



NUR FAZLYNA BINTI ZAINAL ABIDIN

Meticulous and highly motivated individual with experience in the quality management and engineering sector for 11 years. Proficient in using software such as Microsoft Office, EQMS and Document Controller for Regulatory Compliance system to maximise task's productivity. Equipped with exceptional problem solving and critical thinking abilities which also thrives in a fast-paced environment. Keen to pursue a career in the related field to apply my knowledge, skills and grow professionally within the organisation.

✉ fazlyna10@gmail.com

☎ +60 13-918 6119

📍 No 45, Jalan RK 4/1 Rasah Kemayan, 70300 Seremban, Negeri Sembilan

🌐 www.linkedin.com/in/fazlyna-zainal-8688625b

WORK EXPERIENCE

Assistant Manager cum Head of GDPMD Unit Pharmaniaga Berhad

10/2021 - Present,

Shah Alam, Selangor

- Successfully handling quality and compliance matters between subsidiaries companies by reviewing quality documentation, auditing and assessing processes on site.
- Successfully monitoring and assisting in a group of companies' quality management system and compliance to current requirements besides assessing that manufacturing processes comply with relevant guidelines (PICS, MDA) and national regulations.
- Providing engineering and compliance advice or knowledge transfer to other departments for internal compliance and for regulatory compliance for pharmaceutical processes and products (drugs and medical devices).
- Providing constructive and innovative recommendations including expressing clear opinions on the state of internal controls to relevant levels of management.
- Conducting ad hoc projects and audits in which all audit findings will be presented to the management while maintaining quality work papers for reference.
- Assessing if internal controls in daily processes and systems are effective and efficient for the implementation of CAPA.
- Developing and facilitating the yearly audit plan and defining its scope, objective and duration.
- Preparing a report of audit findings and reviewing all audit points with relevant persons prior to final wrap-up as well as conducting wrap up meetings and inform management of audit findings.
- Sharing and advising auditor or Head of Regulatory Compliance on issues observed during fieldwork and audit for discussion.
- Ensuring follow-up and concluding the audit program to ensure proactive follow-up on recommendations before the due date and closing out the audit.

Senior Executive Pharmaniaga Berhad

05/2018 - 10/2021,

Shah Alam, Selangor

- Overlooked on troubleshooting and investigation such as batch failure, OOS, deviation and contamination.
- Reviewed the documentation management such as SOP, change control, deviation, batch record, logbooks and records.
- Monitored the progression of preventive maintenance and calibration activities with the maintenance and instrumentation team.
- Inspected the plant upkeep including the cleanliness, records, status, documentation upkeep and inventory management (raw material and consumables).
- Reviewed all proposals prior to presentation to department head for approval.
- Ensured profitability by capturing all cost and revenue for the department by doing a cross charge for all activities conducted.
- Responsible for the department training plan and financial plan report.

WORK EXPERIENCE

Validation Engineer

Inno Biologics Sdn Bhd

06/2017 - 04/2018,

Nilai, Negeri Sembilan

- Introduced validation standards, initiated testing protocols, prepared equipment, recorded test results including maintained records.
- Validated the HVAC systems by preparing the requalification reports. Arranged
- the water utilities activities and water testing schedule.
- Checked the water systems including RO, WFI, PSG then prepared the requalification reports.
- Verified the computerised system for both software and hardware.
- Drafted and compiled the audit reports for Internal Quality Audit (IQA).
- Monitored and controlled the calibration and equipment master list for all departments.
- Controlled and kept all AutoCAD layouts and drawings related to cGMP.
- Performed all activities related to validation of water, HVAC, computerised system and compressed air. Summarised
- the IQA audit finding according to the covered area by each employee.

Facility Engineer

Inno Biologics Sdn Bhd

06/2013 - 06/2017,

Nilai, Negeri Sembilan

- Responsible for system designing and maintenance including repairing and testing.
- Engaged in NPCB Audit and prepared the cGMP compliance and QA documentation.
- Purchased requisition work for new valves or sensors.
- Analysed and prepared daily reports and projects progress.
- Arranged all sensors' calibration schedule besides monitored technicians for utilities areas.
- Performed Work Risk Assessment (RA), Investigate Root Cause, Mitigation Measures, Automation and Instrumentation Measurements.
- Designed room layouts, valve and piping systems using AutoCAD.
- Ensure renewal of licenses and permits (LPG and disposal)

Project Coordinator

Abcar Global Sdn Bhd

09/2012 - 06/2013,

Georgetown, Pulau Pinang

- Handled and monitored the renovations progression.
- Remodelling projects and scheduling consultations with independent contractors.
- Responsible for assisting the project manager.
- Attended official meetings with government agencies such as MARDI and DOSH.

EDUCATION BACKGROUND

Bachelor of Engineering (Hons) Biosystems Engineering

Universiti Malaysia Perlis (UniMAP)

06/2008 - 06/2012,

Kangar, Perlis

Malaysian Matriculation Program

Kolej Matrikulasi Pahang

06/2007 - 05/2008,

Gambang, Pahang

Sijil Pelajaran Malaysia (SPM)

Maktab Rendah Sains MARA

02/2005 - 12/2006,

Jasin, Melaka

ACHIEVEMENTS

Master of Ceremony for International Generic and Biosimilar Medicines Association (IGBA) - MOPI Conference 2022.

Master of Ceremony for MOPI Patent Seminar 2020.

ACHIEVEMENTS

Directly involved as internal compliance auditor vaccine fill and finish project for Covid 19 national vaccination.

S&M Department special team of Sales Executive2015.

0 major finding for the manufacturing plant was achieved during regulatory body inspection in 2019.

Gold award in 2018, 2019, 2020

Auditor for the Internal Quality Audit Team atInno Biologics from 2014 until 2017.

TECHNICAL SKILLS

Microsoft Office Word, Excel, PowerPoint

Management Plan and System Managing Risk and Risk Assessment, Engineering Project Management, Quality Management System (CAPA, Deviation, Change Control), Quality Management, Quality Assurance, EQMS, DocumentController for Regulatory Compliance

Engineering and Improvement Tools AutoCAD, Lean Six Sigma

Computer Languages C Programming, C++

CERTIFICATION

- ISO 9001: 2015 Quality Management Systems (QMS) Internal Auditor
- ISO 37001: 2016 Anti-Bribery Management Systems (ABMS) Internal Auditor
- ISO 45001: 2018 Occupational Health and Safety Management Systems (OHSMS) Internal Auditor
- ISO 14001: 2015 Environment Management Systems (EMS) Internal Auditor

SOFT SKILLS

Able to convey and receive information professionally.

Ability to think clearly and rationally besides understand the logical connection between ideas.

Overcome barriers or obstacles that prevent goals achievement by resolving problem effectively.

Thrive in a team environment and able to adapt effectively to changes

LANGUAGES

Malay & English
Native or Bilingual Proficiency

MISCELLANEOUS

License
D

Availability
2 Months

REFERENCE

Mr. Mohd Latiffi Abdul Aziz
Assistant Vice President Corporate Compliance
+6013 9155117