

Theu Zhi Yao Production Pharmacist

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Skills

Team Player
Ability to Work in a Team
Communication Skills
Fast Learner
Ability to Work Under
Pressure
Ability to Multitask

Critical Thinking and

Problem Solving

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Chir	nese	5		

English			
Malay	_	_	_

Profile

A hardworking and dedicated production pharmacist who has been working in Sterile Manufacturing since January 2020. Have been involved in management, administrative and operation of Sterile Manufacturing Area which include Supervision and Participation in Production Process, Production Document Checking and Managing, Dangerous Drug Handling, SOP management, Qualification and Validation of machine and process, Incident Reporting, Corrective Action & Preventive Action management, Change Control Managing and Process Optimization. Profound knowledge of manufacturing in sterile condition. Well versed in the PIC/S guidelines and EUGMP. Highly communicative and detail oriented. A team spirited person which is eager to join a new team and new environment.

Employment History

Production Pharmacist (Sterile), Y.S.P. Industries (M) Sdn. Bhd., Bandar Baru Bangi

January 2020 - Present

- Ensure SMA operation fulfill the requirements of the latest PIC/S guidelines.
- Participate in Quality Review Meeting in ensuring quality objectives of Sterile Manufacturing Area are achieved.
 Achieved production out of 2.2 mil units in 2022.
- Monitoring of Production Output and carry out necessary steps in optimizing and expanding production capacity.
- Train and supervise line leader, staff and provisionally registered pharmacist in daily operation and document handling.
- Ensure manufacturing process proceed smoothly and all SOP was adhered by staff
- Pharmaceutical function included authorization of processes, line closure and manufacturing process involvement.
- Handle and control Dangerous Drug in manufacturing process.
- Ensure Batch Manufacturing Record were recorded, reviewed and updated accordingly.
- Sterile Manufacturing Area SOP and Quality Form amendment and updating.
- Incident Reporting in case any deviation. Compiling data if necessary, for the incident report.
- Corrective Action and Preventive Action generation and ensuring of their implementation.
- Prepare protocol and report for qualification and validation for machine and production process and to prepare validation deficiency report if any.

- Work with RND, QC and QA section on verifying the quality of products and well as qualification and validation work.
- Assist RND in implementation and document preparation of Process Optimization.
- Assist Regulatory Affair in replying NPRA correspondence regarding product registration.
- Change Control management collaborating with QA to ensure all document relevant to change control was prepared and reviewed.
- Carry out Risk Evaluation Analysis in case change implemented may affect product quality.
- Participate in Internal Audit, External Audit as well as NPRA Audit and ensure all finding are handled and resolved without issue.
- Liaise with supplier and maintenance department to procure new equipment and tools as well as arrangement of reparation, replacement, maintenance and service of machine and equipments to ensure smooth operation in Sterile Manufacturing Area.

Education

Bachelor of Pharmacy (Hons), Aimst University, Sungai Petani

August 2015 – September 2019

Graduated with upper second class honours with CGPA of 3.44