Company Description

Amplify Additive is an early stage venture & privately backed company focused on metal additive manufacturing using GE Additive’s Arcam EBM technology. We are focused on establishing our company to improve infrastructure and to help clients leverage additive manufacturing technology for designs in the Orthopedic Implant & Instrument Market, as well as other markets such as Aerospace, Automotive, Veterinary, and beyond. Our unique offering stems from years of experience developing, manufacturing, and selling unique implants that leverage 3D metal printing, particularly in Titanium.

Summary of Position

We are building a world-class Quality team to solve high-value, industry-wide problems that fully leverages a unique manufacturing platform. As the Additive Manufacturing Quality Manager, you will oversee and manage our company wide quality program, functions and initiatives, including ensuring ISO13485 certification and related. In addition, the Quality Manager/Engineer will ensure products produced meet customer expectations, and lead quality investigations to address deficiencies. The right candidate will serve on the leadership team and promote Amplify’s commitment to Safety, Quality, Productivity and Regulatory Compliance.

Quality Management:

- Engage and interact with company teams to bridge/resolve customer expectations and drive a quality focused company
- Establish and maintain Quality Management processes and procedures. Ensure accurate documentation and statistical analysis on quality related issues.
- Lead and manage the QA team; train, coach, and develop a collaborative approach in their dealings with each other and with peers, colleagues, customers and suppliers. Facilitate the development of long-range goals and objectives for quality team direct reports and deliver meaningful individual performance guidelines.
- Lead Quality Management Reviews and Internal Audits, deploy quality improvement strategies and initiatives, identify and share best practices, lead cross-functional focused improvement teams and report to top management on the effectiveness of the Quality Management System.
- Lead root cause analysis of non-conformances, corrective actions, initiate follows-up, and cost-effective resolutions; this includes quality process improvements (scrap reduction, rework reduction, due to process, product, material and service, etc.).
- Manage departmental budget and assess productivity and cost effectiveness of the QA department; develop projects to improve efficiency, streamline processes, and reduce costs.
- Monitor Change Management and assure compliance to internal and external requirements, including customer requirements.
- Oversee document management system, company quality control guidelines and procedures, other controlled policies and procedures, instructions, forms, and records.
- Analyze and interpret quality data, conduct research on product defects and recommend modifications in processes, products or quality standards to eliminate waste.
- Oversee implementation of measurement tools that enable effective evaluation. Track, and report on quality measurement systems and Key Performance Indicators.
- Solicit feedback from customers to assess whether their requirements are met.
- Understand customer needs/requirements to develop effective quality control processes to promote a quality driven culture.
- Stay abreast of the latest quality management best practices and concepts
- Demonstrate responsibility for personal development.
Soft Skills:

- Strong interpersonal communication skills
- Ability to learn, take direction and adapt to changes
- Team Player with the ability to speak up as needed
- Adaptable with Positive attitude
- Enjoys a challenge
- Natural leader who teammates want to follow
- Ability to motivate others and drive to company results
- Ability to connect the dots and understand/guide quality efforts to company objectives
- Ability to teach others and be a change champion

QUALIFICATIONS:

- BS/BA degree in Business or Technical Discipline preferred and 5-7 years of quality management experience or process engineering in a manufacturing environment.
- ASQ Certified Quality Engineer/Professional Quality/Statistical Application certification strongly desired.
- Microsoft Office, Statistical Software
- Statistical methods & process improvement techniques
- Superior mathematical & statistical ability
- Familiarity with the MEP/MRP/ERP software a plus
- Ability to work a flexible schedule
- Lean Six Sigma experience preferred

Preferred

- Functional business experience in medical manufacturing, precision manufacturing, engineering or supply chain with a proven track record of connecting in multi-functional forums, project management, business process improvement and team leadership
- Professional Quality Management credentials (i.e. ASQ CMQ/OE, Six Sigma, Certified Auditor/Lead Auditor, etc.)

Experience

- ISO13485
- Proven record of creating and/or maintaining a quality management program in another organization
- Proven record of managing quality staff to deliver quality inspection results

Job Type: Full-time

Experience:

- relevant: 5 years of Quality Management Experience in Medical Device manufacturing (Preferred).
Work Location:

- One location: 68 Mussey Rd. Scarborough, ME 04074

Benefits:

- 401(k)
- Flexible work environment – distributed working environment
- Unlimited vacation time

This Job Is:

- A job where military experienced candidates are encouraged to apply

Company's website:

- [www.AmplifyAdditive.com](http://www.AmplifyAdditive.com)

Contact: [hr@amplifyadditive.com](mailto:hr@amplifyadditive.com)