



SEPTIARDI RAMDANI

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SUMMARY

I am a graduated in industrial engineering with over 10 years experienced in quality control and process control roles in the pharmaceutical industry. Passionate and highly motivated professional with a deep-rooted enthusiasm for the manufacturing industry. During my time there, I developed a deep understanding about quality roles and process control of the production and packaging processes with good analytical skills and problemsolving skills. Familiar with good manufacturing practice (GMP), good laboratory practice (GLP), good documentation practice (GDP), HACCP, 5S/5R, ISO 9001:2015, ISO 45001, quality control, and process control of the production and packaging processes. As an adaptable individual with good leadership skills, I am able to work effectively as a team in complex environments and under pressure. I am open and interested in new opportunities to continue my professional career that will further develop myself.

EXPERIENCE

PT. MENARINI INDRIA LABORATORIES – Cikarang, Indonesia

QA In Process Control (March 2024-Present)

- Carried out in process control during the production and packaging process at various stage (liquid, semisolid, solid, medical device) to ensure that the process operates according to established procedures, parameters and specifications including Good Manufacturing Practice and Good Documentation Practice aspects.
- Identified any deviations or problems that may arise during the production and packaging process.
- Collaborated with other departments, such as quality control and production to maintain the highest standards of pharmaceutical manufacturing.
- Reviewed and verified batch record during the production and packaging process, ensure the production activities is carried out in accordance with the procedures in the batch record and well documented.
- Conducted initiatives to investigate the deviations and created Issue reports.
- Involved the product complaint investigation.
- Created and revised of SOP related to in process control activities.
- Support qualification, validation and calibration.
- Participated in production and packaging process improvements.
- Carried out sampling activities for inspection of IPC bulk products, intermediate products and also finished product/retained samples.
- Support product release by Inputting retained sample data into Idempiere ERP system.

SELF EMPLOYED

Entrepreneur (January 2019 – November 2023)

- Established and developed my own business as an entrepreneur in the footwear manufacturing field.
- Managed and ensured the smooth operation of the business aligning with strategic plans and achieving set targets.
- Conducted periodic product development.

PT. BAYER INDONESIA – Depok, Indonesia

In Process Control Officer (July 2016 – December 2018)

- Conducted daily inspections and lead the foreman in production and packaging process, ensuring in accordance with GMP procedures from raw materials to finished products.
- Sampled and tested products during production and packaging processes.
- Conducted daily and monthly calibration of instruments in IPC laboratory, production, and packaging areas.
- Provided support for validation processes.
- Monitored temperature, humidity, water levels, and air pressure in production and packaging areas.
- Verified all batch records during production and packaging, ensuring the accuracy of each record.
- Entered testing data into SAP.
- Reviewed and reconciled production and packaging batch record after the processes are completed.
- Conducted initiatives to investigate the deviations, and created deviation reports.

PT. BAYER INDONESIA – Depok, Indonesia

Microbiology Analyst (November 2010 - June 2016)

- Conducted microbiopurity analysis such as TAMC, TYMC, e.coli, salmonella, staphylococcus aureus, and enterobacteriaceae for finished goods samples, stability samples, raw materials, and packaging materials.
- Analyzed of vitamins (Biotin, B12, Folic Acid) for finished products and stability samples using bioassay methods.
- Monitored the environment throughout the factory facilities using microbiological parameters: production and packaging areas, purified water, drinking water, and pressurized air.
- Performed daily calibration of instruments in the microbiology laboratory.
- Supported cleaning validation processes.
- Created analysis data reports and input into SAP.

PT. NOVELL PHARMACEUTICAL LABORATORIES – Bogor, Indonesia

Quality Control Analyst (July 2009 - April 2010)

- Conducted chemical analysis for intermediate and finished product samples using spectrophotometer and HPLC to ensure substance content met specified requirements. This included testing active substance content, content uniformity, and dissolution testing.
- Created analysis data reports on analysis worksheets.

EDUCATION**UNIVERSITAS PANCASILA (2012 - 2018)**

Bachelor of Industrial Engineering – GPA 3.14

SMK ANALIS KIMIA YKPI BOGOR (2005 - 2009)

Chemical Analysis

SKILLS

- Manufacturing industry passion
- Good Leadership and teamwork skills
- Good analytical and problem solving skills
- Quick learner
- Adaptability with company working culture
- Flexibility in working hours
- Manufacturing process control, Quality inspection, Quality control, Microbiology, GMP, CPOB, CPOTB, GLP, GDP, HACCP, 5S/5R, OEE, PPIC
- ISO 9001:2015, ISO 45001
- Microsoft Excel, Microsoft Word, Microsoft PowerPoint, ERP system (SAP & iDempiere)

LANGUAGE

- Bahasa Indonesia
- English

ACHIEVEMENTS

- Successfully minimized of Mestinon tablet defect such as broken and scratch through investigation and created improvement on tablet filling machine modification.
- Successfully eliminated the product complaint of Dermatix tube leakage through created and implementation of Acceptance Quality Limit (AQL) sampling method SOP.
- Successfully increased the Batch Right First Time (BRFT) from 36% to 72% through the implementation of batch record reviewed during production and packaging process.
- Successfully improved the packaging process to minimize the nonconformity finished goods product through sample standardization of check weigher.
- Successfully improved the production and packaging process trough created the production and packaging reference standard as guidelines for operator to ensure of product quality meets standards.
- Successfully support in qualification rooms, machines and tools of new production facility on microbiological parameters.
- Successfully support in life time of cleanliness of production room and machine trough cleaning validation.