

**LIN-ZHI INTERNATIONAL, INC.**  
**STANDARD OPERATING PROCEDURE**

**REF: ADM/0208-19**  
**ISSUE: 3**  
**REV: 1**  
**DATE: 03/14/2025**

**JOB DESCRIPTION**

*Lin-Zhi International, Inc.*<sup>TM</sup> (LZI) was founded in 1998 by Dr. Cheng-I Lin and Dr. Marie Lin in California. LZI focuses on producing innovative and high-quality homogeneous enzyme immunoassay (EIA) and enzymatic assay reagents for the clinical diagnostic industry. As both a cutting-edge biotech company and a small business, LZI seeks employees who will thrive in a small-business setting: self-driven, hard-working, and flexible individuals.

The nature of *LIN-ZHI INTERNATIONAL*'s business dictates that personnel must remain flexible with the ability to accept responsibilities within their educational and training levels. These may be different from those stated on their "Terms of Employment."

**JOB TITLE:**

Quality Control (QC) Supervisor

**RESPONSIBLE TO:**

Production Manager

**GENERAL DUTIES:**

- Responsible for the QC Department and ensuring that all LZI products meet quality standards.
  - Develop and implement quality control testing and product inspection at various stages.
  - Writing and creating reports documenting production or incoming raw material issues.
  - Oversight of QC Department, including distribution of projects, priorities, workloads, and deadlines within the QC Department.
  - Responsible for management, discipline, and evaluation of QC staff.
  - Train staff and determine work quality expectations. Provide advice and assistance on work techniques, best practices, and subject-matter expertise to team members.
- \* Additional duties and modifications may be added as the need arises.

**SPECIFIC DUTIES:**

- Oversees general QC approval of LZI products (Enzyme Immunoassay (EIA) Bulks, EIA kits, Work in Progress Raw Material). Responsible for inspection of final product specifications and approving or rejecting finished products.
- Manages QC retains, testing schedule, data and reports, and related Standard Operating Procedures (SOP) documents. Review and make decisions regarding retain testing and final QC long-term results.
- Oversees raw material qualification/re-qualification and disposal.

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- Coordination and oversight of instrument and equipment validation and equipment maintenance.

**SPECIFIC DUTIES, CONTINUED:**

- Responsible for QC Team project rotation scheduling and assignments.
    - Daily General QC of LZI products
    - Retain testing
    - QC Shipping Checks
    - Certificate of Analysis Generation
    - Discards
    - Receiving and Processing Raw Materials
  - Process improvement, procedure and protocol development. Revise, write-up and implement updated Standard Operating Procedures.
  - Coordination of QC and Quality Assurance (QA) meetings and documentation of meeting minutes.
  - Communicate QC-related troubleshooting issues to the VP of Operations for discussion at Research & Development Meetings.
  - Communication and coordination with respect to other departments (including but not limited to Production, Packaging, Regulatory, Shipping, Customer Service/Technical Support, etc.) and participate in management-related meetings.
    - Coordinate and communicate with Customer Service/Technical Support Associate regarding product and customer issues.
    - Propose corrective actions to improve compliance with quality standards and interface with Regulatory Department regarding corrective action follow-up and audits.
  - Prepare reports for post-launch, specification change risk, and stability meetings.
  - Responsible for the investigation and troubleshooting of product issues.
  - Manage raw material secondary vendor studies and stability studies.
  - Manage QC documentation and records.
  - Participate in QC audits.
  - Hiring, including candidate selection and interviewing and creating relevant job descriptions.
  - Oversee training of new Quality Control team members and for new duties or tasks assigned to team members.
  - Responsible for review of attendance and time keeping for QC staff, or for supervising and assigning timekeeping duties among QC Leads.
  - Communicating information to QC staff including company policies and procedures, and QC staff concerns to Production Manager, Upper Management, and other relevant managers.
  - Staff management, including creating metrics and implementing staff evaluation, discipline, and performance improvement measures.
  - Responsible for the maintenance and cleanliness of QC lab related areas.
- \* Additional duties and modifications may be added as the need arises.

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**QUALIFICATION & EXPERIENCE REQUIREMENTS:**

- B.S. in Biology with 5+ years of QC experience or equivalent.
- 1-3 years supervisory experience required.
- Knowledge and experience with Quality Control Management preferred.
- Excellent writing and communication skills.
- Must be detail oriented and excellent at record keeping.
- Able to think critically, analyze and troubleshoot data.
- Must be able to lift/move up to 40 pounds.
- Familiarity with a laboratory setting and handling of lab related materials.
- Applicants should be well-versed in the use of the internet/email, Microsoft Word, Excel, and PowerPoint program is required.
- Able to work in the cold room periodically, which is kept at 2 – 8°C (35.6 – 46.4°F).
- \* After hiring, require to provide a vaccination record and/or confirm current Hepatitis B status.

**GENERAL ON THE JOB TRAINING REQUIREMENTS:**

- Quality Control training (receiving, raw materials, reagent/calibrator/control testing, shipping checks)
- Team Management

*Lin-Zhi International, Inc.* is committed to building a diverse and inclusive work environment that reflects the society and communities in which we are located. We are committed to diversity and actively seek out applicants from groups facing systemic inequities in the biotech world.

*Lin-Zhi International, Inc.* is an equal opportunity employer. We enthusiastically welcome and accept our responsibility to make employment decisions without regard to race, gender, sex, sexual orientation, gender identity, age, religious creed, color, national origin, religion, marital status, medical condition as defined under State law, disability, genetic information, military service, pregnancy, childbirth and related medical conditions or any other classification protected by federal, state, and/or local laws and ordinances.