



ZAFIRAH MUNIRAH BT MUSTAFA

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PROFESSIONAL PROFILE

Qualified Pharmacist by profession and **highly experienced in handling Operational, Management and Projects** within pharmaceutical and life science industry for **13 years** in different areas such as **Regulatory Management and Trade Compliance, Medical Device, Manufacturing and Production, Warehousing, and Distribution.**

CORE COMPETENCIES

- Leadership
- Problem Solving
- Communication
- Project Management
- Cross Functional Teams
- Legislations and Regulations
- Pharmaceutical Operational Knowledge
- Internal and External Audit
- Medical Device
- Government Advocacy
- Strategy, Process Improvement
- Training
- Root Cause Analysis (RCA)
- Risk Assessment & Evaluation
- Scala & SAP User
- Policies
- Digitalization, Process Automation

EDUCATION

- Apr 2022 – Nov 2024 **Executive MBA** (Part – time, online long distance)
Strathclyde Business School, University of Strathclyde, UK 
- Oct 2006 – Oct 2010 **Bachelor's in Pharmacy,**
Major in Pharmaceutical Science & Technology
Institute of Technology Bandung (ITB), Indonesia 

CAREER SUMMARY



Mar 2019 – Present
Merck Sdn Bhd

Regulatory Management & Trade Compliance Associate

Supported the organisation as the poison A license holder and **led** the importation and exportation activities for regulated products (chemicals, life science, dangerous goods, medical device) **standardized** with the Malaysia Customs Prohibition of Imports 2017, Poison Act 1952, Medical Device Act, and other trade laws regulations locally and globally in Germany and USA.

Commerciality

- Successfully **improved and streamlined** the importation and exportation process for regulated products approved by the local and global authorities (Germany and USA) and **established** expertise in interpreting governmental act and regulations, regulatory agency guidelines, and internal policies, **managed** compliance, and **facilitated** with no impact towards business.



Stakeholder Management

- Successfully **trained** local commercial teams about regulatory and Medical Device GDPMD and **established** good rapport with local authorities.
- Successfully **collaborated** with cross-functional teams compromising sales, marketing, and operations, **streamlined** medical device registration submission strategies and registration readiness to support business commercial strategies.
- **Established** strong alliances with divisional and local stakeholders, **achieved** medical device registration approval and **demonstrated** compliance with company policies.
- **Managed** proactive engagement in government advocacy activities related with policies, legislation and regulations that raise concern from business and industrial perspective.
- **Demonstrated** leadership by **chaired** the Merck APAC Medical Device Working Group.

Customer Focus

- Successfully **coordinated and collaborated** with the cross functional teams locally and globally (Customer Excellence, Supply Chain and Germany and USA Trade Compliance) for any ordering enquiries related with regulatory and trade compliance matters.

Performance Excellence

- Successfully **managed and improvised** the trade compliance activity **impacted** in smooth process during importation, **achieved** no unexpected fines or penalty and **minimized** numbers of Customs enquiries at entry point upon goods arrival.
- Successfully **managed and delivered** the Annual Audits and Inspection Internally and Externally conducted by the authorities every year since 2019 until present and **proved** without major finding and no impact towards business and commercials.

Data Management

- Successfully **administered** the importation and exportation process by regularly **monitored, reviewed, and updated** the compliance database in the ERP system.
- **Corrected and improved** standard operating procedures (SOP) related with regulatory and trade compliance.

Top Achievement

My **expertise** is **leading** the Regulatory and Trade Compliance Management for Merck Malaysia business independently with minimal supervision since 2019 and **mastered** with the Malaysia Customs Prohibition of Imports 2017, Poison Act 1952, Medical Device regulations and other trade and law regulation locally. **Appointed** as the **Head of Merck APAC Medical Device Working Group** starting 2023.



Aug 2016 – Mar 2019

Qualitas Pharma Sdn Bhd

Pharmacist, Warehouse and Distribution

Supported the organisation as the poison A license holder and **led and supervised** the warehouse operational and distribution team around 12-15 staff.

Performance Excellence

- Successfully **achieved** the monthly delivery deadline and **scheduled** for month closing and **completed** the targeted KPI.

Cost and Pricing Management

- Successfully **handled** decision on monthly planning and **improved** purchase for stocks within the **planned** budget and inventory level.
- Successfully **analysed and administered** the price adjustment aligned with the prices changes from suppliers.



Customer Focus

- Successfully **planned and coordinated** the operations workflow to meet the delivery deadline and successfully **reduced** the complaints from customers.
- Successfully **evaluated** products to be offered to customers and **improved** the inventory.
- Successfully **handled** the out-of-stock issues effectively and **achieved** the expectations from customers on ordering.

Supplier & Contract Management

- Successfully **improved and negotiated** with the suppliers on annual price and ordering contracts, **maximized** the benefits as their key customer.
- Successfully **analysed, reviewed** the existing transportation contract agreement, and **addressed** about **improved** the service to the supplier and **convinced** top management, **standardized** with the Good Distribution Practise (GDP) for pharmaceutical products.

Top Achievement

Successfully **achieved budget approval** from the senior management for the **Warehouse Expansion Project** in 2019 and project delivered within the budget and timeline - **corrected, and improved** the workflow for operations and inventory management, **minimized** the errors and **reduced** complaints from customers.

Aug 2015 - Aug 2016

InnoBio Ventures Sdn Bhd



Regulatory Affairs Pharmacist

Supported the organisation as the poison A license holder and **assisted** regulatory and marketing team for regulations topic and **facilitated** the clinical journal and papers reviews for technical presentation and brochures to the customers.

May 2014- Aug 2015



Production Pharmacist, Assistant Manager

Supported the organisation as the poison A license holder and **led and supervised** the production team around 15 – 20 staffs.

Performance Excellence & Customer Focus

- Successfully **executed and monitored** the production activities **standardized** with the Good Manufacturing Practice (GMP) guideline and **achieved** the targeted delivery deadline.
- Successfully **managed and accomplished** the **Good Manufacturing Practise (GMP) Audit proved** without major finding from the auditors and no impact towards business and commercials.

Cost and Pricing Management

- Successfully **planned and achieved** the cost reduction strategy for production department by **changed** to alternative options for parts replacement and **maximized** the existing resources for operations.

Data Management

- Successfully **managed and organized** the production documentation and reports, **reviewed, and approved** each record for every batch manufacturing **standardized** with the GMP guideline.
- Successfully **handled and solved** all pending Corrective Action Preventive Action (CAPA) reports and other relevant reports, readiness for **scheduled** audit and inspection

Stakeholder Management

- Successfully **coordinated and collaborated** with the cross functional teams such as Supply Chain, Technical Service and Quality team, **accomplished** the manufacturing targeted deadline and projects.

Top Achievement

Successfully **achieved budget approval** amounted MYR 350,000 from the Board of Directors for **Production Expansion Project** and **project delivered within the budget and timeline**.

Jan 2013 – May 2014
Sun Pharmaceutical Sdn Bhd

Regulatory Affairs Executive / Pharmacist

Supported the organisation as the poison A license holder and **handled** the regulatory affairs **reviewed** the dossier for new product registration submission and **supported** the commercial by **gained** approval from authority for advertisement materials.



Jan 2011 – Jan 2013
Ministry of Health Malaysia

Enforcement Pharmacist
Performance Excellence & Customer Focus

- Successfully **handled and inspected** customs clearance process at customs entry points for noncompliance items that arrived at Malaysia as per law Poison Act 1952.
- Successfully **assisted** any enquiries raised by customers related with the regulations and law.

Pharmacist
Performance Excellence & Customer Focus

- Successfully **trained** as a licensed and registered pharmacist
- Successfully **managed** the pharmacy and drugs counselling service to patients and hospital staffs **standardized** with the procedures and guideline

TRAINING

- Lean & Six Sigma LS-Q White Belt Training
- Chemical Weapon Convention Item Workshop
- SIRIM Guideline Workshop on Halal Medical Device
- Internal Auditor for Good Distribution Practise for Medical Device (GDPMD)
- Pre and Post Registration Processes and Activities for Medical Device
- Import and Export Customs Tariff
- Halal Roadmap for Medical Device Industry Workshop

PROJECT ACHIEVEMENTS & AWARD

YEAR	ACHIEVEMENT		SKILL SET
2023	Medical Device Dossier Readiness – Cross Functional Team Collaboration Successfully influenced and escalated the pending issues as a top priority in Q1 2023 to the APAC top management and successfully directed global team for dossier readiness considering the impact to the local commercial business.		<ul style="list-style-type: none"> • Leadership • Communication & Negotiation • Cross Functional Team Collaboration • Teamwork
2022	Process Improvement & Automation Project Successfully achieved business process improvement and time saving by changed the manual process data key in into PDF Readable automation process in 2022.		<ul style="list-style-type: none"> • Project Management • Problem Solving • Cross Functional Team Collaboration
2021	Process Improvement & Automation Project Successfully collaborated with the Merck Shared Business Service (SBS) Team from India in 2021 in accomplished project on updating the compliance tagging in the master list system (approx. 100K's SKU) and executed delivery of project within timeline.		<ul style="list-style-type: none"> • Project Management • Problem Solving • Cross Functional Team Collaboration
2021	Kaizen Malaysia Project Successfully received Best Kaizens of Regulatory Management & Trade Compliance APAC Award in 2020 for demonstrated business process improvement enables regulatory & trade compliance excellence.		<ul style="list-style-type: none"> • Leadership • Communication • Project Management • Problem Solving • Cross Functional Team Collaboration
2018-2019	Warehouse Upgrading & Renovation Successfully convinced and executed ideas to the top management improved the warehouse operational workflow and successfully accelerated this project as a top priority.		<ul style="list-style-type: none"> • Leadership • Communication • Project Management • Problem Solving • Cross Functional Team Collaboration
2014-2015	Production Expansion Project for Lyophilized Products Line <ul style="list-style-type: none"> • Successfully participated in Plant Expansion Project and New Product Development project. • Successfully prepared the budget proposal and gained approval from the Board of Director. 		<ul style="list-style-type: none"> • Leadership • Project Management • Problem Solving • Cross Functional Team Collaboration • Presentation • Root Cause Analysis (RCA) • Risk Assessment & Evaluation
2014-2015	Stability Batch Validation Project Successfully coordinated the cross functional teamwork and accomplished the stability batch validation project within the planned deadline in between the commercial batch manufacturing.		<ul style="list-style-type: none"> • Leadership • Problem Solving • Cross Functional Team Collaboration • Communication

LEADERSHIP ACHIEVEMENTS

YEAR	ACHIEVEMENT		SKILL SET
2023	APAC Medical Device Working Group Appointed as the Head for the working group. Led a team in creating a better engagement session between APAC team members with the Merck Global team from Germany and USA, managed to highlight issues / challenges to the global team. Achieved in completion the technical dossier checklist for all APAC countries, to complete the feasibility assessment for global strategic roadmap 2024 for new product registrations in APAC.		<ul style="list-style-type: none"> • Leadership • Problem Solving • Communication • Team Coordination • Planning and scheduling
2019	Pharma Exhibition 2019 held in Lahore, Pakistan Assigned as a Guest Speaker to represent Merck and successfully delivered the presentation and gained positive feedbacks from the audience.		<ul style="list-style-type: none"> • Communication • Pharmaceutical Operational Knowledge • Presentation • Training
2016-2019	Led and supervised the warehouse operational team around 12-15 staff and achieved the targeted KPI.		<ul style="list-style-type: none"> • Leadership • Problem Solving • Communication • Team Coordination • Planning and scheduling
2018	Annual KPI Evaluation and People Management Successfully addressed and convinced the top management agreed on promoted the purchaser executive and increased the staff salary.		<ul style="list-style-type: none"> • Leadership • Communication
2014-2015	Led and supervised the production team around 15 – 20 staffs and monitored the production activities comply with the Good Manufacturing Practice (GMP) guideline and achieved the targeted delivery deadline.		<ul style="list-style-type: none"> • Leadership • Problem Solving • Communication • Team Coordination • Planning and scheduling
2015	People Management Successfully convinced the top management agreed on recommended name (team leaders and operators) assigned for Factory Acceptance Training (FAT) held in Italy and China.		<ul style="list-style-type: none"> • Leadership • Communication

PERFORMANCE REVIEWS & MANAGEMENT FEEDBACK

Employee Profile ▾

Search for actions or people

Zafirah Munirah Mustafa ▾ Regulatory Mgmt & Trade Compliance Associate

INFORMATION ▾
COMPENSATION & PERFORMANCE INFORMATION ▾
CURRICULUM VITAE ▾
CAREER ▾

Ratings

Overall Performance ?	
Overall Individual Performance	A
Source	2022 Performance Management
Overall Individual Performance	A
Source	2021 Performance Management
Overall Individual Performance	A
Source	2020 Performance Management
Overall Individual Performance	A
Source	2019 Performance Management

Line Manager's Comments
As new joiner to Malaysia managing legacy Blue, Zafirah is quick learner and been very helpful to relief Boon Sia operational work in Malaysia. The fact that she is willing to take up the challenge as being the presenter in Pakistan event during her very first month speaks about her guts. She has good ambition and shows adaptability to learn. She also can

Boon Sia Teoh's Comments
Please continue the great effort to build a solid foundation on trade compliance activity. Once you are familiar with the routine process, you'll be able to plan for improvement and implement project. Do keep the motivation for learning and aim for subject matter expert. Thank you.

Line Manager's Comments
Zafirah been working on the ground to stabilize the working process for legacy Merck Malaysia, in view of changes to local commercial and customer service.

Ratings from Others

Manager Rating ?
A

Manager Comment on Individual Objective Rating
Good effort to increase the work flow especially for psy permit. By gaining more experience on audit/inspection, ready to manage these on you own.

Comments
Please keep up the good work and continue to improve on Speed as the expectation is moving faster and faster.

Ratings from Others

Manager Rating ?
A

Manager Comment on Individual Objective Rating
Good job in adopting new technology for work, as this is the way forward. Do put up more effort on closing the excel chemlog project and looking forward for success report in near future. 2021 would be another challenging year for digital enhancement, please remain focus on this.

Vivian Tang's Comments
Appreciate Zafirah's support in routine activities and it would be good to develop ideas to streamline regulatory work processes and continue to work on the IVD regulation recently updated by the authority.

Meredith Ge
To: ● Zafirah Munirah Mustafa; ● Vivian Tang; ● BoonSia Teoh; ● Yin Yin Yee; ● Lee Soon Sim; ● Wafa Tahirah binti Mohd Noordin; ● Nurul Nasyitah Binti Mohd Khalid; ● Thushalini Segaran; ● Nycole Kok; ● Niza Subari; ● Aziah Adnan

Dear Zafirah and all,

Congratulations! Thank you and everyone's joint efforts in supporting authority inspection! So glad to know this is going smoothly and without major findings!

Best Regards,
Meredith Ge 戈萌

Head of Regulatory Management & Trade Compliance China/Taiwan, South Korea, Japan
Life Science | Quality & Regulatory Management

Merck

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RECOMMENDATION FROM LINKEDIN



Adi Martadinata · 1st

Samudera Shipping Line Ltd || Country Manager - Malaysia || MBA Candidate of Strathclyde
May 2, 2023, Adi and Zafirah Munirah studied together

I'm excited to recommend Fira, my talented classmate from our MBA program at Strathclyde Business School. Fira is an intelligent and organized individual with strong analytical skills. She excels at breaking down complex problems and finding innovative solutions.

Fira's open-mindedness and enthusiasm make brainstorming sessions and collaborations truly enjoyable. Her positive energy is especially apparent when we're juggling tight deadlines and balancing priorities between work and study. She manages to maintain a constructive attitude, which is infectious and keeps our spirits high.

Not only is Fira a great thinker, but she's also a kind and supportive teammate who fosters a positive and collaborative atmosphere in every project. Her blend of analytical thinking, well-structured, and open-minded approach, combined with her uplifting energy, make her a valuable asset to any organization. I have no doubt she will continue to succeed in her future endeavors.



Ts. Hamidi Samsuri · 1st

Project Manager at Dutch Lady Milk Industries @FrieslandCampina
May 3, 2023, Ts. Hamidi worked with Zafirah Munirah on the same team

Very knowledgeable person with a vast experiences and know how in cGMP, also the operations of the sterile injectable production and well versed in PIC-S requirement that come from her past experience as an Auditor in Bearue pharmaceutical. This is really help her work and the organization by improving the end to end process of production and compliance.



Mohd Shafiq Abas · 1st

Senior Manager - Technical and Operations at Myvax Sdn Bhd
May 3, 2023, Mohd Shafiq worked with Zafirah Munirah but on different teams

My pleasure to recommend Zafirah to anyone seeking a dedicated and results-oriented professional. I had the pleasure of working with Zafirah at Pharmaniaga LifeScience, and I was fortunate to see firsthand her exceptional work ethic, strong analytical skills, and commitment to achieving outstanding results. During our time together, Zafirah consistently demonstrated leadership and was instrumental in driving several successful projects. Her ability to stay focused and deliver results, even under tight deadlines and challenging circumstances, was truly impressive. Zafirah also has a remarkable ability to communicate complex ideas in a clear and concise manner, which made her an excellent team player. I am confident that Zafirah would make an invaluable addition to the company.

REFERENCES



Nor Idham Bin Che Ghani
Program Director Industry Partnership
& Graduate Employability,
GLE ENERGY SDN BHD



Sufian Hardi Bin Mohamed Zuhair Senior
Manager, Quality Management
Fresenius Medical Care Production
Sdn Bhd



Azleena binti AlJeffri
Head of Regulatory Affairs
Zuellig Pharma Sdn Bhd



Fazleena Jasin
Head of Unit, New Product Development
Pharmaniaga Life Science Sdn Bhd



Mazuriah Binti Abu Darin
Regulatory Development Manager
Pharma Nord Sdn Bhd