QUALITY ASSURANCE AUDITOR I

For over 25 years, SDIX has been a leading immuno-solutions company, developing results oriented and innovative antibody-based solutions that enable customers, worldwide, to meet high performance diagnostic and commercialization objectives. We are ISO 13485:2016 certified and specialize in mono and polyclonal antibody manufacturing for IVD, IHC, and pharma/biotech applications.

SDIX is looking for a part-time *Quality Assurance Auditor I,* to join our team in Windham, ME.

Job Summary:

Ensures that products meet quality standards and applicable regulations. Responsible for the review and approval of documents in support to the manufacturing systems (e.g. batch records, equipment, facilities). The successful candidate:

- Reviews and/or approves records for compliance with SDIX procedures, ISO 13485 Standards and FDA Part 820.
- Assures that commercial finished products are manufactured, labeled, tested and packaged in compliance with industry regulatory standards, customer specifications and SDIX policies.
- Prepares organization for ISO 13485, FDA Part 820 and customer audits. Conducts internal audits according to Master Audit Plan. Reports findings to management and ensures corrective actions are addressed.
- Maintains master equipment list and monitors compliance of equipment maintenance program and associated records to SOP, ISO 13485 and FDA 820. Reports findings to management.
- Performs QA review of deviations, change controls, and validation reports. Reviews lot record and final release of finished product. Ensures nonconforming products are identified and reported.
- Reviews and approves Quality documentation, customer specifications and validation plan to ensure compliance with applicable regulations and standards.
- Maintains the document management system.
- Promotes Quality mindset and positive communication.

Qualifications and Requirements:

- BS in biology, chemistry or related life sciences field.
- Minimum of two years QA-QC experience, preferably in biotech/pharmaceutical field.
- Experience in document control and equipment control systems including working knowledge of IQ/OQ/PQ and process and cleaning validation methodologies.

Work Environment:

The work environment varies significantly from task to task. This position is an in-office position, with occasional exposure to lab or warehouse settings. This position may expose the employee to a variety of physical, chemical or biological hazards. Daily contact with employees in other departments is required.

PHYSICAL DEMANDS: Physical demands as described are representative of those required to successfully perform the essential functions of the position. Reasonable accommodations may be made.

- Ability to lift or move 35 pounds and work/travel throughout plant environment of varied temperatures and humidity; see, grasp and hold small objects, a full range of motion, and to wear personal protective devices.

SDIX, LLC IS AN EQUAL OPPORTUNITY EMPLOYER