DRUG ADMINISTRATION OF VIETNAM
DRUG QUALITY MANAGEMENT DIVISION

QUALIFICATION OF GMP INSPECTORS

Code: QT.CL.16.02

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Signature			

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1. *The concerned people shall research and comply with contents stated in this Regulation.*
2. *Contents stated in this Regulation become effective as directed by Director of Drug Aministration of Vietnam.*
3. *Each unit shall be delivered 01 copy (affixed seal). When units want to receive more documents, they shall request ISO Secretary to obtain the sealed version. Soft copy is provided via Local Area Network to share information.*

RECIPIENTS *(clearly state the recipients and tick X in the next box)*

☐	DAV management board	☐	Drug registration dept.
☐	ISO committee	☐	Drug quality management dept.
☐	Oficial Administration dept.	☐	Drug price control dept.
☐	Pharm. Legislation & international Integration dept.	☐	Drug information and advertising dept.
☐	Planning & financial dept.	☐	Cosmetic management dept.
☐	Drug business management dept.	☐	Inspection dept.
☐	NRA committee	☐	Training Center
☐	Drug and Cosmetic magazine	☐	

REVISIONS

No.	Date	Position	Revised content	Note
01	05/03/2014	Doc. code	From QT.QLD.65 to QT.CL.16.02	

1. OBJECTIVES

This document was prepared to elaborate qualification process of GMP inspectors defines the steps of training and evaluating the inspector to ensure in order to ensure that the competency of the inspection is maintained.

2. SCOPE

This document was prepared covering all of the qualification for staffs involved in GMP inspection.

3. REFERENCES

- Decision No.385/QLD-QD dated December 02, 2013 of the Director General of Drug Administration of Vietnam on providing functions, tasks and power of its office and departments under Drug Administration of Vietnam.
- Decision No.1570/2000/QD-BYT dated 22 May 2000 on promugating regulations, standards of "Good Laboratory Practice" of Ministry of Health.
- Decision No.2701/2001/QD-BYT dated 29 June 2001 on promulgating regulations, standards of "Good Storage Practice" of Ministry of Health.
- Decision No. 3886/2004/QD-BYT dated 03 November 2004 on promulgating "Good Manufacturing Practice" recommended by World Health Organization.
- Decision No.27/2007/QĐ-BYT dated on April 19th 2007 of Minister of Health on promugating the route to deploy application of the regulations, standards of "Good Manufacturing Practice" and the regulations and standards of "Good Storage Pratice".
- Decision No.12/2007/QD-BYT dated 24 January 2007 on promulgating the Principles of "Good Distribution Practices".
- Decision No. 47/2007/QĐ-BYT dated 24/12/2007 of Minister of Health on implementation of applying principles, standard "Good Manufacturing Practice", "Good Laboratory Practice", principles of "Good Storage Practice" and "Good Distribution Practice" for Companies of

manufacturing, testing, trading, distributing, exporting, importing, storing and reserving vacine and medical immuno-biologicals.

- Decision No.165/QD-QLD dated July 31, 2007 of the Director-General of Drug Administration of Vietnam on establishing a Team for inspecting unscheduledly the implementation of regulations, standards of "Good Practices" (GPs).
- Decision No.166/QD-QLD dated July 31, 2007 of the Director-General of Drug Administration of Vietnam on promugating the list of GPs inspectors.
- Other Circulars, regulations related to Pharmacy State management.

4. DEFINITIONS AND ABBRIVIATIONS

4.1	Lead Inspector:	A qualified and experienced person appointed by the Director to be responsible for coordinating and carrying out GMP inspection activities.
4.2	Inspector:	A qualified and experienced person appointed by the Director to be responsible for inspecting along with Lead Inspector.
4.3	Inspection Team	A team which is responsible for conducting the GMP inspection consists of Lead Inspector, Inspectors and experts (if any).
4.4	Expert:	A person who is specialized in specific fields relevant to any issue being inspected such as agency, process, activity or subject being inspected.

5. PROCESS/ Requirements

5.1. Qualification of Lead Inspector

5.1.1. Is an official of the Drug Administration of Vietnam (DAV) in the position of Head of DAV's departments (Manager/ Vice manager) or Head of DAV (General Director, Deputy General Director).

5.1.2. For Inspection of pharmaceutical manufacturers, Lead Inspector is a person

holding a Bachelor Degree in Pharmacy, Chemical, Biological.

For Inspection of vaccines and biological products, Lead Inspector is a person holding a Bachelor Degree in Pharmacy or Biological or Medical Doctor

5.1.3. As minimum, has 5-year experience as inspector and has conducted at least 50 times or 100 working days of GMP inspection, or has been appointed Lead Inspector before (Listed in BM.QLD.01: GMP INSPECTION HISTORY).

5.1.4. Is knowledgeable in GMP principle.

5.1.5 Has been appointed by the Director of DAV to be the Lead Inspector.

5.1.6. Is the person has no conflict of interest with the inspected company.

5.2 Qualification of Inspector

5.2.1. Is an official of the DAV or NICVB

5.2.2. For Inspection of pharmaceutical manufacturers, Inspector is a person holding a Bachelor Degree in Pharmacy, Chemical, Biological.

For Inspection of vaccines and biological products, Inspector is a person holding a Bachelor Degree in Pharmacy or Biological or Medical Doctor.

5.2.3. As minimum, has 1-year experience of participating in inspection with qualified inspector and has participated in GMP inspection at least 10 times or 20 working days in the last 6 months, or has been appointed inspector before (Listed in BM.QLD.01: GMP INSPECTION HISTORY).

5.2.4. Has been trained on the subjects as defined in the Procedure of Training GPs inspectors (refer to SOP .46) or GMP training course organized by NICVB

5.2.5. Has passed the performance evaluation conducted by the Head of Drug Quality Management or Head of NICVB following the desired performance standard.

5.2.6. Has been appointed by the Director of DAV or NICVB to be the inspector.

5.2.7. Is the person has no conflict of interest with the inspected company.

5.3 Qualification of Expert

5.3.1. Is an official of from National /Ho Chi Minh City NIDQC (National Institute of Drug Quality control).

5.3.2 Has the knowledge and well understanding of drug quality control.

5.3.3. Has participated in GMP training courses or participated in GMP inspection before.

5.3.4. Has been appointed by the Director of National /Ho Chi Minh City NIDQC to be the expert participating in GMP inspection.

5.3.5. Is the person has no conflict of interest with the inspected company.

5.4 **Qualification of Observer**

5.4.1. Is an official DAV's departments or Health Provincial Services to follow, understand production/ manufacturing condition of local manufacturers.

5.4.2 Holds a Bachelor Degree in Pharmacy.

5.4.3. Has participated in GMP training courses or participated in GMP inspection before.

5.4.4. Is the person has no conflict of interest with the inspected company.

6. APPENDIX

BM.CL.16.02/01: GMP INSPECTION HISTORY

GMP INSPECTION HISTORY

- Full name:.....
- Date of birth:.....
- Degree:.....
- Graduation year:.....

No.	Duration (Days)	From date	To date	Name Inspected Company	Type GMP, GLP, GSP	Role	
						Lead inspector	Member