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EJHP Practice

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Stability and compatibility of oncology drugs

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Berner International GmbH has been engaged in occupational and drug safety for pharmaceutical and biotechnological application areas for over 24 years. Protection systems for the GMP compliant production and application of potentially toxic aseptic parenteral preparations (e.g. cytostatics) are the core competence of this company.

PPE for cytostatics

The personal protection equipment (PPE) was developed for the especially safe handling of CMR-drugs during production, transport, storage, application, cleaning and disposal.



In particular, these include chemical protective clothing, chemical protective gloves (see figure 1), protective respiratory masks, and protective goggles. All products are type-tested, certified and monitored by a notified body in Germany, based on the EC directive 89/686/EEC [1] and harmonised standards [2-5].

Figure 1: Chemical protective glove **Z⁺** and prep mats **Z⁺** during the production of cytostatics

Laboratory planning and implementation*

Advice, planning and design of ventilation systems, implementation of safety cabinets including the connection of exhaust systems, up to the complete concept as a functional unit 'Safety cabinet – laboratory' are a strength of this company. Laboratory equipment and fittings round the programme off.

Technical services*

Comprehensive technical services for safe and reliable functioning of safety cabinets, product protection cabinets, LAF- devices and ventilation technology. Highly qualified engineers and TÜV person-certified service technicians carry out various tasks including inspections, maintenance, and filter changes up to the determination of the particle purity level [10-13].

Research and development

In order to actively shape the state of the art of science and technology, Berner International GmbH is a member of standards committees and represents or advises several working groups.

Since 2002, this firm operates a unique laboratory in Europe for fundamental examinations of ventilation systems and safety cabinets. Here tests can be performed for, amongst other things, the protective functions of safety cabinets, the so-called personal, product and cross-contamination protection, using the microbiological method.

In addition, Berner International GmbH has initiated or participated in numerous research and development projects.

For the list of references, further information and literature see www.berner-international.eu

* Not available for all countries!

Medical single use items

Comprehensive single use items, such as withdrawal cannulae, tubular foil, light protection pouches, infusion sets, cloths and wipes etc. keep the daily work safe.

Outstanding products are the emergency and cleaning sets, the so-called „SpillKits“. The **BERNER SpillKit XP**



Figure 2: Removal of liquid contamination using the **BERNER SpillKit XP**

(see figure 2) is the only type-tested and certified product in Europe and guarantees the reliable and overall protection for the safe disposal of cytostatic agents at the highest level. The cytostatic prep mats (see figure 1), which have been especially designed for the use in safety cabinets, ensure with their proven 3-layer system an even dispersion, maximum absorption and reliable barrier properties.

Laboratory devices

Cytostatic safety cabinets were first used in 1985, in line with local production in hospitals. The efficient work and product protection cabinets have been consistently advanced and are now in their fifth generation.

The **BERNER FlowSafe**® safety cabinets (see figure 3) guarantee, due to the novel 3-filter-system, innovative detailed solutions and unique ergonomic properties, the highest level of protection for personal, product and cross-contamination.



Figure 3: GMP compliant production of cytostatics, **BERNER FlowSafe**® safety cabinet for cytostatics

An exceptional and proven packaging concept for toxic and **BERNER SealSafe**® infectious laboratory waste is the waste sealing unit. It serves for the collection and aerosol-tight sealing of contaminated waste.

Independent type-testing, certification and regular monitoring based on the German device and product safety law ensures high quality and safety [6-9].

BERNER

the safety system

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Glossar

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Documents and further informations

- Standards: www.beuth.de
- EU directives: www.europa.eu
- German law: <http://bundesrecht.juris.de>
- General: www.berner-international.eu