## Senior QA Specialist Position

**About EnGeneIC and the New Role:**

EnGeneIC Pty Ltd is a clinical stage innovative Australian biotechnology company which has developed a novel targeted nanocell for cancer treatment called EDV™. Although EnGeneIC has developed its EDV™ nanocell for oncology applications, a new COVID-19-EDV has been designed and proven to stimulate a strong and broad anti-COVID-19 response in preclinical animal studies. This work is now progressing to Phase I Clinical Trial. We have a unique manufacturing facility, and a new position has become available as part of this exciting manufacturing project. We are currently seeking a Senior QA Specialist for our site to join our highly dedicated team.

The successful candidate will report directly to EnGeneIC's joint CEO's but will work closely with members of Manufacturing team, Quality Control department and Regulatory Affairs members. The Senior QA Specialist will play a key role in assuring high quality manufactured products and ensuring properly documented batch reports and communication.

Critical to the role is a GMP orientated, methodical and organised approach person with an ability to act as a liaison between different EnGeneIC departments. The candidate will also have exceptional written communication skills with a high level of attention to detail. The successful applicant will also be a team player with excellent interpersonal relationship skills and a positive can-do attitude.

Please note that this role is only open to Citizens or Permanent Residents of Australia. Remuneration commensurate to experience.

**Responsibilities and Accountabilities:**

- Develop, implement, maintain, and improve EnGeneIC Quality Management System (QMS) relating to manufacturing processes.
- Develop training material and effective competency assessment in conjunction with process owners.
- Assist the Document Controller in the management and approval of QMS documents (URS, IQ, OQ, PQ, SOP, NCR, WI, etc.).
- Provide subject matter expertise with regard to EnGeneIC QMS, PIC/S GMP Guide, TGA and FDA requirements.
- Implement and maintain CAPA and Nonconformities (i.e., deviations) of raw materials, intermediate products, and final drugs during the entire manufacturing process.
- Participate in Change Control process, including approval, QA checklist completion and initiation.
- Represent QA on cross functional project teams.
- Liaise with stakeholders and process owners to identify process quality improvement opportunities.
- Compile reporting data of issues in relevance of on-going QMS process for ensuring product quality.

**Skills, Knowledge, and Experience:**

- Tertiary qualification in Science, Engineering, or a related discipline.

**EnGeneIC Pty Limited**
**ABN 59 091 336 499**
**Building 2, 25 Sirius Road, Lane Cove West, NSW, 2066**
**Phone: 61 2 9420 5844 Fax: 61 2 9420 5877**
**www.engeneic.com**

- Minimum six years' experience in quality assurance department of a pharmaceutical or high regulated manufacturing facility. Very valuable, if experience is related to sterile or aseptic drugs.
- Good knowledge and understanding of the practical implementation of PIC/S GMP Guide (Part I, Part II and Annexes) and FDA CFR21 210, 211 and 600-680.
- QMS auditing skills.
- Knowledge of any document control system and enterprise resource planning (ERP) software such as QAD or similar.
- High level skills in using Microsoft Package (word, excel, power point)
- Previous experience in GMP facilities (FDA/TGA).
- Ability to work effectively in a team, as well as independently.
- Self-motivated and proactive approach to daily operations.
- Attention to detail.

**Joining us:**

If you have a positive attitude and thrive in a team environment, and if you have a strong commitment to quality and you are meticulous in detail, then working at EnGeneIC will prove to be exciting and satisfying. Preference will be given to those applicants with a background in cGMP manufacturing. If you feel that you are ready for a new challenge, please forward your CV with a cover letter including the names of two referees to:

**Juan Dux-Santoy**

EnGeneIC Pty Ltd,
Building 2,
25 Sirius Road, Lane Cove West,
Sydney, NSW 2066
Email: jdux-santoy@engeneic.com
Website: www.engeneic.com

**Closing Date:**

22nd of October 2021