## Pharma & Hospital Pharmacy

### Risk Management for Development of Safe Pre-Use Post-Sterilization Integrity Testing (PUPSIT) Strategies

*Alain Vanhecke, Pall Life Sciences, Belgium*

The Pre-use Post-sterilization integrity testing on the final sterilizing grade filter before filling is a EU GMP requirement in Annex 1 since 2007. This test will remain in the revised version of Annex 1 that is expected to go for public consultation early 2018. While this test is allowing for the detection of marginal filter defects before running the filtration, a significant part of the industry is considering it as a higher risk for contamination of the filtered product. Starting with the current regulatory specifications and the justification for this test, the speaker will present on the Risk based strategies that have been successfully developed by a filter manufacturer for an easier implementation of PUPSIT in single-use systems and the mitigation of the risks associated with this test.

### General Requirements for Good Projecting of Facilities through GMP

*Esa Högel, Alpiq InTec Switzerland Ltd., Switzerland*

There are different alternatives in cleanroom constructions for flooring, walls, doors, windows and ceiling. The customer preparation for coming project is needed and should be agreed: customer room card, technical parameters of cleanrooms and medias for process equipment, the room parameters of cleanrooms (T, H, Pa), summary of medias for process equipment (Equipment Utility Matrix), supplier quota-tion, clear definition of interfaces and time schedule. The customer control practice about suitable supplier for the project includes: similar references from same customer field and from last two years, enough sufficient technical and financial resources, competitive prices and purchasing procedures, own QA-department and is able to show about own qualification procedures some, references, knowledge about local and global requirements of authorities, quality certificate ISO 9001, audited suppliers, competence and common understanding about customer process etc.

## Hospitals

### Air Distribution in Hybrid Operating Rooms

*Kim Hagström, Pekka Kanerva & Ismo Grönvall, Halton Oy, Finland*

Unidirectional downflow common in conventional operation rooms aims to reach protected zone below UDF-plenum This, however, is not realized in most operations. The challenges of fitting UDF-plenum into the physical installation and inability of vertical down-flow to reach critical areas obstructed by devices is present especially in hybrid operating rooms. In a hybrid cardiac catheterization lab for example, a C-arm and other devices are attached to ceiling and operational instruments are prepared further away from the operational area. Thus, the clean area to be covered is more than just the area around operating table. Halton Vita OR Space 5 solution, a smart controlled-dilution flow provides the ultraclean conditions into the whole operating room. It has gone throughout verification by simulated operations for conventional operating rooms. Solution has also been applied to various Hybrid operating rooms with a success. This presentation discusses the specific challenges of hybrid operating room ventilation design compared to conventional general-purpose operating rooms. A specific design example and a comprehensive pre-verification using CFD is presented. The simulation confirmed that even for a very complex procedure, Halton Vita OR Space 5 can enable operational cleanness in all hygienically critical areas, which outperforms the conventional alternatives.

## Food & Biotech

### Good Manufacturing Practice in the Food Industry – Requirements in Manufacturing Unit Design

*Riina Brade, Elomatic, Finland*

Good Manufacturing Practice or GMP is a term that is recognized worldwide for the control and management of manufacturing, as well as the quality control of foods, pharmaceutical products, medical devices, and even packaging and materials that come into contact with food. EU GMP guidelines include EudraLex VOL 4 Good Manufacturing Practice (GMP) and for food manufacturing the code of practice and hygiene published originally by Codex Alimentarius. With the above-mentioned guidelines and related legislation, as well as with the support of manufacturers' hazard analyses and risk assessments, the minimum requirements are set which manufacturers must meet to safeguard the health of consumers and produce good quality food. So, what is the challenge?
The GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company sets up its quality program and manufacturing process, it can fulfil GMP requirements in many different ways. It is the company's responsibility to determine the most effective and efficient procedures, facilities, materials, equipment and controls.

### High Quality Ph. Eur. Water by Membrane Technology

*Reijo Ahonen, Veolia WaterTechnologies, Aquaflow, Finland*
The European Pharmacopoeia is responsible for compulsory quality standards throughout the pharmaceutical industry in Europe. It is used for controlling the legal and scientific quality of medicines, and the ingredients used to develop, manufacture and market them. European Pharmacopeia Monograph Water for Injections (0169) was taken under revision to re-determine the specifications of production. Since April 2017 European Pharmacopeia allows generation of WFI by non-distillation methods such as double-pass reverse osmosis (RO) coupled with other suitable techniques. The decision was based on survey, expert workshops and multidisciplinary forum involving various stakeholders. The new monograph states that correct operation monitoring and maintenance of system are essential to ensure the appropriate quality of water.
Distillation techniques have traditionally been considered less risky than reverse osmosis-based systems due to biofilm formation. Hot water sanitization (HSW) membrane systems can control the biofilm formation and tied with adequate control system offers low risk solution. In order to assure the quality of produced water, technologies such as ultrafiltration, electrodeionization and UV-treatment should be considered during the design phase. Distribution and storage systems should be designed to allow thermal sanitization as a routine. Any system for Water for Injection, regardless of technology must be designed by experienced company in accordance with regulations. Installation and validation are followed by careful monitoring and maintenance to a high standard.