NeXtGen Biologics, Inc. is a Developer of extracellular matrix biomaterial products, bringing novel and transformative treatments to a variety of medical disciplines for the benefit of patients. We are looking for a lead engineer/manufacturing professional to join our manufacturing group as a manager in our Alachua, FL facility.

**Position Summary**

The lead engineer/manager is responsible for production, project management and engineering functions within manufacturing. The position includes oversight and maintenance of the manufacturing environment, equipment and processes with the responsibility of producing safe and effective products on time and within budget. Duties also include motivating/mentoring technical staff, supporting strategic planning, resource planning and continuous improvement. The position requires the ability to work in a team environment, to establish production metrics. Must also ensure effective communication between Operations with other areas of the company such as Marketing, R&D, Quality, and Regulatory Affairs.

* Works with development and manufacturing team to optimize systems and processes for the orderly, safe and efficient flow of manufacturing processes
* Provides clear, consistent and measurable direction regarding timelines and deliverables
* Ensures the quality and integrity of production and project management activities
* Works with Marketing, Regulatory, and R&D in generating timelines and budgets for development projects
* Motivates employees and efficiently in realizing our ultimate goal to launch safe and effective products that will positively impact the lives of patients.

**Education/Experience Desired**

* 1 year minimum management experience
	+ BA / BS degree and 5 years of industry experience in manufacturing of extracellular matrix tissue-based products or,
	+ MA / MS degree and 3 years of in industry experience in manufacturing of extracellular matrix or tissue-based products experience

 **Knowledge, Skills and Abilities:**

* Knowledgeable in aseptic technique and production in clean room environments and cGMP concepts, establishment of production metrics, validation requirements, maintenance cycles, calibration programs, sterilization validation programs and dose audits, environmental monitoring reporting,
* Familiarity with Medical Device regulations 21CFR Part 820, ISO 13485:2016, EudraLex, etc.
* Sense of urgency and initiative with demonstrated ability to act independently to enact the company’s strategic goals.
* Familiarity with the product realization cycle or a formal design controls process
* Ability to support new product development in complex environments.

Candidates, please send your resume to dhealy@nextgenbiologics.com