



# Nguyen Thi Huyen

Regulatory affair executive

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**Gender:** Female

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## OBJECTIVE

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- Excellent staff at work, good relationship with the management agency
- Legal advice senior about drugs, dietary supplements, cosmetics and medical device in the next 2 years.

## EDUCATION

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2008 - 2013

### **Hanoi University of Pharmacy**

Major: Industrial Pharmacy

- Major subjects: Pharmaceutical chemistry, Traditional medicines, Pharmacology, Clinical pharmacy, Pharmaceutics, Industrial Pharmacy, Pharmaceutical economics and administration
- Graduate thesis on Pharmaceutical analytical chemistry (a review subject).
- Current average academic result: 7.69

## WORK EXPERIENCE

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June 2015 - Present

### **VNP Pharmaceutical Company Limited and Novopharm Company Limited**

Regulatory affair:

- Coordinate with manufactures and preparing Registration Dossiers (Technical Part) for new product, product with expired visa number, product with changes (Change of product labeling, change of batch size of drug product, addition of manufacturer of drug substance....) or product import quota and submission to Regulatory authorities.
- Checking and support manufactures (Japan, Korea, Turkey, Italy, India, China...) about Drug substances Registration Dossier.
- Preparing Registration Dossiers for Food health protection, cosmetic.
- Preparing Supplement Dossiers complies with the requirement of Vietnam's MOH.
- Preparing Registration Dossiers export to Myanmar, Campuchia.
- Get artworks and PI, prepare Vietnamese label in line with current regulation on labeling.
- Ensure timely approval according to product registration plan.
- Supply the required information/documents for requirements of external or internal colleagues including Health Authorities (Ministry of Health) to conform to Company's regulations and law.
- The job will prepare all applications for the permits, license, certificates, authorization of the organization's products to conduct the

business activities

- Preparing Registration Dossiers for Medical devices (type A, B, C, D)

July 2013 - May 2015

**Vietnam Institute of Dietary supplements**

Quality control employees:

Highly skilled staff on testing by HPLC, volumetric titration for dietary supplements, raw materials, pharmaceutical herbal, toxins

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## SKILLS

**Personal skills and abilities**

- Communication: experiences in presentation and able to persuade.
- Nice at both dependent and team-work.
- Having principle in working and good at managing time.
- Hardworking, careful, enthusiastic, ability work pressure.

**Computer**

- Excellent skills of using office software (Word, Excel, PowerPoint) and other software.
- Good at searching information from the Internet.

**Language**

English: Reading and writing: Good

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## INTERESTS

- Going out with family and friends, cooking with family.
- Discovering new things.
- Like simpleism.
- Reading books, news on the paper and the internet.

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## REFERENCES

Nguyen Duy Tuyen

Regulatory affair staff of VIPHARCO PHARMACEUTICAL JOINT STOCK COMPANY

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