

Director of Quality and Manufacturing Excellence

Job Information

Recruiter
JAC International Co., Ltd.

Hiring Company
Global Bioprocess Solutions Company

Job ID
1617182

Industry
Other

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
Negotiable, based on experience

Refreshed
November 27th, 2026 23:00

General Requirements

Minimum Experience Level
Over 3 years

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Business Level

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

Build “Japan Quality” from the Ground Up

A growing international bioprocess solutions company is seeking an accomplished Director of Quality and Manufacturing Excellence to establish and lead its quality assurance platform in Japan.

This is not a conventional maintenance-focused QA position. The successful candidate will have the opportunity to build a Japanese Quality Management System, shape the company’s quality culture, and create the standards that will support its next stage of growth in Japan and internationally.

The company provides single-use products and related equipment used within biopharmaceutical manufacturing processes. Although these products are not pharmaceutical products themselves, customers expect exceptionally high levels of quality, reliability, traceability, and manufacturing control.

The successful candidate will lead the creation of a GMP-aligned quality framework for Japan while supporting the transfer of technology and production capabilities from an overseas manufacturing base to Japan. The role will also help integrate

Japanese manufacturing expertise, materials technology, and quality standards into products intended for international markets.

This is a rare opportunity for an experienced quality leader to move beyond operating an established system and instead design, build, and lead a quality organization with significant influence over the future of the business.

Key Responsibilities
Quality Management System Leadership
-Establish, maintain, and continuously improve the Quality Management System for the Japanese organization.
-Develop a quality assurance framework aligned with GMP principles.
-Create, review, and manage SOPs, quality manuals, operating procedures, and related documentation.
-Lead change control, deviation management, CAPA, risk management, and other core quality processes.
-Build quality awareness across the organization through training, leadership, and effective communication.
-Develop a sustainable quality culture appropriate for a growing international business.

Technology Transfer and Manufacturing Excellence
-Lead quality activities associated with technology and production transfer from overseas manufacturing operations to Japan.
-Establish the quality framework required to support future manufacturing operations in Japan.
-Ensure that Japanese customer expectations and relevant quality requirements are reflected in products and manufacturing processes.
-Identify opportunities to use Japanese materials, components, manufacturing expertise, and quality methods to improve product performance and reliability.
-Collaborate with international manufacturing teams to apply quality improvements developed in Japan to global products.

OEM and External Manufacturing Quality
-Establish and operate the quality assurance framework for OEM and contract manufacturing partners.
-Conduct quality audits of external manufacturing sites.
-Standardize manufacturing processes and quality-control methods.
-Lead corrective actions and continuous quality-improvement initiatives with manufacturing partners.
-Prepare the quality foundation required for a future transition to manufacturing operations in Japan.

Sterile Manufacturing and GMP
-Provide quality leadership based on a strong understanding of sterile and biopharmaceutical manufacturing processes.
-Ensure appropriate application of GMP principles and quality-risk-management practices.
-Review validation strategies, protocols, reports, and associated quality documentation.
-Provide expert quality guidance concerning sterile manufacturing and bioprocess applications.

Regulatory and Customer Quality Leadership
-Represent the organization in quality-related communication with customers and relevant regulatory stakeholders in Japan.
-Lead responses to customer quality inquiries, assessments, and audits.
-Prepare professional quality presentations and technical documentation for customers.
-Communicate the company’s approach to quality at industry exhibitions, seminars, and technical meetings.
-Establish a compelling and credible “Japan Quality” identity for the organization.

Why This Role Is Different
This position offers the opportunity to:
Build a Japanese quality organization rather than simply inherit one.
Define the company’s quality standards, systems, and culture.
Lead a major international technology and manufacturing transfer.
Influence product development and manufacturing quality across multiple markets.
Introduce Japanese materials, manufacturing capabilities, and quality practices into global products.
Serve as the senior quality representative for customers, manufacturing partners, and external stakeholders in Japan.
Play a central role in the future establishment of manufacturing operations in Japan.
Develop “Japan Quality” into a genuine source of competitive advantage.

Employee Benefits:
-Full social insurance coverage, including health insurance, employees’ pension insurance, employment insurance, and workers’ compensation insurance.
-Commuting expenses reimbursed in accordance with company regulations.
-Five-day working week.
-Saturdays, Sundays, and Japanese national holidays off.
-Year-end and New Year holidays.
-Annual paid leave in accordance with Japanese law and company regulations.
-Special leave, childcare leave, nursing-care leave, and other applicable leave.
-Annual health examination.
-Salary review based on individual performance, company performance, and responsibilities.
-Performance-related annual bonus.
-Other benefits provided in accordance with company regulations.

Required Skills

Essential Requirements
At least 10 years of quality assurance experience within the pharmaceutical or biopharmaceutical industry.
Strong knowledge of sterile manufacturing or biopharmaceutical manufacturing processes.
Comprehensive understanding of GMP principles and quality requirements.
Practical experience establishing, developing, or significantly improving a Quality Management System.
Experience preparing and managing SOPs and other controlled quality documentation.
Experience with quality systems such as deviations, CAPA, change control, audits, and quality-risk management.

Excellent Japanese communication skills.
Ability to communicate effectively with customers, manufacturing partners, internal stakeholders, and external organizations in Japan.
Willingness to take a hands-on role in building quality systems, documentation, and operational processes.

Preferred Requirements
Leadership experience as a QA Manager, Head of Quality, Quality Director, or equivalent.
Experience leading or supporting technology transfer projects.
Experience managing quality for OEM, CMO, or contract manufacturing operations.
Experience supporting PMDA inspections or communicating with regulatory stakeholders in Japan.
Experience conducting supplier, manufacturing-site, or customer quality audits.
Experience working with overseas manufacturing sites.
Business-level English communication skills.
Experience with validation activities within sterile or biopharmaceutical manufacturing environments.
Experience establishing quality systems for a new business, manufacturing site, or Japanese subsidiary.
Desired Leadership Profile

The ideal candidate will be a quality leader who combines strategic judgment with practical execution. The position will suit someone who is comfortable creating systems from the ground up, working across cultures, and influencing stakeholders without relying solely on established organizational structures.

The successful candidate should demonstrate:
Strong quality leadership and personal credibility.
A practical, solutions-oriented approach.
Ability to translate GMP principles into proportionate and effective quality systems.
Strong stakeholder-management and influencing skills.
Ability to work across Japanese and international teams.
Commercial awareness combined with a firm commitment to product quality and customer trust.
The communication skills required to represent the organization externally.

Company Description

新たに日本マーケットに参入される外資系企業や、日本でさらなるビジネス拡大をお考えの外資系企業のお客様に、私たちは最適な採用サポートを提供いたします。1975年に英国初の日系人材紹介会社としてロンドンで創業し、その後シンガポール、日本、マレーシア、インドネシア、タイ、中国の7カ国 (また2011 年には香港・韓国にも拠点を新設予定) でグローバル人材紹介会社として事業を拡大してきたジェイ エイ シーは、そのバックグラウンドから、海外文化への深い理解を持ち合わせています。グローバルに事業を展開する日系人材紹介会社のリーディングカンパニーとして、私たちは他に類のない人材ネットワークから、日本人の優秀なバイリンガル人 材や外国人のプロフェッショナル人材をご提供することが可能です。幅広い業種、職種においてのエキスパートである当社のネイティブあるいはバイリンガルコ ンサルタントが皆様のパートナーとなり、適材適所で人材のご紹介をいたします。ジェイ エイ シーが築いてきた特有の歴史、文化、そしてグローバルマーケットでの強みを揺ぎない核として、日本マーケットで躍動する外資系企業のお客様のニーズにさら に的確にお答えするために、ジェイ エイ シー インターナショナルは誕生しました。私たちはアジアやヨーロッパのJAC Recruitment Group海外各社と緊密に連携を取り、お客様の真のニーズを把握した上で、最適なキャンディデイトをご紹介いたします。

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We provide specialized proactive recruitment support tomultinational clients who are setting up new operations or areexpanding existing business and seeking further growth in theJapanese market.As the first Japanese recruitment company to set up operations in theUK in 1975, understanding foreign cultures is second nature to us.With our extensive global network and historically leading position asrecruitment consultancy to Japanese corporations, we have access toan unrivaled pool of bilingual Japanese and foreign professionals.Our professional consultants are experts in a range of Industries andfunctions and all have extensive multicultural experience.Based on JAC’s unique history, culture and market strength, JACInternational was founded to provide dedicated support to ourmultinational corporate clients in Japan.

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