# 【972～万円】 品質保証部 コンピュータシステム品質保証（CSQA）/課長/P2 P3/西神工場（神戸市内）

**日本イーライリリー株式会社での募集です。 品質保証のご経験のある方は歓迎です。**

## Job Information

**Recruiter**
JAC Recruitment Co., Ltd.

**Hiring Company**
日本イーライリリー株式会社

**Job ID**
1561852

**Industry**
Pharmaceutical

**Company Type**
International Company

**Job Type**
Permanent Full-time

**Location**
Hyogo Prefecture

**Salary**
9 million yen ~ Negotiable, based on experience

**Work Hours**
08:45 ～ 17:30

**Holidays**
【有給休暇】初年度 10日 2か月目から付与及び使用可能 【休日】完全週休二日制 土 日 祝日 夏季休暇 年末年始 年途中で入…

**Refreshed**
November 13th, 2025 18:00

## General Requirements

**Career Level**
Mid Career

**Minimum English Level**
Business Level

**Minimum Japanese Level**
Native

**Minimum Education Level**
Bachelor's Degree

**Visa Status**
Permission to work in Japan required

## Job Description

【求人No NJB2323082】
Overall Job Purpose:

This position is responsible for supporting the site department（s） and/or Project（s） to which they are assigned with respect to computer system development validation and maintenance. This role is responsible for procedural interpretation

and training. The QA ensures inspection readiness within those areas supported and participates in regulatory agency inspections as needed.

Job Responsibilities:

Provide direct quality oversight of computerized systems.
Review and approve documents supporting computerized systems and validation including but not limited to procedures deviations periodic reviews and change proposals.
Provide quality guidance and recommendations with regard to computer system issues.
Conduct gap assessments of global requirements and ensure implementation of the governing standards.
Review and approval of computer system （automation） related work orders.
Provide coaching feedback and mentoring to QA and site personnel as it relates to computerized systems and validation.
Understand data integrity requirements and practice during validation and routine operation.
Participate in site data integrity strategy and assessment activities.
Lead/Support investigation and evaluation of computer system related incidents and/or deviations
Participate in the review/revision of global quality standards related to computerized systems if needed.
Ensure areas are inspection ready and compliant to established systems/procedures.
Participate in and/or support regulatory inspections and audits.
Assist others in the interpretation of regulatory and corporate requirements supporting computerized systems.
Establish and maintain site quality system for computer system to meet regulations including Japanese GMP Computer system guideline GQSs and LQSs.
Attend Process Team（s） （e.g. Manufacturing Utilities QC etc.） Flow Team（s） （i.e. FUME QC Engineering） Lead Team（s） （i.e. Data Management Continuous Improvement IDS QA etc.） as required.

## Required Skills

Required Experience: （mandatory for hiring）

Bachelor’s Degree （or above） in chemistry engineering computer science mathematics or science related field or equivalent experience.
GMP work experience in a pharmaceutical industry
Experience with manufacturing process and/or computer system including validation.
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Desirable Experience:

海外での就業経験もしくは日常的な英語での業務経験
Essential Skills / license: （mandatory for hiring）

ネイティブレベルの日本語力
TOIEC750点以上、又は英語を用いた業務経験が半年以上ある方
Understand local and global applicable regulations （ex. CFR Part11 etc.）.
Strong written and verbal communications skills.
Strong problem solving and decision making skills
Strong attention to detail.
Proficiency with GMP computer system validation including regulations governing them.
Strong leadership.
Excellent interpersonal skills and networking skills.
Ability to organize and prioritize multiple tasks.

## Company Description

医療用医薬品の輸入・製造・販売