**ELISABETH M. GEORGE**

[redacted]

## Education

- Northeastern University Boston, MA — Masters Certificate in Engineering Management
- Boston University — Bachelor in Science in Biomedical/Electrical Engineering
- Boston Latin School

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## Professional Summary

- More than 25 years of increasing responsibility in global government affairs, standards, quality and regulatory affairs
- More than 15 years of "hands on" and strategic supervisory/management experience
- Strong, multi-disciplinary technical and professional skills

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## Professional Experience

**December 2010 – Present** — ***Philips Healthcare*** — **Vice President of Global Government Affairs, Regulations and Standards**

Manage strategic planning and technical aspects of Global Government Affairs, Regulations and Standards for Philips Healthcare Businesses (Imaging Systems, Home Healthcare and Patient Monitoring/Cardiac Care). FDA Emergency Response Contact. Chairperson for MITA Technical & Regulatory Affairs Committee. NEMA MITA Board of Directors and Member of X-Ray Committees. AdvaMed Regulatory Committee and Board Member. Industry Risk Communication FDA Panel. MITA MDUFMA Negotiating Committee. Frost & Sullivan Medical Devices Advisory Board. Interface with global regulatory authorities and government agencies. US Access Board Advisory Committee for Medical Diagnostic Equipment.

**April 2006 – December 2010** — ***Philips Healthcare*** — **Vice President of Quality, Regulatory, Sustainability, Product Security & Privacy**

Manage strategic planning and technical aspects for quality, regulatory, security and sustainability compliance for twenty-seven design and manufacturing facilities for Imaging Systems Businesses. Responsible for technical teams ensuring worldwide compliance and continuance improvement in product submissions, post market surveillance, product reliability improvement, quality systems (ISO13485, 21CFR), environmental management system (ISO14001 & OHSAS 18001) and business systems for the following product families: X-Ray Systems, MR Systems, CT Systems, Nuclear Medicine Solutions and Generators, Tubes and Components. Responsible for ISO 14971 Risk Management Program. PH Q&R Focal point for Supplier Quality Network, Product Security & Privacy Councils. FDA OB/GYN and Rehabilitation Advisory Panels Manufacturer's Representative. FDA Emergency Response Contact for PH. Chairperson for MITA Technical & Regulatory Affairs Committee. Industry representative and Secretary to GHTF SG 4. NEMA MITA Board of Directors and Member of X-Ray Committees. Advamed Regulatory Committee and Board Member. MITA presentation to Congressional Health Ways & Means Committee in 2008. Industry Risk Communication FDA Panel.

**December 2001-** ***Philips Medical Systems*** **Vice President of Quality, Regulatory,**
**April 2006** **Sustainability & Product Security**
***(formerly Agilent Technologies & HP)***

Manage strategic planning and technical aspects for quality, regulatory, security and sustainability compliance for seven design and manufacturing facilities. Responsible for technical team ensuring worldwide compliance in product submissions, post market surveillance, quality systems (ISO13485, 21CFR), environmental management system (ISO14001) and business systems for the following product families: patient monitoring, cardiographs, information systems, wireless devices, in vitro diagnostics, homecare products, defibrillators and associated services and supplies. Responsible for ISO 14971 Risk Management Program. Focal point for PMS for Training Systems, HIPAA, JCAHO and Product Regulatory Submissions Strategy and Requirements. PMS Q&R Focal point for Supplier Quality Network and Product Security Councils. FDA Emergency Response Contact for PMS. FDA OB/GYN Advisory Panel Manufacturer's Representative.

**Jan. 1998 –** ***Philips Medical Systems*** **WW Quality & Regulatory Director**
**December 2001** ***(formerly Agilent Technologies & HP)***

Manage strategic planning and technical aspects for quality and regulatory compliance and WW submissions programs (US - 510(k), PMA and Rest of World for medical, information and telecom systems for domestic and international laws and regulations for software and hardware solutions. Manage quality and regulatory personnel . Define, implement and maintain QSR, EN46001 and ISO13485 quality programs for Patient Monitoring Division, Point of Care Business and CHF Home Products Business. Supported ISO 14001 certification. Interface with FDA, European Competent Authorities, Canadian, AP and South American Ministries of Health on submissions and vigilance reporting and analysis. Responsible for EMC, LVD, RTT&E, MDD and IVD Compliance. Champion quality improvement programs including six sigma programs. Manage engineering personnel located in US and International Facility. Member of executive staff for $800 million patient monitoring, clinical information, point of care diagnostic, home care and wireless solutions. Responsible for FCC petition for medical telemetry radio frequency management program and PTT international submissions and licenses. Responsible for petition for Fetal Scalp Electrode with FDA to extend utilization. Define technical requirements necessary for meeting country patient safety regulations. Responsible for third party partnership quality and regulatory agreements for software and hardware contracts. Interface with cross-functional project management to support development and product life cycle management. Manage post market surveillance investigations and corrective action programs. Six Sigma training classes and project management of Six Sigma Black Belts direct reports. Partnership and contract Q&R analysis for OEMs and future potential procurement.

**Oct. 1993 –** ***Hewlett-Packard Company*** **Regulatory Manager**
**Dec. 1997** ***Healthcare Solutions Group***

Responsible for regulatory submissions and strategy definition for medical systems for domestic and international laws and regulations for software and hardware solutions including bedside patient monitors(fixed & mobile), clinical information systems, central stations, cardiographs and defibrillators. Defined, created and implemented a quality system in Healthcare Management Division.

**May. 1993 – Oct. 1993** ***Sterimatics Corporations a subsidiary of Millipore*** **Quality/Regulatory Manager**

Manage technical and administrative aspects of quality, regulatory and documentation control departments for a military/medical device design and manufacturing operation. Setup quality program including training program. Interfaced with regulatory agencies.

**Nov. 1991 – May 1993** ***Haemonetics Corporation*** **Equipment Operations Manager**

Managed production schedules and staff. Provided technical guidance for pilot production and low to high volume production lines in the manufacture of sophisticate electromechanical blood washing and separating equipment. Reduced manufacturing floor space required by 50% while increasing output by 30% using cell design and time study principles. Eliminated kit pulling for monthly scheduled builds of up to 250 machines by implementing min/max system to support daily shipments. Responsible for training personnel and implementing SPC improving out of box quality levels 20% over 6 months. Trained personnel in manufacturing processes, policies and procedures to meet quality and regulatory requirements.

**Dec. 1989 – Nov. 1991** ***Haemonetics Corporation*** **Director of Quality & Regulatory**

Managed technical and administrative aspects of quality and regulatory departments. Extensive experience with supplier selection, qualification and management. Significant experience with new product hardware and software introduction and current product maintenance. Responsible for UL, CSA, TUV and City of LA applications, renewals and audits . Responsible for quality and regulatory programs for electromechanical and disposable equipment design, manufacturing and distribution facilities. Reduced quality control inspection and testing of finished devices by 75% through use of SPC and training of manufacturing personnel. Principal contact with FDA, Ministries of Health and DCAS. Prepared product approval and vigilance submissions. Established policies, procedures for document control systems. Established comprehensive ESD Program and audit program. Certified quality auditor.

**Additional Professional Experience**

- *Electro-Optics, a division of Honeywell* – Quality Assurance Manager: 1983-1989(included Secret Level Security Clearance)
- *MicroSwitch, a division of Honeywell* – Test Engineer: 1982-1983
- *Stone and Webster Engineering Corp.* – Control Systems Engineer: 1980-1982
- *Teledyne Crystalonics* – Junior Engineer: 1979-1980
- *Boston Children's Hospital* – Orthopedic Lab Engineer Technician: 1976-1979

**Technical Memberships/Affiliations**

Institute of Electrical and Electronics Engineers(IEEE) since 1979
Biomedical Engineering(BME) Society since 1977
Who's Who in Professional and Executive Women since 1986
American Society of Quality(ASQ) since 1989
Member of Advance Medical Technology Association (AdvaMed) since 1991
Member of AdvaMed Technical and Regulatory Council since 2007
Member of AdvaMed Medical Technology Preparedness Council since 2001
American Association for Medical Instrumentation(AAMI) since 1991
American National Standards Institute (ANSI) since 2012

Regulatory Affairs Professionals(RAPS) since 1993
The Organization for Professional in Regulatory Affairs(TOPRA) since 2006
Industry Representative to FDA OB/GYN Advisory Panel April 2005-January 2009.
Substitute Industry Representative to FDA Rehabilitation and Orthopedic Advisory Panel 2008
FDA Emergency Response Contact for Philips
Member of National Electrical Manufacturer's Association (NEMA/MITA) since 2006
Chairperson for the MITA Technical & Regulatory Affairs Committee since 2007
Member of MITA X-Ray Committees and Board Member since 2007
Industry Representative to GHTF SG4 since 2007.
Secretary to GHTF SG4 2008 thru' 2011
Industry Representative to FDA Risk Communication Advisory Committee since 2010
Primary Industry Representative for Radiological Devices Panel Advisory since 2012
DITTA Representative since 2010
MITA MDUFMA Steering and Negotiating Committee since 2010
Technical and Keynote Speaker at Conference since 2000 : India, China, Brazil, EU, Canada & US
National Association of Professional Women since 2010
Frost & Sullivan MindExchange Presenter/Panel Representative 2008 – present
Frost & Sullivan Medical Devices Executive Advisory Board 2011-present

. **Miscellaneous**

- Presenter at Global Conferences – Advamed, AAMI, RAPS, Frost & Sullivan, Opal Events and Government Sponsored - US, India, China, Brazil & Europe.
- Experience with SPC, TQM, Supplier Certification, Risk Analysis and Taguschi Principles
- Extensive training/certifications in Medical Device Quality Regulations and Standards ISO9001/EN46000/ISO13485, MDD, LVD, IVD, EMC, FCC, RTT&E, ISO14971, IEC601 and associated global standards and regulations and Environmental Management Systems ISO14001 and associated product standards
- Certified Trainer in Visual Factory Design, Quality Auditing, Regulatory Submissions
- Fluent in German
- Testified in Congress Energy & Commerce Committee on FDA Globalization Act – May 08.
- Assisted paper,"Mouse Bone Collagenase" Archives Biochemical/Biophysics Vol.189, #1,8-7/78

**Hobbies and Other Affiliations**

Local Cable Access TV – Videographer, Audiographer, Set Design & Manager 1997- 2004
Co-Owner of Twin Star Media (Video, Audio and Photography) since 1997
Co-Coach for Little League Baseball 1992-1999
Coach Pop Warner Cheerleading 1995-1999
Assistant Coach for High School Cheerleader Squad 2000 - 2004
Member of High School Booster Club 2000 - 2004
Chairperson of Family Services Committee and Education Program Committee at JCC 1992-98
Co-chairperson of Social Activities Committee at JCC 1994-1998
Board of Director's at JCC 1995-1997