

Director of Quality and Manufacturing Excellence

募集職種

人材紹介会社
株式会社 JAC International

採用企業名
Global Bioprocess Solutions Company

求人ID
1617182

業種
その他

雇用形態
正社員

勤務地
東京都 23区

給与
経験考慮の上、応相談

更新日
2026年10月29日 21:00

応募必要条件

職務経験
3年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ビジネス会話レベル

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

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.

スキル・資格

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.

会社説明

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