

Stephanie L. Skipper

M.S., CMQ/OE, CQA, PMP

Leesburg, Virginia

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QUALIFICATION SUMMARY:

Mrs. Skipper has eleven years of pharmaceutical experience with over seven years of direct, hands-on experience in leading the design, development and management of quality assurance and quality management systems; including the commissioning and oversight of GMP/GLP, GCP, registered ISO 13485:2003, registered ISO 9001:2008 and IT Biomedical (Medical Device) quality management systems. Mrs. Skipper has a Master of Science in Pharmaceutical Quality Assurance and Regulatory Affairs from the Temple University School of Pharmacy. Mrs. Skipper has attained professional certifications in Quality Auditing, Quality Operational Management, Project Management, and IT Service Delivery.

EDUCATION

M.S., Quality Assurance and Regulatory Affairs, Temple University School of Pharmacy, 2005
M.B.A. Foundations, Temple University Fox School of Business; 18 cr. core courses only, 2003
B.A., English, Temple University, 2001

CERTIFICATIONS

ASQ Certified Quality Auditor (CQA) 2007 to present
ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE), 2008 to present
PMI Project Management Professional (PMP) 2009 to present
ITIL v3 Foundations 2010 (no expiration)

PROFESSIONAL ACTIVITIES:

Accepts invitations to serve on the ASQ Certified Quality Auditor Exam Committee
Accepts invitations to serve as a preliminary round judge for the ASQ International Team Excellence Award
Accepts invitations to serve as an assistant proctor for ASQ certification examinations

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WORK EXPERIENCE

As a **Principal Consultant at Ticalion Quality Management Services LLC, Leesburg Virginia | June 2004 to Present**, Mrs. Skipper deploys and remediates quality management systems to support global regulatory compliance requirements, third party certification/registration and organizational business process improvement. She performs assessments (audits) of systems and data to assist customers with establishing system baselines, eliminating systemic deficiencies. Mrs. Skipper's expertise and experience include:

- quality management system deployment and remediation,
- IT/medical device quality systems
- deployment of complex quality systems for simultaneous compliance to multiple standards and regulatory requirements
- complex risk assessment and risk management
- biosurety/biosafety BSL 1-4 safety
- validation (cold chain, laboratory equipment, computerized systems, and process)
- quality audit and
- Corrective/Preventive Action

Projects/Assignments under Ticalion

- **Aseptic Liquid Manufacturing Quality Management SME to Nopras Technologies for the Quintiles Consulting / Hospira Project| January 2012 to present**, Mrs. Skipper works with a team of quality assurance consultants to provide 24/7 quality management expertise on the manufacturing floor for a sterile liquid drug product. Mrs. Skipper performs quality assurance activities such as batch record review and reconciliation, aseptic cleaning verification, environmental monitoring, and other activities required under the 21CFR210 and 21CFR211 Good Manufacturing Practice regulations and the FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing.
- **FDA Regulated Quality Management SME to CSC Global Business Solutions | September 2011 to Present**, Mrs. Skipper works with the contract team as a quality management strategy SME advising quality management strategy for CSC's re-competition bid for the continuation of the American Red Cross contract.
- **Medical Device Quality, FDA Compliance and Computer System Validation SME to CSC North American Public Sector for the American Red Cross Project | November 2009 to January 2012***, Mrs. Skipper deployed and maintained a tailored quality management system that is compliant with requirements documented in Title 21 of the Code of Federal Regulations for medical devices and blood products including but not limited to 21 CFR 820, 21 CFR 210, 21 CFR 211, 21 CFR 11, and 21 CFR 606 and

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the American Red Cross-FDA consent decree requirements. The quality system attained and maintains ISO 9001:2008 registration. Mrs. Skipper assured that program activities are in compliance with regulatory requirements including validation requirements for IT infrastructure classified as medical devices. She develops and oversees the maintenance of quality assurance documentation including quality metrics. She developed and maintains the quality system manual, quality plan and directs the implementation of the manual and plan. She determines quality department staffing needs and maintains appropriate staffing levels. She manages and mentors quality assurance staff. She directs internal and external quality audits. She interfaces with CSC's customer (the American Red Cross) to resolve quality concerns and to facilitate third party and FDA audits of the American Red Cross as related to CSC's work for the American Red Cross.

- **Computer Validation and FDA Compliance SME to CSC Government Health Services Division | November 2009 to contract end December 31, 2011**, Mrs. Skipper prevented significant contract abatement charges and threat of contract loss through rapid and effective design and commissioning of a Biomedical Information Technology Quality Management System merging the medical device, blood and cGMP regulatory requirements with consent decree requirements and corporate ISO 9001:2008 requirements for CSC's American Red Cross program. She successfully deployed a QMS compliant to multiple standards that attained ISO 9001:2008 registration in September 2010.

She successfully represented CSC as the Biomedical IT Quality Management subject matter expert during oral presentations for the contract proposal to CareFusion; a potential customer whose IT infrastructure and applications are regulated as medical devices.

She successfully represented CSC as the Biomedical IT Quality Management subject matter expert in CSC's proposal to Gambro Healthcare, a global medical technology company that supplies medical devices and therapies for kidney and liver dialysis.

She has performed as a subject matter expert advising CSC project teams on the installation and operation qualification requirements for infrastructure transfer from customer locations to CSC data centers.

- **Clinical and Quality Assurance SME to CSC Government Health Services Division / Dynport Vaccine Company | March 2006 – November 2009**, Mrs. Skipper performed as a clinical quality assurance subject matter expert and auditor for assigned project teams supporting phase 1 through phase 3 bio-defense vaccine studies conducted in the United States and Europe. She assessed clinical trial proposals and activities, vendor

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qualification and vendor compliance to GCP regulatory requirements. She evaluated data transfer specifications, data format specifications, data management systems and data management processes for suitability, adherence to CDISC, ICH and FDA compliance requirements.

Mrs. Skipper served as a key member of bio-surety, bio-safety and risk assessment strategic teams responsible for feasibility, bio-safety and risk mitigation planning for building a U.S.-based vaccine manufacturing facility utilizing a whole virus select agent construct.

- **Quality System Deployment for ISO registration with NuGEN Inc. | June 2004 to October 2006**, Mrs. Skipper performed gap analysis assessments of the quality management system and facilitated the deployment of an ISO 13485:2003 quality system compliant to FDA regulations for an analytic reagent manufacturer and supplier to regulated industry. Mrs. Skipper assisted in the development of standard operating procedures and the quality manual. Mrs. Skipper retrospectively validated the REES Scientific environmental monitoring system that was installed in the facility.
- **GCP Quality System Deployment with Shin Nippon Biomedical Laboratories | January 2005 – October 2005**, Mrs. Skipper advised the start-up team on GCP regulatory requirements, deployed the basic quality system and created quality system documentation (Quality Manual, Validation Master Plan, Standard Operating Procedures) for start-up phase I/IIa clinical trial facility. Mrs. Skipper worked with the software vendors to validate the Perceptive Informatics electronic data capture system and Reese Scientific temperature monitoring system.

As an **Associate Director of Quality Assurance with Morphotek, Inc., Exton Pennsylvania | February 2004 – July 2005**, Mrs. Skipper commissioned a QSR-based GMP/GLP/GCP compliance and quality management program for a startup biopharmaceutical company to manage activities associated with Research and Development, technology transfer, cGMP manufacturing, pre-clinical development and clinical development of therapeutic recombinant monoclonal antibody products. She participated on senior management strategic teams supporting investigational product selection, manufacture and development from R&D stage through phase I clinical studies. She represented the company externally to regulatory authorities, business partners, contract research organizations, contract manufacturing organizations, and by participating on professional committees. She was responsible for product stability programs and the release/rejection of components, active pharmaceutical ingredient (API), bulk drug substance (BDS), finished dosage form (FD) and container closure systems.

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As a Clinical Project Manager/Quality Assurance Compliance Group Manager at Bio-Imaging Technologies, Inc., Newtown, Pennsylvania | January 2003 to February 2004, Mrs. Skipper coordinated and managed activities associated with the acquisition, processing, read sessions and data output deliverables for the medical imaging component of clinical studies for corporate clients in the pharmaceutical, biotechnology and medical device industries. She performed technical and regulatory writing in the form of project specific work instructions, communications documents, workflow and specifications documents, imaging guidelines, project status reports, methodology reports, computer assisted masked read (CAMR) outlines and export specification outlines.

As a member of the Quality Assurance Compliance Group, Mrs. Skipper assisted the Director of Quality Assurance in identifying internal quality control issues and in formulating and implementing solutions. She facilitated client audits and prepared written documentation such as project specific work instructions, project specific SOPs, and other audit related follow-up and supplemental documentation.

As a Clinical Drug Packaging Project Manager at Quintiles Transnational Corporation, Mount Laurel, New Jersey | July 2001 to December 2002, Mrs. Skipper generated \$1.425 million in revenue in a single month, successfully managing the clinical packaging for 22 concurrent projects. Mrs. Skipper coordinated and managed GMP activities associated with the design, packaging, storage, distribution, return and destruction of clinical study IP and supplies for corporate clients in the pharmaceutical, biotechnology and medical device industries. She identified and procured supplies to accomplish package design, maintain product stability and protect blind integrity.

Experience prior to July 2001 consists of project management and paralegal experience outside of the pharmaceutical/biopharmaceutical industry.