

RESUME

TIBOR DULISKOVICH, MD

14960 SHAMROCK LANE, BROOKFIELD, WISCONSIN 53005
(262) 391-6852, TIBOR@DULISKOVICH.COM, WWW.DULISKOVICH.COM

Overview of Industry Experience

- 2011 - present **Medical Director, Patient Safety Center of Excellence, GE Healthcare (from April 2014)
Previously Medical Director, MICT, DoseWatch and Advanced Workstation**
- **Promoting medical consciousness** and being the “Voice of the Patient” to the Leadership Team.
 - **Conducted 300+ post-market safety risk assessments, supported MDR reportability determinations, presented recalls at the Post-Market Safety Review Board (PSRB).**
 - **Supporting MICT, MR, PET/MR, Ultrasound, DGS, Surgery, Lunar, HCIT/AW with teams spread all over the globe.** Covering pre-market design safety and post-market complaints for 17 product lines in CT, 80+ applications on AW platform, IDI and DoseWatch, 20+ products in HCIT, 4 Lunar, 7 MR and PET/MR and 50+ platforms/product lines in ultrasound businesses and surgery.
 - **Designed and served as medical monitor for over 40 GE sponsored clinical trials for cardiac, pulmonary, neuro, oncology, pediatric, mammo indications and for radiation dose reduction.** Supported close to 80 investigator initiated studies resulting publications.
 - Interpreted clinical trial results and communicated to regulatory resulting in FDA 510(K) and CFDA (China) registrations and extension of indications for use for virtual-unenhanced imaging and nephrolith characterization in dual-energy CT, MR MAGIC and SAR, PET/MR SUV MR-based bone correction.
 - Continue to provide medical input into the IMDRF Software as a Medical Device: Clinical Evaluation (SaMD, <http://www.imdrf.org/workitems/wi-samd.asp>) workgroup.
 - **Worked with CHU to consolidate CT, AW, DoseWatch, mammo, Lunar and MR RACs with the global RAC. Wrote multiple guidelines to empower CHU.**
 - **Completed clinical literature evaluation summaries (CESR) to support safety and performance claims for CE mark** of CT products, AW products, mammography products and DoseWatch.
 - Built a portfolio of medical evidence to support NPIs, marketing claims and reimbursement strategy, including a **first-for-GE eDossier published on Academy of Managed Care Pharmacy System.**
 - **Lead five Medical Advisory Boards** for lung and breast cancer indications, coronary disease and myocardial viability, and dose management.
 - Revised multiple CT and X-Ray reference protocols against the AAPM Dose Check recommendations resulting in **10-15% dose reduction for patients.**
 - **Met face-to-face over 200 KOLs** in academia and research institutions to help advance Company’s luminary and research strategy.
 - Presented medical affairs vision, strategies and programs to major customers.
 - **Performed medico-clinical and risk assessments for acquisition due diligence for projects totaling \$500M+ USD.**
 - Medical Affairs representative into GE’s Government Relationships team (until April 2014)
 - **Created a Colab “GE Physicians” group to facilitate interactions amongst GE doctors in various roles, businesses and geographies.**
 - Supported HealthImagination, ValueLabs (UPMC CESM), i3 Innovation, London Olympics, PET/CT innovation workshop and PET/MR innovation summit.
 - Supported GEHC Education-As-A-Business strategies.
 - Published four articles in CT Clarity magazine on topics important for business, all related to radiation safety and diagnostic performance.
 - Continue to serve as medical liaison for medical societies (RSNA, ACR, ESR, SHR) and industry advocacy groups (DITTA, MITA, Dose Index Registries, ImageWisely).

- 2008 – 2011** **Sr. Product Manager, Enterprise Imaging Informatics at Philips Healthcare**
- **Member of Philips Healthcare global Medical Leadership Team, supporting strategic goals of Office of Medical and Health Affairs** lead by dr. Eric Silfen CMO.
 - Managed complete life-cycle of iSite Enterprise and iSite Radiology product lines and integration with clinical applications, including roadmaps, 3rd partner strategy, sales support, AOP. Delivered 9 releases, all on time of iSite PACS product lines that represented 95% of global customer base.
 - NPI launch responsibilities, positioning, pricing, promotion, sales tools and knowledge transfer, collateral owner, interface to clinical end-users.
 - Marketing owner of pre-development projects based on Scrum agile technology.
 - Co-authored two patents on user interface and image manipulations by radiologists (<http://www.freepatentsonline.com/WO2012001625.pdf>, <http://www.freepatentsonline.com/WO2012001637.pdf>)
 - Supported day-to-day quality, regulatory and patient safety activities, including but not limited to PACS, RIS, pathology and cardiology PACS, CT, XRays, PET/CT, MRI and ultrasound. Performed root cause analysis and closed numerous CAPAs.
 - Validated a “gold dataset” of images for automated software testing.
 - Virtualized entire RSNA demo environment.
 - Medical Science Liaison to Field Organization.
 - **Started "Innovations in Radiology" Philips' LinkedIn group and grew to 6000+ members.**
 - Member of Emergency Response Team.
- 2008 – current** **Owner of largest LinkedIn group dedicated to radiology (33K+ members)**
- Diagnostic Imaging Group www.linkedin.com/groups?home=&gid=80424
- 2009 – 2010** **Medical Consultant to Animage, LLC**
- Consulted in a clinical trial for veterinary imaging modality.
 - Prepared supporting documentation and the team for regulatory submission.
- 2009** **Medical Consultant to National Semiconductor, division of Texas Instruments**
- Due diligence on a medical technology acquisition deal worth \$20M+ USD.
- 2001 – 2008** **Medical Director, Aspyra, Inc.**
- Led a team of clinical application specialists and medical writers.
 - Developed requirements for PACS software and diagnostic mammography viewing station, redesigned GUI to assist radiologist workflow.
 - Personally introduced our products into two international markets, found local integrator companies, formulated contracts and closed the deals.
 - Coordinated clinical end-user training, performed on-site trainings. Introduced web-casts and CME-approved CBTs. Maintained demo database.
 - Supported major sales deals, dealt with unhappy customer sites.
- 2000 – 2001** **Sr. Manager of Research and Development, Wuestec, Inc.**
- Contributed to product definitions and design of digital X-ray detector.
 - Transformed a concept into an X-ray film scanning production line and business.
 - Participated in revising company's Quality System in response to a FDA consent decree.
- 1998-2001** **Medical Consultant to Medimon Engineering Service and Trading Co. Ltd.**
- MEDING (member of IFMBE-CED) postgraduate continuing education program lecturer.
 - Input into PACS/RIS software development.
- 1997-2000** **Consultant to Medicor Roentgen Corporation, later acquired by GE Healthcare**
- Input into R&D of medical equipment design, usability testing.
- 1995-2000** **Medical Consultant to Variotrade Co. Ltd (Toshiba)**
- Medical device testing and input into R&D.
 - Web design, medical literature translation, education of team.
- 1994-2000** **Consultant to Medicare Trading Co. Ltd. (GE ultrasound dealer)**
- Educating and training ultrasound demo personnel.
 - Medical and technical literature translation.

Academic, Clinical and Regulatory Experience

- 2015 – current Industry expert in IMDRF (International Medical Device Regulators Forum)**
I have the honor to represent GE and the medical devices industry via DITTA (Diagnostic Imaging, HCIT, and Radiation Therapy Trade Association, <http://globalditta.org/about/about-ditta/>) and work with global regulators in IMDRF (International Medical Device Regulators Forum, <http://www.imdrf.org/>), providing feedback into guideline development, clinical examples, and being voice of industry in the Software as a Medical Device (SaMD, <http://www.imdrf.org/workitems/wi-samd.asp>) workgroup.
- 1991 - 2000 Head of Organizational and Methodological Department at National Institute of Radiology and Radiation Physics, Budapest, Hungary**
The role of NIRRP was similar to the role of FDA's Center for Devices and Radiological Health.
- Responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from imaging devices.
 - Made financial decisions up to 30-40% of the Institute's annual budget. Built outstanding attrition record. Started with a team of 5 and grew it to 16.
 - Validated and certified imaging equipment and software in clinical environment on patients (ultrasound and CT, bone densitometers, X-ray film scanners, RIS and PACS).
 - Coordinated activities with national and international regulatory bodies. As part of a team, revised Hungarian medical devices regulations to harmonize with European ISO 9001 and EN 46001 prior to Hungary joining European Union.
 - Pursued funding opportunities (grant applications, industrial contributions).
- 1996 Visiting Consultant Radiologist at Health Center, Godollo**
- 1995 Radiology Fellow at Haynal Imre Medical University, Budapest**
- 1994 - 2000 Co-founder of Medirex 2000 Corp., a small primary care provider in Tura, Hungary serving several thousand patients.**
- 1991 - 1995 Radiology Resident at Haynal Imre Medical University, Budapest**
- Residency training necessary for radiologist qualification.
 - Research in the field of transrectal Color Doppler sonography and in 3D sonography technical solutions, particularly in examinations of human eye.
 - Performed various forms of professional training, graduate and resident teaching.

Education

Regulatory

2016 USA certified by the Board of Regulatory Affairs Professionals Society, <http://raps.org/>

Academic and Clinical Medicine

2016 Certified Magnetic Resonance Medical Director/Physician (MRMD) by the American Board of Magnetic Resonance Safety (<http://www.abmrs.org>)

1991 - 1995 Board Certified Diagnostic Radiologist, Haynal Imra Medical University, Budapest

1985 - 1991 Medical Doctor, Semmelweis Medical University, Budapest

1990 Paramedic Doctor, Semmelweis Medical University, Budapest

Certifications and Awards

2013	Strategic Excellence Award of GE Healthcare QRM business.
2010	Certified Adult/Child First Aid Provider, American Heart Association.
2006	Certified PACS Associate (PACS Administrator Registry and Certification Association).
2000	European Computer Driver License (ECDL) certification.
1999	Nycomed research award.
1998	The Society of Hungarian Radiologists ultrasound school educational grant.
1997	European Federation of Organisations for Medical Physics summer physics school grant.
1995	The Royal College of Radiologists research and travel grant.
1993	Medicom-Glaxo research award.
1985	Gold Medal of USSR Government for excellence in education (first in my school in 20 years).

Faculty Appointments

2000	Nominated for board member position in The Society of Hungarian Radiologists (declined due to relocation to Canada).
1998 - 2000	Medimon Corporation and MEDING (member of IFMBE-CED) postgraduate continuing education program lecturer and writer.
1996 - 2000	Member of several governmental grant review committees.
1998 - 2000	Served via NIRRP as independent expert in law suits.
1994 - 2000	Editor of Radiological Bulletin (HU-ISSN 0133-2791)
2000	Lectured at Kandó Kálmán College of Electrical Engineering, Budapest
1999	Established internet website for Society of Hungarian Radiologists.
1998	Several month long healthcare policy project as an external expert in Ministry of Health.
1994 - 1995	Educational activities (principal investigator, student dissertation discussant).
1992 - 1994	Launched lecture tours on digital radiology for countryside hospitals in Hungary together with two other radiologists, visited over a dozen rural hospitals.

Professional Affiliations

2015 - present	Member of Regulatory Affairs Professionals Society.
2014 - present	Member of Society of Radiologists in Ultrasound
2009 - present	Member of American College of Radiology
2008 - 2010	Member of The Association for Medical Imaging Management (AHRA)
2007 - present	Member of Radiological Society of North America
2006 - 2008	Member of PACS Administrator Registry and Certification Association
2004 - present	Member of Medical Industry Technology Alliance
1998 - present	Member of Association of Physicists in Medicine
1995 - present	Member of Roland Eotvos Physical Society
1994 - present	Fellow of the Hungarian Medical Chamber
1994 - present	Fellow of the The Society of Hungarian Radiologists
1994 - present	Member of European Society of Radiologists

Languages

Native in Russian, Hungarian. Proficient in English (Academic IELTS test score 8.5 out of max. 9) and Ukrainian.

References and Recommendations

<http://www.duliskovich.com/recommendations/index.htm>

<http://www.linkedin.com/in/duliskovich>

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