**No.33 lorong sungai bertih 2, Taman Gembira, 41100 Klang, Selangor Darul Ehsan, Malaysia**

**Mobile: 016-2041304**

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**NESHALENI PERAKASAM**

**PROFESSIONAL GOAL & PROFILE**

Results-focused, quality-driven individual with experience in the field of pharmaceutical, research, and development. Discipline and commitment when working on an objective. Driven to be a part of a team that benefits the society’s healthcare.

***Knowledge & Skill Areas:***

|  |  |  |
| --- | --- | --- |
| * Quality Control * Laboratory skills * Column chromatography * Dissolution test * Friability test * ICH-GCP * Protocol * HA/Regulatory * CREDI | * FTIR * Moisture content analysis * Tableting machine * Raw material testing * Method validation * IRB/EC * ICF * CTMS/IMPACT | * Electrophoresis * X-ray Photoelectron spectroscopy * Disintegration test * Finished product testing * Stability testing * Investigator Brochure * Safety reporting * SAE/SUSAR * eTMF |

**RELEVANT EXPERIENCE:**

**Malaysiann Institute of Pharmaceutical and Nutraceutical (IPHARM April 2015-2015)**

# JOB RESPONSIBILITY: INTERN

* Worked with buffer preparation, titrations, pipetting, analytic balances,

TLC, HPLC, UV spectrometry, analysed sample using X-ray, Photoelectron Spectroscopy and electrophoresis

* Worked with rotary evaporator and moisture content analysis
* Worked with column chromatography
* Undertaken all basic laboratory practice
* Ability to keep accurate laboratory records
* Experience using Microsoft Word, Excel and Powerpoint
* Familiar with Chemistry related computer software such as *Chem*draw
* Deliver docking studies using PyRx,autodock tools.
* Analyses and interpret the result
* Update the database of all the natural products.
* Synthesis of Shagoal, a derivative of Gingerone as my final year research project in International Medical University
* Perform partition and evaporation of crude product.

# Maxter Glove Manufacturing (September 2015 to August 2016)

## JOB RESPONSIBILITY:QUALITY CONTROL EXECUTIVE

* Planning and work allocation, assurance the completeness of the activity.
* To perform analysis of finished Products and in-process samples.
* To perform analysis of stability samples.
* Preparation of worksheet along with Specification
* Analysis of in-process samples and finished samples allotted by seniors with online documentation and calculation sheet completion.
* Reporting of day to day activities immediately to superiors.
* Responsible for documentation process necessary for ISO Standards.
* Responsible for In-coming,In-line and Final Checking Operations.
* Controlling overall Quality Control department.
* Demonstrated the quality assurance procedures to customers on factory visits.

# PRA Health Sciences (Embedded Program-Novartis Corporation (M) Sdn Bhd )

**(September 2016- 31 January 2018)**

## JOB DESCRIPTION: IN HOUSE CRA-1

* Establish and be the central contact between study team and study sites (Investigators) as delegated
* Organize International Meetings (Support Investigator Meetings and set-up and participate several international Meetings)
* Track study progress via trackers and provide this information to Manager
* Create and maintain tools, tracking to report, and measure study progress.
* Ensure timely and accurate study-related communication to internal and external study team (including CRO and site personnel as appropriate)
* Assists in preparation, distribution and tracking (as needed) of clinical trial correspondence, newsletters and assists with the creation of study-specific manuals, tools, and templates.
* Set-up, maintain and perform quality checks of study documentation / Trial Master Files (TMF)/ Investigator Site Files (ISF)
* Work side-by-side with CTM, CML and/or CRA assisting in some of their tasks as delegated
* Provide support for FORUM field based clinical personnel via maintenance and communication of site visit tracking information and metrics
* Develop, review and/or facilitate review of various study documents (Investigator letters, Source Docs etc.)
* Establish and be the central contact between the contract laboratories, study team and study sites as delegated
* Create and maintain tools, tracking to report, and measure study progress.
* Assist with invoicing, and vendor oversight/management as delegated
* Create a Budget Plan and maintain this
* Assist the CRAS in prepare all the documents needed for SIV.

•Point of contact for issuing permit for medical devices

* Distribute safety notification on daily basis to the sites.

# PRA Health Sciences (Embedded Program-Novartis Corporation (M) Sdn Bhd ) 1 February 2018-Present

## JOB DESCRIPTION: IN HOUSE CRA-2

In addition to the above:

* Liaises with internal and external customers to meet project specific goals including participation in sponsor and project related meetings
* Acts as a liaison with clinical supply/service vendors and other functional area team members to meet project team goals.
* Identifies, monitors, documents, and tracks out-of-scope activities.
* Supports Clinical Team Manager (CTM)/Start Up Lead (SUL) and Clinical Research Associate (CRA) in the management of investigational sites to ensure compliance with study timelines, the trial protocol, ICH/GCP and applicable regulations.
* Assists with Investigational Product accountability, subject screening/enrollment, Case Report form retrieval and query

distribution to/from investigational sites.

* Proficient in the development and review of Informed Consent Form templates.
* May serve as an Independent Essential Document Reviewer and/or perform second review of Essential documents .
* Assists in the creation and maintenance of clinical project documents including, but not limited to Clinical Management
* Plans, monitoring Guidelines, Site Operations Manuals, Monitoring Visit Letter templates and Project Start-up Plans

under the guidance of the SUL/CTM.

* Supports the CTM/SUL/CRA to resolve internal and external clinical issues for client research projects managed by PRA.
* Interacts with site, clients, vendors and PRA functional areas as secondary project contact for site issues and questions.
* Supports CTM/SUL/CRA in the management of clinical budget and evaluation of study processes.
* Evaluates metric data to identify process improvements.
* Assists with managing and training staff.
* Manages time and project requirements based on study contract.

**EDUCATIONAL BACKGROUND**

* + **International Medical University, Malaysia**

**Bachelor of Science (Hons) Pharmaceutical Chemistry**

September 2012-2015

Second Class Honours

Graduation: 12th September 2015

* + **AIMST University, Kedah,Malaysia**

**Foundation in Science**

Mei 2011-2012

* + **SMK (P) Methodist Klang,Malaysia**

2006-2010

SPM : 7A’S 3B’S

PMR: 7A’S

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| --- |
| **INTERESTS & AFFILIATIONS**  Passion for discovering new territories has been life changing in many ways. It feeds the imagination and broadens the vision by interacting at all levels.  **Associations:**   * Member of Royal Society of Chemistry * Ex Interact member, * Volunteer at PAWS Malaysia * Ex School Prefect   **Certifications:**   * Attended Good Clinical Practice workshop at (1st-3rd Aug 2017) and obtained certification from CRC University Malaya |