# LE THI MINH NGOC

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## I – GENERAL INFORMATION

### Education

- Specialist pharmacist 1 *(Toxic, analyze)*
- Pharmacist

- Third prize (Literature)
  *Excellent student of National examination*
- Third prize (Biology)
  *Excellent student of Provincial examination*

### Achievement

- Excellent personnel 2011
- Excellent personnel 2015
- Year-end evaluation 2017: Level A
- Year-end evaluation 2018: Level A

### Language

- English:
  TOIEC 615
  C certificate
- Japanese
  N5 certificate
  Conversation

### History of working

- 2017 – 2019: Nippon Chemiphar Vietnam Co., Ltd.
  - Manager of Regulatory Affairts
  - Person in charge of pharmacy expertise
  - GMP control team
- 2006 – 2016: Stada VN J.V. Co., Ltd.
  - 2011 – 2017: Deputy Manager of Regulatory Affairs
  - 2006 – 2011: Staff of Research and Development

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|  | **Training course**<br>- ACTD courses (by DAV, German expert)<br>- Legal documents training (by DAV)<br>- ISO 9001:2000 training (by Bureau Veritas)<br>- EU GMP (by ISPE, Singapore)<br>- GMP WHO<br>- Management skill for middle managers (by Corporate Training Solution)<br>- Working standard preparation (by IDC) |
|  | **Computer skill**<br>- Word, excel, power point<br>- Corel<br>- Internet searching skill |
| **II – EXPERIENCE** | |
| **GMP, EPB certificate** | - Dossier to get WHO **GMP certificate**, CAPA dossier (corrective action and preventive action dossier)<br>- Dossier to get **EPB certificate** (Eligibility for Pharmaceutical Business) |
| **Drug registration** | - Got more than **500** visa numbers in Vietnam market<br>- Got more than **200** visa numbers in exported markets, such as Singapore, Taiwan, Myanmar, Malaysia, Philippines, HongKong, Cambodia |
| | - ACTD: Part 1 - Administration, Part 2 – Quality document.<br>- Process validation, Analytical validation protocol and report.<br>- Bioequivalent study: protocol and report<br>- Renewal, variation dossier<br>- Package insert, Patient Information Leaflet, Artwork for carton boxes, blisters |
| | - DMF review (Drug Master File of API) |

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| **Legal documents** | - Pharmacy Laws<br>- Decrees of Pharmaceutical field<br>- Circulars of GMP, GLP, GSP, circulars of pharmaceutical field |
| **Reference** | Good understanding in:<br>- eMC, Martindate, PDR, AHFS, Vietnamese National formula<br>- Pharmacopoeia: EP, USP, JP, VN pharmacopoeia |
| **SOPs** | - Understand Warehouse management, prepare all SOPs for GSP such as Receipt of raw material, Delivery sheet, monthly report of Warehouse, Mapping of temperature.<br>- BMR, BPR for production such as granulation, compression, film-coating, tablet printing, blistering, cartoner, carton box filling (film-coated tablet, tablet) |
| **Medical Officer** | - Prepare, suggest List of products for Research and Development<br>- Study about Safety Warning, ADR report, recall products |
| **Functional food, Cosmetic** | - Prepare and submit dossier for Functional food to VFA, cosmetic product to DAV |
| **Management, Co-operation skill** | - Co-operated with Hong Kong, Japanese, India, German experts more than 7 years<br>- Managed RA staff (more than 18 – 20 persons)<br>- Co-operated with Formulation department, QC, QA, Production, Warehouse departments<br>- Contacted directly with DAV agents |