Robert Z. Phillips
MBA, RAC, CMQ/OE, PMP, RMP

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PROFILE

An accomplished transformational leader, proven strategist, skilled communicator, team builder, and adept negotiator who blends expertise in global regulatory affairs and quality management with exceptional skills in business development and operations management. Proven ability to analyze global regulatory and quality trends, products, and services, and develop and deploy solutions that improve compliance, product quality, and competitive performance while aligning with corporate objectives and maintaining budgetary commitments.

CORE COMPETENCIES

Global Regulatory Compliance
Quality Engineering/Assurance/Control
Corporate & Product Risk Management
Organizational Development & Restructuring
Strategic Planning & Tactical Execution
Government/Legislative & Trade Association Engagement
Acquisitions, Licensing, & Joint Ventures
Investment Gating Management
Collaborative, Cross-functional Partnerships
Business Process Enhancement & Optimization
Customer Loyalty & Advocacy Improvement
Multi-industry Expertise - Medical Device/Pharma /Biotech

PROFESSIONAL EXPERIENCE

Siemens Healthcare, Malvern, PA. 10/2012 - Present

Vice President, Quality & Regulatory, North America for this medical device manufacturer (Class I, II, III). Responsible for regional quality operations, systems, and regulatory compliance across the regional sales and service organization for the entire healthcare product portfolio. Reports to EVP Regional Unit and Global SVP RA/QA. Member of Management Team. Primary focus: Medical Imaging (e.g., MR, SPECT, PET, CT), Radiation Therapy Planning, and *In vitro* Diagnostic devices (automation, instrumentation, & assays). (3/2016 – Present)

Regional Responsibilities:

- Quality Systems, Quality Assurance, Regulatory Compliance, Regulatory Agency Inspections, Executive Management Reviews, Regulatory Intelligence, Adverse Event Reporting, Corrections & Removals, Import & Export Compliance, Supplier Quality, Sustainability, Corporate Auditing, Objective Planning & Execution, Facility Registrations, Product Submissions & Approvals, Technical & Regulatory Standards, Government/ Legislative & Trade Association Engagement, Innovation Program, Product & Solution Security, and Environmental, Health & Safety.

Key Activities/Accomplishments:

- Developed and implemented a regional strategic vision and mission consistent with Corporate Objectives and industry-leading Quality, Regulatory, and Compliance performance requirements.
- Assembled a high performance team to assure effective and efficient execution of strategic vision.
- Established future-state regulatory intelligence and compliance strategies to predict and respond to emerging global requirements well in advance of need.
- Established and maintained relationships with key regulatory authority personnel (inc. FDA) and industry organizations (inc. MITA, AdvaMed) to influence/garner support for Siemens Strategic Objectives.
- Planned and completed a comprehensive restructure of Quality and Regulatory teams and cross-functional processes across USA and Canada into a centralized organization. Led regional business-critical processes to drive top and bottom line financial improvements.
- $65+ million increase in top line (revenue increase) and $7+ million decrease in bottom line (efficiency savings) financials in one (1) year due to improved regulatory clearance times, efficiency improvements, and resource utilization across USA and Canada.

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Prior Role:

- Vice President, Quality Operations, Systems, & Regulatory Compliance for this medical device manufacturer (Class I, II, III). Responsible for global quality operations, systems, and regulatory compliance across ten (10) domestic and international manufacturing sites. Reported to Global SVP RA/QA. Member of Management Team. Primary focus: *In vitro* Diagnostic devices (automation, instrumentation & assays). (10/2012 – 3/2016)

Key Activities/Accomplishments:

- Planned, initiated, and managed a restructure of key Quality Operations teams and cross-functional processes across ten (10) domestic and international manufacturing sites to a centralized organization. Led global business-critical processes.
- Cleared FDA three (3) Warning Letters inc. hosting of multiple FDA and ISO NB inspections/audits.

Teleflex, Reading, PA. 5/2010 – 9/2012

Vice President, Regulatory Affairs & Quality Assurance for this medical device manufacturer (Class I, II, III). Responsible for global quality and regulatory affairs across five (5) strategic business units and two (2) regional organizations. Reported to Global VP RA/QA. Member of Management Team. Primary focus: Vascular Access, Respiratory, Anesthesia, Surgical, and Cardiac Assist devices.

Global Responsibilities:

- Quality Systems, Quality Engineering, Quality Assurance, Quality Control, Regulatory Compliance, Regulatory Agency Inspections, Executive Management Reviews, Regulatory Intelligence, Adverse Event Reporting, Corrections & Removals, Import & Export Compliance, Supplier Quality, Sustainability, Corporate Auditing, Objective Planning & Execution, Facility Registrations, Product Submissions and Approvals.

Key Activities/Accomplishments:

- Developed and implemented a global strategic vision and mission consistent with Corporate Objectives and industry-leading Quality, Regulatory, and Compliance performance requirements.
- Directed global Quality and Regulatory Affairs during the transformation of a predominately aerospace business to a pure-play medical device company. Inspired others to create a culture of quality and enable compliance and accountability throughout the transformation.
- Restructured key Quality and Regulatory processes and teams across five (5) strategic business units, two (2) regions, and one (1) corporate team to a centralized organization servicing all divisions and support functions. Led global business-critical processes and product line activities.
- Assembled a high performance team to assure effective and efficient execution of strategic vision.
- Performed due diligence on acquisition targets. Integrated acquisitions and licensing activities to enable operational synergies and realize efficiencies.
- Provided regulatory guidance and risk statements for Press Releases, SEC disclosures, Underwriter assessments, and Independent Accounting Firm certifications.
- Established future-state regulatory intelligence and compliance strategies to predict and respond to emerging global requirements well in advance of need.
- Established relationships with key regulatory authority personnel inc. FDA, EMEA CAs, PMDA, HC, etc. to foster confidence in regulatory compliance and the safety/efficacy of novel technologies.
- Cleared FDA Corporate Warning Letter inc. hosting of multiple FDA and ISO NB inspections/audits.
- Proactively managed and reduced 2011 functional spend by 7% over 2010. Forecasted functional spend for 2012 reflects an additional 12% reduction as a result of realizable 2011 improvements to process efficiency and resource utilization.

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Philips Healthcare, Cleveland, OH. 1/2007 – 5/2010

Sr. Director, Quality, Sustainability, & Regulatory Affairs for this medical device manufacturer (Class II). Responsible for global regulatory affairs, quality, and sustainability across three (3) strategic business units. Reported to Global SVP Imaging Business Unit. Member of Management Team. Primary focus: Medical Imaging (e.g., SPECT, PET, CT) & Radiation Therapy Planning.

FORMER ROLES/EXPERIENCE

Medical Device

Vice President, Sales, Marketing, & Business Development – Primary focus: Reconstructive & Neuro Surgery
Director, Quality & Regulatory Affairs – Primary focus: RF Ablation & Reconstruction Implants
Sr. Manager, Regulatory Affairs – Primary focus: Intravascular Ultrasound
Manager, Regulatory Affairs – Primary focus: Cardiac Assist

Pharmaceutical

Supervisor, Quality Control – Primary focus: OTC & Prescription Pharmaceuticals (multiple dose types)
Sr. Engineer, Validation – Primary focus: OTC & Prescription Pharmaceuticals (multiple dose types)
Team Leader, Packaging Operations – Primary focus: OTC & Prescription Pharmaceuticals (solid doses)
Chemist, Product Development – Primary focus: OTC & Prescription Pharmaceuticals (solid doses)

Biotechnology

Director, Quality & Regulatory Affairs – Primary focus: Biotech Formulation & Manufacturing

AFFILIATIONS/CERTIFICATIONS

Siemens Leadership Representative, Advanced Medical Technology Association (AdvaMed)
Siemens Leadership Representative, Medical Imaging and Technology Alliance (MITA)
Siemens Leadership Representative, Association for the Advancement of Medical Instrumentation (AAMI)
Senior Member, American Society of Quality (ASQ)
Member, Society of Regulatory Affairs Professionals (RAPS)
Member, Project Management Institute (PMI)

Industry Representative, FDA Device Good Manufacturing Practice Advisory Committee
Vice Chair, Technical Regulations Committee, Medical Imaging and Technology Association (MITA)
Vice Chair, Service Committee, Medical Imaging and Technology Association (MITA)
Vice Chair, Ultrasound Committee, Medical Imaging and Technology Association (MITA)

Certified Regulatory Affairs Professional (RAC), RAPS (United States, European Union, Canada)
Certified Project Management Professional (PMP), PMI
Certified Risk Management Professional (RMP), PMI
Certified Manager of Quality and Organizational Excellence (CMQ/OE), ASQ
Certified ISO 9001:2008/2015 & ISO 13485:2003/2016 Lead Assessor, RABQSA

EDUCATION

Masters of Business Administration, Santa Clara University
Bachelors of Science of Business Administration, University of Phoenix
Extensive undergraduate work in Chemistry & Microbiology