

**Systems Engineering Manager**

Job Reference: SEM Location: Carlsbad, US

Posted: April 2024 Weekly Hours: 40

# The Role

DNAe, the inventors of semiconductor-based next-generation sequencing (NGS) technology, is developing a revolutionary new platform that enables NGS-based diagnostic capability in an easy to use, cartridge-based system that will allow direct from clinical specimen to clinically relevant, actionable results in a matter of hours.

We at DNAe are currently looking to hire additional outstanding talent to join the existing multi-disciplinary NGS Engineering Group, filling key roles in the rapidly expanding program. The specific role described here is for Systems Engineering Manager reporting into the Platform Integration Team of our NGS platform and associated assays.

**Job Description**

We are seeking an experienced and dynamic Systems Engineering Manager to lead our team in the development of the groundbreaking LiDia-Seq platform for root-causing Sepsis. As the Systems Engineering Manager, you will play a pivotal role in driving innovation and ensuring the successful realization of this first-of-its-kind diagnostic device platform to meet the business goals of DNAe.

# Responsibilities

We are looking for people with drive, enthusiasm and a strong work ethic who desire to play a key role in the creation of a paradigm shifting platform that will have major impact on the health and wellbeing of patients around the world. The successful candidate must have the ability to conduct informative research and deliver effective solutions to challenging problems in a fast-paced environment with adherence to tight timelines.

* Provide technical leadership to the company’s Systems Engineering team.
* Provide innovative solutions and creative insights for the development of the LiDia-Seq platform, ensuring it meets the highest standards of sensitivity, versatility, comprehensiveness, and cost efficiency.
* Collaborate with commercial teams and external stakeholders to derive a comprehensive set of user needs and use scenarios relevant to the LiDia-Seq platform.
* Develop and manage resources, timelines for deriving comprehensive product specifications that align with clinical needs and business objectives.
* Synthesize designs in collaboration with science, engineering, and software teams to realize the LiDia-Seq platform that meets the defined product requirements.
* Ensure compliance with ISO13485 standards through rigorous analysis and integration processes.
* Oversee design changes and Bill of Materials to ensure product requirements are adequately met, while continuously integrating improvements to meet business objectives.
* Practice model-based systems engineering to synthesize designs and achieve the product objectives of the LiDia-Seq platform.
* Mentor engineers and scientists in conducting technical reviews to demonstrate how designs meet product requirements.
* Collaborate with Quality, Science, Engineering and Software teams in evaluating the risk profile associated with the LiDia-Seq platform.
* Establish dashboards for efficient communication of project progress and integration activities to leadership.
* Conduct and release technical reports to communicate with cross-functional teams, senior leadership teams, and external stakeholders.
* Develop integration, verification, and validation test plans; execute study protocols and generate reports.
* Analyze large data sets, troubleshoot complex issues, and suggest creative solutions to system-level issues.
* Promote both technical depth as well as functional excellence, through hands on integration experimentation, document management, and involvement in new product development activities.

# Qualifications & Experience Required:

* M.S./Ph.D. in Engineering, Materials Science, Physics, or related field with minimum of 10 years relevant industry experience.
* Track record of commercializing biomedical technologies in both RUO and Dx markets.
* Proven experience in developing and launching medical/IVD products to the regulated market.
* Demonstrated experience in writing quality technical documentation and developing test plans for validation and verification studies of complex instrumentation systems.
* Highly experienced in the practice of design controls with extensive knowledge of ISO13485, ISO14971, ISO62366, ISO62304 and FDA QSR 21 CFR 820, 21 CFR Part 11.
* Experience overseeing complex development projects and successfully commercializing product designs, verification, validation, and launch in a highly multi-disciplinary environment.
* Practical experience in a manufacturing environment with an understanding of manufacturing processes.
* Ability to communicate technical knowledge effectively with stakeholders with varying backgrounds.
* Experience with good laboratory practice and workshops for the effective execution of R&D projects.
* Experience with project management tools for effective monitoring and control of projects; knowledge of Earned Value management, risk-based project management is a plus.
* Experience with systems modeling tools and requirements engineering tools. Prior modeling experience using SysML like Cyber Systems Modeling is preferred

# Location

The role is being filled as an on-site role at DNA Electronics Inc . is based in Carlsbad, CA with a hybrid work model.

# Apply

If you believe you meet the above criteria and would relish playing a key role in developing a revolutionary technology, we would be delighted to hear from you.

We offer a competitive compensation package to successful candidates.

Please email your CV and cover letter to: HR-US@dnae.com quoting

**Your name and the** **job title** in the subject line.

For more information about DNAe, please visit our website [www.dnae.com](http://www.dnae.com)

DNAe is committed to offering staff a competitive remuneration package, alongside compelling benefits. As the primary part of the process, we conduct a rigorous market data review where each role is individually benchmarked using a vast amount of recent data. The estimated base salary range for the Systems Engineering Manager role based in Carlsbad, California is: $158,300 to $175,900. Compensation decisions are dependent on several factors including, but not limited to, an individual’s qualifications, location where the role is to be performed, internal equity, and alignment with market data. Should the level or location of the role change during the hiring process, the applicable salary range may be updated accordingly.

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