PHYLLIS MARIE WELDON

Quality Assurance | Global Compliance | Audits | Data Integrity
Software Quality | Software Development and Validation Methodologies
Information Technologies | Facilitation | Training | Process Improvement

Accomplished executive level professional with progressive career success including evaluating and designing global quality management systems, complex software systems, informatics, information technologies, quality and operational plans in various sectors. Proven capacity for leading a complex organizations and programs and providing vision to serve the needs of diverse stakeholders, with oversight across multiple business units, global operations, and quality system processes. Extensive background in audits, software, quality systems, gap analysis, design control, electronic records, data integrity, software development lifecycle (SDLC). Natural talent for leadership with an ability to motivate and drive continuous process and quality improvement.

Leadership Proficiencies:

Quality System Design & Implementation (GxP) • Executive Leadership • Quality Assurance / Regulatory Compliance • Gap Analysis • Corrective Action Preventative Action (CAPA)
Process Improvement • Software Lifecycles • Software Evaluations
Risk Management • Informatics and IT Management • Facilitation, Training & Lectures • Audits
Change Management/Strategic Planning • Global Management of People, Projects and Processes

CONSULTANCY AND AUDIT EXPERIENCE

EOLUS COMPLIANCE SOLUTIONS, LLC, Raleigh NC **2000-Present**
Principal / Director, Quality Consultant and Auditor

Founded and managed professional services consultancy providing quality management and regulatory compliance advisory to clients operating in pharmaceutical, biotechnology, clinical research, medical device and diagnostics.

Led and conducted audits for *various* pharmaceutical, medical device and biotech companies worldwide to include: QSR/QSIT audits, Vendor Supplier Audits, EDC, IVRS/IWRS, GLP audits, GCP, Site Monitoring visits, System Audits, cGMP Audits, Data Audits, Quality Surveys, Mock FDA inspections in preparation for FDA and regulatory audits to include 21 CFR Part 820, ISO13485, ISO9001, ISO62304, ISO14971 and ISO27001.

Provided quality focused lectures, presentations and training, strategic planning, systems and process design, process improvement and integration consultancy worldwide. Advised in relation to FDA 483s/warning letters/consent decree, integration and harmonization planning, IT systems, software quality, compliance gap assessments and remediation activities. Selected examples of audit and consulting engagements follow:

DUKE CLINICAL RESEARCH INSTITUTE, Durham NC, Periodic **Dec 2005- Present**

As a consultant/auditor :

- Led and conducted various internal audits and external vendor audits of software vendors.
- Authored training for Quality Systems for GCP and 21 CFR Part 11.
- Authored suites of procedures to ensure quality systems compliance and best practice adherence to 21 CFR Part 11 and HIPAA for the hosting of clinical research data systems.
- Authored Software Quality Assurance, Software Life cycle, and Risk Management Policies.
- Authored CAPA Management, Risk Management and Quality Incident system procedures
- Authored Quality Agreement policies, procedures and templates
- Conducted CAPA investigation, root cause analysis and action planning

CONSULTANCY AND AUDIT EXPERIENCE, CONTINUED

Philips Life Sciences, Global, Periodic **Jan 2016- Present**

As a consultant/auditor led and conducted international internal audits and external supplier audits and global assessments based on ISO13485, ISO62304 and ISO14971 for complex Medical Devices. Performed Design History file reviews. Developed recommendations based on audit findings/gaps.

DUKE Reading Center (DRC), Durham NC, Periodic **August 2015 – Present**

As a consultant/auditor developed quality management system, processes and procedures for inspection readiness 21 CFR Part 11 and GCP compliance for clinical studies. Conducted mock FDA inspection / internal audit / gap analysis to determine compliance gaps. Hosted vendor sponsor audits.

Medsource, **Jan-February 2017**

Developed and conducted one day training for 21 CFR Part 11 and GCP at Medsource, a CRO.

Ashfield Healthcare, Periodic **August 2014-Present**

Performed vendor evaluations and software evaluation and implementations. Conducted vendor audits for eClinical vendors including but not limited to CRO, IVRS/IWRS, EDC, CTMS, Imaging, Patient Diaries.

BioDelivery Sciences, Periodic **August 2014-Present**

Performed vendor evaluations and software evaluation and implementations. Conducted vendor audits for eClinical vendors including but not limited to CRO, Clinical Supplies, Imaging, IVRS/IWRS, EDC, CTMS, and Patient Diaries.

CooperVision, Global **Dec 2013- Aug 2014**

As a consultant/auditor reporting to EVP QA/RC in role as Sr. Director of Software Quality

- Led and conducted international audits and global assessments based on ISO13485 and ISO62304.
- Collaborated with IT to provide a SLC with templates to ensure quality systems compliance and best practice adherence to 21 CFR Part 11, Annex 11, SOX and HIPAA.
- Developed, authored and conducted 21 CFR Part 820, Part 11, Design Control and Software Development Lifecycle (SDLC) and CSV training courses.

HOSPIRA, Rocky Mount, NC **Aug 2011- Dec 2011**

Worked with Quintiles team to provide quality oversight to Hospira manufacturing for 483 remediation including:

- Hired and trained Manufacturing Quality Oversight Team at Hospira with Quintiles with a focus upon quality systems for IVD and Parental; Aseptic, TS Filling, Solution Prep.
- Conducted and wrote >10+ CAPA investigations.
- Performed quality oversight, gap assessments and periodic batch record reviews.

ABBOTT LABORATORIES, Advanced Medical Optics, Global **2009-July 2011**

Reporting to the Division Vice president of QA/RA, managed quality integration of merger and acquisition of Advanced Medical Optics including harmonization of design control, systems and compliance life cycle for this $35 billion leader in pharmaceuticals, medical technologies, and other health related businesses.

Evaluated internal controls, design control, advertising, and promotional practices to enforce quality standards and regulatory inspection readiness. Designed and implemented enterprise-wide quality procedures/guidelines for M &A in collaboration with the VP and Abbott Quality Council.

- Led a two-year international QA/RA integration following the acquisition of Advanced Medical Optics (AMO); successfully fulfilled transition of QA, manufacturing, SAP, core and quality systems.
- Served as Independent Reviewer / Trainer / Mentor of Design Control quality improvement initiatives for Medical Optics divisions based on ISO13485
- Led and conducted initial Medical Device QSR audits for AMO division manufacturing sites worldwide; the project started with QSIT style audits, including reviews of the quality systems; Medical Device Reporting, Safety systems, Medical Device Records, Design History Files, Design Controls, Hazard and Risk Analysis, Systems Quality, Systems and Equipment Validations, CAPA and Complaints.
- Developed and harmonized quality systems procedures, creating a global quality system.
- Lead a global remediation team which focused upon Supplier Management, Validation, 21 CFR Part 11 compliance, MDR, and CAPAs.

- Designed, developed and deployed the System Validation Lifecycles, Design Control processes, and vendor supplier management processes and procedures.
- *Developed Design Control and QSR training materials and conducted training at globa sites*
- Wrote CAPA action plans and implementing gap solutions.
- Led a team of validation experts on various software validation projects across the globe and in various process and compliance areas (GMP, QSR, GLP, and GCP)
- Conducted system compliance assessment and created master validation plans across all GMP sites.
- *Developed and conducted SDLC and Design control training programs*
- Managed global implementation of SDLC and Validation processes for division.
- Provided oversight to validation projects at AMO Hangzhou China in aseptic manufacturing/lab areas.
- Developed processes and procedures for internal and external auditing programs including third party suppliers including software vendors, clinical supply vendors, API providers, manufacturers, packagers, and QC testing labs.

CROSS INDUSTRY SURVEY (Blinded Quality Practice Study) 2009

Conducted cross industry survey of systems validation practices and produced industry best practice report for safety reporting systems for blinded cross industry group, sponsored by Novo Nordisk.

- Authored study report and presentation.
- Presented data and presentation to industry interest group.

Phase Forward, IVRS Vendor Qualification Audit 2008

Conducted IVRS vendor qualification audits and evaluations, which lead to Phase Forward acquisition of IVRS vendor.

BILCARE, Global, Director Supply Chain/IVRS and Clinical Services 2005 - 2008

As Director of Supply Chain/IVRS/Clinical Services, provided management oversight to clinical systems and processes including:

- Provided international Clinical Trial Project Management for B&L clinical IVRS/IWRS study, including managing site initiation, randomization, patient enrollment, drug assignment, dosing, visit schedules, study drug manufacture, packaging, supply logistics and distribution, and expiration date tracking.
- Implemented eClinical systems including IVRS/IWRS for study conduct.
- Provided systems oversight to manage clinical trial material supply and distribution.
- Implemented a web based clinical trial management systems for India based CRO.

BIOVERIS CORPORATION, Gaithersburg, Maryland 2005-2007

Reporting to Senior Director of Quality Assurance, established QA compliance vision and tactical plan for a manufacturer of IVD diagnostics equipment and systems that is now a subsidiary of Roche Holding AG. Oversaw development and implementation applicable to QA, QC, document control, regulatory affairs, software development, validation and calibration, as well as contract services QA. Provided QA oversight to the New Product Development Board.

- Spearheaded a quality system development project that resulted in ISO 9001:2000 re-certifications, and prepared the operation to pass a pre-assessment audit for ISO 13485.
- Conducted a gap analysis to assess operations and develop policies in line with ISO 13485, ICH, and FDA 21 Code of Federal Regulations (CFR) 820.
- Authored SDLC and trained employees on QSR, 21 CFR Part 11, SDLC, and Software Validation.

THE COGNITION GROUP, Global 2006

Provided consultancy for international CRO systems.

- Implemented eClinical systems for study conduct.
- Developed and implemented quality system processes.
- Trained personnel on GCP, 21 CFR Part 11, SDLC, and Software Validation.

GLAXO SMITH KLINE (GSK), Global, Period 1996-2005

Project manager for international clinical trial management system facilitation and requirements analysis. Led quality process and harmonization initiatives for GSK SVP. Through an initial process assessment at

several disparate sites to identify opportunities for quality, process and systems harmonization in the clinical research systems and processes, a quality report with finding and recommendations was presented to the SVP.

AMERICAN TYPE CULTURE COLLECTION (ATCC), Manassas, Virginia **2004-2005**

Reporting directly to the VP of Quality Systems managed quality systems development and execution for this non-profit, global biological resource center and research organization. Established best practices in QA, QC, and document controls, maintaining a high standard of quality in products, processes, and facilities. Managed a team in the performance of quality audits and implementation of continuous quality improvement initiatives based on ISO13485.

ABBOTT DIAGNOSTICS DIVISION, North Chicago, Illinois **2002-2004**

Assisted in the development of QA/QC policies and resolution of non-compliance issues relating to QSR, GXP / ICH regulations and FDA correspondence for ADD Consent Decree.

- Guided clients through audits, FDA 483 responses, quality system implementation, product submissions, consent decrees, and regulatory agency inspections.
- Advised leadership team on matters relating to quality systems, systems development, and validation.
- Led auditing team for systems audits including device, platforms, and lab systems, as well as 21 CFR Part 11 during consent decree project at Abbott Diagnostic Division (ADD).

Gilead/Triangle Pharmaceuticals, Periodic **1995-2008**

Performed vendor evaluations and software evaluation and implementations. Conducted vendor audits for eClinical vendors including IVRS/IWRS, EDC, CTMS, and Patient Diaries.

AMGEN, Global **2000**

Led change management initiatives with a focus on process integration for Amgen. This began with an initial process assessment at several disparate sites to identify opportunities for quality, process and systems harmonization in their clinical research area. The final deliverable was a report and presentation.

PROFESSIONAL EXPERIENCE

DATASCOUT SOFTWARE **2001- 2002**

Executive VP of Product Development and Chief Technology Officer, Cofounder

Successfully conceived and brought to market a new software product for clinical studies, which provided randomization, enrollment and drug supply management services for clinical trials.

- Managed software development project and delivered on time and within budget.
- Authored system requirements, specifications, test protocols, lifecycle methodology, patent application, training materials, marketing materials and product user manuals. Managed software development lifecycle and technology architecture. Provided clinical trials management for clinical study for TAP. Responsible for clinical trial project management for eDiary (ePRO) and IVR/IWR projects.
- Developed patented software and successfully sold IP to a company in Northeast.

SEC ASSOCIATES **2000**

VP of Compliance Consulting Services

Successfully built consultancy services practice in regulatory and quality systems consulting arena.

- Responsibilities included managing and providing international quality, systems, auditing, training and consulting services to various medical device, and pharmaceutical companies worldwide.
- Activities included systems compliance consulting and training for GXP, 21 CFR Part 11 and HIPAA with a focus on system security, data integrity, electronic records security and confidentiality.
- Participated in the PDA's 21 CFR Part 11 Task force, which produced a document on Good Electronic Records Management. Researched and authored a 100-page report for best practice and regulatory research regarding eCommerce use of the Internet in the Pharmaceutical and Healthcare industry for Abbott. Performed ISO audits and full IT audit for Novo Nordisk.
- Conducted GCP audits, systems audits, ISO audits, vendor evaluation audits and mock FDA inspections.
- Managed implementation projects for document management systems, EDC, and other eClinical systems. Implemented software validation processes and methods.

Duke Clinical Research Institute (DCRI) **1996 to 2000**

Chief Information Officer, Director of Information Technology

Successfully organized and developed the IT department to support the growing academic research organization in its support of clinical research and GCP activities.

- Performed audits of VIGOUR partner CRO organizations worldwide.
- Participated in the Heart Knows No Borders initiatives with a focus on improving clinical trials conduct worldwide.
- Strategic planning, training and management of an IT department of 100+ technical professionals.
- Initiated and led international technology collaborations with other academic medical centers worldwide.
- Managed computing environment to support 1120+ users in diverse geographic locations with a budget of 7.5million
- Responsible for managing technology strategy, advanced technologies, infrastructure, applications development and support, database design and administration, INTRANET services, EXTRANET services for B2B, technology training, systems quality assurance and quality control hardware acquisition and support, help desk services, networks, telecommunications (voice, data and video), and operations for two data centers.
- Created and managed a distributed computing environment which consists of 45 NT servers and 12 Sun UNIX servers.
- Initiated and implemented a systems lifecycle methodology and a systems validation program. Provided SDLC, software validation and 21 CFR Part 11 training to the organization.
- Initiated development of a web enabled remote data entry system for clinical data capture.
- Participation in evaluation and selection of key systems; R/3 SAP, POMS MES, OpenText.
- Installed and implemented Domain's CLINTRIAL software for clinical data management.
- Implemented IVRS technology for clinical trial randomization and study management.
- Initiated and implemented secured INTRANET and EXTRANET B2B services for collaboration with global partners.
- Initiated disaster recovery and business resumption planning
- Developed and taught a courses in data integrity, systems compliance and data integrity for the Duke Master Program for Clinical Research.

BURROUGHS WELLCOME CO. **1986-1995**

Corporate Information Systems, IT Senior Manager

Successfully developed and managed processes and software applications to support executive decision makers throughout the company; including R&D management, Clinical Trials Reporting, Daily Sales, and Promotional Management.

- Provided international project leadership to design, build and support applications for Clinical Trials Management.
- Developed executive information management systems to support decisions in Medical, R&D, and Clinical Research, Manufacturing, Marketing and Sales and various other units throughout the company.
- Successfully managed an IT budget and developed appropriate business plans. Managed multiple software development teams and projects. Managed a transition to client/server while maintaining, integrating, and converting legacy systems.
- Participated in various cross-functional leadership /excellence teams, one of which developed a customized systems lifecycle methodology.

OTHER KEY EXPERIENCES

Designed, developed and built the first electronic medical record system for an orthopedic surgeon to capture images of patient knees along with the patient electronic medical record.

Recognized industry expert on 21 CFR Part 11, Data Integrity, Quality Systems, Software Development Lifecycles and Validation Methodologies, Design Controls and Medical Devices.

PHYLLIS MARIE WELDON

EDUCATION

University of North Carolina at Chapel Hill, Kenan Flager, Graduate School of Business, Executive Programs, Burroughs Wellcome Management Institute.

Virginia Commonwealth University, Richmond, VA, Graduate School of Business, Post Baccalaureate Certificate, Information Systems

Virginia Commonwealth University, Richmond, VA, Undergraduate School of Arts, Bachelor of Arts

TRAINING COURSES AND CERTIFICATIONS

ISO9001, ISO12207, ISO17799, ISO13485,
ISO27799, ISO14971 & ISO62304
Electronic Data Capture (EDC) for Clinical Data
21 CFR Part 11, Annex 11, HIPAA, HITECH, SAS70
CDISC, HL7, CRISC, FISMA, PCI, SOC-2
SDLC for Product Software in Medical Devices
Leadership for Executive Managers
GCP, GLP, cGMPs, QSR, GDP, GAMP
Design Controls for Medical Device Software
Managing Change in a Business Environment
Negotiating Skills for Executive Managers
Computerized System Validation
Lean Six Sigma, Six Sigma Process Improvement;
CAPA Rubric, DMAIC, Fishbone, Root Cause
FMEA, Hazard Analysis, Risk Analysis
Design Controls for Medical Devices
Project Management for Project Leaders
Corrective and Preventative Actions, CAPA
ANSI RAB Accredited ISO9000, ISO9001 Lead Auditor Training
PDA/ARC Computer Supplier Auditor Training Certificate #1064

KEY INDUSTRY ASSOCIATION PRESENTATIONS

DIA Conference on EDC - October 1999: "*Electronic Data Capture; a Lotus or Onion Blossom?"*

Fraser Williams Users Group Meeting - May 2000: "*To Validate or Not to Validate, That is the Question"*

Barnett & PDA/FDA conferences - June 2000: "Electronic Records: Real Life Scenarios"

PDA Annual Meeting - Dec 2000: *"A Project Management Approach to Compliance Programs*"

DIA Annual Meeting - July 2001: "IVR Case Study for Success"

PATENTS

US Patent serial number 10/132,537 (Weldon et al) filed April 25, 2002, related to systems, methods and computer program products for designing, deploying and managing interactive voice response (IVR) systems for Clinical Research - April, 2002

KEY PUBLICATIONS

"Electronic Records: An IVR Case Study for Success". Quality Assurance Journal, volume 6, issue 2 - June 2002, Wiley & Sons, LTD.

"Good Practice and Compliance for Electronic Records and Signatures (Part 1) Good Electronic Records Management (GERM)", **CoAuthor, and PDA Task Force member, 2002**

"Good Practice and Compliance for Electronic Records and Signatures (Part 2) Complying with 21 CFR Part 11, Electronic Records and Signatures", **GAMP Forum, PDA Task Force, 2001**

"Good Practice and Compliance for Electronic Records and Signatures (Part 3) Models for Systems Implementation and Evolution" **CoAuthor and PDA Task Force member 2004**

"Current Concepts in Validation and Compliance, Computerized Systems Used in Non Clinical Safety Assessment"; GLP, **DIA RED Apple II Committee Member, Collaborator and Co-Author. 2007**

"System and Data Integrity for Clinical Trials"; GCP, **DIA Peach Committee member and Co-Author, 2008**

CURRENT AND PREVIOUS PROFESSIONAL ASSOCIATIONS

ASQ, American Society of Quality

DIA, Drug Information Association,

PDA, Parental Drug Association

Medical Device Engineers and Consultants

NCCSQA; NC Society of Quality Associates

TTEC, Triangle Technology Executive Committee

ANSI RAB Accredited ISO9000 Lead Auditor

PDA/ARC Computer Supplier Auditor Certificate #1064

Triangle PEERS: Electronic Records/Data Integrity