QuapoS 4
guidelines for
ADMINISTRATOR

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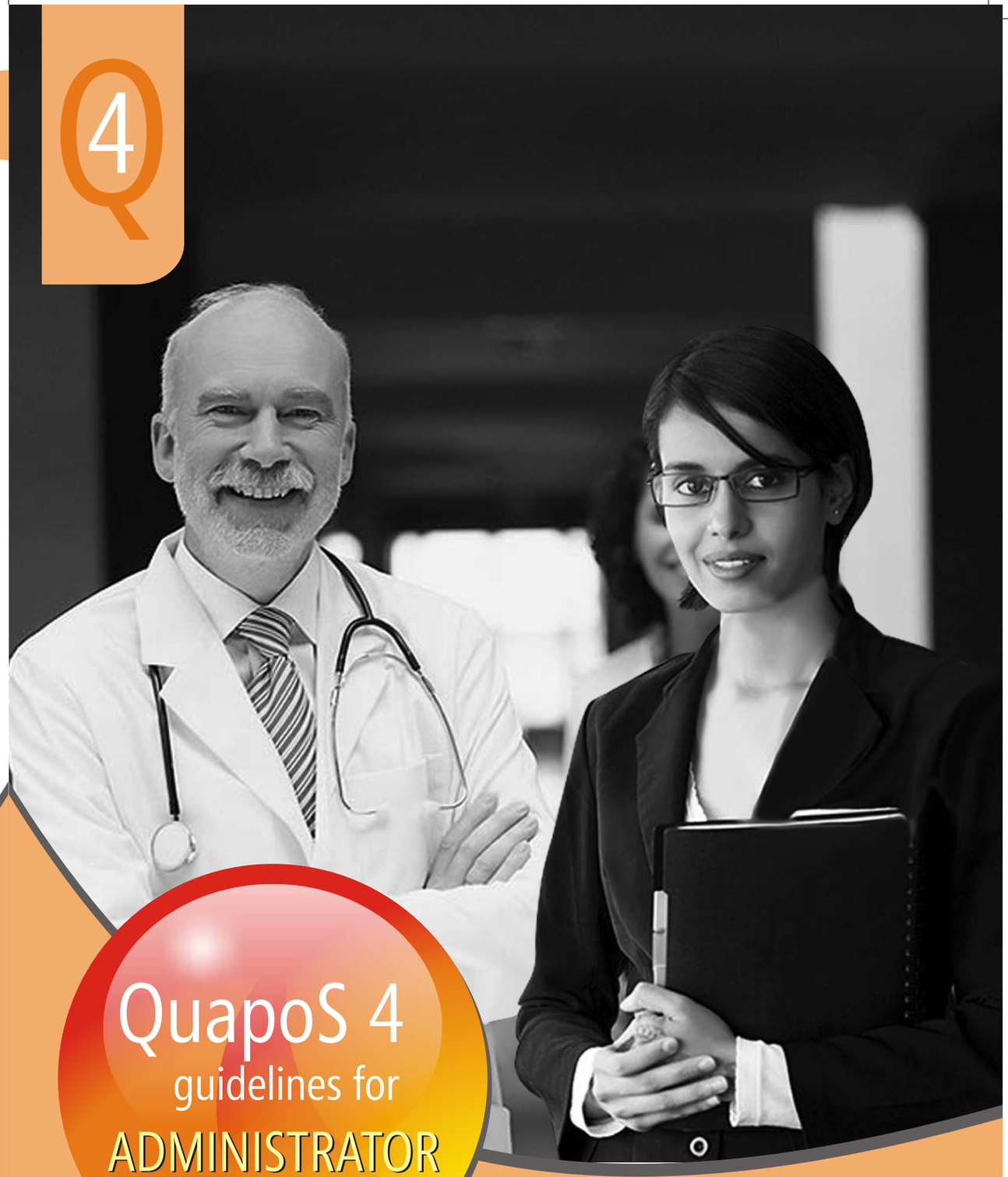
For use for an oncologist or a rheumatologist or a Hospitals or a Laboratory only.

Q4



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QuapoS 4 guidelines for administrator

Quality Standard for the Oncology Pharmacy Service (QuapoS), as developed by German hospital and public oncology pharmacists who were members of the DGOP (German Association for Oncology Pharmacy), should be seen as a symbol of progress. These guidelines can help administrator in making protocols to handle the cytostatic drugs safely and understand the requirement of equipments during cytostatics drug production which can be applied globally.

1. Personnel

1.1. Persons dealing with cytostatics

Persons dealing with cytostatics under the direct influence of the pharmacy include:

Pharmaceutical personnel:

- Pharmacists and persons being trained as pharmacists
- Pharmacy technicians and persons being trained as pharmacy technicians
- Pharmacy assistants
- Pharmacy engineers

Non-pharmaceutical personnel:

- Pharmacy auxiliary staff
- Professionals employed by the pharmacy
- Pharmacy sales staff
- Employees in the store
- Cleaning staff
- Transport staff

1.2. Persons in production

Categories of persons working in the cytostatics department include:

Pharmaceutical personnel:

- Pharmacists and persons being trained as pharmacists
- Pharmacy technicians and persons being trained as pharmacy technicians
- Pharmacy assistants
- Pharmacy engineers

Non-pharmaceutical personnel:

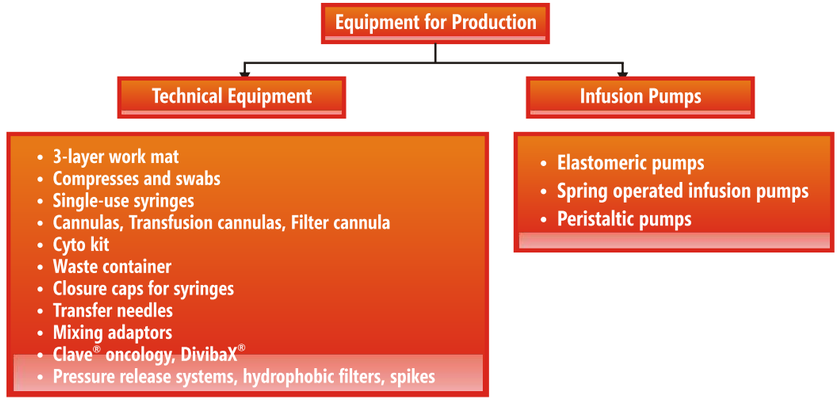
- Pharmacy auxiliary staff
- Professionals employed by the pharmacy
- Pharmacy sales staff
- Cleaning staff
- Maintenance personnel

Only pharmaceutical personnel may be employed in the production of ready-to-administer cytostatic solutions. Before these employees begin their work, they must be adequately educated and trained in aseptic working procedures and in the handling of hazardous substances. Quality standards must be discussed with all employees in order to arouse and promote understanding for and awareness of the diverse problems associated with an oncology pharmacy service.

1.3. Hazard evaluation, working rules and instruction

Before starting work in cytostatics production the hazardous risks of cytostatics handling need to be evaluated and documented (industrial safety act, hazardous substances regulations). The employees must be instructed based on these findings.

3.3. Equipment for production

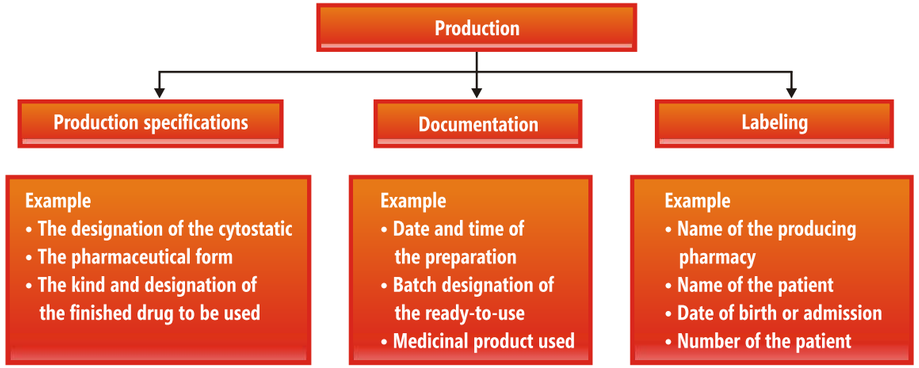


3.4. Aseptic technique

Aseptic technique embraces all coordinated, necessary steps that lead to a sterile product by using optimal conditions for germ reduction and avoidance of microbial contamination. Preparing for and going over the actual compounding process significantly influences the quality of the product.

3.5. Production

Production takes place on the basis of the working rules (hazardous substances regulations)) and the production specifications which integrates the results of the hazard evaluation. The work techniques defined in the working rules and production specifications are mandatory. Compliance with them must be regularly inspected.



3.6. Delivery of the finished products to the entity providing oncological therapy

For "In-house" transport, the finished products are delivered in unbreakable, liquid tight, closable containers labelled with the inscription "Caution Cytostatics". If the finished product will be transported out of the institution it needs to comply with hazardous freight regulations. Cytostatic compounds partially belong to the group of hazardous freights. They have the UN number 1851 and need to be arranged under 'drug, liquid, toxic'.

3.7. Valuation

The costs of a preparation are divided between the following areas:

1. Material costs
   - Medicinal product
   - Carrier solutions
   - Consumables
2. Personnel costs
3. Extra charges
   - The applicable contracts must be taken into account when billing the health insurance provider

2. Central Cytostatics Department

The centralized preparation of CMR (carcinogenic, mutagenic and reprotoxic) drugs must take priority over distributed preparation.

2.1. Rooms and equipment

Preparation takes place in a separate, clearly designated clean room work area, which is separated from the remaining areas by one or more air-locks. The general requirements for workrooms must be met. The rooms used must not be combined with the remaining pharmacy rooms. In addition to the technical equipment, the equipment of the department includes the fixtures and furnishings associated with preparation, production and documentation. The entire equipment of the preparation room must be defined in a fixtures plan and reduced to the necessary minimum.

2.2. Room air equipment

1. A cytostatics workbench of type H (or "other design, e.g. with isolated work room") must be used, type tested in accordance with DIN 12980 as laminar airflow (LAF). Cytostatics workbenches with an additional high efficiency particulate air (HEPA) cassette filter stage beneath the work surface are to be preferred.

2. A workbench exhaust air system should be installed as a further safety measure.

3. Should an exhaust air system not be realizable for technical reasons, it is mandatory to use an LAF with two HEPA filter stages before the air is returned to the production room. If a workbench is operated with recirculated air, the air changes must not exceed 8, and all regulation of the BuBAV need to be met.

4. In any case, a ventilation system must be installed that leads adequately conditioned and purified fresh air complying with DIN 1946 into the room for compensating the flow of exhaust air in accordance with TRGS 560 and ArbStättV, without impairing the protective function of the cytostatics workbench. The velocity of the input air must not exceed 0.2 m/s.

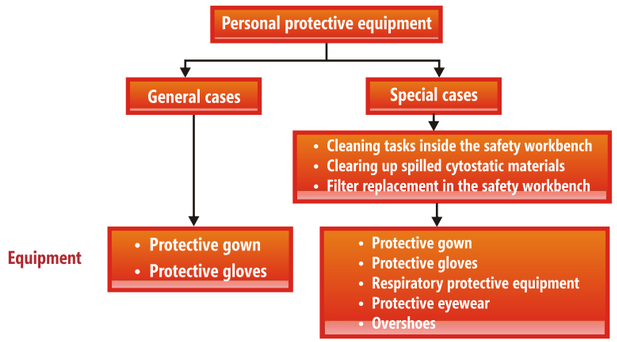
3. Cytostatics Production

3.1. Handling of cytostatic shipments

Only trained pharmacy personnel may be allowed to accept shipments of cytostatics. Packages or shrink–wrapped cytostatics need to be opened in a separated location with personnel wearing a protective gown. Notification of breaks, contaminations or other damages needs to be documented and reported to the manufacturer and the occupational safety department. The cause of the defect needs to be evaluated and eliminated as soon possible.

3.2. Personal protective equipment

The directives, regulations and guidelines currently in force (hazardous substances regulations), TRGS (technical rules for hazardous substances) 525, Cytostatics Directive of the Länder, regulations and leaflets of the BGW / GUV) stipulate the use of protective equipment for the employees of a cytostatics department. The personal protective equipment must meet the CE (Communaute' Europe'enne) standards and needs to be specified in the hazard evaluation. Personnel assembling drug products for the cytostatic compounding process and personnel packaging the final product also should wear personal protective equipment.



In addition to the persons carrying out the production, all employees dealing with and using cytostatics must be instructed in the sense of hazardous substances regulations. This also includes, for example, the cleaning staff and persons employed in the transport service.

The instructions given must be appropriate to the different job categories. Depending on the respective requirements, it includes the following items:

- Effects of drugs
- Proper procedures for dealing with hazardous substances (cytostatics, latex, etc.)
- Hazards and protective measures
- Aseptic technique
- Disposal of contaminated materials and devices and residues of cytostatics
- Occupational preventive medicine
- Action in the case of accidents

These instructions must be repeated annually. In addition, written working instructions must be prepared specific to the particular workplace. Cytostatics are classified according to their properties and are included in the pharmacy list of hazardous substances.

This list must be amended to accord with major changes and must be inspected at least once every year. If any changes have been made a new documented risk evaluation has to be performed.

Accidents must be documented in an accident protocol. In the case of personal injury, statutory instrument it is required in addition that the accident be either recorded in the first aid logbook (minor injuries, incapacity to work for a period of less than three days) or notified to the responsible statutory insurance body.

1.4. Permanent workplaces

Well-trained permanent employees must be available in adequate number for the scope of the production. Permanent workplaces should be avoided in the area of centralized cytostatics production. Pursuant to, however, the number of persons potentially exposed should be reduced to a minimum.

1.5. Occupational preventive medicine

Employees working in the area of cytostatics production in the pharmacy are dealing with potential carcinogenic, mutagenic and reprotoxic (CMR) drugs. They must be offered regular occupational medical check-ups taking into account all the relevant factors at the specific workplace. These check-ups include:

1. Initial examination before taking up employment.
2. Follow-up examinations during the employment at intervals of 1 to 2 years.
3. Examinations at the request of the employee if there is a suspicion of work-related impairment to health.

It is recommended that the follow-up examinations include biomonitoring to test the effectiveness of the existing protective measures.

Exposure to cytostatics must be documented by the employer in a suitable form. This documentation must include the types and amounts of cytostatics used and the frequency of their preparations for each employee handling these drugs. Furthermore, a continuous use of technical and personal protective measures has to be ensured by implementing standard operating procedures regarding compounding, disposal, and clean-up of cytostatics as well as cytostatics-related accidents and their acute management.

1.6. Training, continuous education and professional specialization of employees

The goal of training, continuous education and professional specialization is to provide personnel with theoretical knowledge and practical skills.

Theoretical knowledge:

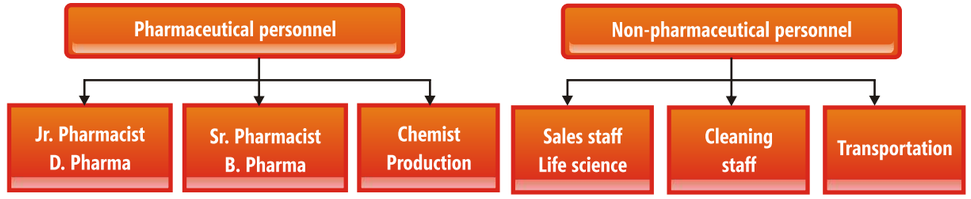
- Rules and regulations
- Safe handling of hazardous substances
- Hazards and protective measures
- Accident prevention and acute management
- Emergency management
- Disposal of contaminated material
- Drugs and dosage forms
- Stability and incompatibility
- Working in an aseptic area
- Drug effects and pharmacology
- Clinical pharmacy
- Pathology
- Departmental and organisational responsibilities
- Quality assurance
- Personal protective equipment

Practical training:

- Product handling after shipment acceptance
- Aseptic working techniques and their validation in simulations of work flow during compounding
- Handling of disposable articles
- Simulation of accidents and their acute management
- Checking cytostatic prescriptions
- Handling different documentation systems
- Packaging, distribution and disposal
- Handling a decontamination set

PERSONNEL INSTRUCTIONS (GUIDELINES)

WHO



WHAT

Training for dealing with hazardous substances and biologicals

- Effects of drugs
- Proper procedures and protective measures for dealing with hazardous substances
- Aseptic technique
- Disposal of contaminated materials, devices and residues of cytostatics
- Occupational preventive medicine
- Action in the case of accidents

WHERE

Pharmaceutical industry
- **WRITTEN working instructions**
- **ACCIDENTS should be documented**

Hospitals

Pharmacy chain
- **Stockist**
- **Distributor**
- **Retailer**

HOW

Proper procedures
- Definition of the work areas to be evaluated
- Ascertainment of hazards and burdens
- Evaluation of these hazards and burdens
- Specification of the necessary measures
- Testing the effectiveness of the measures
- Documentation

Disposal of contaminated materials
- Name of the hazardous substance
- EU number
- Classification of the hazardous substance with R and S phrases
- Range of quantities of the hazardous substance in the establishment with location
- Comments

Occupational preventive medicine
- Initial examination before taking up employment
- Follow-up examinations during their employment at intervals of 12 to 24 months
- Examinations at the request of the employee if there is a suspicion of work-related impairment to health