Our growing company is hiring for a quality system. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

Responsibilities for quality system

- Provide back up for the US data analyst
- Run RCC local compliant metrics reports as needed
- Triage customer escalations and escalate to the business units for response and resolution as needed (non-IDN customers)
- Perform history check on previously submitted complaints by customer to ensure that the customer is receiving an appropriate closing response
- Review customer letters to ensure accuracy and appropriateness of the letter content
- Provide feedback to complaint leadership and complaints team regarding letter content and provide guidance for improvements
- Contact the customer as needed to provide updates to outstanding quality issues
- Develop & document site Quality manual
- Documentation of Global Quality standards & conduct internal audit program to assess effectiveness of Quality standards at site
- Document CAPA for all NCRs at site & close the same in coordination with site leadership team

Qualifications for quality system

- BS Engineering or Scientific discipline
- Keen understanding of FDA regulations
- Prior exposure to Biologics and/or blood products

- Extensive experience (7 plus years) with at least 5 years of experience in quality management in a manufacturing environment
- 8+ years experience with Quality Assurance programs in a PCBA manufacturing environment preferred, especially in QMS area