AMR **ADVANCED MEDICAL RECRUITMENT, INC.**

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Rapid Response and Follow-Through for Employment Needs

Make your dreams come true - we can Help

EXECUTIVE NOTES

By Otis Archie

Happy New Year! I am very excited about this up coming year as it if full of possibilities. Already this month, I am seeing positive movement in regards to the medical employment market. Beside the CFO and VP of Sales and Marketing positions (Orange County CA) for which I am contained; I have also obtained positions this week for a Sr. Manufacturing engineer (catheters) (Bay Area CA), Hardware engineer, and Software engineer, manufacturing engineer and Supply chain Manager for the (San Diego County Area, CA). If this trend continues and I believe it will, the medical industry will continue to drive the economy forward. Engineers and executives in the medical industry can with confidence look for new opportunities that will expand their careers as well as their wallets. They will continue to be creative in finding ways to save lives.

I am also encouraged to see is that there are several start-ups getting ready to gear up; so please continue to check out our website: http://www.advancedmr.net/Home there will be changes made and new information added soon and you don't want to miss any updates. Together we can and will make a difference.

2009 is well under way. Please send us any changes to your employment status and contact information so we can keep you updated and apprised of job opportunities. If we only had a dime for the amount of people that say they wished they heard about a miss opportunity.

Thanks to all of you that referred friends and cohorts last year. Any referral fees given; were given with a smile and a great deal of appreciation. Please continue referring people to us as we love to work with people you know.

Medical device companies will soon be able to advertise on our website. Retained companies will get a month free advertisement space in a key area.
Anyone interested call 949-340-2136

Take Care of Your References

By Nick Corcodilos

It's a wonderful world; you can buy anything. Now, for about a hundred bucks, you can hire a service to call your references and find out if they're saying nasty things about you. (Judging from their ads, some of these services are actually in the business of helping you sue people for defaming you.) But, what nut would provide an employer with list of questionable references in the first place?

In fact, you can check your own references to find out what they're saying and you can even influence – within ethical boundaries – what they say. There's no magic to this; it won't cost you any more than the price of a phone call; and you're less likely to encounter surprises if you act preemptively.

What no one tells you about references

Before we get further into this, let's cover a few important things about references. First, any smart employer (and certainly any good headhunter) will check not only the references you provide, but also additional references that he will dig up on his own. Face it, an employer wants to know whom he's hiring. So, if you have a spotty history, expect that someone is going to find out. It's your responsibility to do what you can to alleviate possible problems.

Don't rob the reference to pay the resume writer

Second, references are the poor relations to the resume. People will spend hundreds of dollars and lots of time on their resume, but they'll do next to nothing to spruce up their references. Let me remind you: people matter more than paper when you're looking for a good job. Devote twice as much time to your references as to your resume. In fact, if you handle your references properly, you won't need a resume because a good reference can introduce you to a good employer. (That's another topic.)

Give them what they can't ask for

Finally, in a world where detailed reference checking is almost impossible because legal risks make references zip their lips, you can positively startle your prospective new employer by ensuring that he gets very informative

reference reports on you. Employers are thrilled when references volunteer lots of detailed information – information the employer can't come out and ask for. (Many employers are restricted from asking for anything but confirmation of employment.) So, giving your references permission to talk about you can give you a real edge over competitors whose references will provide nothing more than dates of employment.

Take care of your references

In a nutshell, it pays to tend to your references. Here's how to do it.

Select your references carefully. Pick references who will emphasize your wonderful attributes, but make sure they will satisfy the employer so he won't need to track down more references on his own. This is a good mix: a recent boss, a recent co-worker, and a recent customer or vendor who knows the quality of your work.

Call your references before you need them. I don't mean the week before an employer needs to talk to them. I mean before you start job hunting. It's very important to stay in touch with people you may need to use as references *long before you need them*. Then, give them a heads-up just before the reference call comes. But, if you're stuck and the need is immediate, don't leave anything to chance. Call the reference and renew your acquaintance.

Ask permission. Before taking the next step (below), ask the person if he'd feel comfortable being your reference. If he says yes, thank him and say, "I hope I can return the favor someday." The reciprocity will remind the reference to put some thought into what he's going to say about you.

Refresh the reference's memory. The single biggest problem references have is remembering you in enough detail to provide useful information to an employer. Help them out. This is where you can be influential without compromising anyone's integrity. "I was going over in my mind the projects I did during the time we worked together. Would you mind if we reviewed that together?"

Review your work relationship. Briefly outline projects you worked on together and the outcomes; your contributions to the company's success; special challenges or problems you encountered and how you dealt with them; awards or recognition you received; and so on. Rather than dominate this discussion, mention a topic and ask, "Do you recall anything about that?" Let the reference take the lead, and keep it honest.

Get the reference to talk. Basic psychological research about memory shows that a person remembers something better if he says it out loud first. Let your reference recount his knowledge of your work history in his own words. Ask him questions that induce him to verbalize his judgment of you. Odds are good that, having used certain words and expressions once, he'll use them again when the employer calls. (This cuts two ways, of course.)

The point of talking to your reference in advance is to help refresh his memory so he can speak intelligently and accurately about you. Do not suggest any exaggerations or make an argument about how great a worker you were. Just help the person with the timeline and the facts. But let him do the talking. In the end, you will decide whether or not to present this person as a reference.

Check your own references – for free. If you think you have a problem reference, test it. You need not hire a special service to do this for you. Have a trusted friend who is also a manager at a company (any company) call and check the reference. If the reference is a sour one, you may have a problem. What you do about it is up to you, but I believe the best defense is an offense: have enough credible positive references to offset the bad one. Just remember that while a bad reference doesn't necessarily make a bad reputation or cost you a job, a truly bad reputation is likely your own fault – and an employer deserves to know about that. (I never said I'd help you fix truly bad references. That's another matter entirely. I'm a great advocate of the freedom to provide candid, honest references. These are important not only in business, but in life.)

You would never walk into an interview without thoughtfully preparing your presentation in advance (at least, not if you've been reading Ask The Headhunter regularly). Would you want a reference to talk to an employer about you with any less thought and preparation?

Take care of your references. Do it with respect and do it responsibly. But do it, if you want your references to take care of you.

Mechanical Engineer

Researches, plans, and designs mechanical parts and assemblies for ventilator and related equipment by performing the following duties. Design of mechanical parts and assemblies for ventilator and related equipment. SolidWorks and AutoCad experience is mandatory. Design of pneumatic components and assemblies. Perform the fabrication and assembly of prototype parts, assemblies, and complete units. Write the qualification and other test protocols. Perform engineering and qualification testing. Bachelor's degree or higher degree in engineering or physical science. Knowledge of standard mechanical drawing practices, CAD software; SolidWorks and AutoCad is mandatory.

Software Engineer

Researches, designs, and develops computer software for microprocessor systems for ventilators and related equipment. Research, design, and develop computer software from inception of project to end of project. Write the qualifications and other test protocols. Perform

engineering and qualification testing. Write specifications, provide appropriate materials for validation testing. Must be familiar with engineering equipment (i.e. scope, emulator, data acquisition). Manage a project from conceptual design to production release. Occasional travel may be required. Bachelor's degree or higher degree in software design, engineering, physical science, or mathematics

Quality Assurance Manager
Develops and maintains a system to assure that all products manufactured by the organization meets required specification and achieves superior quality and reliability levels. Assists the Director of Quality Assurance in all matters related to Quality, Compliance, Governmental and Operational activities. These would include the agencies of NIOSH, FDA, State DHS, ISO and Australian SAI Global. Ensure compliance with national and international standards and legislation. Identify and implement relevant quality-related training needs. Perform statistical analysis on processes and make recommendations for improvements as appropriate. Oversee, maintain and improve company ISO 9001: 2000 program. Troubleshoot and resolve product quality problems by researching problems, analyzing data and developing solution to problems. Bachelors in Engineering or Science Knowledge of regulatory requirement such as FDA. Experience in manufacturing and/or quality related field. Ability to effectively work with other department heads and upper management.

Manager, Hardware/Electrical Engineering
An ideal candidate in this role would have strong technical background in analog/digital electronics design, hands-on product development experience, and has successfully managed medical products through market adoption. Execute electrical design projects, manage schedules and report to the senior R&D executive. Perform analog, digital circuit design and system testing, write test plans, protocols and test summary reports. Develop system architecture, select electronic components, microprocessors for critical function of medical devices. Work closely with mechanical and software engineers to develop product & system requirements, hardware specifications, and system risk analyses. Lead product design reviews, project management, and other project team activities as required. Supervise fabrication of PCB assemblies at vendors and ensure release into production following the design control process. Provide sustaining engineering support to existing products and participate in improvement projects for increased reliability, weight, and cost reduction. Strong background in analog & digital design, and medical device system design. Embedded & control system design and implementation. Schematic capture with Orcad and PCB layout with PADS. Microprocessors: ST Micro and PIC Micro, or similar devices. System Architecture: Familiar with memory options, power supplies, electromagnetic interference, LCD and touch sensitive displays, and design for reliability. Sufficient knowledge of software to work with real time operating systems. Analog Circuits: Experience with Signal Conditioning, Active Filters, Electrical Isolation

Quality Assurance Technician
Support manufacturing and quality assurance groups to ensure quality product and compliance with quality system policies and procedures, FDA and international requirements, and ISO Standards for Class III Medical Devices. Examine and use prints, schematics, work instructions and procedures. Responsible for the maintenance of the NCMR program. Responsible for ensuring SPC data is accurate and collected in a timely manner. Assist in the analysis and reporting of SPC data. Assist in more complex inspection and verification of materials and product and associated documentation. Assist and perform quality systems training to company employees. Assist in the establishment of accept/reject limits for product. Assist and perform disposition, analysis, and reporting of deviations and NCMRs. Assist and perform trending and reporting of NCMRs, internal and external yields, and supplier corrective action. Qualifications: Bachelors degree, or Associates degree with 2 years related experience (medical device experience preferred), or equivalent. ASQ Certified Quality Technician (preferred). Knowledge of quality control and quality standards, handbooks, and specification. Sound working knowledge of computer software [Microsoft Word, Microsoft Excel] (required) along with various statistical programs [Minitab, SPSS, WinSPC] (preferred).

Senior Mechanical Engineer
Senior R&D Mechanical Engineer with a proven track record of designing and developing a variety of medical devices or scientific instrumentation from concept through prototype and into production. The candidate shall be experienced in effectively managing interdisciplinary projects while working in an ISO 13485/FDA regulated environment, and be responsible for key product design and development work. The candidate shall have broad experience and demonstrated creativity and effectiveness in implementing materials and fabrication processes during the development of commercial medical devices, including injection molding, machining, welding, casting, and bonding of plastics, elastomers, metals, coating and plating, and other high and low volume manufacturing techniques. Also required is experience in developing protocols, measurements and tests, and design of experiments for development of medical devices and electromechanical devices. The candidate shall have experience in the integration of electronics, software, industrial design, and design for manufacturability of medical devices. Demonstrable proficiency with SolidWorks is required (Pro/E expertise may be substituted). Experience in performing engineering analysis and modeling such as stress-strain, heat transfer, fluid flow, and machine dynamics is desired. Must have a BS/MS in Mechanical Engineering and minimum of four years experience in the medical device industry and 8-10 years experience in electro-mechanical packaging design, analysis and documentation.

Sr. Biomedical Engineer
Designs, executes and interprets experiments that contribute to product strategies. Guides a cross-functional engineering team to complete biomedical engineering tasks like developing proof-of-concept and prototype stage

medical devices. Plans and conducts applied research in the engineering lab and on large animal models of cardiac arrest and myocardial infarction with in collaboration with team members. Makes detailed observations, analyzes data and interprets results. Prepares technical reports, summaries, protocols and quantitative analyses. Provides regular status and research updates to multiple stakeholders. Investigates, creates and develops new technologies for product advancement.
SKILLS: The requirements listed below are representative of the knowledge, skill, and/or ability required: in-depth knowledge of physiology, biomedical engineering, sensors and general engineering is essential; strong background in medical devices or instrumentation; very strong communication and interpersonal skills; knowledge of cardiovascular physiology, blood-contacting biomaterials, and in vivo experimentation; exposure to product development; ability to work in a cross-functional, matrixed work environment with multiple stakeholders; ability to travel domestically and internationally; exposure to clinical studies is optional. Master's degree or doctorate in biomedical or electrical engineering or equivalent, plus 1-5 years related experience or equivalent combination of education and experience. Experience with statistical analysis, Excel, and MATLAB or other numerical computation package.

Manufacturing Catheter Engineer
Responsible for developing, implementing, and validating processes and procedures to manufacture electromechanical and catheter-based medical devices in full compliance with the company's quality system. Apply Lean Six-Sigma concepts to reduce waste and maximize efficiency. Troubleshoot production issues. Work with vendors to drive cost reductions to existing components and assemblies. Works closely with R&D engineers during the product design phase to ensure Design for Manufacturability requirements are considered and implemented. Understands the product design to implement and improve manufacturing processes. Works with vendors to address issues and to identify opportunities to reduce cost. Coordinates efforts with Supplier Quality Engineer. Troubleshoots production issues and implements appropriate solutions. Uses DOE techniques to characterize and improve processes and production yields.
Skills & Experience: Solid background in electrical, mechanical, and/or materials engineering.
Able to use Solid Works or Pro-E to document fixtures and assembly aids. B.S. in Mechanical or Electrical Engineering. Minimum 5 years manufacturing engineering experience, preferably in a regulated environment. Experience with Design for Manufacturing (DFM), Design of Experiments (DOE) and product/process Failure Mode and Effects Analysis (FMEA). Medical device manufacturing involving electromechanical and/or catheter-based products.

Manufacturing Engineer
Responsible for developing, implementing, and validating processes and procedures to manufacture electromechanical and catheter-based medical devices in full compliance with the company's quality system. Apply Lean Six-Sigma concepts to reduce waste and maximize efficiency. Troubleshoot production issues. Work with vendors to drive cost reductions to existing components and assemblies. Works closely with R&D engineers during the product design phase to ensure Design for Manufacturability requirements are considered and implemented. Understands the product design to implement and improve manufacturing processes. Works with vendors to address issues and to identify opportunities to reduce cost. Coordinates efforts with Supplier Quality Engineer. Troubleshoots production issues and implements appropriate solutions. Uses DOE techniques to characterize and improve processes and production yields.
Skills & Experience: Solid background in electrical, mechanical, and/or materials engineering.
Able to use Solid Works or Pro-E to document fixtures and assembly aids. B.S. in Mechanical or Electrical Engineering. 3-5 years manufacturing engineering experience, preferably in a regulated environment. Experience with Design for Manufacturing (DFM), Design of Experiments (DOE) and product/process Failure Mode and Effects Analysis (FMEA). Solid Works exp. a plus. Medical device manufacturing involving electromechanical and/or catheter-based products.

Research Scientist/Engineer, Senior
Conducts applied industrial research using scientific methodology, which is ultimately incorporated into a commercially viable medical device, or how an existing medical device is applied therapeutically. Designs, executes and interprets experiments that contribute to product strategies. Guides a cross-functional engineering team to complete research tasks like developing proof-of-concept and prototype stage medical devices. Plans and conducts applied research in the engineering lab and on large animal models of cardiac arrest and myocardial infarction with in collaboration with team members. Makes detailed observations, analyzes data and interprets results. Prepares technical reports, summaries, protocols and quantitative analyses. Provides regular status and research updates to multiple stakeholders.
EXP: In-depth knowledge of physiology, preclinical research and medical devices is essential; track record of preclinical research leading to successful product development in the medical device industry; very strong communication and interpersonal skills; knowledge of cardiovascular physiology, blood-contacting biomaterials, and *in vivo* experimentation; extensive interaction with product development. Exposure to medical devices and biomedical instrumentation routinely used in biomedical research is required. Master's degree or doctorate in biomedical engineering, systems physiology or equivalent, plus 1-5 years related experience or equivalent combination of education and experience.

Sr. Project Engineer
Assumes cross-functional leadership role on new product development projects. Develops project schedules, manages schedules, reports progress against schedules. Identifies project roadblocks, proposes options to remove roadblocks. Understands product cost targets and manages project to those targets. Works with Sales and

Marketing to create technical specifications for new product concepts. Creates new part and assembly designs in 3D / 2D, Solidworks CAD. Creates new product test protocols, designs test fixtures, performs tests, report results, works with QA personnel to have new products tested
EXP: Bachelor Science Mechanical Engineering (BSME), Bachelor of Science Plastics Engineering, or equivalent. Eight+ years professional experience in plastic product development. 3D / 2D CAD Solidworks, expertise with surfacing. Project management, preferably with tools such as MS Project and use of Critical Path Method. Injection molded plastic part design and materials. Basic knowledge of injection molding tooling and processes.

Sr. Quality Engineer
Collaborates with the VP of Quality Assurance & Regulatory Affairs to ensure compliance with the corporate quality system that includes compliance with the QSR and applicable ISO Standards, providing support to product development for product assurance and reliability testing, risk analysis, internal and third-party audits. Work with R&D on product development projects. Work with Manufacturing Engineering on product/process improvement projects. Works closely with software, mechanical, and electrical engineers to define system requirements. Define a verification/validation process and develop protocols in conjunction with appropriate functions, perform analyses, and document results in a report format consistent with process requirements. Investigate and analyze internal failures and customer complaints. Recommend and implement corrective and preventive measures as necessary. Perform trend analysis and generate reports and maintain an effective CAPA system. Provide training and assistance to inspectors. Develop, implement and maintain inspection and test methods for finished products and in-coming components and materials. Evaluate precision and accuracy of testing, measurement and production equipment.
EXP: Previous experience in Quality Engineering in medical device industry is a must. Experienced in sterile disposable products such catheters is highly preferred. Hands-on experience with sterilization process, environmental monitoring, biocompatibility requirements. Demonstrated experience/skill in risk analysis, failure analysis, CAPA and Audits.
Thorough knowledge of QSR and ISO 13485 (2003) requirements in a Class III environment.. B.S. in Engineering, Quality Assurance or Life sciences or equivalent experience is required. Experience in the medical device industry in a Quality Engineering capacity is desired. Minimum 3 years (Quality Engineer) or minimum 5-7 (Sr. Quality Engineer)

Electrical Engineer
Develop analog and digital electronics for a new series of medical instruments and devices. Responsibilities will cover a wide range of hardware development. Define overall product requirements and hardware specifications. Work closely with software and mechanical engineers to define system requirements. Design, test and document electronic products. Help to select microprocessors, system architecture. Evolve early feasibility designs into commercial products. Assist defining test plans for verification and validation. Lead and participate in design reviews. EXP: Strong background in analog and digital design. Embedded system design. Microprocessors: Motorola 68000 or HCXX, Intel 80X86 or 80X51 families, or similar devices. Minimum BSEE or related degree or equivalent experience - MSEE and advanced degrees desirable. Minimum of 0-3 years related experience. Analog Circuits: Experience with Signal Conditioning, Active Filters, Electrical Isolation

Manufacturing Lead
As a working lead, provide guidance and leadership for the day to day activities to the subordinate staff. Also is the acting supervisor when the department head is out. Sets forth daily work schedules for production personnel with supervisor approval. Monitors, guides, and disciplines subordinates as needed. Works with manufacturing engineering to improve processes and reduce assembly time. Coordinates with Sr. Planner Buyer to smooth work order and material flow. Works with Quality Assurance to coordinate in process inspections. Prepares reports, stats, etc as required by the production supervisor.
EXP: A minimum of 5 years related experience preferably with medical device. Lean /flow manufacturing a plus.

Manufacturing Operator
Assembles medical device components and electronic systems
Reads work orders, follows production drawings and sample assemblies, or receives verbal instructions regarding duties to be performed. Positions and aligns parts in specified relationship to each other in jig, fixture, or other holding device. Crimps, stakes, screws, bolts, rivets, welds, solders, cements, press fits, or performs similar operations to join or secure parts in place. Mounts assembled components, such as transformers, resistors, transistors, capacitors, integrated circuits, and sockets, on chassis panel. Connects component lead wires to printed circuit or routes and connects wires between individual component leads and other components, connectors, terminals, and contact points. Performs intermediate assembly tasks, such as potting, encapsulating, sanding, cleaning, epoxy bonding, curing, stamping, etching, impregnating, and color-coding parts and assemblies.
EXP: Associate's degree (A. A.) or equivalent from two-year college or technical school; plus one year related experience; or equivalent combination of education and experience.

Formulation and Technical Assistant
Assist with the formulation, manufacturing and testing of polyacrylamide electrophoresis (PAGE) gels, kits and reagents. Installation, training and support of Lipoprint System including preparation of training materials. Provide technical support on research and development of electrophoresis kits and reagents as needed. Perform verification and validation studies of electrophoresis methods and equipment. Create, review and update documents such as Manufacturing Documents, Material Specifications, Operating Procedures and other documentation according to company requirements.

Skills: Bachelor's degree in Chemistry, Biology or equivalent; or equivalent of two to four years' related experience and/or training, or equivalent combination of education and experience. Knowledge of iMac computers. Experience in a cGMP working environment required.

Sr. Quality Assurance Specialist

Functions as a management representative for ISO and FDA. Resolve all conflicts between the quality program and any other policies, procedures or operation within the company and implement the necessary changes. Develop and effectively implement quality system procedures to assure maintenance of GMP Class II Device Compliance, ISO 9001, ISO 13485 and CE Mark Certifications. Review and approve Technical Dossiers for submission to governing bodies. Manage internal and vendor audits according to FDA CFR 820, ISO 13485:2003 and European regulations. Responsible for obtaining and renewing licenses with US, Canada and International agencies. Manage document control activities, nonconformance, corrective and preventative action processes as well as other processes as assigned.
Skills: Bachelor's degree in Science or Engineering and minimum of 5 years industry knowledge. Experience in quality assurance and regulatory affairs for IVDD and MDD. In depth knowledge of the FDA Quality System Regulation and ISO 13485:2003 and related regulations and standards. Experience escorting FDA Investigators and ISO notified body auditors.

Sr. Manufacturing Engineer, Supply Chain

The Sr. Manufacturing Engineer is responsible for providing leadership and insight, as appropriate, into the supplier base toward quality improvement, cost reduction and new product development programs. This position ensures that supplier manufacturing processes deliver consistently high quality products to the company at competitive pricing throughout the product life cycle. Oversees supplier efforts resolving quality problems including performing root cause analysis of nonconforming materials and developing corrective action plans. Works with suppliers to disposition non-conforming product and recommends revisions as required. Lead and facilitate cross functional team in the identification and qualification of new suppliers thorough evaluation of the suppliers manufacturing capabilities in accordance with company policies and procedures. Participates in activities required to establish and maintain supplier rating at appropriate level of approval.
Skills: Bachelor's Science Degree in Engineering with 5 years experience in a medium-volume electronics manufacturing environment. Knowledge of CGMP and ISO 9000 requirements are desirable.

Clinical Sales Support Specialist

The Clinical Sales Support Specialist provides Clinical Sales Support to their designated regional territory. Will be responsible to perform in-service and train clinicians in the hospital and home care arena about ventilators. The Clinical Sales Support Specialist is responsible to provide Clinical support pre-purchase of product and on-going clinical support after the product is purchased. Train Dealers and Distributors on the product. Explain product features, use and advantages to customers' pre and post sale. Provide and respond to requests for clinical support assistance in proper use of products. Assess training needs of customers and deliver product training as needed or requested by the Sales Manager. Stay current in the knowledge of respiratory care/mechanical ventilation practices relative to company products and competitor ventilators. Be knowledgeable of all ventilators in the market and all new modes of ventilation. Travel is required. ***Must reside in California.***
Skills: ***Must be a RRT or Registry Eligible*** with current RCP License, must have a minimum of 3 to 5 years of recent critical care experience. Candidate must have a strong knowledge of mechanical ventilation including all the newest modes of ventilation. The candidate should have Neonatal, Pediatric and Adult ventilation experience. The candidate should have excellent knowledge of clinical procedures and medical terminology.

QA Manager

Responsible for the management and supervision of Quality Assurance activities including Receiving Inspection, In-process Inspection, Final Release, Non-conforming material control and Supplier Control. Responsible for Supplier Management including maintenance of Approved Supplier List, Supplier Files and documentation as required to demonstrate compliance with regulatory requirements. Creating statistical analysis and reports from supplier and nonconforming material databases to identify trends and drive corrective actions. Conducts investigations into nonconformities and supplier issues in accordance with CAPA procedures. Quality Auditor for internal and supplier processes.
Skills: Bachelor's degree and/or equivalent work experience. Five (5) to ten (10) years Quality Assurance experience with emphasis in Quality control, Material Review Board, Documentation Control and Data Center, Internal Audits, Corrective Action, Training, Receiving Inspection, Supplier Quality Assurance. Compliance related to cGMP, ISO13485, and the Medical Device Directive (MDD), or other government related quality systems preferred.

Manager Firmware Engineering

Responsible for performing firmware management including the development and verifications for all of company's implantable defibrillators. Provide project management for all engineering resources in the department to include estimating, planning and tracking all firmware development and verification. Demonstrate the capability to specify, design, implement, and verify firmware. Manage root cause analysis activities to identify firmware defects.
Skills: BSEE, BSCS, BSCE or equivalent. Advanced degree preferred. 5-7 years minimum experience in Real-Time Embedded Systems development. 3-5 years minimum experience in technical leadership and/or management positions.

Manufacturing Engineer

Support Operations group through development and support of manufacturing equipment and processes in

assembly of an implantable medical device. Support production through efficient and effective identification and resolution of line issues. Identify and initiate process improvement projects that have meaningful impact on product quality and process yield. Interface with Design Engineers to provide timely feedback on proposed designs and influence organization to develop a strong design for manufacturability culture.
Skills: Bachelor of Science degree in manufacturing, mechanical engineering, or electrical engineering and 3 years of experience in medical or other high-reliability manufacturing environment, or equivalent combination of education and experience. CAD Mechanical design experience developing tooling and fixtures Equipment knowledge and process experience with electromechanical assembly, such as welding, soldering, adhesive bonding, hermetic sealing, surface finishing, packaging, or sterilization. Experience with Statistical Process Control, Design of Experiments, Just in Time, and Lean manufacturing techniques.

Principal Engineer
This position provides leadership responsibility for design, development and ongoing technical support for the implantable hybrid electronics packaging for an implantable defibrillator. Defines technical objectives, identifies technical risks and options, and execute design and development tasks in support of project objectives. Actively participate in hybrid package design. Conduct thermal modeling to predict potential design issues relating to thermal dissipation. Physical design of the hybrid including floor planning, integrated library development and routing.
Skills: Bachelor Minimum -- Bachelors of Science in Engineering. Minimum – 5 years industry experience in microelectronics. Must be familiar with microelectronic assembly processes such as the following:

Conductive and non-conductive adhesives
Hybrid layout and package assembly technologies
Chip packaging design and assembly techniques
SMT processing and validation
Interconnect processes such as flex circuit, soldering

Quality Engineer
Support quality assurance activities to ensure compliance with quality system policies and procedures, FDA and international requirements, and ISO Standards for Class III Medical Devices. Develop and initiate standards and methods for inspection, testing, and evaluation of production and product quality conformance. Develop and initiate methods and process for corrective and preventive action program and related processes (medical device reporting, product experience reporting, etc.). Develop and initiate methods and instructions for recording, evaluating, and reporting quality training activities. Develop and initiate methods and instructions for recording, evaluating, and reporting quality internal audit activities. Monitor, trend, and create periodic quality reports that pertain to quality system management reviews. Collaborate with Operations and Engineering personnel in writing and reviewing quality related procedures and work instructions.
Skills: Bachelors degree in Engineering or related field. Minimum four years experience in quality assurance (medical device experience preferred). Knowledge of ISO Standards (Class III Medical Device preferred) Knowledge and experience with CAPA or similar closed-loop failure reporting processes. Sound knowledge of Microsoft Office (Word, Excel and PowerPoint) along with various statistical programs (SPSS, Minitab, JMP).

Reliability Engineer
Support engineering to ensure high reliability product design and compliance with quality system policies and procedures, FDA and international requirements, and ISO Standards for Class III Medical Devices. Participate in writing and reviewing design verification test (DVT) protocols, especially with regard to sample size, test power, and related statistics. Support and guide quality control activities, including: PFMEA, IQ/OQ/PQ, process capability, gauge R&R, and SPC. Perform and facilitate product risk analyses, including: Failure Modes, Effects, and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Risk Analysis, and HAZOP. Assist with performing root cause analysis of field returns, including data analysis (mining), identifying trends (systemic issues), and common cause issues for systems, peripherals, software, and components.
Skills: Bachelors degree in Engineering or related field. ASQ Certified Reliability or Quality Engineer (preferred). Minimum four years experience in quality and/or reliability engineering (medical device experience preferred). Must possess sound knowledge of Microsoft Word, Microsoft Excel, along with various statistical programs (Minitab, SPSS). Expertise using reliability analysis software tools such as Minitab, SPSS, and Relex is preferred.

Sr. Principal Digital Design Engineer
This position exists to provide expertise and assistance in the conception, design, development and testing of detection algorithms. Conceptualize, design, develop and test detection algorithms to discriminate cardiac arrhythmias from normal sinus rhythm in an implanted medical device. Verify and validate firmware implementation of detection and discrimination algorithm within an implanted medical device. Build and populate internal signal databases for use during algorithm development activities.
Skills: BS degree in Electrical/Biomedical Engineering, Computer Science, Mathematics, Applied Physics, or equivalent related technical discipline. MS or PhD preferred. A minimum of 3 years experience with ECG rhythm analysis relating to atrial and ventricular arrhythmia detection. A minimum of 3 years of working knowledge of signal processing software (MATLAB preferred). Experience in electrophysiology highly desirable.

Sr. or Principal Algorithm Engineer
This position exists to provide expertise and assistance in the conception, design, development and testing of detection algorithms. Conceptualize, design, develop and test detection algorithms to discriminate cardiac arrhythmias from normal sinus rhythm in an implanted medical device. Verify and validate firmware implementation of detection and discrimination algorithm

within an implanted medical device.
Skills: BS degree in Electrical/Biomedical Engineering, Computer Science, Mathematics, Applied Physics, or equivalent related technical discipline. MS or PhD preferred. A minimum of 3 years experience with ECG rhythm analysis relating to atrial and ventricular arrhythmia detection. A minimum of 3 years of working knowledge of signal processing software (MATLAB preferred).

Sr. Principal Analog Design Engineer
The Senior Principal Analog Design Engineer is responsible for assisting in the electrical design and development of an implantable defibrillator. Participate in the design and development for the implantable defibrillator system. Participate in design of low-noise ECG amplifiers, RF telemetry, switch-mode power supply design, and high voltage circuit design. Involvement in all activities of the system, from custom ASIC requirements to hybrid/board level development, through to qualification and production.
Skills: BS in Electrical Engineering is required. An advanced degree is highly desired. Minimum of 5 years of experience in analog design. Low-power design or high voltage circuit design desirable. Medical device or related biomedical experience is highly desired. ASIC development experience is a plus.

Sr. Test Technician
The Senior Test Technician assists in the design, development and evaluation of new circuits and systems. Assist in the design, development and evaluation of new circuits and systems. Design, layout, and build prototype circuits and test fixtures. Troubleshoot and repair circuits and fixtures. Perform tests on circuits and designs using OTS or internally developed test equipment.
Skills: An AA or 2 year technical college certificate in electronics, minimum. 5 years, minimum, experience in prototyping and evaluation of digital and analog electronic circuits in an R & D or Engineering Lab environment. 1 year, minimum, experience in programming microprocessor or FPGA based new products or test fixtures, desirable. Expertise in the use of electronic equipment such as oscilloscopes, logic analyzers, DVM's, spectrum analyzers, etc.

Leader, Clinical Affairs
Directs all clinical affairs activities for our medical device products. Able to execute parallel clinical trials in accordance with Good Clinical Practices and FDA or other regulations. Uses depth and breadth of experience and knowledge of cardiovascular medicine as well as relationship network to advance successful medical devices to market. Manages clinical affairs employees, consultants, external services providers and clinical trial sites. Establishes clinical programs and translates into operational plans and schedules; manages the approval, direction, planning, execution, and interpretation of clinical trials/research and the data collection activities. Assists in regulatory activities for sales worldwide. Analyzes activities, costs, operations, and forecast data to determine departments' progress toward stated goals and objectives. Makes appropriate adjustments as required to better facilitate the implementation of company business strategy.
Skills: Must have extensive experience developing and executing clinical programs for Class III cardiovascular medical devices, particularly interventional cardiology or ICU-based clinical trials. BS degree in life sciences plus 10 years of related experience, or equivalent combination of education and experience. Prior people management and project management experience required. Experience leading trials under 21CFR50 "Exception to informed consent for emergency research".

Material Control Clerk
Perform stockroom functions as required by management. Receive materials and supply items into the stockroom. Process work orders according to procedural guidelines. Prepare kits for manufacturing as required to keep production moving. Physically and systematically move materials and supplies to the appropriate kanbans within the manufacturing area. Maintain accurate inventory logs and perform cycle count activity as required. Perform other functions within materials or other departments as assigned by management. Computer skills MS Word, Excel, email, FedEx and UPS shipping systems experience.
Skills: High School Diploma or GED Certificate preferred. Proficient with the UPS and FedEx on line system. At least one year experience in all warehouse functions including shipping/receiving, stock put away, stock retrieval and cycle counting.

CFO
Call for job description

VP Sales & Marketing
Call for job description

Updated newsletter is also on our website!

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