CHAPTER 4 – SANITATION AND HYGIENE

Prepared by:
Thailand

Approved by:
ASEAN TMHS GMP Task Force
30 November 2016

Endorsed by:
ASEAN TMHS Product Working Group
ACKNOWLEDGEMENT

We would like to thank the following review team for their input to this training module.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muhammad Lukmani Ibrahim</td>
<td>Chair of ASEAN GMP TF</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Quitevis, Ludivina Fama</td>
<td>Co-Chair of ASEAN GMP TF</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Mega Valentine</td>
<td>ASEAN Secretariat</td>
<td>Myanmar</td>
</tr>
<tr>
<td>Hasmilawaty Mohammad Taib</td>
<td>Brunei Darussalam</td>
<td>Brunei Darussalam</td>
</tr>
<tr>
<td>Jamilah Metusin</td>
<td>Brunei Darussalam</td>
<td>Brunei Darussalam</td>
</tr>
<tr>
<td>Hean Kimseat</td>
<td>Cambodia</td>
<td>Cambodia</td>
</tr>
<tr>
<td>Som Samnang</td>
<td>Cambodia</td>
<td>Cambodia</td>
</tr>
<tr>
<td>Kristiana Haryati</td>
<td>Indonesia</td>
<td>Indonesia</td>
</tr>
<tr>
<td>Widiastuti Adiputra</td>
<td>Indonesia</td>
<td>Indonesia</td>
</tr>
<tr>
<td>Bounleuane Douangdeuane</td>
<td>Lao PDR</td>
<td>Lao PDR</td>
</tr>
<tr>
<td>Solivanh Sengchanh</td>
<td>Lao PDR</td>
<td>Lao PDR</td>
</tr>
<tr>
<td>Sivong Sengaloundeth</td>
<td>Lao PDR</td>
<td>Lao PDR</td>
</tr>
<tr>
<td>Mohd Nasrul Mohamad Noor</td>
<td></td>
<td>Malaysia</td>
</tr>
<tr>
<td>Sharifah Mastura Ahmad Fuad</td>
<td></td>
<td>Malaysia</td>
</tr>
<tr>
<td>Thiri Kyaw Soe</td>
<td></td>
<td>Myanmar</td>
</tr>
<tr>
<td>Wah Wah Aung</td>
<td></td>
<td>Myanmar</td>
</tr>
<tr>
<td>Mary Angeline V. Francisco</td>
<td></td>
<td>Philippines</td>
</tr>
<tr>
<td>Ms. Rochel Averion Francisco</td>
<td></td>
<td>Philippines</td>
</tr>
<tr>
<td>Ong Hai Ann, Terrance</td>
<td></td>
<td>Singapore</td>
</tr>
<tr>
<td>Pinpong Intarapanich</td>
<td></td>
<td>Thailand</td>
</tr>
<tr>
<td>Thida Thaveerit</td>
<td></td>
<td>Thailand</td>
</tr>
<tr>
<td>Lam Quoc Hung</td>
<td></td>
<td>Vietnam</td>
</tr>
<tr>
<td>Luu Duc Du</td>
<td></td>
<td>Vietnam</td>
</tr>
<tr>
<td>Mak Sum Shing, Andrew</td>
<td></td>
<td>AAHSA</td>
</tr>
<tr>
<td>Tamotsu Iwai</td>
<td></td>
<td>AAHSA</td>
</tr>
<tr>
<td>Robles, Frances Evelyn</td>
<td></td>
<td>AATMI</td>
</tr>
</tbody>
</table>
OUTLINE

• Principle

• Personnel:
  – Practice of Good Personal Hygiene
  – Training of Good Personal Hygiene

• Premises

• Equipment and Utensils
PRINCIPLE

• A high level of sanitation and hygiene shall be practised in every aspect of the manufacturing of TM/HS.

• The scope of sanitation and hygiene covers personnel, premises, equipment and utensils; in fact, anything that could become a source of contamination to the product.

• All employees shall be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the quality of products.
PRINCIPLE

Taking necessary precautions to protect components, TM/HS products and contact surfaces against the contamination of:

- micro-organisms
- filth
- other extraneous materials
<table>
<thead>
<tr>
<th>Action</th>
<th>Particle Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting</td>
<td>448,000</td>
</tr>
<tr>
<td>Twisting</td>
<td>4,450,000</td>
</tr>
<tr>
<td>Standing (bending)</td>
<td>2,240,000</td>
</tr>
<tr>
<td>Walking</td>
<td>5,380,000</td>
</tr>
<tr>
<td>Standing (right)</td>
<td>1,285,000</td>
</tr>
</tbody>
</table>

According to:
Takasago Thermal Engineering Co – Fläkt
SANITATION

Hygienic control on manufacturing processes, including personnel, premises, equipment and handling of materials [from starting materials to finished products].
HYGIENE

Conditions and practices that help to maintain health and prevent the spread of disease
PERSONNEL

Type of Contaminant

- Microorganism: Bacteria, fungi, yeast and mold.

- Particulate: All particles which are not part of the product component, such as filth, glass fragment, fiber, hair, metal.

- Extraneous Materials: Lead to cross contamination, mixed up and false.
<table>
<thead>
<tr>
<th>Activity</th>
<th>Particle Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seated</td>
<td>448,000</td>
</tr>
<tr>
<td>Standing</td>
<td>142,000</td>
</tr>
<tr>
<td>Sitting down</td>
<td>14,920</td>
</tr>
<tr>
<td>Walking</td>
<td>4,450,000</td>
</tr>
<tr>
<td>Standing</td>
<td>462,000</td>
</tr>
<tr>
<td>Sitting down</td>
<td>48,600</td>
</tr>
<tr>
<td>Eating</td>
<td>2,240,000</td>
</tr>
<tr>
<td>Standing</td>
<td>390,000</td>
</tr>
<tr>
<td>Sitting down</td>
<td>31,700</td>
</tr>
<tr>
<td>Drinking</td>
<td>5,380,000</td>
</tr>
<tr>
<td>Standing</td>
<td>1,285,000</td>
</tr>
<tr>
<td>Sitting down</td>
<td>157,000</td>
</tr>
</tbody>
</table>

According to:
Takasago Thermal Engineering Co – Fläkt
All personnel, prior to employment shall undergo health examinations. During the course of their employment they shall also routinely undergo health examinations which shall include relevant examinations appropriate to the tasks that they are required to perform.

E.g. General health examination for all personnel
     Eye examination for all personnel
PERSONNEL

Procedure and record of personnel hygiene for employees who perform manufacturing processes should be available:

Annex 1 - SOP on Personal Hygiene
Annex 2 - Record Daily Inspection on Personal Hygiene
**Annex 3 - General Health Examination**
Annex 4 - Employee Illness Report Form
All personnel shall practice good personal hygiene. They shall be trained in the practices of personal hygiene. High level of personal hygiene shall be observed by all those concerned with manufacturing processes.

Training

• Appropriate practices in personal hygiene
• Related written procedure and instructions
PERSONNEL

Personal Hygiene
Refers to cleanliness of a person’s body against
• Disease causing microorganisms
• Filth/dirt
• Extraneous materials
PERSONNEL

Some examples to maintain Personal Hygiene

**Bath/Shower**
- Wash off dead skin cells and disease-causing microorganisms

**Brush teeth**
- Clear up the food residue which are source of microorganisms

**Wear clean working clothes (uniform), gloves and footwear**
- Clothes, gloves and footwear can carry bacteria into the premises

**Keep fingernails clean, trimmed and without polish**
- No artificial nails
- (Polish or artificial nails can fall off)
Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products shall not be allowed to handle raw materials, packaging materials, in-process materials, and finished products until the condition is improved.
Hand Washing

Direct contact shall be avoided between the operator's hands and, raw materials, intermediate or, bulk product. Proper washing of hands and wearing of gloves shall be used if contact with hands is unavoidable.
Hand Washing

Ensure that the hands are washed properly before entering the production areas and rewashed or have the gloves changed when contaminated.
Hand Washing

• After using the toilet
• After touching bare body parts (skin)
• After coughing, sneezing, using a handkerchief or tissue
• After consuming food, drinking, smoking
• Before entering/returning to manufacturing areas
PERSONNEL

How to wash your hand

1. Palm to palm
2. Between fingers
3. Back of hands
4. Base of thumbs
5. Back of fingers
6. Fingernails
7. Wrists
8. Rinse and wipe dry
PERSONNEL

Use of Gloves

Gloves are used to protect materials and products from directly contacting bare hands

- Hands should be washed properly and thoroughly before putting gloves on
- Minor cuts, scrapes, etc. should be covered with an approved bandage prior to putting on gloves
Protective garments

Assure protection of the product from contamination as well as the safety of the personnel, appropriate protective garments shall be worn. Soiled uniforms shall be stored in closed containers until properly laundered.
PERSONNEL

Appropriate protective garment (uniform)

Ensure that clean uniform, footwear and hair covers are sufficiently provided to all production employees.

Ensure that clean, dedicated uniform, footwear and hair covers are worn when entering the manufacturing area.
Appropriate protective garment (uniform)

To prevent hair from falling into materials, products and equipment, hair net and effective hair restraints must be worn.

- Hair net should be of appropriate quality to contain hair and be replaced when damaged or worn out
- All hair must be tucked inside the net
- The net should be sufficiently large to cover both ears
- Wear beard net (where applicable)
PERSONNEL

Appropriate protective garment (uniform)

Production Coverall

Bouffant Cap/ Hair Net

Shoe Cover

Gloves
Only authorised personnel shall be allowed to enter production areas.

Visitors or untrained personnel shall, preferably, not be taken into the production and quality control areas.

If this is unavoidable, they shall be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They shall be closely supervised.
Smoking, eating, drinking and chewing or keeping of plants, food, drink, smoking materials and personal medicines shall be restricted to specific areas and not permitted in production, laboratory, storage or other areas where they might adversely influence product quality.

A separate dedicated area for eating shall be provided outside the production area.

Personnel medicines should be stored in the individual locker to avoid false and/or mixed up during production process.
The wearing of makeup, wrist watches and jewelry shall be prohibited in the production area.

However for jewelry or objects that cannot be removed; it must be covered by material (e.g. gloves) that is maintained in an intact, clean and sanitary condition.
Sanitation of Premises

Premises used for the manufacturing of products shall be of suitable design and construction so as to facilitate good sanitation.

Ensure that the premise is neat and clean and is free of puddled water.

Floorings of the equipment washing rooms could be sloped to allow draining of water.
Hand washing and well ventilated toilet facilities and changing rooms shall be provided for personnel at suitable locations.
Suitable locker facilities shall be provided at appropriate locations for the storage of employees clothing and personal property.
The preparation, storage and consumption of food and beverages shall be restricted to specific areas, such as meal rooms and canteen.

Facilities in such rooms must meet sanitary standards.

Meal rooms and canteen rooms shall not have direct access to controlled areas (e.g. production area and areas use to store materials used for production and finished products).
Waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.

Ensure that there are no harborages and breeding areas for pests at the site.

Ensure that properly closed areas are used for storage of waste materials.
PREMISES

Rodenticide, insecticides, fumigating agents and sanitizing materials used must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products. There shall be a pest control programme, documents such as layout, trending and expectations.

Contract agreements shall be established, where applicable.

Annex 5 - Sample of Pest Control Inspection Record
Annex 6 - Sample of Pest Control Monitoring Record
Annex 7 - Sample SOP on Pest Control
Chapter 4 - Sanitation and Hygiene

PREMISES

Layout of pest and insect control in Processing Area

= Bait stations
First rotation

= Bait stations
Second rotation

= electric insect eradicators

= Mechanical traps
**PREMISES**

**Layout of pest and insect control in Warehouse**

![Diagram of Warehouse layout with pest and insect control measures]

- **1** = Bait stations
  - First rotation
- **2** = Bait stations
  - Second rotation
- **3** = Electric insect eradicators
- **4** = Mechanical traps

** submodule:**

- Sampling room
- Weighing room
- Emergency doors
- Finished products
- Packaging materials
- Starting materials
- Quarantine
- Receiving area
- Warehouse

**Explanation:**

- **Example**

---

ASEAN Guidelines on GMP for Traditional Medicines / Health Supplement 2015

Chapter 4 - Sanitation and Hygiene

MODULE CHAPTER 4 - Sanitation and Hygiene
There shall be written procedures assigning responsibility for sanitation and describing cleaning schedules, methods, equipment, materials to be used and facilities to be cleaned in sufficient detail. Such written procedures shall be followed and the result shall be documented.

Annex 8 - SOP on Cleaning of Equipment and Accessories
Annex 9 - Cleaning Schedule Form
Annex 10 - Cleaning Record Form
Annex 11 - Cleaning Inspection Record
PREMISES

Pets are not allowed within the vicinity of the manufacturing plant.
Equipment and utensils shall be cleaned both inside and outside after use according to established procedures. Cleaned equipment shall be kept or stored in a clean condition and identified with the status of cleaning, and checked for cleanliness prior to each use.
Vacuum or wet cleaning methods are preferred. Compressed air and brushes shall be used with care or avoided if possible, as they increase the risk of product contamination.
Cleaning agents, washing and cleaning equipment shall not be a source of contamination.

The choice of cleaning method and agents shall be carefully considered and justified.
Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.
EQUIPMENT AND UTENSILS

A separate room may be needed for storing clean, idle equipment which should be kept dry at all times.
Written procedures shall be established and followed for cleaning and sanitising of equipment, utensils and containers used in the manufacture of health supplements.

Please see Annex 9 on Cleaning Schedule
These procedures shall be prepared to prevent equipment contamination by cleaning or sanitising agents and shall at least include the following:

1. Responsibility for cleaning
2. Cleaning schedule
3. Cleaning methods
4. Equipment and materials used in cleaning operations
5. Methods of disassembling and reassembling equipment
6. Removal of previous batch identification
7. Protection of clean equipment and utensils from contamination prior to use
EQUIPMENT AND UTENSILS

Records of cleaning, including the appropriate sanitising and inspection conducted prior to use shall be maintained.
REFERENCES

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

ONE VISION, ONE IDENTITY, ONE COMMUNITY