Storage and transportation of pharmacy compounded drugs

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Barbara Wimmer,
barbara.wimmer@gespag.at
Conflict of interest:

- nothing to disclose
1. Receipt of goods
2. Transportation into storage rooms
3. Storage
4. Compounding of the drugs
   • Transportation to final users/wards
1. Receipt of Goods
2. Transportation into storage rooms
3. Storage
4. Compounding of the drugs
   • Transportation to final users/wards
1. Receipt of goods
(flow of material is defined via SOPs)

How can we make sure nothing is transferred into our cleanrooms that is inappropriate?
Receipt of goods

- Delivery of defined material (drugs, solvents and consumables)

Inspection for
- Correctness and
- Integrity
- Sterile products: Certificate (batch)

... Documentation
1. Receipt of goods
2. Transportation into storage rooms
3. Storage
4. Compounding of the drugs
   • Transportation to final users/wards
2. Transportation into storage rooms

• Storage
  (ensure appropriate storage conditions)
• Unpacking
• Flow of material: SOPs
1. • Receipt of goods

2. • Transportation into storage rooms

3. • Storage

4. • Compounding of the drugs
   • Transportation to final users/wards
3. Refrigerator defect or breakdown

- **In-house building control system** *(surveillance of the refrigerators, temperature, pressure differences...)*
- **Deviation** *(rise out of defined ranges of e.g. refrigerators, cleanroom area): Alarm*, doorkeeper of the hospital gets an alert and calls pharmacy
- If breakdown outside of office hours of the pharmacy: doorkeeper of the hospital alerts engineers, SOPs for emergencies available with the doorkeeper
- Plan where goods are going to be transferred
- Documentation of the deviation
Displays of pressure differences and temperatures within the different parts of the cleanroom area as pass-throughs, storage rooms and locks.
1. Receipt of goods
2. Transportation into storage rooms
3. Storage
4. Compounding of the drugs
   Transportation to final users/wards
4. **Compounding of the drugs**

- Transportation protocol
- Transportation to the wards/final users (in-house or to external hospitals)
Implementation of compounding of cytotoxic drugs into pharmacy premises

**Transportation logistics** of in-house pick up and delivery service

- Analysis of established routes and procedures
- Analysis of needs of end-user (=supplied wards)
- Definition of requirements of end-user
- Definition of new routes and timetables for the pick-up and delivery service
Transportation

Transportation had to be validated

External transportation:
- Ratified contract with the transportation company and the pharmacy
- Time within the span as defined in qualification of transportation boxes

...appropriate temperature
Equipment

On the basis of risk analyses the following documents were generated:

- User requirement specification (to describe the required functions of the device)
- Design specification
- Plan and subsequent report of qualification of the refrigerators and the boxes for transportation
Qualification of equipment

- Definition of the number and positions of the measuring equipment
- Qualification of the refrigerators and the transportation boxes via temperature sensors and data loggers
- Adherence to appropriate and consistent temperature
- Worst case scenarios
Equipment qualification (refrigerator)

Temperature detectors are placed on defined positions
Equipment qualification (refrigerator)

Temperature graphs were analysed
Annual check of the refrigerator

Loaded, data loggers
Annual check of the refrigerator

Without load, data loggers
Annual check of the refrigerator

Moderately loaded, data loggers
Cooling packs used in the transportation boxes
Cooling packs with temperature indicators
Eviter tout contact avec le produit
En cas de contact avec la peau ou les yeux, rincer abondamment avec de l’eau froide uniquement pendant au moins 10 minutes, puis consulter un médecin ou un ophtalmologue sans délai.
En cas de casse, ne pas toucher et contacter +.../.... ........
Les femmes enceintes ou qui allaient ne doivent ni manipuler ni entrer en contact avec ces produits.

Avoid any contact with the product
In case of contact with the eyes and/or skin rinse thoroughly with cold water for at least 10 minutes and consult a doctor or ophthalmologist immediately.
In case of spillage or damage, do not touch and contact immediately +.../.... .... ... Any contact with pregnant or breast-feeding women must be avoided.

Labelling of the transportation boxes
Source: ESOP recommendation for transport of highly potent drugs, the text must be written in the language spoken in the region
Transportation box
Safe disposal of spilt cytotoxics
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (1)

1. Keep calm!
   - Don’t panic
   - People before material decontamination
   - Care for affected people immediately
   - Take off contaminated clothing straight away
   - Keep emergency and clean up “SpillKit” accessible
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (2)

2. Follow instructions!
   - Adhere to workplace and material related operating instructions
   - Proceed systematically in accordance with yearly briefing
   - Cleanup only with trained staff
   - Cleanup with two people

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (3)

3. Wear suitable PPE!

- Protect all people involved
- Respiratory mask, safety goggles, overall or gown, protective gloves, overshoes
- Important: Leak tight respiratory mask
- Note the size of protective clothing
- Gloves: No protection from broken glass

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (4)

4. Seal off and mark scene of accident!

- Block off easily accessible areas
- Widely mark scene of accident
- Protect cross-contamination: close windows and doors, stop people traffic, possibly switch off ventilation system in the laboratory
- Safety cabinet: venting system on

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (5)

5. Observe type of cleanup!
   - Remove broken glass with scoop and sweeper or tongs
   - Take up liquid contamination with wipes
   - Remove powdery contamination with moist wipes
   - Cleaning direction from outside to inside
   - Do not use a hand brush
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (6)

6. Waste into blue disposal bag!
- Broken glass in cardboard box
- Cardboard box, auxiliary and cleaning implements in blue waste disposal bag
- Seal disposal bag
- Multi-stage cleaning of contaminated areas
- All articles: use once only

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (7)

7. Waste bag and PPE in hazardous waste disposal bag!

- Waste bag and protective clothing in the hazardous waste disposal bag
- Systematically remove PPE
- Attention: PPE could be contaminated
- Seal hazardous waste disposal bag
- Waste in need of special monitoring: European waste code: 18 01 08*

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-point-handling-instructions (8)

8. Shower thoroughly!
   - All people involved should clean themselves thoroughly

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (9)

9. Visit a doctor!

- If necessary visit a doctor
- Essential in case of personal injury or contamination
- Document examination

Figure source: www.berner-international.de, April 2012
Safe disposal of spilled cytostatics
10-Point-Handling-Instructions (10)

10. Document incident!
- Write report
- For personal injuries entry in accident book and notice of accident
- Employer has duty of disclosure
- Notice of accident to employers liability insurance association, government safety organisation or staff association
- If necessary inform the occupational safety and company medical officer

Figure source: www.berner-international.de, April 2012
Pharmacy entrance
Transportation boxes are collected here
Good distribution practice (GDP) ensures that the level of quality determined by GMP is maintained throughout the distribution network, so that medicines are distributed without any alteration of their properties.
References

- Useful links:
  http://www.gmp-compliance.org/eca_link_navigator.html

- Guidelines on good distribution practice of medicinal products for human use (94/C 63/03), Good distribution practices (GDP): practices as specified in the European Commission.
- ICH Q9 Quality risk management, 2005.
- QuapoS Quality standard for the oncology pharmacy service, 2009.
- Resolution CM/ResAP on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, 2011.
Thank you very much for your attention!

Source photos: Pharmacy LKH Steyr