

MERISKA SUKANDAR

PHARMACEUTICAL TECHNOLOGY – BUSINESS AND PROJECT MANAGEMENT ENTHUSIASM

♣ Jakarta, January 25, 1983
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Depok, West Java

ABOUT ME

A hard-working with the ability to work well both independently and in a team, creative, energetic, strong analytical thinking, communicative, good planner, and discipline. I have experience of working with the public which has taught me the value of friendliness, open-minded and willing to learn the new things has now given me the confidence to start my own career in ahead

SKILL

English Oral & Written

★ ★ ★ ★ ★

Computer Literate (MS)

★ ★ ★ ★ ★

Document Controlling

★ ★ ★ ★ ★

Validation Process and packaging

★ ★ ★ ★ ★

Product Transfer

★ ★ ★ ★ ★

Technically in machine

★ ★ ★ ★ ★

Laboratory Instrumentation

★ ★ ★ ★ ★

Data Interpretation

★ ★ ★ ★ ★

Time Management

★ ★ ★ ★ ★

Communication

★ ★ ★ ★ ★

Negotiation

★ ★ ★ ★ ★

JOB DESCRIPTION

Business owner of Bakery online (Dec 2021- now)

To leading, monitor and coordinate the activities like planning, purchasing, development product, production, controller, branding, marketing and selling bakery product such as : breads, cakes, cookies, pasta, pastry, and pizza.

Technology Transfer Specialist PT Actavis Indonesia (MS&T Department, 2013-Dec 2021)

To coordinate and monitor the trial/optimization and validation activities including the documentation activities required in MS&T Department such as MPPCR (Master Production and Process Control Record) and RCF (Regulatory Compliance File)

1. Coordinate and monitor the trial/optimization activity to ensure that the process stages and the product quality are within the required specification before continuing to the validation stage
2. Coordinate and monitor all validation works after optimization phase in order to comply with the current GMP and company policy
3. Supporting product development activities in accordance to technical issues
4. To lead, monitor and ensure that all documents relating to MS&T activities and on going projects are completed according to the procedure in timely manner
5. To provide accurate MPPCR/RCF and trial/optimization protocol and report
6. To support regulatory affairs department by providing accurate registration document in related with MS&T
7. To propose improvement of related procedure in MS&T documents process to ensure the continues improvement in the areas
8. To monitor and provide necessary training for MS&T technicians to ensure that they will be able to perform the trial/optimization, validation activities according to the procedure and generate quality documents
9. Control and follow up for closing/completing all existing CAPA and the other document to the quality system requirements
10. To perform any other activities as guided by the manager in timely manner
11. Implement QEHS policy in working area
12. Coordinate new product launch
13. Being part of toll product (toll in and toll out)
14. Material control management MS&T department

Technical Support PT Actavis Indonesia (Production Department, 2011-2013)

1. Handling new product transfer from R&D Department to Production area
2. Manage and prepare for Master Production Process Controlling Record (Bulk and packaging)
3. Perform validation process : New product, API change source, machine change
4. Manage support documents such as change control/deviation/CAPA

	INTERNAL QC and Lab. Coordinator in PT. SCHOTT Igar Glass (2010-2011) 1. Manage process control of incoming materials and finished goods (ampoule, vial and pipette) 2. Manage complain and investigation related to the laboratory 3. Manage qualification for lab instrument 4. Preparing SOP related to laboratory 5. Manage analytical validation process 6. Perform audit supplier
PROFESSIONAL TRAINING: 1 PROFESSIONAL TRAINING in PT. Kimia Farma Apotek, Jakarta, 2007 2 PROFESSIONAL TRAINING in PT. Phapros, Tbk, Semarang, 2007 3 PROFESSIONAL TRAINING in National Agency of Drug and Food Control RI, 2007 ACHIEVEMENT AND TRAINING: Outstanding performa employee of 2018 (PT Actavis Indonesia) COURSES: 1. General English Pre Beginner I in Boston English Course, 1994-1995 (Passed) 2. Computer Course (Microsoft Windows, MS Words, MS Excel, MS Power Point) , 1998-1999 (Passed) 3. General English Basic Levels in LIA, 1998-1999 (Passed) CV class LIA Depok , 2013 (Passed) 4 CV class LIA Depok , 2013 (Passed)	QC STAFF in PT. Novell Pharmaceutical Laboratories (2008-2010) 1. Manage analysis for in process control of finished product 2. Handling RM and FG which analysis using GC 3. Manage reporting for release product 4. Perform problem solving for analytical method using GC PROJECTS : 1. PT Novell Pharmaceutical Labs. Coordinator for analysis using Gas Chromatography (Raw Material and Finished product) 2. PT Actavis Indonesia - Improvement in Beta Lactam Area Improve tableting machine to decreasing disintegration time/repairing flowability of granules/maintain weight and hardness - Improvement in sieving process of sucrose which used for dry suspension product and processing data - Japan Project : Collecting, preparing and presenting all documents related with Master Product from Pharmaceutical technology Actavis Indonesia to PMDA Japan for export purpose until submission batches approved accordingly to JAPAN requirement - DHA Projects : Transfer product from DHA Drug Houses to Actavis Indonesia and Processing data from validation process then execute data for registration and submission - Product Transfer from Debrecen to Actavis Indonesia - Improvement of weak product - Rejuvenating of OTC product (Re-formulation/New Packaging/Validation/Submission) - Provide Regulatory Compliance File of Product Transfer EDUCATION 1. Bachelor Degree in Industrial Pharmacy University of Indonesia, 2001-2006 (Passed) with GPA 3.07 scale 4.00 2. Apothecary Program University of Indonesia, 2006-2007 (Passed) with GPA 3.15 scale 4.00

INTEREST AND HOBBY:



SEMINARS AND TRAININGS

1. DOE (Design of Experiment) by SSCX
2. Technical training Basic of Tablet Formulation & Tablet Compression Tooling by Natoli Engineering
3. Pharmaceutical Technology in 4.0 Era
4. "Handling Difficult People" at Sahid Hotel by Dunamis Org
5. Seminar Pharmacy "UHPLC" at JIAC by PT. Surya Buana
6. Seminar Pharmacy "Issue in Pharmaceutical Industry" at Arya Duta Hotel by PT. Merck, Tbk
7. Seminar Pharmacy "Entrepreneurship and The Ethics of Working" by Department Pharmacy University of Indonesia
8. Seminar Pharmacy "Trend of Growth Pharmacy Company in Globalization Era" by Department Pharmacy University of Indonesia
9. Seminar Pharmacy The Strategic Indonesian's World of Pharmacy for Challenging AFTA by Department Pharmacy University of Indonesia
10. Seminar Pharmacy "Optimizing of Pharmacist Role in Information Service Medicine for The Chronic Disease Patient (Cardiovascular and Diabetes Mellitus)" by Department Pharmacy University of Indonesia
11. Training course Bakery at KRJ, 2023
12. Indonesia Pharmacy Expo and Conference, 2024