

## Systems Architect Lead Engineer

Job Reference: SA  
Posted: December 2020

Location: Carlsbad, US  
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 an experienced technical leader to play a pivotal role in end-to-end product design and development of DNAe's technologies.

### **Responsibilities**

- Project management of new product development activities from concept through to validation.
- Generate architecture ideas and define system concepts for future-proofing core technology platform.
- Initiate, direct, and execute robust scientific experimentation with cross-functional project teams to inform product design and implementation.
- Provide mentorship to engineers, scientists and technicians on development projects and functional activities.
- Critical assessment of processes (e.g, assay, software) and innovate novel solutions to solve complex workflows which ultimately meets system platform flexibility and product requirements.
- Oversee and provide technical leadership and direction with internal stakeholders and external partners involved in system design and development activities.
- Collaborate closely across multiple disciplines and functions within organization.
- Develop, organize, and maintain product development documents for hardware.
- Develop verification and validation test plans with team members for consumable and instrumentation; and execute study protocols and generate reports.
- Analyze large data sets, troubleshoot complex issues, and suggest creative solutions to improve system-level issues.

## **Person Specification**

We are looking for proactive individuals with drive, enthusiasm and a strong work ethic who thrive working in a fast-paced environment with aggressive deadlines. We are developing 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 take charge of teams whilst having the technical background to solve challenging problems which has successfully been translated from research to commercial success.

This role requires advanced knowledge of multiple areas of engineering and biophysics, molecular assays, micro-fluidic systems, electro-mechanical systems, and instrument control (software/firmware). This can be demonstrated through research publications in journals and/or patents granted.

## **Qualifications & Experience Required:**

- Ph.D. in Engineering or Physics, or related field with minimum of 7+ years industry experience in a similar technical lead role
- Experience in leading engineers and technicians in development of sample-to-answer molecular diagnostics platforms for PoNT or PoCT applications
- Proven experience in design & development, and launching medical/IVD products (consumables and instrumentation) to the regulated market
- Demonstrated experience in writing quality technical documentation and developing test plans for validation and verification studies of complex instrumentation systems.
- Detailed design review of micro- bioprocess implementation (fluidics), instrument control software, consumables, and hardware.
- Solid knowledge of regulatory standards such as ISO13485, ISO 14971, FDA QSR 21 CFR 820, 21 CFR Part 11.
- Strong skills in influencing and coordinating development of hardware and software designs by external partners and internal teams across borders to deliver to company's product requirements.
- Experience problem-solver, comfortable designing, conducting, and continuous optimization of physical and/or scientific experiments.
- Advanced skills using engineering and project management tools (e.g., CAD packages, programming).
- Maintaining schedules and implementing corrective action where appropriate to keep project timelines on track.
- Able to develop risk analyses, hazard analyses and failure modes and effects analyses across platform system.
- Must be detailed orientated, hands-on, and a highly motivated team player.
- Exceptional communication and influencing skills are a must.



## **Location**

DNA Electronics is based in Carlsbad, California, USA

## **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](mailto: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, Inc. is an equal opportunity employer that does not discriminate on the basis of race, color, national origin, ancestry, religion, sex, gender, age, marital status, physical or mental disability, military or veteran status, sexual orientation, gender identity, gender expression, genetic information, or any other characteristic protected by applicable federal, state or local law.