# Russell G. Hodge

25 Center Ct Laguna Niguel, CA 92677 (978)239-7315 russell.g.hodge@gmail.com

**OBJECTIVE:** To secure a senior leadership position with a company in the Medical Device Industry offering excellent growth potential for a resultoriented individual.

## PROFESSIONAL

Proven Leadership Abilities in Operations/Research and Development

#### **QUALIFICATIONS:**

- Proven Leadership Abilities on Cross-functional New Product Teams
- Demonstrated Ability to lead complex organizations to achieve results
- Excellent Problem solver/Hands-on engineering skills
- Strong Background in Development and Implementation of Engineering and Manufacturing Systems

#### **EXPERIENCE:** Sr. Program Director

Medtronic CoreValve

Irvine, CA 92618

- Provide overall leadership to the \$700MM CoreValve acquisition within the April 2009 Medtronic SH business. Responsibility includes leading a cross-functional team of director level individuals to drive R&D, RA, Clinical, Finance, Marketing, Mfg and Quality to achieve geographic access and market leadership across the world. Activities include regulatory approvals, including IDE/PMA, pivotal clinical studies in all major geographies and a suite of product development projects including new indications. Responsible for 100+ people across 6 different geographies and an annual total budget of \$85MM.
  - Created the CoreValve strategic plan to deliver acquisition economics.
  - Successfully initiated US IDE study for first SES valve technology.
  - Created an operating structure that drives results across 6 locations
  - Delivered development programs on schedule to achieve ~40% growth.

#### Vice President/Site Leader

Medtronic Vascular Danvers, MA 01923

November 2005

DOCKE

Provide overall leadership to 600+ employees at the Danvers Medtronic Vascular Site. Responsible for the development, manufacturing, marketing and distribution of over 5000 disposable devices that contributed \$230MM in revenue. Additional areas of responsibility include quality assurance, regulatory affairs, clinical research, finance and human resources. Worked with the Cardiovascular division senior leadership to develop a site charter that creates/leverages technologies across multiple Medtronic businesses. Changed the perception of the site from primarily manufacturing to that of a technology development center.

- Authored the Danvers site 5 year strategic plan.
- · Created an environment of collaboration and developed site-wide objectives.
- Lead a division-wide team to "operationalize" the division's 5yr strategic nlan

Find authenticated court documents without watermarks at docketalarm.com.

 Created an innovation initiative that drove process improvement and increased intellectual property generation by 200%.

#### Vice President of Research & Development

*Medtronic Vascular Danvers. MA 01923* 

December 2003

O3 Provide R&D leadership to the Medtronic Vascular's Coronary Research and Development group. Responsible for the development of products to treat atherosclerosis including guiding catheters, wires, embolic protection, and other minimally invasive catheter technology. Created a team to develop percutaneous structural heart therapies that work across multiple Medtronic divisions. Additional areas of responsibility included advanced technologies, process engineering, equipment engineering and a patent group. Managed a \$12MM R&D budget and about 60 engineers/technical personnel.

- Created R&D functional plans including a 5 year technology map.
- Implemented Design for Lean Sigma principles into R&D process.
- Developed a comprehensive Program Management curriculum.
- Worked with researchers to develop and refine potential therapies.
- Created intellectual property positions in the area of Structural Heart Disease.

#### Vice President of Coronary Research & Development

Medtronic Vascular

Santa Rosa, CA 95403

February 2001

Provide leadership to the Medtronic Vascular's Coronary Research and Development group. Responsible for the development of stents, drug eluting stents and stent delivery systems. Additional areas of responsibility included process engineering, equipment design/development, machine shop and design control functions. Collaborated with external partners to develop combination drug/device therapies to locally treat vascular disease. Lead a group of 100 engineers, technicians and responsible for a \$30MM research and development budget.

- Created and implemented new technology research and development plans.
- Developed and initiated the clinical study of the Endeavor DES and went from a 5<sup>th</sup> to market position to 3rd.
- Developed and commercialized the Driver Cobalt Chromium stent system.
- Worked with researchers to develop and refine potential therapies.
- Integrated acquisitive R&D programs into internal development.

#### **Director of Science and Technology**

Arterial Vascular Engineering-Medtronic Incorporated Santa Rosa, CA 95403

June 2000

DOCKE.

Responsible for the development of treatments for the reduction of restenosis. Collaborated with external partners to develop drug/radiation/device therapies to locally treat vascular disease. Directed a focused group of thirteen engineers and eight technicians in the creation and prototyping of catheter based devices used in local drug delivery, optical transmission and radiation devices. Worked with researchers and physicians to evaluate viability of various devices and drugs and potential restenosis treatments.

• Created and implemented 5 yr new technology strategic plans.

- Performed external technology evaluations of potential acquisitions.
- Worked with researchers to develop and refine potential therapies.
- Created intellectual property positions in areas of PDT, Drug delivery and IRT.

#### **R&D Program Manager**

Arterial Vascular Engineering Billerica, Massachusetts 01821

April 1998

Responsible for the development of treatments for the reduction of restenosis. Collaborated with external partners to develop drug/radiation/device therapies to locally treat vascular disease. Directed a focused group of three engineers and two technicians in the creation and prototyping of catheter based devices used in local drug delivery, optical transmission and radiation devices. Worked with researchers and physicians to evaluate viability of various devices and drugs and potential restenosis treatments.

- Created and implemented new technology research and development plans.
- Developed preclinical protocols for evaluation of concepts.
- Performed external technology evaluations of potential acquisitions.
- Worked with researchers to develop and refine potential therapies.
- Created intellectual property positions in areas of PDT and IRT.

#### **R&D Program Manager**

# USCI division of C.R. Bard Incorporated Billerica, Massachusetts 01821

April 1997

Responsible for the development and implementation of two new guiding product lines. Directed a multi-disciplined program team in all aspects of product development and commercialization including; R&D, Mfg, Mktg, RA, and QA. Introduced over 400 new items within sixteen months Worked with physicians to evaluate proposed designs. Performed technical sales training for all domestic and European sales personnel.

- Created and executed detailed Program Plans.
- Delivered 400 new end items 5% ahead of schedule within cost targets.
- Negotiated OEM contract to acquire new technology rather than internally develop.
- Presented monthly updates to Cardiology Management Board.
- Authored Program resource models and associated capital request.

### Enc

January 1994

DOCKE

- Engineering Section Manager Responsible for managing all aspects of USCI's Extrusion Engineering group, including the development and on-load of new extrusion processes, the development of equipment and the support of existing core technologies. Developed new extrusions for Bard's Angiography, Electrophysiology and Angioplasty Business Units. Directed a group of twelve engineers and ten technicians. Responsible for a two Million dollar departmental engineering budget.
- Created Project resourcing models and technology capital plan.
- Developed a cost improvement plan for an annualized savings of 750k.
- Created a process validation plan for validating over 130 extruded components.

• Received approval to purchase \$1.4MM in new extrusion equipment.

#### May 1993 Senior Project Engineer Responsible for managing

Responsible for managing the product on-load process for multiple new angioplasty products. Presented monthly progress updates to Division Management Board. Managed six engineers and three senior technicians to plan and attain goals to reach departmental strategic objectives for time-to-market, product cost and availability.

- Lead New Product Introduction teams in developing and introducing new balloon dilatation catheters.
- Managed the process development of balloon molding for all new products.
- Introduced a new Hydrophilic coating process into manufacturing.
- Performed Due Diligence Assessment of a potential business acquisition.
- Developed a comprehensive source inspection program with a critical supplier.

#### Project Engineer

DOCKET

May 1991 Responsible for managing the on-load of new products from R & D into manufacturing. Worked on USCI's top priority new products. Developed project time-lines and resource requirements using project management software. Developed repeatable production processes using experimental design techniques. Created all process/inspection specifications in accordance with GMP requirements. Performed comprehensive Process Validations on all new processes in accordance with FDA guidelines. Process experience includes: injection molding, thermal bonding, solvent bonding, UV curable solvent bonding, plasma surface treatment, ultrasonic welding, balloon molding, and hydrophobic and hydrophilic coating. Authored manufacturing sections of PMA supplements submitted to the FDA. Provided leadership and direction for one engineer and three senior technicians.

#### Advanced Manufacturing Engineer

January 1990 Represented manufacturing on new product introduction teams that were responsible for the release of USCI's Force, Sprint and Solo Balloon catheters. Provided manufacturing engineering support on the above products and all associated processes. Created and updated manufacturing documentation as required. Developed poka-yokes and fixturing for continuous yield and efficiency improvements.

#### Manufacturing Supervisor/Engineer (2nd Shift)

December 1988 Supervised 12 hourly workers in the production of Balloon catheters. Developed and carried out monthly production plans. Participated in the development of selfmanaging work teams. Teams were responsible for all facets of manufacturing, including; materials planning, production planning, and operator training. Responsible for all Manufacturing Engineering support of second shift operations. Implemented a Zero Defect successive inspection program that increased production yields from 65 to 90%. Introduced basic Just-in-Time manufacturing techniques that reduced lead times from 45 to 5 days and worksteps from 14 to 7 operations.

EDUCATION:	University of Massachusetts at Amherst; Amherst, Massachusetts 01003 Bachelor of Science in Mechanical Engineering - December 1988	
	New Hampshire College; Portsmouth, NH 03801 Master of Business Administration – 1996-1998 <u>75</u>	<u>% Completed</u>
PROFESSIONAL TRAINING:	Coopers & Lybrand-Design for Excellence, Fall 1989 M.I.TDesign of Experiments, Summer 1992 FMEA - Worcester Polytechnic Institute; Spring 1994 Member Society of Plastics Engineers, since 1991 Member American Society of Quality Control since 1996 Medtronic Sr. Leader Training April 2003 WPI Program Management Certification 2007	
ACTIVITIES:	Family, surfing, car restoration, hunting, photography and n	nusic
REFERENCES:	Will be furnished upon request	