ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements (TM/HS)

CHAPTER 2 - PERSONNEL

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Approved by:
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OUTLINE

- Objective
- Principle
- Organisation, Qualification and Responsibilities
  - Key Personnel
- Training
- References

OBJECTIVE

- To provide an understanding of the general requirements for Personnel in the TM/HS manufacturing facilities

PRINCIPLE

- Establishment and maintenance of a satisfactory quality assurance (QA) system and the correct manufacture of TM/HS relies upon **PERSONNEL**
- Sufficient qualified personnel at all levels to carry out tasks
- Individual responsibilities should be clearly defined and understood by individuals concerned
- All personnel should have knowledge on the principles of GMP that is related to their scope of responsibilities

GENERAL

- Adequate number of personnel with necessary qualifications and practical experience
- An individual's responsibilities should not be so extensive as to present any risk to quality of product
- All responsible personnel should have:
  - specific duties recorded in individual written job descriptions
  - adequate authority to exercise responsibilities
- New employee shall not be assigned to any job prior to receive appropriate training related to their function

JOB DESCRIPTION TEMPLATE

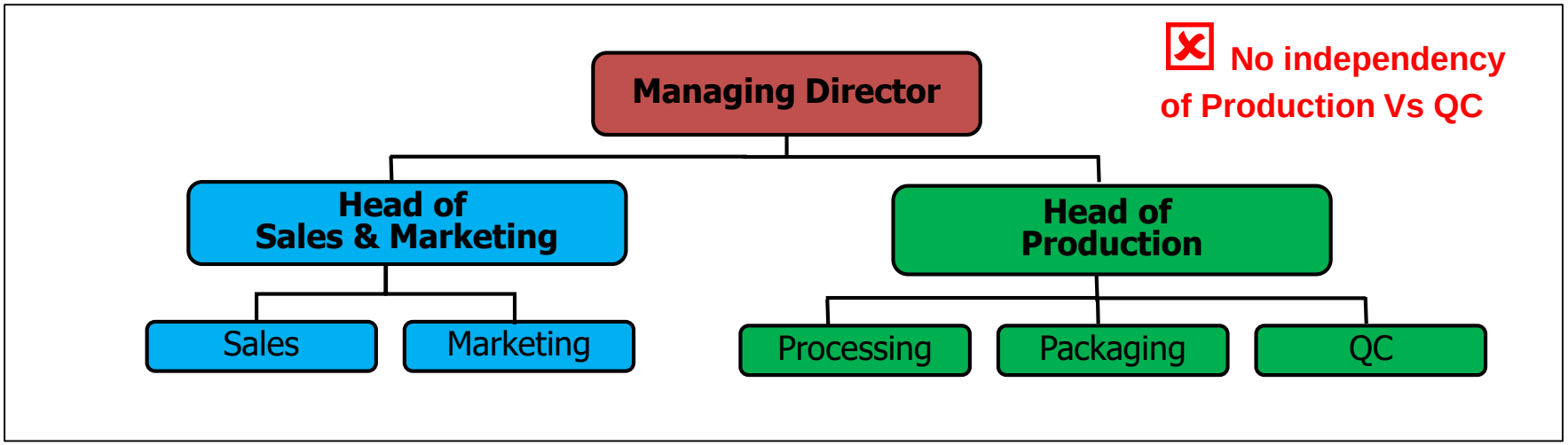
Example of Job Description Template:

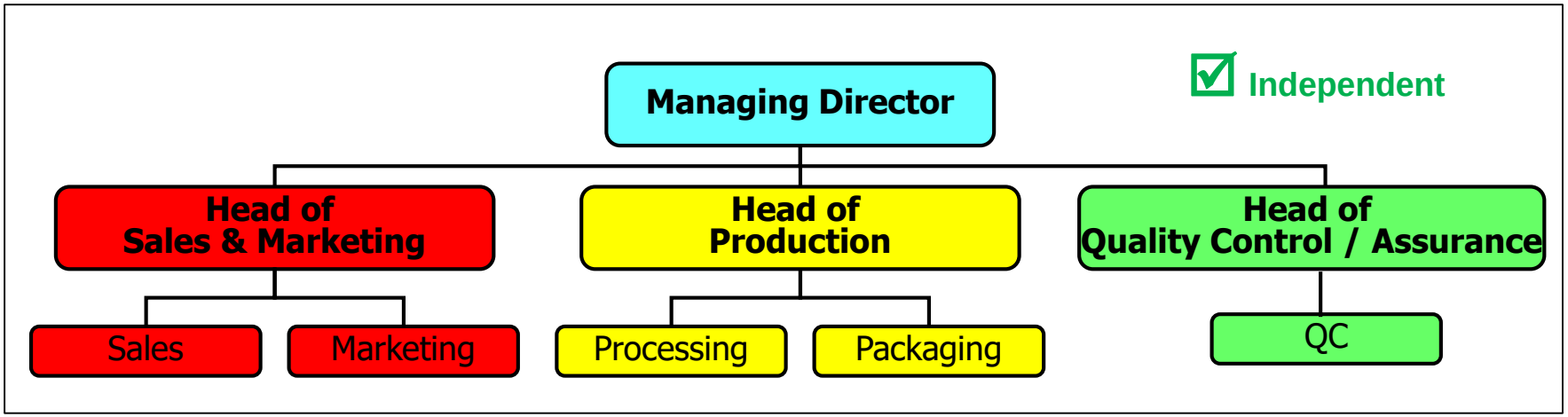
Head of Quality Control *(please refer to Chapter 2 Module - Annex 1)*

GENERAL

- May delegate duties to designated personnel with appropriate qualifications and/or experience within the same department (e.g. QC/QA Manager to QC/QA supervisor or Production Manager to Production Supervisor)
- No gaps or unexplained overlaps in the responsibilities of those personnel concerned with implementation of GMP
- Organisation chart should be available

ORGANIZATION CHART (EXAMPLE)





KEY PERSONNEL

- Key posts (full time) include:
  - Head of Production
  - Head of Quality Control (QC)

- Heads of Production and QC should be independent of each other

KEY PERSONNEL

- Key personnel should possess acceptable qualifications such as:
  - Pharmacy, chemistry, biochemistry, food science and technology, chemical engineering, microbiology, pharmaceutical sciences and technology, pharmacology and toxicology, physiology
  - other related science subjects relevant to the responsibilities to be taken

KEY PERSONNEL

- Key personnel should possess appropriate practical experience e.g. in the manufacturing and QC/QA of TM/HS
- Education and experience should enable personnel:
  - to take decisions in an independent, professional and scientific way
  - to identify root cause and resolve the problems encountered in manufacturing and operations

HEAD OF PRODUCTION: RESPONSIBILITIES

- Ensures that products are manufactured and stored according to the appropriate documentation
- Approvals and ensures strict implementation of instructions relating to production operations
- Ensures that the production records are evaluated and signed by a designated person
- Checks the maintenance of production department, premises and equipment
- Ensures that the critical processes are appropriately verified
- Ensures initial and continuing training of production personnel

HEAD OF QUALITY CONTROL: RESPONSIBILITIES

- Approvals or rejections of starting materials, packaging materials and intermediate, bulk and finished products
- Evaluations of batch records
- Ensures that all necessary tests are carried out
- Approvals of quality control procedures e.g. sampling instruction, specification, test methods
- Approvals and monitoring of all contract analysis
- Checks the maintenance of quality department, premises and equipment
- Ensures that the critical processes are appropriately verified

HEAD OF QUALITY CONTROL: RESPONSIBILITIES

- Establishes expiration date and shelf life specifications on the basis of available stability data
- Approvals of raw materials and packaging materials' suppliers
- Evaluates all complaints received about any batch, and takes appropriate action accordingly
- Maintains adequate analytical records concerning the examinations of all samples taken
- Recommends contract-manufacturing operations which shall meet the company's specified quality standards
- Ensures initial and continuing training of QC/QA personnel

SHARED RESPONSIBILITIES

- Head of production and QC may share/jointly exercise some responsibilities relating to quality:
  - ensuring establishment and authorisation of written procedures and relevant document including amendments
  - monitoring and control the manufacturing environment, sanitation and hygiene
  - verifying critical processes
  - training

SHARED RESPONSIBILITIES

- Head of production and QC may share/jointly exercise some responsibilities relating to quality:
  - approval and monitoring of suppliers and contract manufacturers
  - establishment and monitoring of storage conditions for materials and products
  - retention of records
  - monitoring of compliance with GMP
  - inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality

TRAINING

- All personnel whose duties take them into production, control laboratories and for others whose activities could affect the quality of the product should be trained in particular operations and in the principles of GMP

- Training in GMP shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with GMP requirements relevant to their functions

TRAINING

- Training in GMP shall be in accordance with written programmes approved by the Head of Production and the Head of Quality Control
- Personnel training records including GMP shall be documented and maintained
- The effectiveness of training programs shall be assessed periodically and documented
- The concept of quality assurance and all the measures capable of improving its understanding and implementation shall be fully discussed during the training sessions

TRAINING PROGRAMME

Training Plan 2016
ABC Health Supplements Ltd.

EXAMPLE

Topics	Trainee	Quarter				Responsible Department
		1st	2nd	3rd	4th	
GMP Principles for Manufacturing Operations						Production
Good Documentation Practice						QA
Calibration of Laboratory Equipment						QC

TRAINING RECORD

Employee Training Record/ Log Book

EXAMPLE

EMPLOYEE NAME:	START DATE:
JOB TITLE:	TELEPHONE:
UNIT:	ADDRESS:
DEPARTMENT:	

No	Description of Training	Training Date	Training Time		Total Hours	Training Effectiveness	Signature	
			From	To			Trainee	Instructor

POST-TRAINING ASSESSMENT

ABC Health Supplements Ltd.

EXAMPLE

GMP Principles for Manufacturing Operations
Written Assessment Questions

This questionnaire is conducted to assess your understanding of the essential principles of the topic. It must be completed within 15 minutes at the end of the topic presentation.

Name:

Date:

1. What is Good Manufacturing Practice (GMP)?

   _____

2. Why GMP is important for manufacturing operations?

   _____

REFERENCES

1. ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines.
2. ASEAN Guidelines on Good Manufacturing Practice for Health Supplements.

THANK YOU!

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