

# Good Submission Practice 2.0

## for Generic Medicines

20 - 21 November 2024



### Course Overview

The objective of a Good Submission Practice Workshop for generic medicines is to prepare the applicant to submit Good Quality Dossiers to National Pharmaceutical Regulatory Agency (NPRA). By the end of the workshop, participants should be more competent and equipped to navigate the complexities of regulatory submissions.



### Learning Objectives

- Understanding Regulatory Requirements:** Familiarize participants with the relevant guidelines and regulations for pharmaceutical products.
- Enhancing Submission Quality:** To improve the clarity, accuracy, and completeness of submissions to reduce the likelihood of queries or rejections. To address challenges face during registration submission.
- Risk Management:** Discuss potential pitfalls in the submission process and how to mitigate risks through proactive planning and quality checks.
- Case Studies:** Provide case studies or examples of successful submissions and common mistakes, allowing participants to learn from practical scenarios.



### Speaker

#### NPRA Speakers & Facilitators

- |                             |                                   |
|-----------------------------|-----------------------------------|
| 1. Nik Shamsiah Nik Salleh  | 7. Nurul Intan Shafinas Md Nasir  |
| 2. Sarawani Hassan          | 8. Woon Yoke Yee                  |
| 3. Haw Shin Ee              | 9. Lim Sze Ne,                    |
| 4. Soon Thien Loong         | 10. Norafaziah Mohd Jalil         |
| 5. Nasyrah Amalina Sarginan | 11. Zarith Nadia Mohamad Zulkifli |
| 6. Chen Yoke Shan           | 12. Tan Mui Kiat                  |

#### Industry Speakers

1. Lee Xui Kin - MOPI
2. Roziana Abd Rahim - MOPI
3. Alvinder Kaur - MOPI
4. Siti Azura Zainon - MOPI
5. Sharvin A/LA Subramaniam - MOPI
6. Nithiya Raj Rajalingam - NVS Regulatory Services

### Who Should Participate

- Regulatory Affairs Executive
- Regulatory Affairs Managers
- Personnel involved in dossier preparation

### Tentative Agenda

#### Day 1 (20 November 2024, Wednesday)

- |                   |   |
|-------------------|---|
| 8:30 am – 9:00 am | Registration of participants  |
| 9:00am – 9:05 am  | Emcee housekeeping note   |
| 9:05am – 9:15am   | MOPI opening speech   |
| 9:15am – 10:15am  | Overview of generic medicines application: current issues, updates and gap analysis with the international requirements. (Speaker: Nik Shamsiah Nik Salleh, NPRA) |
| 10:15am – 10:30am | Q&A   |
| 10:30am – 11:00am | Tea Break   |
| 11:00am – 12:00pm | Part I and common deficiencies (Speaker: Nasyrah Amalina Sarginan, NPRA)  |
| 12:00pm – 1:00pm  | Q&A   |
| 1:00pm – 2:00pm   | Lunch   |
| 2:00pm – 3:00pm   | Part II- API and common deficiencies (Speaker: Chen Yoke Shan, NPRA, Industry: Lee Xui Kin)   |
| 3:00pm – 3:15pm   | Q&A   |
| 3:15pm – 4:15 pm  | Part II- P, Lab and common deficiencies (Speaker: Woon Yoke Yee, NPRA, Industry: Alvinder Kaur)   |
| 4:00pm – 5:00pm   | Q&A (together with Tea Break)   |

#### Day 2 (21 November 2024, Thursday)

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|-------------------|--|
| 8:30 am – 9:00 am | Registration of participants   |
| 9:00am – 10:00 am | Variation, renewal and common deficiencies (Speaker: Nurul Intan Shafinas Md Nasir /Lim Sze Ne, NPRA, Industry: Roziana Abd Rahim) |
| 10:00am – 10:30am | Q&A  |
| 10:30am – 11:00am | Tea Break  |
| 11:00am – 12:00pm | Facilitated Registration Pathway (FRP) (Speaker: Industry: Siti Azura Zainon)  |
| 12:00pm – 1:00pm  | Q&A  |
| 1:00pm – 2:00pm   | Lunch  |
| 2:00pm – 3:00pm   | Screening checklist V2.0 & Case Studies (Facilitators: Soon Thien Loong, NPRA & Industry: Nithiya Raj Rajalingam)                  |
| 3:00pm – 4:00 pm  | Q&A (together with Tea Break)  |
| 4:00pm – 4:15pm   | Closing by NPRA  |

**Duration:**  
2 Days

**Date:**  
20 - 21 November 2024, 9am – 5pm

**Venue:**  
Eastin Hotel Kuala Lumpur

**Fee: Group of 5 or more with 10% discount**  
**MOPI Members**  
RM1,300.00 nett per pax

**Non MOPI Members**  
RM1,500.00 nett per pax

**Register:**  
<https://forms.gle/Z2V9ZSwxH2ABpMtA6>



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Organised By: In collaboration with:



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(NPRA)  
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