Diane Uriell, MBA, RAC

(b) (6) [redacted]

A Regulatory Affairs Professional with extensive experience in leading teams that achieve strategic and operating plans critical to the realization of timely global regulatory approvals. Areas of expertise include:

- Product Development Strategy and Execution
- Project Management and Implementation
- Global Medical Device Regulations
- Global Regulatory Agency Interactions/Negotiations
- Develop/Retain High Performing Teams
- Regulatory and Scientific Standards

PROFESSIONAL EXPERIENCE

GE HEALTHCARE — 2015 – Present

Sr. Director, Global Regulatory Affairs Xray and Women's Health

Led global team of 10 professionals supporting the Xray and Women's Health business units. Team established and implemented regulatory strategies and processes for research, development and product continuation projects for timely global product regulatory approvals.

- Provided regulatory leadership to General Managers for Xray and Women's Health in support of the business annual operating plan and strategic plan that resulted in timely worldwide product launches in support of planned revenues.
- Played critical role in developing global regulatory strategies for PMA/510k mammography and 510k xray devices. Interacted and negotiated with global agencies to achieve a least burdensome regulatory approach whereby reducing the cost and timeline to gain product approval.
- Developed team members through coaching, mentoring and high profile project assignments resulting in 100% retention.
- Provided critical input to the regulatory department annual operating plan to establish the appropriate funding and resources needed to support business goals. Successfully managing pace and volume of projects was critical to obtaining work life balance attributed to employee satisfaction.
- Nominated for non-voting industry member on the National Mammography Quality Assurance Advisory Committee.

MEDTRONIC, INC. — 2001 – 2015

Director Regulatory Affairs (2013 – 2015)

Led team of 16 professionals supporting the Cardiac Rhythm Heart Failure, Bradycardia Therapy Business Unit. Team established and implemented regulatory strategies and processes for the development and product continuation projects for timely global product regulatory approvals. Led department regulatory operations professionals supporting electronic submissions, filing, product release and Unique Device Identifier processing.

- Played critical role in developing global regulatory strategies for PMA implantable cardiovascular devices, including novel combination product technology. Interacted and negotiated with global agencies to achieve a least burdensome regulatory approach whereby reducing the cost and timeline to gain product approval.
- Developed team members through coaching, mentoring and high profile project assignments. Specific results include promotion of 2 team members in 2014 and retaining 100% of team.

- Provided regulatory leadership to the General Manager in support of the business annual operating plan and strategic plan that resulted in timely worldwide product launches in support of planned revenues.
- Provided critical input to the regulatory department annual operating plan to establish the appropriate funding and resources needed to support research and development projects. Successfully managing pace and volume of projects was critical to obtaining work life balance and attributed to employee satisfaction.
- Selected to represent Medtronic through the Advanced Medical Technology Association (AdvaMed) to advocate FDA regulatory policy and guidance.

Sr. Manager, Regulatory Affairs (2006 – 2013)
Provided leadership for 7 professionals in the Cardiac Rhythm Disease Management Business Unit to develop and implement regulatory strategies and processes for development and product continuation projects for timely product approvals.

- Developed and implemented global regulatory strategies for software, Medical Device Data System (MDDS), mobile applications, instruments, and implantable cardiovascular devices through collaboration with internal team members, physicians, consultants, and global regulatory agencies that resulted in timely regulatory approvals.
- Developed onboarding process for new employees that resulted in a relevant and meaningful training with employee's ability to contribute to department in a shorter period of time.
- Developed process for product development teams to plan and compile critical documentation to ensure suitability for global submissions that resulted in reduction of agency questions.
- Reviewed submissions (510k, pre-IDE, IDE, PMA) for regulatory professionals and provided coaching and mentoring that resulted in continued development of teams regulatory skills and mitigated potential agency questions for timely product approvals.

Sr. Principal Regulatory Affairs Specialist (2004 –2006)
Maintained and expanded responsibilities from previous position to include more complex projects and leadership as global regulatory point of contact representing worldwide geographies. Provided work direction, training and regulatory coaching to less experienced members of the regulatory department.

- Developed Regulatory Change Control Board within department that resulted in consistent and efficient processing and assessment of design and manufacturing changes.
- Participated in development of GLP animal studies and GCP clinical trial designs (device and combination) that resulted in meeting agency expectations without unduly burden to the business.
- Reviewed and approved labeling, website content, promotional and educational materials that resulted in compliance with applicable regulations while still meeting the marketing goals.
- Provided continuing regulatory education and dissemination of regulatory information to the development, marketing, manufacturing and clinical groups. The cross functional collaboration resulted in greater understanding of the regulatory process and requirements.

Principal Regulatory Affairs Specialist (2001 – 2004)
Developed and implemented global regulatory strategies for software, instruments, and implantable cardiovascular devices through collaboration with global regulatory agencies to achieve timely product approvals.

BOSTON SCIENTIFIC SCIMED, INC. 1994 - 2001

Senior Regulatory Affairs Specialist (1998 – 2001)
Maintained and expanded responsibilities from previous position to include more complex projects and leadership as global regulatory point of contact representing worldwide geographies. Supported product development and product continuation projects through development and implementation of regulatory strategies to gain timely product global regulatory approvals and maintain regulatory compliance.

Regulatory Affairs Specialist (1996 – 1998), Regulatory Affairs Associate (1994 – 1996)

Supported product development and product continuation projects through development and implementation of regulatory strategies for Class II and Class III devices to gain timely product regulatory approvals and maintain regulatory compliance.

LIFECORE BIOMEDICAL - Regulatory Affairs Specialist **1990 - 1994**

Supported product development and product continuation projects through development and implementation of regulatory strategies to gain timely FDA regulatory approvals and maintain regulatory compliance.

EDUCATION AND PROFESSIONAL ORGANIZATIONS

- MBA, University of Phoenix
- BS, Biology, Winona State University
- Regulatory Affairs Professional Society (RAPS)
- RAPS Regulatory Affairs Certification (RAC)
- RAPS Atlanta Chapter
- Healthcare Business Women's Association (HBA) Atlanta Chapter, Board of Directors, Corporate and Public Relations