Background

The Aspects of Compounding Summit is the third in the BEAM series of projects underpinned by the European Association of Hospital pharmacy. It is under the auspices of the Academy which is part of the educational ?arm? of the EAHP.

The BEAM project is a sponsored training and facilitation series of summits based on the cascade principle of dissemination. Specifically Aspects of Compounding is the ?A? of BEAM (Biotechnology, Evidence-based medicine, Aspects of Compounding and Management). Funding has been secured from Amgen, Bayer and Pfizer.

Introduction and short description of the course

The aim of the Aspects of Compounding Summit is to train participants in the realisation of a state of the art facility for a compounding process in a European hospital pharmacy. Participants will choose on beforehand from 4 selected processes (the topics). The participants will work on their topic during the course. Since there will be 64 participants (from 31 countries), 8 groups of 8 participants will be formed. There are 4 topics, so every 2 groups will work on the same topic. This set up will stimulate the competition. During the course subjects necessary to design a compounding facility will be presented plenary by experts. After most plenary presented subjects the groups will work on their topic. Facilitators will help in this process (1 per 2 groups). The groups will design lay outs, describe processes, describe the facility and the organsation, design a product list etc. Each group will appoint a secretary and a president. The status of the topics will be presented in between and finally on the last morning.
The final results and all necessary/relevant literature will be available on de EAHP website. Participants will take home all results and present them in their own country. The website of the EAHP will be open for a compounding forum on which participants can report their progress and exchange ideas.
Next EAHP congress a follow up will be organised.

Description of the topics from which 4 will be chosen by the participants

1. Small scale compounding for individual patients

Compounding for (individual) patients used to be the core business of all pharmacists. To date it is a unique service that can be provided in daily care if registered drugs do not fit with the

individual need of a patient. For this service a facility with several work places for sterile and non sterile processes (eg. ointments, capsules, eyedrops etc) is needed. Validation of the products and the processes is a difficult task; training of personnel is mandatory. Both standardized and non-standardized designs of products are used. Non standardized are often based on few data and design, compounding and release for use is done within a tight time frame.

2. TPN

The preparation of total parenteral nutrition is a risk full process, both from a microbiological and a stability point of view. Manipulating the components has to be done in a class A environment. Adding drugs can effect the stability of the emulsion and has to be supported by analytical and physical data. Parenteral nutrition for neonates requires special knowledge. An understanding of pharmaceutical microbiology is necessary for process validation and personnel certification.

3. Cytotoxic drugs

In the preparation of cytotoxic drugs both the product and the operator have to be protected. Environmental contamination of connected rooms and the wards has to be avoided by containment measures. This requires a special design for the facility, thorough interpretation of the possible risks during preparation, the transport and the administration.

4. Preparations prior to use

Several drugs, especially parenterals, have to be prepared prior to use to administer the drugs to the patients. The preparation of an antibiotic infusion or simply the breaking of a tablet if half a dose is needed, are examples of preparations prior to use. This process can be done in the pharmacy or on the ward. The facilities in the pharmacy and on the ward are different. However, in all cases the intrinsic quality of the drug has to be maintained and cannot be jeopardized. Organisational aspects, responsibilities and quality control differ from classical compounding.

5. Advanced therapy medicinal products (ATMP)

ATMP?s are described under EU directive 1394/2007. To date, several therapies and or products in the field of gene therapy, cell therapy and tissue engineering also fall under regulations of medicinal products as so called ATMP?s.
There are registered ATMP?s; ATMP?s in trials and not registered products in a hospital described as hospital exemption. Considering the definitions hospital pharmacists are involved is the preparation of advanced therapy medicinal products. If ATMP?s are a hospital exemption the hospital pharmacist will need an organization and a facility to manipulate and deliver these products. The hospital pharmacist is responsible for the quality and pharmacovigilance.

6. Aseptic preparations for a limited number of patients

Aseptic handling with drugs is done prior to use. In some cases it is more efficient to prepare small batches for several patients at a time. This process is done in pharmacies and also on

the wards. The process is comparable but still differs from industrial aseptic production. A facility for this process could be based on an interpretation of annex 1 of the GMP and a thorough risk evaluation. Robots and automated processes will be introduced in this process.

7. Investigational medicinal products

The production of investigational medicinal products can be a hospital pharmacy service especially in investigator initiated trials. The production of investigational medicinal products requires a legal production license and a full blown GMP facility. Beside GMP, also GCP play an important role. It is mandatory for the research in hospitals that several hospital pharmacies have a production license and a GMP facility to fulfill their task in clinical trials.

8. Semi industrial production

In some hospitals around Europe production is done on a semi-industrial scale. Still the processes may differ from the industrial scale. Batch sizes are substantial but still small as compared to industry and a large number of different products can be manufactured. The industrial GMP rules are applicable but also need an interpretation for the hospital environment. This requires thorough knowledge of the processes, GMP and risk evaluation.

Last update: 4 December 2012