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PROFESSIONAL SUMMARY

Experienced Clinical, Medical, Regulatory professional with global responsibility encompassing national and international strategic planning for biological and device based interventional cardiology/radiology/neurology, active implantable, peripheral/central circulatory implantable, perfusion, cell-based therapy, drug elution and vascular/non-vascular stent products to support regulatory and marketing approvals.

PROFESSIONAL EMPLOYMENT

ALFA MEDICAL **2017-Present**
VP TECHNOLOGY, REGULATORY, CLINICAL AND MEDICAL AFFAIRS
Medical Device company developing minimally-invasive device-based and biological products to treat neurological, peripheral and cardiovascular disease states.

BOSTON SCIENTIFIC, INC. **2014 – 2017**
GLOBAL DIRECTOR, MEDICAL AND CLINICAL AFFAIRS
Global responsibility for Medical Affairs and the Investigator Sponsored Research program managing up to 55 active studies with a 3M annual budget.

Led Global Medical Affairs functions to support Peripheral Intervention business.

- Lead Investigator Initiated Studies (IIS) for PI business which encompasses between 35 to 55 studies researching vascular disease, pulmonary disease, urology, interventional oncology, stem cell and drug elution technologies.
- Led Clinical Affairs team to assure appropriate protocol development, effective reporting, monitoring, data analysis and management of IIS clinical studies designed to support regulatory submissions for market approval and indication expansion in the US and worldwide.
- Manage departmental budget, project timelines and resourcing
- Function as in-house resource for current medical treatment modalities as well as anatomy, physiology and pathophysiology as it relates to interventional medicine and vascular device implants.
- Support publication and presentation efforts of IIS study physicians.
- Led physician interaction and customer development to effectively evaluate protocol strategies and publications to support product claims and marketing requirements through IIS.
- Prepare and present clinical data to investigators, scientific groups and regulatory agencies.
- Recruit, coach and develop organizational talent across geographies

BAYER HEALTH CARE (Company was acquired by Boston Scientific) **2006 – 2014**
RADIOLOGY & INTERVENTIONAL, COON RAPIDS, MN
GLOBAL DIRECTOR, MEDICAL AND CLINICAL AFFAIRS
Global responsibility encompassing national/international clinical/medical/regulatory affairs for interventional cardiology/radiology and surgical products.

- Participate in strategic planning and product development functions and Led clinical trial strategy development for the Radiology and Interventional business units.
- Led Global and US pre-approval, post approval and IIS clinical studies (IDE, PMA, CE mark submissions).
- Led Medical Affairs functions to support Radiology and Interventional business.
- Led Clinical Affairs team to assure appropriate protocol development, effective reporting, monitoring, data analysis and management of clinical studies designed to support regulatory submissions for market approval and indication expansion in the US and worldwide.
- Led physician interaction and customer development to effectively evaluate protocol strategies and publication to support product claims and marketing requirements.
- Led Clinical Quality Management, Compliance and Training within Clinical Affairs.

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- Led safety surveillance activities and provide subject matter medical expertise while interfacing with internal groups responsible for product performance and regulatory patient safety reporting
- Responsible for Clinical Safety management and reporting.
- Led data interpretation, manuscript/report writing, scientific justification and result presentation activities to Regulatory agencies, IRB, Clinical Investigators and Medical Meetings.
- Responsible for Legal, Medical, Regulatory (LMR) review to support marketing and commercial activities.
- Recruited, coached and developed organizational talent across geographies
- Managed departmental budget, project timelines and resourcing
- Participated as Global team member for Bayer Heart Health Program, Global Quality Counsel and Global Medical Device Counsel

CVRx INC., MAPLE GROVE, MN **2004 –2006**
SENIOR MANAGER, CLINICAL RESEARCH
Responsible for the management of a global first in man clinical study with an active implantable device for the treatment of refractive hypertension.

- Responsible for the management, implementation and strategic direction for field clinical research to support US FDA IDE/PMAA, and worldwide regulatory submissions for novel investigational new products.
- Educated/trained surgeons, physicians, neurologists, study coordinators and medical staff on study protocol and use of investigational device.
- Managed the implant procedure and activities of surgical team to ensure adherence to the study protocol and all applicable regulations.
- Performed patient follow-ups and programming of investigational device at each follow-up interval.
- Recruit, select and train investigators for clinical studies.
- Support publication and presentation efforts of study physicians.
- Prepare and present clinical data to investigators, scientific groups and regulatory agencies.
- Solicit customer feedback on new device concepts/requirements.
- Manage and conduct study budget negotiations, investigator agreements and informed consent process.
- Mentor new clinical employees, ensuring that the team is staffed with highly motivated and skilled professionals.

CLINICAL / REGULATORY CONSULTANT **2004 – 2004**
Consultant to the medical device industry and biotech specializing in national/international clinical/medical and regulatory affairs.

- Provide Clinical and Regulatory support to individuals, associations and organizations to support US and worldwide regulatory submissions to meet long term business objectives and product development programs.
- Design worldwide post market clinical studies to support regulatory and payer requirements as well as cost benefit analysis requirements to ensure successful product commercialization.

ST. JUDE MEDICAL, ST. PAUL, MN **1998 - 2004**
SENIOR MANAGER, CLINICAL PROGRAMS, CARDIAC SURGERY DIVISION
Responsible for the management of the global clinical team to support mechanical and tissue heart valve clinical trials to support regulatory approval and marketing indications.

- Responsible for the design, implementation and strategic direction for clinical programs to support US FDA IDE/PMAA, 510K, and worldwide regulatory submissions for all cardiac surgery products.
- Develop annual operating budgets to meet business objectives as well as long term product development programs.
- Led and mentored the clinical programs department, ensuring that the team is staffed with highly motivated and skilled professionals.
- Represent clinical programs on project teams and executive level management review meetings.
- Manage the monitoring activities of clinical studies for investigational new products, product enhancements and product changes to ensure adherence to all applicable regulations and company policies.

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- Prepare and present clinical data to regulatory agencies, study investigators and scientific groups.
- Recruit, select and train investigators for investigational and post market clinical studies.
- Define, assist, prioritize and support appropriate publication and presentation efforts of study physicians.
- Manage biostatistics/data management department to meet departmental as well as company objectives.
- Implement and manage worldwide post market clinical studies to support regulatory and payer requirements as well as cost benefit analysis requirements to ensure successful product commercialization.
- Function as one of the primary customer support personnel regarding product usage/application and product resolution.
- Cardiac Surgery representative to AdvaMed heart valve focus group.
- Frequently traveled to 40+ worldwide clinical sties.
- Managed 9 direct employees.

WORLD MEDICAL INC., MIAMI FL. **1998 –1998**
EXECUTIVE DIRECTOR CLINICAL AND REGULATORY AFFAIRS
Responsible for the global clinical and regulatory affairs teams supporting AAA and TAA stent graft approvals in a start-up medical device company.

- Responsible for the direction and strategic planning for clinical and regulatory affairs worldwide for all stent and stent-graft products.
- Represent clinical and regulatory affairs on project teams and executive review meetings.
- Serve as clinical and regulatory expert with U.S. and worldwide regulatory agencies and notified bodies.
- Recruit, select and train investigators for clinical studies.
- Support publication and presentation efforts of study physicians.
- Prepare and present clinical data to investigators, scientific groups and regulatory agencies.
- Implement and manage worldwide post market clinical studies.
- Mentor new clinical and regulatory employees.
- Managed 7 direct employees.

FOOD AND DRUG ADMINISTRATION, WASHINGTON, DC **1997 - 2001**
INDUSTRY REPRESENTATIVE, CIRCULATORY SYSTEM DEVICES ADVISORY PANEL
I was elected to serve a 4-year term as the industry representative to the circulatory devices advisory panel for the CDRH division of FDA.

- Represent and serve as a liaison with interested individuals, associations and organizations on behalf of regulated industry before the circulatory system devices advisory panel and the FDA.
- Industry representative discuss an issue before the committee from the perspective of the affected industry and not as an individual from a specific sponsor.
- Industry representative serve a four-year term.

BOSTON SCIENTIFIC INC., MINNEAPOLIS, MN **1997 - 1997**
CLINICAL PROGRAM MANAGER
Responsible for managing the coronary stent clinical trial programs as well as the US field clinical monitoring specialists.

- Responsible for the design, implementation and strategic direction for clinical programs to support US FDA IDE/PMAA, 510K, for all BSC products.
- Led and mentor the clinical programs department, ensuring that the team is staffed with highly motivated and skilled professionals.
- Manage the monitoring activities of clinical studies for investigational new products, product enhancements and product changes to ensure adherence to all applicable regulations and company policies.
- Recruit, select and train investigators for clinical studies.
- Support publication and presentation efforts of study physicians.

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MEDTRONIC INC., MINNEAPOLIS, MN **1995 – 1997**
SENIOR CLINICAL PROGRAM MANAGER, CORONARY STENTS–VASCULAR DIVISION
CLINICAL PROGRAM MANAGER, BIO-MEDICUS
Responsible for the management of the global coronary/vascular stent and cardiac perfusion clinical programs to support FDA and worldwide regulatory approvals.

- Responsible for design, implementation and management of clinical studies to support US and worldwide regulatory submissions for coronary stents, vascular stents, perfusion and cardiac surgery products.
- Responsible for physician interface within pre-clinical new product development and manufacturing teams for centrifugal blood pumps, cardiopulmonary bypass equipment, coronary and vascular stents as well as their delivery systems.
- Function as in-house resource for current medical treatment modalities as well as anatomy, physiology and pathophysiology as it relates to cardiovascular medicine.
- Recruit, select and train investigators for clinical studies.
- Support publication and presentation efforts of study physicians.
- Review data collection received from study investigators to insure compliance with study protocol and FDA/Worldwide regulatory requirements.
- Implement investigator compensation programs.
- Design, implement and manage worldwide post market clinical studies to support marketing outcomes as well as cost benefit analysis requirements.
- Perform GCP monitoring for IDE/PMAA and 510K track studies to insure compliance with the study protocol and FDA/Worldwide regulatory requirements.
- Managed 2 direct and 3 indirect employees.

SCHNEIDER (USA) INC., MINNEAPOLIS, MN **1992 – 1995**
SENIOR CLINICAL RESEARCH ASSOCIATE
Responsible for the management of the peripheral and biliary stent clinical trial programs to support worldwide regulatory and marketing approvals.

- Responsible for the management of clinical studies to support FDA regulatory submissions for vascular, carotid, biliary and gastrointestinal stent and stent-graft products.
- Recruit, select and train investigators for clinical studies.
- Support publication and presentation efforts of study physicians.
- Review data collection from study investigators to insure compliance with study protocol and FDA requirements.
- Perform GCP monitoring for IDE studies to insure compliance with the study protocol and FDA requirements.
- Function as in-house resource for current medical treatment modalities as well as anatomy, physiology and pathophysiology as it relates to interventional medicine and vascular device implants.
- Successfully managed one IDE/PMAA study to approval by FDA through the expedited review process without a panel meeting (9.95).
- Managed 2 indirect reports.

UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN
SENIOR SCIENTIST, DIRECTOR INTERVENTIONAL CARDIOLOGY RESEARCH **1989 - 1992**
Responsible for the management of the pre-clinical and clinical studies for the interventional cardiology division.

- Organization and supervision of the Interventional Cardiology Research Laboratory and its research technicians.
- Implement study protocols for all animal and human studies as well as physician sponsored investigational studies done within the hospital and research laboratory.
- Perform surgical and invasive procedures using sterile technique.
- Calculate and document all data and parameters accurately within the studies reports.

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- Design, develop and test, following FDA/GLP regulatory guidelines, coronary angiography catheters, electrophysiology mapping catheters, coronary Doppler catheters, intravascular ultrasound catheters, vascular/coronary stents, stent-grafts and septal closure devices.
- Perform GLP monitoring and auditing for other research labs and outside companies as required.
- Managed 2 direct employees and 5 medical students.

UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN (Full Time) 1986 - 1989
CARDIOVASCULAR TECHNICIAN, (On Call Position) 1989 - 1991
Supported the interventional, surgical and intensive care units for placement and day to day oversite on invasive monitoring catheters and circulatory support systems.

- Initiate and maintain invasive monitoring equipment as required in the operating rooms, intensive care units and emergency room.
- Set up, calibrate and troubleshoot all monitors and equipment.
- Assist with invasive monitoring catheter placements.
- Perform clinical maintenance of catheters and monitoring equipment until discontinued.
- Select and adapt equipment to meet clinical monitoring needs.
- Calculate and document electrocardiographic and hemodynamic derived data.
- Act as Clinical Educator/Resource person to new employees, nurses and medical staff within the clinical area.
- Operate intra-aortic balloon pumps as required.
- Test, evaluate and make recommendations regarding new equipment.
- Monitor and document all data required per study protocols for any investigational devices being used within the operating room, intensive care unit or general care areas.

ST. PAUL RAMSEY MEDICAL CENTER, ST. PAUL, MN (On Call Position) 1990 – 1998
CARDIOVASCULAR TECHNICIAN
Supported cardiac Cath-lab cases during coronary interventions in a general and emergency settings.

- Monitor, document and calculate all electrocardiographic and hemodynamic data during coronary angiography, angioplasty, laser, stenting and electrophysiologic studies.
- Assist cardiology staff as scrub technician as required.

EDUCATION

The Ohio State University, Columbus, Ohio.
BS Industrial Technology 1979

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PUBLICATIONS

Shammas NW, Asaen N, Bailey L, Budrewicz J, Farago T, **Jarvis G**
Number of Blades-up Runs Using JetStream XC Atherectomy for Optimal Tissue Debulking in Patients with Femoropopliteal Artery In-Stent Restenosis December 2015 - Journal of Vascular and Interventional Radiology 26(12):1847-1851

Shammas NW, Asaen N, Bailey L, Budrewicz J, Farago T, **Jarvis G**
Two Blades-Up Runs Using the JetStream Navitus Atherectomy Device Achieve Optimal Tissue Debulking of Nonocclusive In-Stent Restenosis-Observations from a Porcine Stent/Balloon Injury Model
Journal of Endovascular Therapy 2015, vol. 22, 4: pp. 518-524

Peter Henke, Frank Vandy, MD, Anthony Comerota, MD, Susan R. Kahn, MD, MPH, B.K. Lal, MD, Joanne Lohr, MD, Mark Meissner, MD, Joseph Caprini, MD, Robert McLafferty, MD, Dean Bender, **Gary Jarvis**, Peter Meyer, Diana Wu, Thomas Wakefield, MD.
Prevention and Treatment of the Postthrombotic Syndrome.
November 2010Volume 52, Issue 5, Supplement, Pages 21S–28S

Das GS, **Jarvis GJ**, Voss GS, Wyche K, Gunther R, Wilson RF, Experimental Atrial Septal Defect Closure with a New Transcatheter Self Centering Device. Circulation. 1993;88:1754-1764

Vanyi J, Bowers T, **Jarvis GJ**, White CW. Can an Intracoronary Doppler Wire Accurately Measure Changes in Coronary Blood Flow Velocity. Catheterization & Cardiovascular Diagnosis. 1993;29(3):240-246

Wilson RF, Balin SJ, Voss GS, Liu C, Wyche K, **Jarvis GJ,** White CW. Selective Measurement of Pulmonary Artery Blood Flow Velocity Using a Loop Doppler Catheter.

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Chang MW, Coffeen P, Lurie KG, Schultz J, Bache RJ, **Jarvis GJ**, Voss GS, Lindstrom P, Andreini SJ, White CW. Active Compression-Decompression CPR Improves Vital Organ Perfusion in a Dog Model of Ventricular Fibrillation.

ABSTRACTS

Shammas NW, Asaen N, Bailey L, Budrewicz J, Farago T, **Jarvis G**
Minimal Plaque Surface Area and Minimal Luminal Area Needed for Effective Atherectomy using the JetStream Navitus in Treating In-Stent Restenosis of Femoral Artery in a Porcine Model
CRT 2015 Abstract-February 2015 - JACC Cardiovascular Interventions 8 (Suppl S): S3

Shammas NW, Asaen N, Bailey L, Farago T, **Jarvis G**
Optimal Number of Runs Using the JetStream Navitus Device to Achieve Maximum Tissue Debulking of in-Stent Restenosis in a Porcine Stent/Balloon Injury Overstretch Model
CRT 2015 Abstract-February 2015 - JACC. Cardiovascular Interventions 8 (Suppl S): S35

Shammas NW, Asaen N, Bailey L, Budrewicz J, Farago T, **Jarvis G**
Intravascular Ultrasound Assessment of the Optimal Number of Runs Using the JetStream Navitus Device to Achieve Maximum Tissue Debulking in Femoral Artery in-Stent Restenosis Porcine Model
CRT 2015 Abstract-February 2015 - JACC Cardiovascular Interventions 8 (Suppl S): S35

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Number of Blades Up Runs Using JetStream Navitus Atherectomy for Maximum Tissue Debulking in Femoropopliteal in-Stent Restenosis. TCT 2015

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Das GS, Voss GS, **Jarvis GJ**, Meyer SM, Snider JR, Gunther R, Wilson RF. Modular Stents: A Potential New Strategy for Reducing Coronary Restenosis. University of Minnesota, Minneapolis, MN. American Heart Association 67th Scientific Sessions, May 1994.

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