

Sample Candidate

Medical Device Experience Overview

Note: You should have a page for each type of technology or clinical focus area with which you have expertise to include 1-3 examples of your expertise. A minimum of 3 pages are recommended, with a maximum of 8. Note that examples given are for illustrative purposes only and may not refer to actual products or technologies.

SAMPLE CANDIDATE

MEDICAL DEVICE EXPERIENCE OVERVIEW

Product/Device	Market/Clinical Focus Area <i>(Ex: Urology, Ortho, Robotics, Diagnostic Imaging, Interventional Radiology, CRM, etc.)</i>	Involvement <i>(Title/Role, Scope of responsibility, Management, Architect, Strategic, etc.)</i>	What was unique about this project/product? <i>(Product Life Cycle Stage, Market conditions, Intellectual property, competitive environment, FIM, Disruptive technology, etc.)</i>	Technology used <i>(HW/SW, Platform, Language, Systems, Program, etc.)</i>
Image Guided Surgery System – R&D Example				
Stealth System	Image guided surgery for neuro applications using CT scans	CTO Directed software architecture, formulated clinical trial plans, setup IP management to protect key inventions.	Received FDA clearance in 75 days on this class II device. Managed major release of SW interface using GUI with	C/C++ application under utilizing advanced inter-process communication and signaling as well as X11 and OpenGL for GUI and advanced imaging, respectively. Optical tracking provided via third party device interfaced via RS232.
BrainSuite	Cranial/ENT and stereotactic neurosurgery software applications	Director of R&D Pioneered establishment of pre-launch services for international phase II/III I trials involving convection-enhanced delivery	Led R&D from an undeveloped system to an interdependent team and product to 2 commercial releases and 11 major SW/HW updates within 3 years.	SDRC-Ideas , Pro-Engineer 2001 & Wildfire 2.0, ANSY\ASME, FEA & FMEA
Navigated Brain Stimulation Suite	Deep brain stimulation DBS	Systems Engineer Wrote user requirements, software and hardware specifications in collaboration with marketing team, clinical advisors, software and hardware design teams	FIM. Engineered a computer-guided measurement, digital signal analysis which integrated in a current product suite with successful commercial release in Europe.	PC Board Design, CAD/CAM, PC, PLC, CLC, NC, CNC, SCADA, HMI, DCS, Grafcet, LAD, STL, SCL, FBD, VB, VB.Net, C++, C#, SQ

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Spine Implants – Marketing Example				
Lunar Pedicle Screw System	Lumbar pedicle screw placement for Spine	Senior Product Manager Had PLC management of major line extension #2 deformity rod system	This project provided a first-to-market capability by allowing the insertion progress of a pedicle screw to be monitored in real-time without x-rays.	Various designs executed in 316L SS compatible with a majority of the screws available on the market incorporating unique capture/release mechanisms.
Pedicle Screw Taps	Lumbar pedicle screw placement	Director of Product Marketing Responsible for the planning, organization, and control of the product management group	This was part of the overall application to allow for the navigation of pedicle screws with minimal use of x-rays.	Various designs executed in 316L SS compatible with a majority of the screws available on the market.
Bone Biopsy Needle	Percutaneous thoracic or lumbar pedicle screw placement, Vertebroplasty, or kyphoplasty	Managed the cross-functional program resources indirectly (matrix) as well as the mechanical engineering resources directly	This product was developed to address many new MIS procedures currently under development at various implant and reconstructive therapy manufacturers.	A Jamshedi based needle biopsy and cannula system based on 516L tubing, ABS, PEEK elements molded at high tolerances for accurate placement of an EM or optical reference.

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Cardiac Rhythm Management – Clinical Example				
Defibrillator	Cardiac Rhythm Management	Senior Field Clinical Representative	I developed on-going corporate and technical relations with teaching institutions and was the primary resource for identifying clinical needs	Microsoft Office Suite
thoracic aneurysm stent-grafts	Vascular Intervention	Clinical Project Manager	Rescued a 20 site, 200 subject study with insufficient control enrollment by creating new guidelines and retraining site clinical support staff.	web-based electronic data capture system, CRO monitors
Pacing Lead	Cardiac Rhythm Management	Clinical Program Manager	Obtained FDA approval of pacing lead. Led study from start to finish including study design, regulatory strategy, investigator recruitment, case report form design, report writing, PMA submission and auditing.	Microsoft Project, proprietary Clinical software; various Microsoft Office SW

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Patient Monitoring – Engineering Example				
PET scan-guided robotic system	Patient Monitoring	Ultrasound Engineering Manager	Developed new documentation and drawing format to facilitate introduction of entire new product line	C++, autoCAD, ANSYS, Non-linear FMEA, Minitab
OB Monitoring	Fetal Patient Monitoring	Product Development Engineer	Helped design team creatively incorporate a critical feature into the fetal monitor	Pro/Engineer, Wildfire, ISO Process Documentation, I-DEAS,
Trans-Esophageal Echocardiology	EKG Monitoring	Product Engineering Manager	Once the market leader (over 90% share) in OEM endoscopes for echocardiology, my company saw its market share drop to 30%. Conceived and implemented plans that increased sales by 40% over a 3 year period.	MS Project, MATLAB, Anvil 2000 CAD, Geomagic, SolidWorks

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Surgical Products – Sales Example				
Coloplast Slings and Grafts	Urology, Surgical	Surgical Sales Consultant	Also responsible for setting up cadaver workshops for current and prospective clients	SalesForce.com, iPad, various CRM software platforms
Polyform Synthetic Mesh	GYN, Surgical	Senior Sales Representative	Ranked 3 out of 40 in my territory; promoted to sales trainer, sent to UK to do global sales training with WW sales force	Microsoft Office Applications - Outlook, Excel, Word, Power Point, Access
VIABIL biliary stent implant	Surgical, Cardiovascular	Account Manager	Achieved highest scores in training classes over anatomy, product knowledge, and sales techniques. #16/239 salespeople	Microsoft Office Applications - Outlook, Excel, Word, Power Point, Access