Noor Emilina Fizrin Zulkifli, Senior QA Executive/ Specialist

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Profile | Summary

I have 14 years working experiences in QAQC role jobs including as quality management representative in diversified industries such as manufacturing, technical servicing, warehousing, distribution and sales commercial of multinational corporation company. I am expert in establishing quality management system for certification, implementation and maintenance as well as dealt with internal and external stakeholders to ensure meet the product quality and regulatory compliance requirements of products supply in the market. Consistent results driven in accomplished the performance objectives and projects. Looking for any long term career opportunities. I am available to start immediately and willing to relocate.

Employment History:

Dec 2023 - Current
Admin Clerk (Temporary) | Noah Maritime Coastguard Sdn Bhd / Lebar Lagenda Sdn Bhd– Cyberjaya

- Attended and assisted visitors receptions.
- Maintained office security via safety procedures and controlling access.
- Maintained office supplies and keep inventory stock. Kept updated record of office expenses and cost and performed clerical duties.
- Performed and keep expenses claim records and all admin controlled forms.
- Supported Operations and Business Marketing Team for projects documentations, filing and prepared slide presentation for Managing Director.
- Communicated with vendors and suppliers for office appliances sourcing for new branch office setup.

- **Reason for leaving:** Looking for better and long term career opportunities.

Mar 2021- Jul 2021
Senior Specialist In-Market Quality | Organon Malaysia Sdn Bhd, - Kuala Lumpur

- As Quality pioneer and appointed as Quality Responsible Person for quality management system pertaining to importation, distribution, and wholesale of the products for Malaysia markets - Good Distribution Practice (GDP).
- Collaborated with local Top Management and Global Compliance representative to guide on local quality compliance adherence and appointed distributor on Quality Agreement approval process during the company transition from MSD to Organon.
- Established and chaired a Local Recall Team by collaborating with Global Compliance, Legal and Top Management committees.
- Overseen GMP redressing for secondary packaging conducted by distributor in distributor facility and provide and approval for the working instructions. Collaborated with Supply Chain Team and Regulatory Affair Team on product redressing and market authorized holder transition project activities.

- **Reason for leaving:** Took a career break due to family matters.

Apr 2019- Feb 2021
Senior QA Executive MY-SG | Alcon Laboratories (M) Sdn Bhd – Petaling Jaya
Nov 2014- Mar 2019
QA Executive | Alcon Laboratories (M) Sdn Bhd – Petaling Jaya

- As Quality pioneer and responsible established, implemented and maintained Quality Management System Good Distribution Practice Medical Device (GDPMD) of Malaysia Act and Quality Management System of Global Quality Standard in local process and business as authorized market holder of Alcon's product in Malaysia.
- Acknowledged as local point of contact for Malaysia pertaining to quality issue and product quality compliance.

- Appointed as Superuser for QA SAP system Malaysia and Singapore IDOC batch management troubleshooting and maintenance. Engaged with internal stakeholders for solutions rectification and executed the troubleshooting.
- Appointed as IRIS Change Agent Lead- Managed and lead change agent ambassador for Alcon MY transformation as well as ensure all change impact activities are conducted successfully.
- Supported Alcon's QMR in reviewing Business Contingency Plan(BCP) to ensure all BCP measurements are aligned with company's QMS and regulatory requirements. Communicated with Business Owner for any required quality measures for further implementation or improvements.
- Established local Management Review program. Drafted management review input and documentation readiness for management review meeting. Managed management review output and monitored any feedbacks and improvements required. Managed the minutes documentation.
- Conducted change control activities as required. Coordinated and delegated any information and action required to all respective stakeholders. Ensure documentation compliance prior closure and management approval.
- Established IQA SOP and led in planning and executing Annual Quality Audit programs which included Supplier Quality Audit, QMS certification and re-certification audit, Global QA audit program. Conducted annual training to all Internal Quality Auditors for Internal Quality Audit Team. Coordinated site visit audit with the GxP Suppliers. Prepared final internal quality audit reports for management reviews.
- Established local controlled documents management SOP and responsible as Documents Controller. Coordinated with Non-GxP SOP owners for SOP Simplification projects across the company. Managed controlled documents maintenance annually.
- Established local GxP Training SOP and managed GxP training program compliance in annual basis. Conducted annual GxP training to GxP's respective employees and suppliers. Trained and appointed as a MY-SG Training Plateau Administrator who identified GxP syllabus and assigned via plateau to local affected GxP role job.
- Established local NCR and CAPA SOP. Led NCR investigation as CI trained, conducted CAPA (manual & TrackWise) monitoring and documentation, closure and conducted annual training.
- Established local SOP of Supplier Quality Management program, managed interval GxP supplier evaluation, coordinated with Suppliers and internal stakeholders to conduct any supplier site visit audit.
- Managed GxP training programs for Employees and respective
- Collaborated with suppliers and internal stakeholders pertaining supplier quality management implementation and compliance. Managed and conducted supplier audit visit for initial assessment and base on reassessment requirements.
- Conducted monthly product verification in 3PL facility. Managed to monitor and improve 3P Deviation Reporting timeline and complied within 48 hours reporting as per QAA. Supported QMR in drafted QAA with 3PL and GxP Transporter supplier. Coordinated with 3PL and supply chain team and provided quality disposition for any Quality matters during daily operations of warehousing and distribution activities in daily basis.
- Led and managed local voluntary product recall and field safety corrective actions as per Global Compliance and local Medical Device Authority (MDA) instructions. Communicated with local MDA for notifications and consultation on market hold activities instructed by Global Compliance. Managed all documentation for updates and closure.
- Managed product complaint handling from end to end process included Trackwise logged in, investigation follow up and sample handling. Collaborated with Distributor and reconciliation of product complaint receiving by 3PL and appointed vendors and reporting to Local MDA for all Adverse Event complaint. Supported Sample conversion project. Established local SOP throughout the process.
- Collaborated with technical service team to oversee the maintenance of Corporate TS QMS compliance, activities of storage and distribution of MD machines and spare parts, conducted IQA, reviews calibration certificates, led any market action included FCA that affected Malaysia market, led conducted supplier assessment for TS and monitored TS controlled documents management implementation.
- Supported Philippines, Singapore and India by liaised with their local distributor and internal stakeholders on QA daily operations activities such as providing quality disposition on nonconformance products, cold chain products temperature approval activities and redressing working instructions approval during the interim period of the vacancy in their local QA position.

- Created and published Quality Bulletin for internal communications on quality memo and updates to business.

- **Achievement**:
  - Accomplished Gap Assessment GDPMD with Certified in within 2 weeks deployment on Nov 2014 and Alcon successfully achieved GDPMD Certification in Mar 2015
  - Received awards Value & Behavior Award for category "Quality" in 2015 and 'Collaboration' in 2017.
  - Accomplished secondment job role managing product complaints in 2016-2017 due to manpower issue and global management transition from Novartis to Alcon.
  - Conducted training and shared best practice on QM Implementation with other 5 APAC Countries, India, China, Hong Kong, Korea and Taiwan.
  - Accomplished owned projects called 'Project BEE' in 2017 on GxP training program implementation and compliance across the company.
  - Promoted from Quality Executive to Senior Executive in April 2019
  - Accomplished secondment position as QA Data Migration from August 2019 to Feb 2020 and helped Alcon successfully deployed UAT and DiTL for SAP Local-(Malaysia) batch Migration in timely manner. Alcon succeed to Go-Live on early Feb 2020.
  - Received Team Award Appreciation Award from management for the team achievement.

- **Reason for leaving:** Career growth in pharmaceutical industry.

May 2014- Nov 2014
Quality & Technology Executive | Siemens Healthcare Sdn Bhd – Petaling Jaya

- Assisted Head of QT to Implement and maintenance of Quality Management System. Document controller and maintains H sector ISO9001:2008 & GDPMD
- Supported product registration documentation accordance to Medical Act 737 and Atomic Energy License renewal for Application Engineers.
- Collaborated with QA Corporate in Annual Quality Audit programs and conducted audit to cross functional and division.
- Supported Business team and conducted quality review for ensuring all required QMS measures and compliance on Service and Business Level Agreement for clients are in placed.

- **Reason for leaving:** I got offered from Alcon – Novartis to support the Alcon's GDPMD certification projects (Nov 204-Mar2015).

Feb 2012- Apr 2014
Quality Executive | Zuellig Pharma Sdn Bhd – Shah Alam

- As Quality pioneer and appointed as Deputy Quality Management Representative for Medical Device Department (MDD). Established and implemented QMS based on GDPMD, ISO13485, ISO9001 and regionals requirements for GDPMD certification. Managed the Certification Audit Day and attended the audit with Certified Body.
- Established and implemented Risk Management programs for QMS certification. Collaborated with Top Management for commitments, implementation and monitoring for any mitigation action required.
- Overseen 4 client's small in-house warehouse and distribution activities in order to assure it comply within client, company and regulatory requirements.
- Conducted the temperature room calibration and monitored the room temperature as accordance to the local SOP.
- Conducted foam box validation for cold chain products distribution.
- Collaborated with Technical Service Engineers to established technical service device history records documentation. Managed and implemented '5s' program in Technical Service workshop and storage facility. Monitored decontamination process and area in TS workshop. Overseen and collaborated with TS engineer to maintain compliance of calibration program.
- Attended Asean Regional Quality meeting and shared
- Responsible to established local procedures and managed Quality Audit Program, CAPA Management, Quality Risk Management, quality disposition of any quality issue during warehousing and distribution

of products, temperature room and boxes validations, technical service storage and records release activities, GxP training programs and control of documents managements.

- **Achievement**:
  - Awarded ZP "Core Value Card- Passion for Excellence": Successful managed one of the Principal's Global Audit on Oct 2013
  - Successfully achieved GDPMD QMS certification on Nov 2012 and re-certified on Oct 2013.

- **Reason for leaving:** Career growth in QA Commercial Sales and Marketing industry.

Apr 2008- Feb 2012
QC Superintendent | Ciba Vision (Alcon) Johor Sdn Bhd – Gelang Patah
Sep 2007- Mar 2008
Product DHR Release | Ciba Vision (Alcon) Johor Sdn Bhd – Gelang Patah

- Supervised total 30 Operators and QC activities including in-process, Formulation- Molding- Finishing release and Shipment.
- Conducted training to new operators and evaluated their competency.
- Reviewed and revised QC SOPs as per interval.
- Supported Compliance Team and conducted quality audit to across departments and processes. Appointed Quality Auditor and conducted audit across the manufacturing processes.
- Reported any nonconformance, conducted investigation, proposed and implemented CAPA. Monitored QC department NCR and CAPA closure.
- Collaborated with QC Engineer to conducted equipment calibration (Ion Permeability test for contact lenses) which put under QA Lab as per interval.
- Prepared QA Daily Report, QA release Monitoring, OT % and etc.
- Appointed as QC Molding Subject Matter Expert and Quality Culture facilitator for Manufacturing Quality Awareness Program.

- **Achievements**:
  - As QC pioneer for Molding department and successfully implemented the technology transfer process and aligned with local processes.
  - Completed 100% Procedures alignment to reduced document review and release cycle time during project SAP migration.
  - Completed conducted Multi-skill Training among 30 QC operators within various QC areas.
  - Managed and supervised a QC Team (4 QC operators) to conduct a few days of QC inspection for over 2000 sample lenses in Batam Manufacturing facility due to QC Lab malfunctioned issue.
  - Promoted to QC Superintendent in Apr 2008.

- **Reason for leaving:** Relocating to Klang Valley area due to follow husband after marriage.

Jul 2007- Sep 2007
Assistant Engineer / Chemist | Thosco Treatech Sdn Bhd – Gelang Patah

- Ensured and monitor process parameters by chemical analysis method.
- Prepared a variance anodized material specification as per customer requirement.
- Prepared raw material consumption for anodizing, blackening and bonderizing process.
- Performed monthly stock inventory report.

- **Reason for leaving:** Better career opportunities in multinational corporation company.

May 2006- Jul 2006
Industrial Trainee | SAJ Holdings Berhad – Batu Pahat

- Handled water quality analysis and water treatment process monitoring.
- Handled analysis equipment such as AAS, GC-MS and DR-Meter within

- **Reason for leaving:** Internship period ended.

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Education:

Bachelor's Degree in Engineering (Chemical) (2003-2007), Universiti Teknologi Malaysia (UTM)

Skills: Leadership and Teamwork, Communication and Collaboration within all stakeholders, Problem Solving, Creative Thinking, ISO 9001, ISO 13485, ISO 14971 Risk Assessment, ERP-SAP transition, Bronze Six Sigma, SPC Tools, QMS certification, QMS Auditing, Certified Body and Government Authority Engagement, Supplier and Client Engagement, Trackwise CAPA & Product Complaint Handling system, Supplier Management System, Learning Management System Plateau Administration Project Management, Document Control Management, SAP Superuser, Data Analysis, UAT & DiTL Proton testing SAP Batch Management, Microsoft Office literacy, Visio, Canva.

Referees:

1. **Norlida Ab Wahab from Alcon Laboratories (M) Sdn Bhd**
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