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PHARMACEUTICAL PLANT MODELS AND TRAINING CENTRES 1/

by

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Many developing countries endeavour to establish local pharmaceutical factories. Is it possible for us to help them effectively? It is absolutely necessary, amongst broad market analysis

- 1) to set up a scheme for the construction of industrial plants and
- 2) to provide for the training of the staff in economic and technical respects.

This paper will now deal with these two problems.

The term "pharmaceutical factory" signifies not only the single function factory which is purely equipped with a packing department but also the multi function factory which is at the utmost equipped with a production-programme which includes all necessary production steps from the active substance till the finished preparation.

It is difficult to create a scheme which is practicable for all these types of factories. Above all this scheme makes it possible to expand the single function factory to a multi function factory, if needed, or to establish separately any kind of intermediate stage (for instance packing + manufacturing of tablets). It is also possible to establish the multi function factory all at once without considering any intermediate stages.

The completion of a pharmaceutical factory is demonstrated by means of some graphs, where the following departments have been considered:

- a) packing department i.e. production of the finished preparations
- b) galenic departments concerning the manufacture of tablets, coated tablets, liquids, ointments, capsules, suppositories and so on.
- c) Quality control.
- d) Production of the active substances.

Graph 1 shows schematically the horizontal projection of a packing plant. This type of plant can be considered as the first step for establishing a pharmaceutical factory. Therefore an eventual enlargement must be taken into consideration. It might be possible not only in the horizontal but also in the vertical direction.

The packing plant is divided into 2 sections:

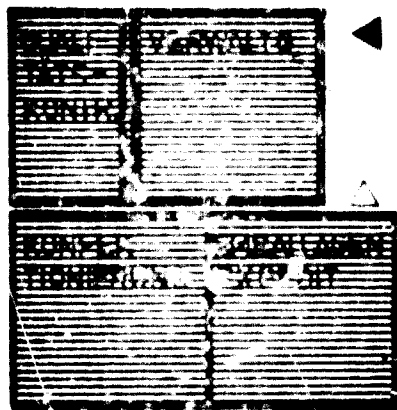
a) the downstairs part, flush with the ground, is composed of the hall for the packaging and the delivery department and the cellar. The cellar is used as a storeroom for semi-finished products, the packaging material and the finished preparations. The finished preparations move with the help of an inclined conveying belt into the cellar and are then, when required, transported by means of this conveyor to the delivery department.

b) the floor part which is necessary for the administration and the quality control departments. An enlargement into the vertical direction is possible.

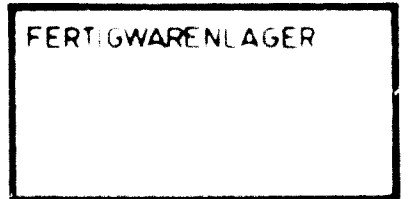
Provided that the semi-finished products are imported with certificates of analysis the quality control might be restricted to specific identity tests to avoid an intermixing of different products. The graph at the bottom is an international screen for industrial buildings.

Here you see the nucleus from the former graph which can be enlarged gradually by incorporating galenic departments.

Graph 1

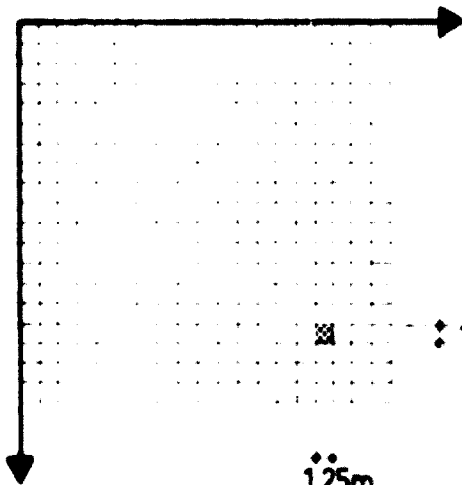


NUKLEUS



E.G.

K.G.



1.25m

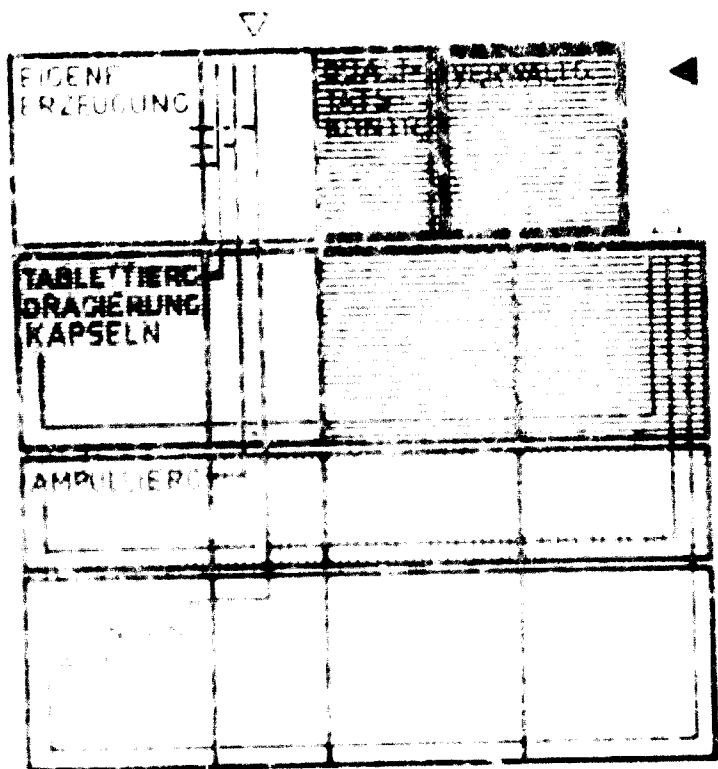
1.25m

INTERNATIONALER
INDUSTRIERASTER

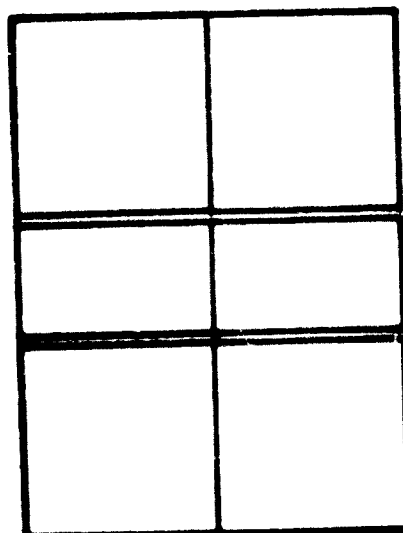
Graph 2

VERWALTUNG

- 100 EMPFANG, DRUCKEREI, GRAFIKER, PAPIERLAGER
- 200 BUCHHALTUNG, EIN- U VERKAUF, LOHNVERR U KASSA, STATISTISCH BÜRO
- 300 PRODUKTIONSLEITUNG, WISSENSCHAFT
- 400 FIRMENLEITUNG



ERWEITERUNG

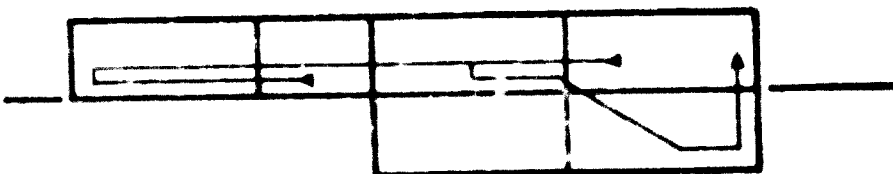


FERTIGWARENLAGER
EMBALLAGEN

E.G.

← ERWEITERUNG

K.G.



SCHNITT

From the manufacturing point of view it is useful to concentrate some departments in one building. As for instance the manufacturing of tablets, coated tablets and capsules.

There is always a storeroom for semi-finished products between the galenic department and the packing plant. The possibilities for arranging are indicated by arrows.

The building where the galenic departments are situated, might be fit out with a cellar under the surface, if necessary. In this way more room is gained for the storage of active substances, ingredients, ampoules, multi dose containers, foils and so on.

With regard to the manufacturing of the ampoules, it must be possible to work under sterile conditions. Sterile filling of antibiotics must be provided.

In the storeroom next to the manufacturing of suppositories, liquids and ointments, tanks might be installed. Out of these the liquids might be pumped to the filling stations, when required.

Next to the quality control department the storeroom for all sorts of raw materials is situated. The raw materials might be purchased or partly manufactured in the own factory, if a manufacturing is taken into consideration (indicated on the left side of the graph).

The production-flow is shown by a cross section. The raw materials are transmitted, by passing the intermediate storeroom, to the respective galenic departments and there they are formed into the special products like tablets, ampoules and so on. The semi-finished products will then be stored in the intermediate storeroom. After the release of the quality control they will be transported to the packing department and there they will be completed to the finished preparations. Now

they are conveyed to the storeroom in the cellar and are dispatched to the delivery department, when required.

Here you see the front view of the factory.

On the left side - the part, flush with the ground, where the packing department is situated which can be enlarged on the left side; on the right wing of this building you see the administrative departments.

The graph on the right side shows another view - you see the administrative departments on the left side as well as a part of the delivery department; on the right side galenic departments which can be enlarged to the right side.

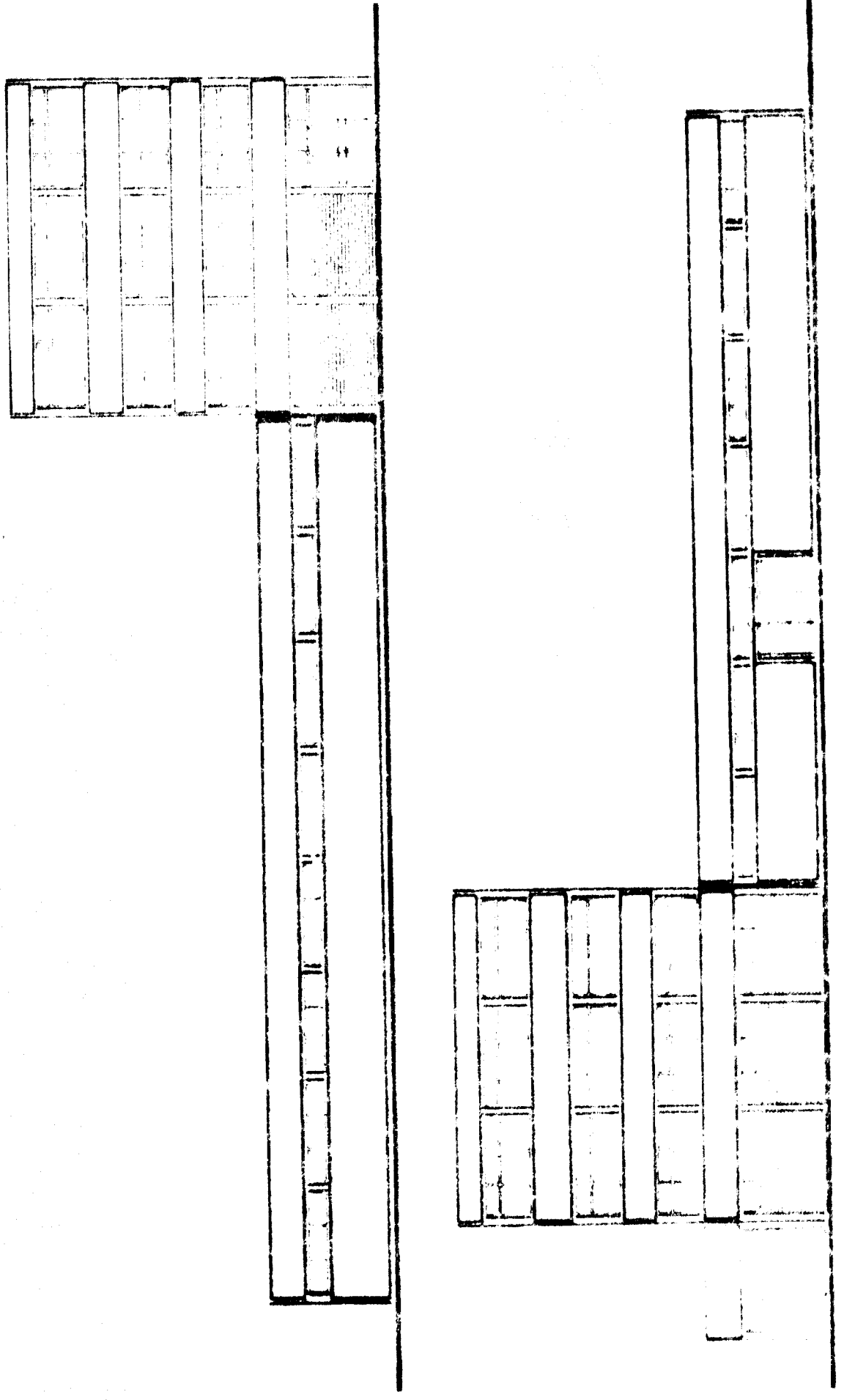
Graph 4 shows a functional scheme. The functional places which have to be created during the first step are drawn out in full line, the enlargements are marked with broken lines.

The circle symbolizes the dynamic, the square the static phases, for instance the storerooms, the triangle the research and development.

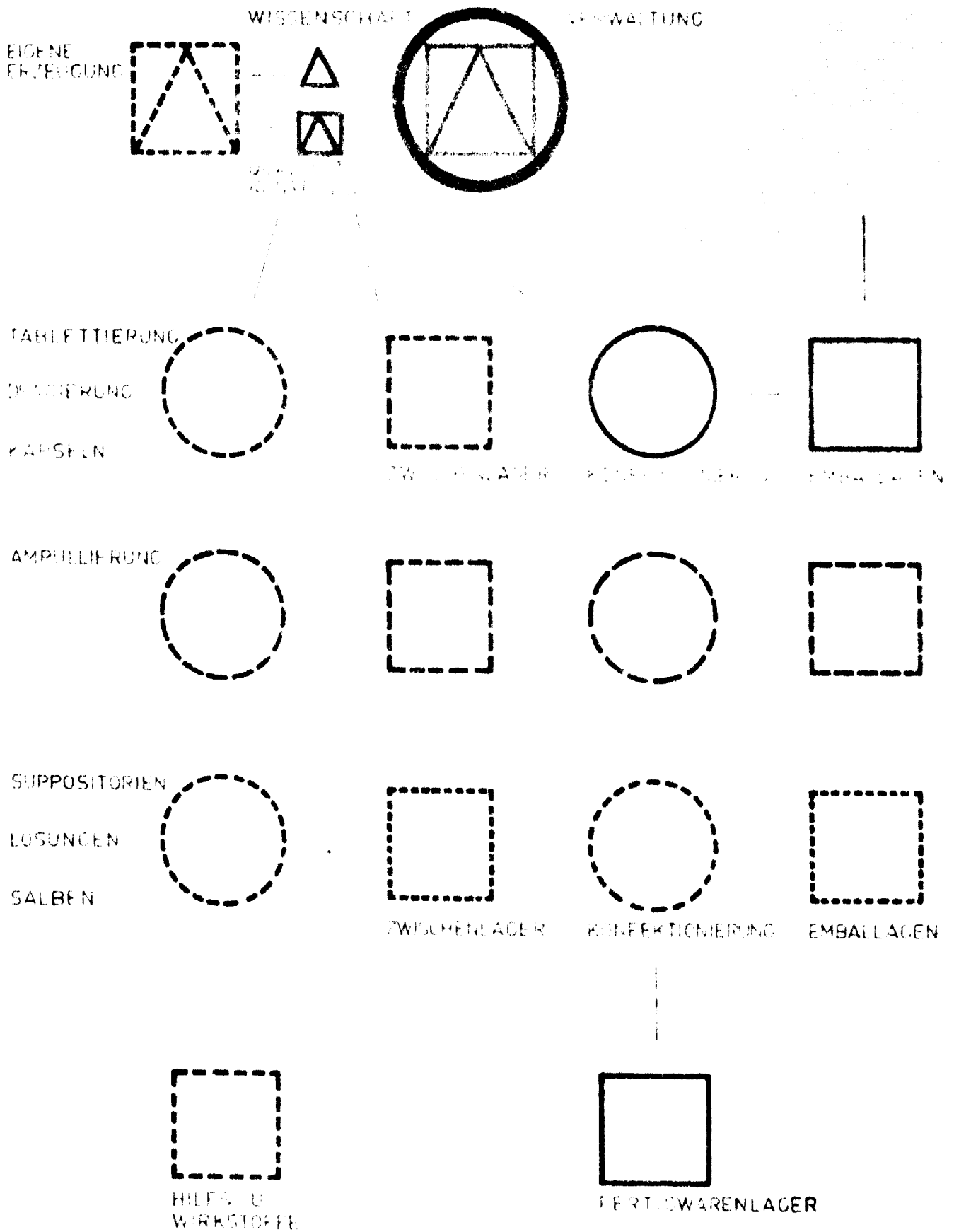
This scheme should be completed by an accurate description of the functional places. A very important and responsible task. The production process should be described exactly, recommendations must be given regarding machine equipments for the different capacities. But there should be also given such details as drafts of forms for the quality control, the manufacturing of tablets, the marking of batches and so on. Regarding this work recommendations of international organizations should be considered.

Here I think especially of the "Specifications For the Quality Control of Pharmaceutical Preparations", 2nd Edition of the International Pharmacopoeia and the "Basic Standards of Manufacturing Practice" prepared by the P.I.A. in the EFTA.

Graph 3



Graph 4



Section 2 of this paper deals with the training of the required staff.

As far as I know there are three possibilities to train the staff.

- 1) in a pharmaceutical enterprise
- 2) in courses arranged either by associations of pharmacists or of the pharmaceutical industry concerning for instance the manufacture of coated tablets or the filling of ampoules and so on or by firms for the training on special apparatus, for instance V-courses of Perkin-Elmer.
- 3) by an adviser.

The disadvantage of all these methods is, that the staff is faced only with specially detailed problems and questions. An allround training which is based on an uniform course of instruction doesn't yet exist.

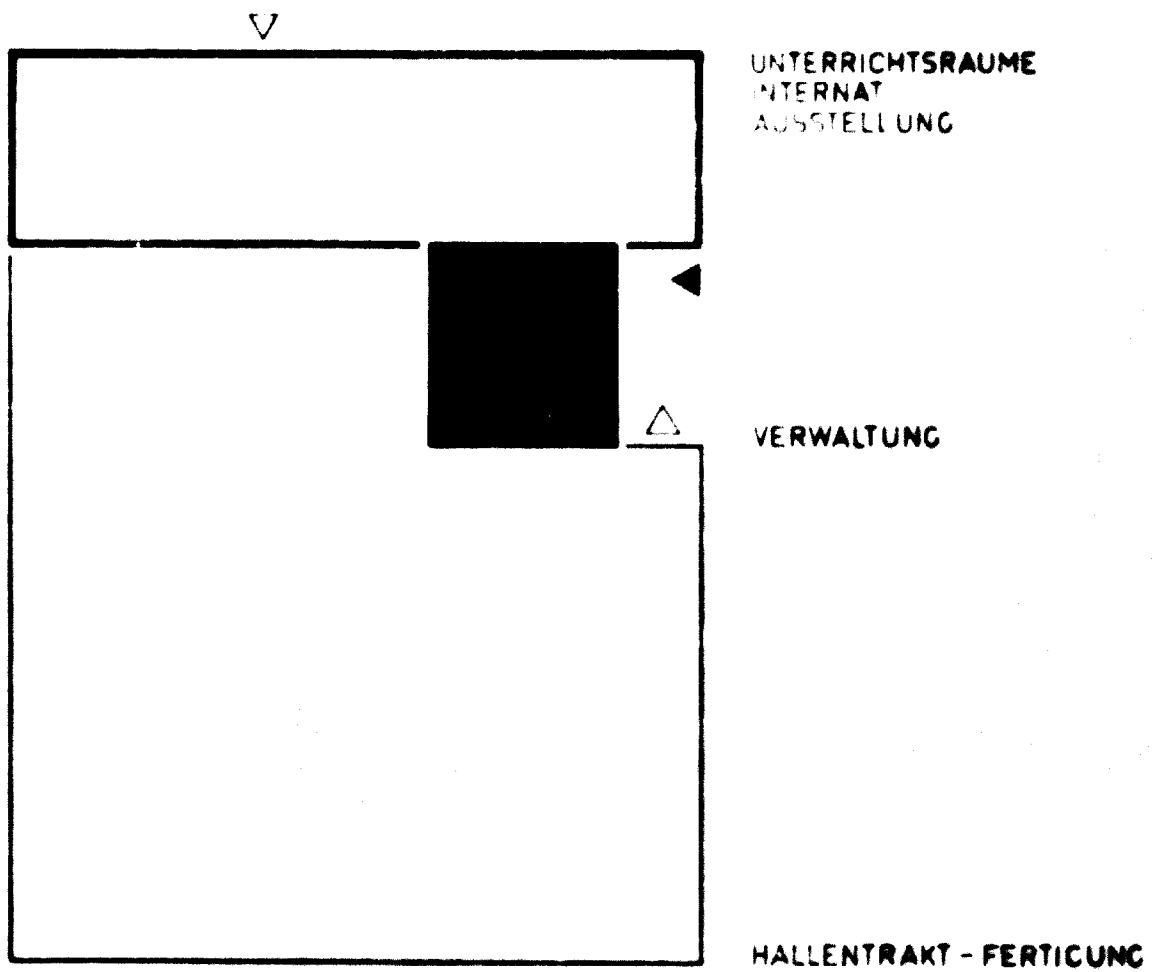
These facts enforce the demand for establishing a training centre and arranging a course of education where technological and economic problems are discussed. Regarding the manufacture and control of pharmaceuticals the following subject matters should be treated -

- 1) raw material instructions including storage of raw materials.
When we think of raw materials we have to consider the active substances and ingredients and also the packaging material as far as it comes into contact with the pharmaceuticals.
- 2) Theoretic and practical engineering.
- 3) Quality control.
- 4) Mechanical engineering.

The directions and instructions recommended by international committees should be considered.

What principles should be predominant for establishing this training centre?

Graph 5



Graph 5 shows a draft?

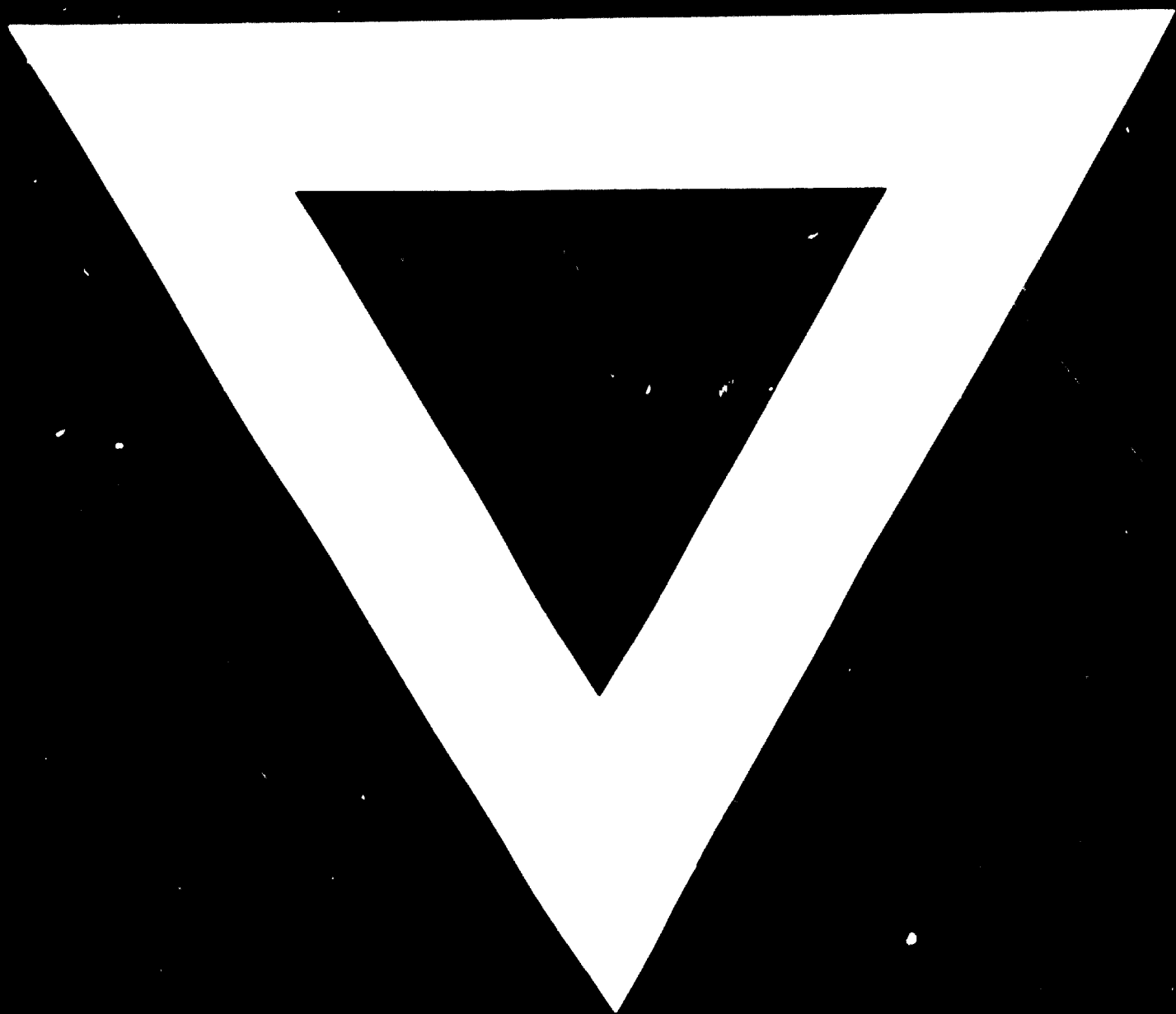
This area is thought for a model plant. It should be constructed in the same way as a multi function factory. It should be composed of a packing department, all necessary galenic departments, a quality control and, if possible, a hall for the manufacturing of active substances, but at least an extraction unit.

The black square symbolizes the administrative wing. In the rectangle, drawn out thicker on the graph, there are the teaching-rooms, the bed-rooms for the staff, the documentation centre and a permanent exhibition placed. This documentation centre should not only give the opportunity for studying the essential literature but there should also be a living resource for all sorts of raw materials. A list should be available, including those firms which are ready to sell procedures and methods of manufacturing and formulas for a certain reality. Newly developed machines and devices for the pharmaceutical industry should be presented in the exhibition rooms. I believe that it will be of great interest for the manufactureres too to participate in this exhibition free of charge with their newly developed machines.

At the end of my paper permit me to make the following proposals:

- 1) Regarding the prescribed schemes, detailed plans should be worked out to establish pharmaceutical producing units considering eventual enlargements.
- 2) A committee of experts should give exact and accurate descriptions of the functional places.
- 3) A professional training centre should be created with a permanent exhibition of newly developed machines, devices and chemical engineering, connected with a documentation centre.





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