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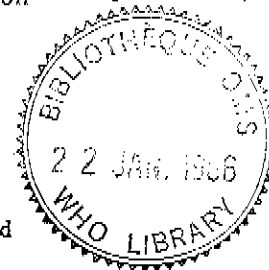
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Places of Training of Inspectors in Drug Quality Control and  
 Good Manufacturing Practices offered by the  
 World Federation of Proprietary Medicine Manufacturers (WFPMM)

Since 1975 the World Federation of Proprietary Medicine Manufacturers has been offering training places in drug quality control and good manufacturing practices to qualified health ministry or health department staff particularly inspectors from developing countries. Training takes place in factories and laboratories of pharmaceutical manufacturers affiliated with a member association of the Federation, following an established syllabus.

The training course covers the following elements: receiving, compounding, control, quality assurance, warehousing and distribution, and finally product development; an outline of this programme is annexed.

This training opportunity is open to nationals of developing countries presently working in government drug control laboratories (not connected with the manufacture), in pharmaceutical inspection services, or in other departments of the health ministry concerned with drug control.

Depending on individual circumstances, the training will extend from six to eight weeks. The companies concerned operate in a wide geographical area so that the training could be carried out in many cases within a reasonable geographical distance from the candidates concerned. It is recognized that some trainees will return to laboratories with limited technical resources and every effort will be made to adapt the training syllabus to the individual's specific requirements.

The procedure for selection of a training place is as follows: The government proposing a candidate submits a Fellowship Application Form through the WHO Programme Coordinator to the WHO Regional Office concerned, which examines it, ensures that funds are available, and transmits the proposal to Headquarters. WFPMM will be requested to identify a suitable training place, after which WHO Headquarters will transmit the relevant information to the Regional Office for further action.

The WFPMM offer covers room, board, local transportation, and an allowance for miscellaneous expenses. Travel between capital city of the home country and the training place will be financed under WHO Regional Office budgets or by the sponsoring government.

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Since each trainee will be selected by a member state's own government, it is assumed that he or she will possess adequate professional qualifications to be capable of benefiting from the training. The training organization will be expected to adjust its program to the professional status and experience of the nominee.

Trainees will be encouraged to learn through direct practical involvement in all aspects of pharmaceutical quality control and the application of GMP standards.

### Outline of Training

#### Training Objectives

To expose the trainee to principles, methods, and techniques of quality control and good manufacturing practices as exemplified by leading manufacturers of non-prescription medicines, to enable him or her to exercise his present or future responsibilities in his home country government regulatory department with increased comprehension of current standards of manufacturing and control.

#### Training Programme

- A. Receiving Department
  - 1. Purchase/receiving relationships
  - 2. Receiving
  - 3. Warehousing
- B. Compounding
  - 1. Drug dispensing
  - 2. Batch preparation
- C. Control
  - 1. Analytical Laboratory
  - 2. Microbiology
  - 3. Packaging Materials
  - 4. Records
- D. Quality Assurance
  - 1. Procedures and procedure writing
  - 2. Manufacturing Self-Inspection Programme (MSIP)
  - 3. Good Manufacturing Practices (GMP)
  - 4. Regulations: FDA, WHO, local and home country
  - 5. Inspections by regulatory bodies
- E. Warehousing and Distribution
  - 1. FIFO
  - 2. Recall procedures
  - 3. Storage conditions related to stability
- F. Product Development
  - 1. Formulation design
  - 2. Ingredient substitution
  - 3. Stability studies and expiry dating pre-marketing
  - 4. Primary packaging components selection and testing
  - 5. Preservatives capability/microbiological testing