerns** following **Sponsor's NDA submission**
2008	**Lead Auditor** of **Australian Sponsor Systems and Processes Audit**, including contracted **Vendor study process** evaluations, applicable **Regulatory submissions** and **Consultant Liaison with FDA**
2008	**Investigator Audit** for **Oncology** protocol with **InForm eCRF**
2008	**Lead Auditor** of **three Vendor/CRO audits** prior to **NDA submission**, with **Pharmacovigilance, Central Imaging Management** and **Project Management and Monitoring**

2008	**Investigator Audit** in **Italy** for **Leiomyosarcoma Oncology** protocol
2008	**CRO Audit** at **five international locations** to evaluate **Global Medical Monitoring, Project Management, Clinical Monitoring, Data Management, IVRS, Biostatistics, Investigational Product Management and Regulatory filing** for **Osteosarcoma** project
2008	**Pre-Qualification CRO Audit** to evaluate **Project Management, Information Management (incl. Part 11 compliance), Medical Writing, Biostatistics** and **Clinical Operations** for **two Cystic Fibrosis** projects
2008	**Investigator Audits** at **three US** and **two EU (UK and Poland)** sites for **Rectal Oncology trial**
2008	**Mock FDA Full-Service Inspection** of **CRO** for **NHL Oncology** trial
2008	**Phase I Unit Audit** of **Subcutaneous Injections** for **Growth Hormone Deficiency** in **Normal Volunteers**
2008	**Vendor Audits** of two **International CROs** and three **laboratories** for a **Medical Device** company
2008	**GCP Audit** of a **Clinical Laboratory** in the US
2008	**Two Pre-Qualification Full Service CRO Audits** to evaluate CRO systems and processes for three **Post-Surgical Pain** protocols
2008	**Mock FDA Inspection** of **Medical Device** company for **two cardiovascular stent** clinical trials
2008-current	**Consultant** with **FDA Office of Criminal Investigation** on Scientific Fraud investigation
2008-2011	**GCP Consultant** for small pharmaceutical company, **managing audit program** and **CAPA surveillance**; '**on-call' regulatory advice** provided to clinical staff and corporate management
2009	**Investigator Audits** at **four US** clinical sites for **Cardiovascular Medical Device** protocol
2009	**CAPA Surveillance** and **Resolution** project for small Biotech company
2009	**GCP/GLP Audit** of **Clinical and Non-Clinical Laboratory** at **two** US locations
2009	**Directed Investigator Audit** in **Lithuania** of **Acutely Psychotic Patients** with **Schizophrenia** protocol
2009	**Mock FDA Full-Service Inspection** of **Pharmaceutical** company for group of **three Lung Oncology** trials with one product
2009	**Investigator Audits** at **two US** clinical sites for **Cardiovascular** trial
2009	**Full-Service Pre-Qualification Audit** of **Five CROs** with comparison evaluation
2009	**GCP and Part 11 Compliance Audit** of **Central Angiographic Core Laboratory**
2009	**Facilitator** of **FDA BIMO Inspection** of **Medical Device Company**

2009 **GCP Audit** of **Trial Master File Management** services provided by a **CRO** for a **international multi-center** trial

2009 **Investigator Audits** at **four US** clinical sites for **Hepatoblastoma** trial

2009 **Develop Response** to **Form FDA-483** following **BIMO Inspection** of **Clinical Investigator**

2009 **Full-Service Pre-Qualification Audit** of **CRO** in **Japan**

2009 **GCP and Part 11 Compliance Audit** of **Central Angiographic Core Laboratory** in **Japan**

2010 **Create Clinical, Medical Affairs and Quality Assurance SOPs** for a small pharmaceutical company

2010 **Vendor Audit** of **Clinical Event Committee (CEC)** for **Cardiovascular Device** protocols

2010 **Vendor Audit** of **IVRS Vendor** for **Cardiovascular Device** protocols

2010 **Vendor Audit** of **Data Management Vendor** providing **electronic data capture**, including **Part 11** and **Software Validation**

2010 **Vendor Audit** of **software development services provider** in **Belgium**

2010 **Directed Investigator Audit** of Clinical Investigator in **Ukraine** of **Acutely Psychotic Patients** with **Schizophrenia** protocol

2010 **Principal Expert Witness to FBI and US Attorney General's office** on Felony Investigation of **Sponsor** and **Clinical Investigator** into Possible **Scientific Misconduct** and **Fraudulent Activity**

2010 **CRO Audit** of **Trial Master File Management** services provided by a CRO for **Psychiatric Pharmaceutical** projects

2010 **Clinical Investigator Audits** at **two** Investigator sites in **Germany** and **France** for sister trials in **Familial Amyloid Polyneuropathy (FAP)**

2010 **Vendor Prequalification Audit** of **Full Service CRO**

2010 **Systems and Processes Audit** of **Biotech company**

2010 **Clinical Investigator Audit** in **Canada** for sister trials of **Cystic Fibrosis** in **Children**

2010 **Systems and Processes Audit** of **Collaborating Pharmaceutical Sponsor**

2010 **Mock FDA BIMO Inspection** of **Pharmaceutical Sponsor** following **NDA submission**

2010 **IRB Prequalification Comparison Audits** of **five central IRBs**

2010 **Vendor Prequalification Audit** of **Full Service CRO**

2010 **Internal Mock FDA BIMO Inspection and Preparation** of **3 Protocols** at **Medical Device Sponsor**

2010 **Two Vendor Audits** for a **Genetic Therapy** in **Extensive Small Cell Lung Cancer** trial; one for **Project Management, Clinical Site**

	Monitoring and **Medical Monitoring**; the other for **Data Management, EDC CRF Design and Hosting, Biostatistics** and **Medical Writing**
2010	**Vendor Audit** of **Data Management, EDC CRF Design and Hosting, Biometrics** and **Medical Writing** services provider
2010	**Vendor Pre-Qualification Audit** of **Full Service CRO**
2010	**Vendor Re-Qualification Audit** of **Data Management and EDC Hosting** service provider
2010	**Vendor Pre-Qualification Audit** of **Full Service CRO**
2010	**Vendor Re-Qualification Audit** of **Data Management** service provider
2010	**Three Clinical Investigator Audits** in US and Canada for **Medical Device** in treatment of advanced **Glioblastoma of the brain**
2010	**Vendor Pre-Qualification Audit** of **Data Management** and **EDC CRF Design and Hosting** services provider
2010	**Mock FDA CDRH BIMO Inspection** of **Sponsor Medical Device** company for **Coronary Stent** trials following PMA submission
2010	**Mock FDA CDER BIMO Inspection** of **Sponsor Pharmaceutical** company for **Cystic Fibrosis** trials following NDA submission
2011	**Vendor Pre-Qualification Audit** of **EDC Design and Hosting** services provider for **Phase I Paroxysmal Nocturnal Hemoglobinuria** trial
2011	**Mock FDA CDER BIMO Inspection** of **Sponsor Pharmaceutical** company for **Hepatitis C** trials following NDA submission
2011	**Vendor Pre-Qualification Audit** of **CRO** providing **Core Angiography Laboratory, Critical Events Committee** and **Data Safety Monitoring Board** for **Peripheral Stent** device trials
2011	**Vendor Pre-Qualification Audit** of **CRO** in **England** responsible for **EU Regulatory submissions**
2011	**Vendor Pre-Qualification Audit** of **CRO** in **Russia** responsible for **Eastern EU Clinical Operations** and **Investigator Site Monitoring**
2011	**Three Clinical Investigator Audits** in **US** and **Canada** on **Advanced Renal Cancer** pharmaceutical clinical trial
2011	**Sponsor Mock EMA Inspection** in **US** of all Sponsor services, including interviews, identification of high-risk areas and CAPA development for **Hepatitis C** clinical trial
2011	**Sponsor Mock MHRA Inspection** in **England** of all Sponsor services, including interviews, identification of high-risk areas and CAPA development for several **Cystic Fibrosis** clinical trials
2011	**Vendor Re-Qualification Audit** of CRO providing **IVRS/IWRS** services for multiple Sponsor **CNS** projects
2011	**Five Clinical Investigator Site Audits** in **US** and **Canada** on **two** pivotal **Hepatic Cancer** clinical trials

2011	**Internal University IRB Audit** of systems, processes and procedures compliance and improvement
2011	**Vendor Prequalification Audit** of **Full Service CRO**
2011	**Mock FDA CDER BIMO Inspection** in **US** of all Sponsor services
2011	**Six Clinical Investigator Audits** in US on two pivotal and one roll-over extension trial on **Alzheimer's Disease**
2011	**Vendor Re-Qualification Audit** of **CRO** providing **Central Angiographic Analysis Core Laboratory** services for **Medical Device Sponsor**
2011	**Vendor Pre-Qualification Audit** of **Early Stage Phase 1 First in Man Unit** for **Oncology** trial
2011-present	**Project Manager** and **Lead Auditor** of multiple **Investigator Initiated Oncology** trials for major NCI Cancer Center
2012	**Two Clinical Investigator Audits** in US on two pivotal and one roll-over extension trial on **Alzheimer's Disease**
2012	**Post-Capability Audit** of **CRO** transferred **all Sponsor services** by a small **BioTech** company for **Renal Function Decline** in Patients with **AA Amyloidosis**
2012	Five-Week **Post-Capability Audit** of **CRO** in **Dublin, Ireland** of global **Pharmacovigilance** and **Regulatory** services
2012	**Consent Process Audit** at Major Cancer Center
2012	**Eight Clinical Investigator Audits** at Major Cancer Center of eight different **Investigator-initiated Oncology** protocols prior to **NIH inspection**
2012	**Sponsor Mock FDA CDER BIMO Inspection** at Pharmaceutical company in **US** of all Sponsor services
2012	**Clinical Investigator Audit** at **three sites** in **US** on **Bronchopulmonary Dysplasia (BPD) in Preterm Infants requiring Mechanical Ventilation**
2012	**Sponsor Mock FDA CDER BIMO Inspection** at Pharmaceutical company in **US** of all Sponsor services on **Idiopathic Overactive Bladder with Urinary Incontinence** protocols
2012	**Four CRO Prequalification audits** for **Medical Device** company
2012	**Twelve Clinical Investigator Audits** at Major Cancer Center of twelve different **Investigator-initiated Oncology** protocols
2012	**Mock FDA BIMO Inspection** at Pharmaceutical company
2013	**Conflict of Interest** reviews of **eighteen Investigators at Major Cancer Center**
2013	**Central IRB Post-Capability Audit** for five different protocols for **hepato-renal syndrome**
2013	**Vendor Post-Capability Audit** of **Neurocognitive Rating** assessment vendor

2013 **CRO Post-Capability Audit** for full-service of **Schizophrenia** trial

2013 **Vendor Pre-Qualification Audit** of **central ECG vendor**

2013 **Vendor Pre-Qualification Audit** of **Cognitive Rater Training** vendor

2013 **Vendor Pre-Qualification Audit** of **Central Laboratory**

2013 **GCP/GLP Audit** of **Bioanalytical Laboratory**

2013 **Clinical Investigator Audits** of **two** sites in the US for **hepato-renal syndrome**

2013 **For Cause Clinical Investigator Audit** of **COPD** protocol

2013 **Sponsor Mock MHRA/EMA Inspection** in the **UK**

2013 **Three Comparison Central ECG Reader Vendor Audits**

2013 **Ten Clinical Investigator Audits** of at Major Cancer Center of different **Investigator-initiated Oncology** protocols

2013 **Trial Master File Audit** at CRO

2013 **Post-Capability Audit** of **Phase I Unit**

2013 **Mock FDA BIMO Inspection** at Pharmaceutical company

2013 **Mock MHRA Inspection** at Sponsor in the **UK**

2013 **Clinical Investigator Audits** of s**even sites** for **Pulmonary Arterial Hypertension** protocol

2013 **Data Management Post-Capability Audit** of **CRO**

2014 **Sponsor Mock EMA Inspection** in **US** of all Sponsor services, including interviews, identification of high-risk areas and CAPA development

2014 **Pre-Qualification Audit** of **Phase I Unit**

2014 **Pre-Qualification Audit** of **Centralized Cognition Testing Vendor**

2014 **Clinical Investigator Audits** of **seven sites** for **four Parkinson's Disease Dementia** protocols

2014 Internal **Sponsor Program Feasibility Assessment and Salvage Plan**

2014 Internal **FDA Inspector Readiness Assessment** of **eTMF Access** at **Sponsor facility**

2014 Internal **Sponsor TMF Audit** and **training** of **Internal Auditors**

2014 **Sponsor Mock FDA CDER BIMO Inspection** at Pharmaceutical company in **US** of all Sponsor services

2014 **Pre-Qualification Audit** of **Phase I Unit**

2014 **Mock MHRA Inspection** at Sponsor in the US

2014 **Vendor Post-Capability Audit** of **PVG** services provided for **Complicated Intra-abdominal Infection** and **Complicated Urinary Tract Infection** protocols

2014	Full-Service **CRO Post-Capability Audit** of **Schizophrenia** protocol in **Russia**
2014	**Vendor Post-Capability Audit** of **Clinical Safety** and **Bioanalytical Laboratory** in the Netherlands
2015	**Electronic Trial Master File Audits** for **twelve multi-center Early Phase Synthetic Antibiotic** protocols
2015	**Investigator Audits** at **five** sites for **Traumatic Brain Injury** protocol
2015	**Investigator Audits** at **two** sites for **Fragile X Syndrome** protocol