Malaysia Jobs Expertini®

Head / Director, Quality

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Company: MY07 CIBA Vision Johor Sdn. Bhd. Company

Location: Malaysia

Category: other-general

At Alcon, we are driven by the meaningful work we do to help people see brilliantly. We innovate boldly, champion progress, and act with speed as the global leader in eye care. Here, you'll be recognized for your commitment and contributions and see your career like never before. Together, we go above and beyond to make an impact in the lives of our patients and customers. We foster an inclusive culture and are looking for diverse, talented people to join Alcon.

As the Head/Director, Quality, you will develop, maintain, and improve quality systems and assure products meet established specifications and are in compliance with various quality and regulatory standards. You will be responsible for Quality Operations for our Contact Lens Manufacturing facilities.

In this role, a typical day will include:

Ensure excellence and consistency in the implementation and execution of the Alcon Quality Systems at the Manufacturing site. Ensure the site Quality Systems, operations, and products are in compliance with all applicable specifications, SOPs, standards, submissions, and regulations. Direct and guide with respect to product, process, and system quality requirements and standards, oversees non-conformance resolution, continuous improvement, quality plan development, risk assessments, change management, and qualification/ validation activities.

Responsible for all quality and compliance related decisions for the site, for implementing all site quality management programs.

Participate in the design, implantation, monitoring and maintenance of an effective Quality Management System.

Chair the site Quality Council and Quality Management Review meetings.

Partner with cross-functional Site Leadership team to establish key quality and performance objectives, corresponding resource requirements, budgets, and forecasts/plans to ensure they are met.

Identify and direct activities to ensure organizational compliance to FDA regulations, ISO Requirements, ISO standards, and internal policies/procedures. This includes: Leading and participating in cross-functional teams to drive improvement in global processes that affect compliance to regulations, standards, and internal Alcon policies and procedures. Manage and facilitate local implementation and deployment of global policies, SOPs, processes, and systems including gap analyses, risk assessments, corrective actions, and relevant training. Support all global initiatives.

Direct and implement the organizations Quality Improvement Plan in accordance with the mission and strategic goals of the organization, federal and state laws, and regulations and standards.

Advise employees and management team on the applicable regulations and standards, Alcon policies, and all other relevant regulatory requirements and notify and take management of any identified patient safety or regulatory risks.

Ensure a robust training program for all levels of Site’s organization that covers: Applicable regulations and standards including cGMP and Safety. Compliance topics and quality systems such as GDP, Change Control, Data Integrity, auditing, and Complaint Handling. Internal Alcon policies and procedures

Execution of manufacturing and testing processes and procedures.

Ensure the development and success of the Site’s Quality Team through: Providing clear Goals and Objectives. Mentoring and Coaching. Talent Management Review. Succession Planning

Assure tracking, evaluating, trending, reporting of key quality indicators, and promotes

awareness of customer satisfaction.

Ensure reporting to top management on the performance of the quality management system and any needs for improvement.

Ensure compliance inspections and audits for monitoring the compliance for the Site and actively support inspection readiness activities.

Manage the Quality budget to ensure spending is within department plans.

Serves as delegate to the PRRC for Device Release Conformance to QMS per Article 15 3 (a) and for Trend Reporting per Article 15 3 (d) and Article 88.

The Site Quality Head is independent from Technical Operations, Development, or other Function Heads. Objectives and priorities for quality management are driven from the functional quality organization. The Site Quality Head reporting lines do not create conflicts of interest relating to quality assurance, quality control, product release or any other compliance decisions taken by the Site Quality Unit.

Other duties as assigned by area management.

WHAT YOU'LL BRING TO ALCON:

Bachelor's Degree (Concentration in Engineering, Science preferred)

The ability to fluently read, write, understand and communicate in English

12 Years of Relevant Experience

8 Years of Demonstrated Leadership

HOW YOU CAN THRIVE AT ALCON:

Site Compliance status; e-Compliance, QA Laboratories Compliance and Manufacturing Compliance

Adherence to Regulatory requirements; US FDA, European MDD and other HA requirements

Customer Complaints

Deviations on all internal and external audits; HA & Regulatory bodies

Meet financial budget for Quality Organization

Development of staff and Succession Planning

See your impact at

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