Material and Methods The dye ingress test with methylene blue was used as CCIT for both CSTDs with ten samples of meropenem drug vials of three brands (n = 60). A media fill test was performed with both CSTDs (n = 300 per CSTD, 150 carried out in a safety cabinet and 150 under non-classified environmental conditions).
Results In all samples of both CSTDs methylene blue was absent after visual inspection and spectrophotometric analysis. The nutrient media of one sample with CSTD A, reconstituted in a safety cabinet, was contaminated whereas none of the CSTD B samples with reconstitution in a GMP grade A environment were contaminated. Under non-classified environmental conditions, one sample of CSTD A and two samples of CSTD B were contaminated.
Conclusion and Relevance In conclusion, both CSTDs connected to meropenem vials of three brands are in compliance with the closure integrity by using the dye ingress. The aseptic procedure of CSTB B was validated with the media fill test when reconstituted in a GMP grade A environment, but failed for CSTD A. The added value of CSTDs in a hospital (pharmacy) remains debatable without a clearly demonstrated closure integrity when bedside reconstitution is done. Hospital pharmacists are strongly advised to perform sufficient and adequate closure integrity tests with CSTDs before implementing them in clinical use.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

3PC-008 SLOW ANAKINRA DESENSITISATION PROTOCOL DESIGN FOR DELAYED HYPERSENSIBILITY REACTION

[1]H Suñer*, [1]M Martín Marqués, [2]O Esteso Hontoria, [2]C Badia Santolaria, [1]A Sanjuán Belda, [1]I Sacanella Anglès, [1]D Pascual Carbonell, [1]S Conde Giner, [1]CJ Cortés Sánchez, [1]A Garcia Molina, [3]L Canadell Vilarrasa. *[1]Hospital Universitari Joan XXIII, Pharmacy, Tarragona, Spain; [2]Hospital Universitari Joan XXIII, Allergology, Tarragona, Spain; [3]Hospital Universitary Joan XXIII, Pharmacy, Tarragona, Spain*

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Background and Importance Anakinra, a recombinant human IL-1 receptor antagonist, is indicated in rheumatoid arthritis (RA) with a good safety profile, nonetheless its administration has been associated with a severe delayed injection-site reaction without a fully understood pathogenesis. To deal with that several desensitisation schemes have been published in the literature.
Aim and Objectives The aim is to describe the design of a slow desensitisation protocol (SDP) for subcutaneous (SC) anakinra for patients who have failed the rapid desensitisation scheme (RDP).
Material and Methods We introduce a 72 year-old patient diagnosed for RA and treated with SC anakinra after failing other treatment lines who presents severe injection-site reactions after 3 weeks of treatment. An attempt was made to desensitise quickly but it was not tolerated either. As there were no more lines of treatment available, it was decided, in collaboration with allergists, to design a SDP.

It was designed for 56 doses of increasing concentrations (until 100 mg dose). Lower dose was 0,1 mg and dose change was performed every 3-4 days. Solutions were elaborated in the Pharmacy Service. Starting from a mother solution (MS) of 100 mg anakinra in physiologic serum 0,9% (SF) to a final volume of 1mL (1:1 solution) two anakinra dilutions were made: 1:10, 1:5. The MS was prepared from anakinra 100 mg/0,67 ml injection. The dilution 1:10 was made by taking 0,5 ml from the MS and SF until 10 ml (concentration 5 mg/ml). The dilution 1:5 was prepared by diluting 1 ml from 1:10 dilution until 5ml final volume with SF (concentration 1 mg/ml).

To prevent hypersensibility reactions it was needed to add antihistamines during the SDP.
Results Although RDP was not well tolerated, the proposed scheme had satisfactory results. At first the lowest dose (0,1 mg) was not tolerated by the patient, so it was decided to add antihistamines during the process. If any dose could react, the dose change was done instead of 3 after 5-7 days. Actually, the patient has completed the doses until 50 mg without adverse reactions.
Conclusion and Relevance The SDP proposed by allergist in collaboration with hospital pharmacist has allowed the safe administration of anakinra, avoiding a loss of the last therapeutic line possible in a patient with RA.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

3PC-009 CYCLOPHOSPHAMIDE SURFACE CONTAMINATION IN A ROBOTIC CHEMOTHERAPY COMPOUNDING PROCESS

[1,2]AC Riestra Ayora, [1]MJ Tamés*, [1]A Iglesias, [1]B García, [1]MJ Argandoña, [1]C Ramajo, [1]O Olariaga, [1]M Urretavizcaya. *[1]Onkologikoa Foundation, Pharmacy Service, San Sebastián, Spain; [2]University of Deusto – Faculty of Health Sciens, Department of Medicine, Bilbao, Spain*

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Background and Importance There is a wild consensus about the risks associated to the occupational exposure to hazardous drugs, but recent studies have shown that there is still surface contamination in pharmacies preparing antineoplastic drugs. The main reason for the implementation of robotic compounding systems is to improve safety; for the patient and for healthcare workers, avoiding repetitive strain injuries and hazardous drugs exposure.
Aim and Objectives The aim of this study was to evaluate cyclophosphamide exposure of pharmacy nurses during the robotic chemotherapy compounding process.
Material and Methods The sampling areas were selected after being identified as the highest risk of personal contamination in a risk assessment. Wipe samples were taken from vials, infusion bags, gloves, and different locations of the robotic system. Surface monitoring was performed using a semi-quantitative device based on thin layer immunochromatography. The sampling was performed at the end of the workday over several days before cleaning process to identify the highest potential degree of contamination to which healthcare workers could be exposed.
Results Cyclophosphamide compounding was performed during the study days and several months before. There was no cyclophosphamide spill in the three months prior to the study. External contamination was measured on 15 vials and 10 bags of cyclophosphamide and on 10 gloves and 5 robot areas after cyclophosphamide compounding during 5 non-consecutive days. There were not Cyclophosphamide contamination over the detection limit of 0.5ng/cm^2 in none of the samples

from the robot; vial, gloves and bags samples were also negative.

Conclusion and Relevance The robotic chemotherapy compounding enables cyclophosphamide preparation with low levels of personal exposure. Cyclophosphamide is a good standard for measuring hazardous drugs contamination because its preparation method, frequency of use and the availability of occupational exposure studies.

To our best knowledge, this is the first study in robotic hazardous drug contamination using a semi-quantitative method. Despite this technology does not allow precise quantification of the amount of HD present the use of semi-quantitative methods could facilitate its widespread determination due to a lower cost and immediacy of results, allowing the implementation of corrective measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-010 FORMULATION OF TACROLIMUS SOLUTION FOR SUBLINGUAL USE

E Kasalova*, S Klovrzova, R Kadlecova, M Hojny. *Institute for Clinical and Experimental Medicine, Institutional Pharmacy, Prague, Czech Republic*

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Background and Importance Tacrolimus is an immunosuppressive agent used in solid organ transplantation (SOT) for prophylaxis of rejection. In our hospital SOT are performed including rare multivisceral transplantations (MTVx). There are clinical situations when oral tacrolimus can not be administered to the MTVx patient because of a non-functional bowel. In home care, patient could be treated with tacrolimus for sublingual use. There is no commercial product for sublingual administration available, so formulation has to be developed.

Tacrolimus is practically insoluble in water; however, suspension can be prepared using tacrolimus capsule powder content. This formulation is unstable with risk of sedimentation, therefore uniform dose can not be achieved. We used solubility of tacrolimus in ethanol and prepared the homogenous sublingual solution from substance.

Aim and Objectives To formulate solution of tacrolimus 10 mg/mL based on ethanol and glycerol. To describe the preparation, container, storage conditions and shelf-life of tacrolimus solution for sublingual use.

Material and Methods Tacrolimus belongs to hazardous drugs, H 361. Biological safe cabinet (BSC) is recommended for tacrolimus preparation.

Solution was prepared using the glass beaker and stick. Tacrolimus was dissolved in ethanol 96%, then glycerol 85% was slowly added. The citric acid was used to adjust pH 5-6, optimal for stability of tacrolimus. Orange flavour was added for higher palatability. The amber glass container with adapter for oral syringe was used.

Results Turbid and homogenous solution with orange scent and pH 6 was obtained. Concentration of tacrolimus was 10 mg/mL. Shelf-life of 30 days was given, stored in 15°C–25°C according to the USP <795>. Oral dosing syringe was used to apply the sublingual solution.

Conclusion and Relevance The formulation of tacrolimus was developed. Variety of concentrations of tacrolimus solution may be prepared. This allows us to prepare solution with higher concentration with the same volume, if needed. Our MTVx patient had a good tolerance to this solution. He has taken this solution since November 2021 and has remained stable without rejection of transplanted stomach, liver and pancreas.

It is necessary to work fast, because of an air flow in BSC, the ethanol evaporates and the solution may precipitate. Clinical effectiveness might be investigated to confirm the utility of this formulation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-011 A VIRTUAL STERILISATION AREA: AN INTERACTIVE TRAINING TOOL

A Crou*, D Boden, P Perot, G Desautez, V Chevalet, R Schofield, A Ghazouani. *Hôpital Marie Lannelongue, Haut-De-Seine, Le Plessis-Robinson, France*

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Background and Importance The training of sterilisation technicians represents a major challenge to ensure the safety, security and limit the contamination of reusable medical devices.

Aim and Objectives The objective was to develop a tool to ensure basic and continuous training of sterilisation technicians, taking into account their professional backgrounds and skills.

The tool aims to contribute to the integration of newcomers and the standardisation of training, which currently is mainly done through mentoring.

Material and Methods A training booklet was developed, covering the different stages of the sterilisation process. It was used as a basis for the realisation of instructional videos, showing the entire sterilisation process.

The videos were then included in a virtual blueprint of the sterilisation area made with 3D mapping software.

Results The guide was written following the French Sterilisation Guidelines and the internal practices of the technicians. It was divided into 4 main parts, corresponding to the different steps of the sterilisation circuit, which are: individual outfitting of technicians, washing of the medical devices, assembly of the sterile boxes, and unloading systems for autoclaves.

These parts were illustrated by 4 videos, which were integrated into the different rooms of the 3D layout. A 3D layout was created with Kozikaza®, 3D mapping software, from the measured blueprint of the sterilisation area. It replicated the technicians' work environment as realistically as possible. To complete their virtual training, the agent decides either to follow the classic circuit or to choose one step specifically. Then, they click on the hyperlink in the virtual room which refers them to a video corresponding to the step of the circuit.

Conclusion and Relevance This interactive tool allows catering to different professional backgrounds, taking into account the technicians' preferences regarding training methods. It enables an improvement of the quality of the circuit, of sterilisation practices, and facilitates the training of sterilisation technicians. This training, systematically offered to employees upon their arrival and annually to the whole team, will be evaluated to identify their needs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest