

LIN-ZHI INTERNATIONAL, INC.
STANDARD OPERATING PROCEDURE

REF: ADM/0203-14
ISSUE: 3
REV: 0
DATE: 12/12/2024

JOB DESCRIPTION

*Lin-Zhi International, Inc.*TM (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:

Production Research Associate Levels I & II

RESPONSIBLE TO:

Senior Manager, DAU Assay Development and Senior Production Manager

GENERAL DUTIES:

- Conduct enzyme immunoassay (EIA) research and manage development projects to obtain FDA 510(k) clearance and CLIA categorizations to bring new products to market.
 - Manufacture diagnostic drug of abuse reagent kits by optimizing and formulating Enzyme Immunoassays (EIA) on clinical analyzers.
 - Perform validation study and/or 510(k) experiments as outlined in development protocols.
 - Assist the Development and Production teams in completing production, quality control (QC), and development projects based on company priorities.
 - Independent troubleshooting, decision-making, and problem-solving working on projects utilizing various clinical analyzers.
- * Additional duties and modification may be added as the need arises

LEVEL I SPECIFIC DUTIES:

- Optimization and formulation of enzyme immunoassay reagents and enzyme hapten conjugations.
- Formulation of calibrator and control solutions.
- Preparation of buffers and solutions.
- Assemble finished good products print, label, fill, cap, and package.
- General lab and equipment preventative maintenance.
- Maintain a clean, sanitary workplace, including washing glassware and bulk containers.
- Follow Standard Operating Procedure guidelines and maintain good documentation practices.
- Properly record and organize data.

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LEVEL I SPECIFIC DUTIES, CONTINUED:

- Meet production and/or development deadlines and handle multiple projects.
- Proficiently work on a variety of clinical analyzers.
- Analyze and interpret data.
- Record methods and results using good documentation practices.
- Present and explain project results at team and project meetings.
- Effectively organize, prioritize, and plan experiment/work schedule.
- Comprehend, articulate, and apply immunoassay theory and concepts.
- * Additional duties and modification may be added as the need arises

LEVEL II+ SPECIFIC DUTIES:

- Assist in the transfer of completed development projects to Production.
- Conduct scientific literature reviews and research into relevant immunoassay topics.
- Organize and analyze validation study data, and explain and present scientific literature research at project meetings.
- * Additional duties and modification may be added as the need arises

QUALIFICATION & EXPERIENCE REQUIREMENTS:

- B.S. in biology or chemistry-related field or equivalent (*M.S. preferred*).
- 1.5 - 3 years of work or research experience in a laboratory (*2 years preferred*).
- Knowledge and experience with immunoassay research (*preferred*).
- 1+ years of research and development experience (*preferred*).
- Completion of one (1) CLIA Validation project or equivalent research project(s) (e.g. thesis research, new product development research) (*preferred*).
- Competency in immunoassay optimization and testing with clinical analyzer (*preferred*).
- Excellent written and verbal communication skills.
- Able to think critically and analyze basic data.
- Ability to learn new laboratory skills or concepts quickly.
- Familiar with a laboratory setting and basic handling of lab-related materials.
- Proficient in understanding basic calculations of concentrations and dilutions.
- Excellent detail, documentation, and organizational skills
- Excellent problem-solving and troubleshooting skills
- Proficient with Internet/e-mail, Microsoft Word, Excel, and PowerPoint programs are required.
- Must be able to lift/move up to 40 pounds.
- Able to work in the cold room periodically, which is kept at 2 – 8°C (35.6 – 46.4°F).

After hiring, required to provide a vaccination record and confirm current Hepatitis B status and COVID-19 vaccination status.



TRANSFER LOT

Lin-Zhi International, Inc.

Init: JT Date: 12/12/2024

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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're 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.