Avitus Orthopaedics, Inc.
6 Armstrong Rd
Shelton, CT 06484
jobs@avitusortho.com

SEEKING: A HUSTLER | A GRINDER | AN EXECUTION MACHINE
A "*WHATEVER IT TAKES*" MANUFACTURING & QUALITY ENGINEER

Why Avitus® Orthopaedics? We're an exciting medical device company that has pioneered the Avitus® Bone Harvester; a product that is revolutionizing autografting for reconstructive orthopaedic surgeries. We are dedicated and committed to excellence, innovation, and solving unmet clinical needs to improve our universe. Our products will continue to be groundbreaking. We are a company that's about hustle, grind, and taking relentless action to execute our goals. You have the opportunity to join us at an intersection of funding, commercial growth, and new product development. In addition to our current products on the market, you will have a critical role supporting ongoing manufacturing, sustainable engineering projects and helping the team launch new game changing products! We're a lean Company without bureaucracy; often decisions are made over coffee.

Who are we looking for? You're passionate about medical device manufacturing and delivering products based on the specifications that you and your team have worked hard to put together. You love figuring out how we can improve the quality of our operations and make life easier for everyone in the chain. You want to be referred to as an execution machine. You manage risk and find creative ways to make a process more efficient. You enjoy thinking how we can do better. You have a good handle on your bandwidth and ask for help when you need it. You must be a no BS kind of person; if you don't know something, you'll let us know and we'll figure it out together. The ethos to who you are as an individual encompasses integrity, intensity, and intellectual honesty. You're someone that can literally do the job of 10 people not because you work longer, but because you work smarter. You're not a 9-to-5 person; you're a get-it-done person. You love the grind. You have ideas, you have suggestions, and you want them to be taken into serious consideration and will trust the right suggestions will be put into motion at their respective right times. Quit is not in your vernacular. You must be a positive mindset individual who sees problems and challenges as opportunities for growth and improvement. Your follow-up game is relentless. You are incredibly proactive. You effectively balance your love for details with keeping projects on-time. You are driven to have an impact; there isn't a day that goes by that you aren't moving the ball. Your best solutions are win-win.

What are you going to do? You will be responsible for driving various manufacturing and quality activities related to the development, market launch, and continuous improvement of orthopaedic medical devices. You will work with the other members of the engineering team to develop and produce game changing solutions to meet the unmet needs of our users while assuring compliance to regulatory and quality requirements. You will be assigned various sustaining engineering projects that will improve existing product manufacturing operations. You will participate in manufacturing and inspection activities to assure compliance to design specifications. You will develop and evaluate efficient methods of testing and inspection of production processes and parts. You will prepare inspection plans and execute them. You will ensure that design intent is maintained throughout the design transfer process. You're going to be called upon to have to wear multiple hats at times to support our dynamic environment. You're going to help us continue evolving our lean, creative, and fun culture. You're going to be an excellent communicator. You will implement a whatever-it-takes mentality to balance costs while engineering significant progress towards our design, manufacturing, and production goals. You will be a resource to the design team in filtering designs from an ease of manufacturing and quality perspective. You will develop, test, document, and implement manufacturing processes. You will visit and work with suppliers. You and your colleagues will march projects down the design control pathway from conceptualization to finished commercial products.

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You will at times have to use some elbow grease and execute tasks to get other operations done. People will depend on you. If duty calls you may need to be a sales rep, a fulfillment specialist, a janitor, a market researcher, or a business development associate for a day.

You will report directly to the VP of Operations.

You will have direct support from the Founders of the Company.

Essential Responsibilities and Duties:

- Participate in the development of medical devices and components from proof-of-concept through design transfer and continuing production
- Ensure that all manufacturing process design changes preserve the design intent and meet the user need before implementing the change
- Identify, design, test, and implement process and manufacturing improvements and optimizations
- Maximize throughput in inspection and manufacturing processes, while maintaining quality compliance throughout the production process
- Provide design feedback from a manufacturing and quality perspective to the team
- Expediently inspect components and finished goods, and complete necessary documentation
- Be an integral part of implementing quality throughout the organization
- Work on various sustaining engineering initiatives
- Assist in DHF efforts such as Product Specifications, FMEA, PFMEA, Statistical Analysis, Risk Assessments, DV/VV plans and their execution
- Collaborate with product development team to assist in testing and documentation as needed
- Swiftly resolve non-conformances and deviations
- Monitor and execute necessary corrective actions
- Apply risk-based problem solving to manufacturing and quality goals
- Analyze and comprehend test results to formulate suggested next steps to the team
- Interface with suppliers, contractors, testing houses, etc., developing strong collaborative relationships
- Conduct supplier audits as needed
- Document work efficiently and thoroughly with attention to detail
- Assist with other ongoing development projects and team needs when needed while balancing own workload
- Provide technical support and documentation support as needed for Regulatory and Quality
- Proactively bring management into decisions and meetings to discuss and decide on actions
- Analyze effectiveness of manufacturing and quality programs
- Constantly find ways to improve processes, implement efficiencies, and optimize workflow
- Develop and support quality control procedures as needed
- Support ongoing operations and firefighting as needed

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Essential Qualifications and Skills:

- Bachelor's degree in Mechanical Engineering, Biomedical Engineering, or related discipline plus 2-3 years of manufacturing or quality engineering for medical devices (orthopaedics is preferred) -OR- 5+ years of professional manufacturing / quality engineering in medical devices.
- 3D CAD, Solidworks (expert)
- Demonstrable experience with DHF, design controls, inspections, and bringing a product through design transfer
- Demonstrable experience with optimizing a manufacturing process to reduce cost or lead time
- Strong in geometric dimensioning and tolerancing (GD&T)
- Experience designing and developing tooling and fixturing
- Experience with Design of Experiment (DOE)
- Experience with FDA regulatory submissions and fielding FDA audits is a plus
- Experience with CE mark and OUS regulatory requirements a plus
- Good working knowledge of standards (e.g., ASTM, ISO)
- Statistical Process Control knowledge
- Microsoft Office Suite proficient, strongest in Microsoft Excel and Word
- Strong understanding of production manufacturing technologies and methods (e.g., molding, CNC, forming etc.)
- Experience developing and manufacturing disposables and implants
- Experience with tray and pouch sterile barrier packaging
- Strong knowledge of orthopaedics preferred
- Previous orthopaedic medical device and design experience preferred
- Very strong analytical skills and creative problem-solving skills
- A straight-shooting, open communicator
- Ability to record actions that are verbally communicated and clarify as needed prior to execution
- Ability to balance business and technical risks with internal and external regulatory/quality compliance requirements
- Ability to define problems, establish facts, and utilize critical and logical reasoning to draw valid, viable conclusions
- Ability to actively acquire knowledge of new and advanced manufacturing/design technologies to help Avitus® continue improvement
- Deploying de-risking techniques to "get it right" the first time when and where appropriate
- Demonstrable bias for action, must be a DOER
- Excellent team collaborator with attention to detail balanced with a long-term vision

Physical Demands:

The team member will be required to have close visual acuity to perform activities such as inspecting small parts and viewing computer terminals and drawings. The team member may be required to lift up to 35 lbs. by themselves. The team member may need to stand in an operating room with 10lb lead vest for long periods at a time.

Expected Work Hours:

This is a full-time position with typical start-up business hours. It may reasonably require additional hours during the week and weekend; specific requirements will be determined with Manager. Occasional remote work may be allowed as needed.

Travel:

Potential for some overnight travel. May require up to 2 hour drives to suppliers.

Work Status:

Must be legally authorized to work In the US on a full-time basis.
Employment visa sponsorship not available.

Ready to take the next step? Apply now!

What we offer:

Competitive compensation
Equity package
Benefits
Flexibility
A team of brilliant and fun people
Gamechanger products to work on