

Profile

Director of Regulatory Affairs with multi-faceted strengths in RA, QSR, Product Safety, Procedure / SOP Development, Pre-Clinical and Clinical Trial Design for FDA and International submissions. Over 10 years of Regulatory Affairs experience as part of a successful 25 year career with increasing responsibilities, demonstrated common sense, enterprise-wide vision, business acumen and RA skills to forge partnership and strategies for worldwide product submissions and approvals. Led diverse groups to reach consensus on complex requirements that deliver safe and effective products. Diplomatic and tactful with professionals and non-professionals at all levels. Accustomed to handling sensitive, confidential records. Committed to earning the trust and respect of peers, executives and business partners through a sincere, energetic and accountable approach combined with continuous personal improvement. Demonstrated ability to drive change throughout various organizational structures from a strategic vision to tactical execution.

Professional Experience

REGULATORY STRATEGY / SOLUTIONS

- ◆ Prepared complex new product submissions using 510(k), PMA submissions.
- ◆ Coordinated and lead pre-submission meetings with regulatory authorities resulting in product commercialization with claims needed for market differentiation.
- ◆ Developed registration strategy that results in product commercialization in markets with greatest opportunity for revenue.
- ◆ Mentored direct reports on use of competitive market information combined with regulatory knowledge to develop RA strategies that have business impact.
- ◆ Developed over 30 510(k) submissions that drove new product introductions within the US
- ◆ Developed original PMA submission for new Class III product, as well as multiple PMA supplements for an existing Class III product line.

EXTERNAL INVOLVEMENT

- ◆ IEC Convener for maintenance team MT-31 that develops international product standards
 - IEC 60601-2-45 Product Safety and Essential Performance of mammography systems
 - IEC 61223-3-2 Acceptance Tests – Imaging performance of mammography systems.
- ◆ MITA Chairman of the mammography sub-committee driving a consensus among industry manufacturers.
- ◆ Industry Representative to National Mammography Quality Assurance Advisory Committee to FDA.

ORGANIZATIONAL LEADERSHIP

- ◆ Manage a team of direct reports to ensure:
 - Regulatory requirements are included in new product development.
 - New product registrations are completed as needed for product commercialization in target markets
 - Regulatory strategy includes business input for registration priorities
 - Business leadership considers regulatory team a trusted partner

Employment History

GE Healthcare - 03/1986 to present

Director of Regulatory Affairs – X-ray

10/2011 to present

- ◆ Responsible for global product development and registration for radiographic, fluoroscopic, bone mineral densitometry, and mammography equipment.
- ◆ Responsible for global regulatory affairs team operating in various product development sites.
- ◆ Lead regulatory strategy discussion with external regulators and with internal business partners.
- ◆ Led development and submission of new original modular PMA.

Regulatory Affairs Manager - Mammography

1/2008 to 10/2011

- ◆ Responsible for global mammography product development and registration.
- ◆ Developed global product regulatory requirement and product registrations including multiple FFDM PMA supplements
- ◆ Responsible for evaluation of product safety standards, QC testing, and interfacing with global regulatory agencies.
- ◆ Responsible for product input on MQSA requirements and interaction with FDA MQSA office.

Regulatory Affairs Program Manager

2/2006 to 1/2008

- ◆ Drove consistent application of the Quality Management System across multiple GE Healthcare business segments
- ◆ Developed procedures to ensure compliance with changing international regulatory requirements
- ◆ Reviewed and provided internal feedback on regulatory submissions for new product development
- ◆ Participated in Global International Standards development committees

Safety and Regulatory Engineer

9/2001 to 2/2006

Steven J. Kachelmeyer

- ◆ Provided regulatory design input for new product development
- ◆ Developed, and cleared 510(k) submissions for over 30 new products including
 - More than 20 510(k)'s for MR systems or MR coils
 - 4 510(k)'s for CT systems or CT options
 - 5 510(k)'s for post processing software application used in CT or MR applications
- ◆ Participated in Global International Standards development committees

Product Development and Marketing Manager

7/1999 to 9/2001

- ◆ Defined product requirements based on user needs
- ◆ Led new product development projects
- ◆ Delivered a revenue target while managing a product development budget

6 Sigma Black Belt

11/1997 to 6/1999

- ◆ Led quality improvement projects to reduce defects and product cost
- ◆ Trained and mentored others on the use of the 6 Sigma methodology and tools
- ◆ Presented project results to business leadership

Service Designer and Integrator – Mammography

10/1995 to 11/1997

- ◆ Defined service requirements to ensure product serviceability after installation
- ◆ Supported customer satisfaction issues including image quality and service issues
- ◆ Developed service procedure input for new products

Service Support Engineer – Mammography

2/1992 to 9/1995

Steven J. Kachelmeyer



- ◆ telephone and on-site when required Supported field service engineers by
- ◆ with mammography image quality Supported customer satisfaction issues
- ◆ product development team Provided service issue feedback to

Field Service Engineer

3/1986 to 2/1992

- ◆ products Installed and serviced X-ray and MRI
- ◆ reports including required FDA assembler reports Completed required installation and service
- ◆ equipment Troubleshot equipment failures and repaired

Education

Keller Graduate School of Management
Waukesha, WI

MBA - Masters in Business Administration, Concentration in Marketing 1997

DeVry Institute of Technology
Lombard, Illinois

BSEET Bachelors Engineering Technology Electronic Technology 1986

Other Qualifications

- ◆ **RAC** - Regulatory Affairs Certification from Regulatory Affairs Professional Society
 - **USA** certification – 2006;
 - **EU** certification – 2007
- ◆ Medical Imaging Technology Association (MITA) - Chairman of Mammography working group
- ◆ International Electro-technical Commission (IEC) - Convener of Maintenance Team MT-31 responsible for Mammography Particular Standard IEC 60601-2-45 and Mammography Acceptance Testing IEC 61223-3-2
- ◆ 6 SIGMA certified Black Belt