

LIN-ZHI INTERNATIONAL, INC.
STANDARD OPERATING PROCEDURE

REF: ADM/0211-10
ISSUE: 3
REV: 6
DATE: 02/12/2025

JOB DESCRIPTION

Lin-Zhi International, Inc.[™] (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 and have 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:

Documentation Specialist

RESPONSIBLE TO:

VP of Operations and Documentation Lead(s)

GENERAL DUTIES:

- Prepare and maintain production and product-related documentation such as but not limited to Manufacturing Procedure Instructions (MPI), Manufacturing Specification Sheets (MSS), Research and Development Procedure Instructions (RPI), Research and Development Specification Sheets (RSS), Protocols, Labels, Product Inserts, Parameter Sheets, and Safety Data Sheets (SDS).
 - Maintain regulatory compliance in updating procedures, forms, and protocols.
 - The Documentation Specialist must follow appropriate document control procedures used by LZI.
 - Other duties may include copying, filing, and maintenance of production and packaging-related documentation.
- * Additional duties may be added as the need arises

SPECIFIC DUTIES:

- Ensure proper updates of production and product-related documentation by following appropriate document control procedures such as Engineering Change Orders (ECOs), Document Change Orders (DCOs), Transfer Lots, Master and Working copies, etc.
- Liaise with Production, Packaging, Quality Control, Development, Regulatory teams, and the VP of Operations to update production-related documentation.
- Liaise with all departments to update procedures, forms, and protocols.
- Establish, implement, and maintain documentation related to Standard Operating Procedures (SOPs), forms, and protocols.

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SPECIFIC DUTIES, CONTINUED:

- Ensure all documents used for production are current, properly identifiable, and traceable (i.e. correct document name, number, revision, stamp indicating Master or Working copy, etc).
 - Part Number Index and Registry and Main Distribution Matrix maintenance. Obsolete DMR binder and Obsolete paperwork maintenance.
 - Correction & updates of labels, product inserts, parameter sheets, protocols, MPIs, MSSs, RPIs, RSSs, Safety Data Sheets (SDS), procedures, forms, and protocols.
- * Additional duties may be added as the need arises

QUALIFICATIONS & EXPERIENCE REQUIREMENTS:

- Bachelor's degree is required
- Applicants should be well-versed in the use of Microsoft Office suite (Word and Excel), Gmail, Google Workspace, and Adobe Acrobat
- Excellent attention to detail and organization skills
- Excellent communication skills
- Maintain good working relationships with various internal departments

GENERAL ON THE JOB TRAINING REQUIREMENTS:

- Document control (creation, update, maintenance, and obsolescence of paperwork)
- Software training for BarTender

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.

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