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Content and Abstracts

In situ study of particles generated from the use of pharmaceutical grade cleanroom wipes

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Cleanroom wipes, saturated with disinfectant, are commonly used within pharmaceutical grade cleanrooms as part of contamination control programmes. Whilst standards are in place for the testing of wipes for particle shedding, there is limited data relating to the particle generation from wipes when they are used in practical conditions. This paper outlines a study of the particles generated as three different cleanroom wipes were used. The study was undertaken within an isolator in order to minimise the background particle levels. The study showed that cleanroom wipes designed for ISO class 5/EU GMP Grade A use are suitable for those areas, but that wipes which are not certified for use in higher grade cleanrooms should not be used in such areas due to the high level of particles generated.

Key words: Cleanrooms, wipes, particle counts, contamination control, pharmaceutical manufacturing.

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Working height velocity measurement in conventional cleanrooms

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The purpose of this article is to share the methods and results of technical studies conducted to select an appropriate anemometer, methodology, and acceptance criteria to perform routine working height velocity (WHV) checks.
A thermal anemometer was selected for its capability to measure low velocities and was determined to be acceptable for this application. WHV acceptance criteria were determined for critical locations. The testing ultimately concluded that velocity measurements at the HEPA filter protective grill are a better indicator of unidirectional air flow hood performance than velocity measurements at working height due to inconsistency in velocity readings at the working height.

Key words: Working height velocity, cleanroom, thermal anemometer, HEPA filter, unidirectional air flow, UAF, smoke test.

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Science and Technology Feature

The closed vial technology: a new way of thinking in aseptic filling

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Aseptic filling is a risky process but also one of the most complex in the pharmaceutical industry. To reduce complexity while improving quality for the patient, a new concept must be imagined. The closed vial technology has been developed to address these two main issues. The objective is to aseptically fill a container with sterile solution, and the closed vial technology has introduced several innovations to address these challenges currently faced by the pharmaceutical industry, i.e. to reduce the risk of contamination for the patient, to simplify the filling process and to provide an easier solution to the healthcare providers. The vial is supplied closed and sterile, i.e. ready-to-fill, the filling is performed with a needle passed through the stopper and the piercing hole is laser re-sealed to restore the closure integrity. To meet the new process challenges (e.g. cleanroom manufacturing, laser re-sealing), the vial has been adapted with dedicated vial body, stopper and cap materials.

Key words: Closed vial, aseptic filling, polymer vial, laser re-sealing.

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Content and Abstracts

Evaluation of the GEN III OmniLog® ID System microbial identification system for the profiling of cleanroom bacteria

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Accurate microbial identification is of importance in assessing product and environmental risks in pharmaceutical manufacturing. Identification is important to assess the origin of contamination and to formulate corrective actions for contamination events. Many of the systems available either require manual manipulation and subjectivity in reading, and are, therefore, prone to errors, or consist of databases than err towards the clinical setting. This paper outlines the validation steps for the evaluation of a microbial identification system capable of screening industrial microflora: the GEN III OmniLog® ID System.

Key words: Cleanrooms, microorganisms, microflora, microbial identification, OmniLog, phenotypic, corrective and preventative actions.

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Facilitating efficient equipment cleaning

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This article explains the importance of action, or surface impact, in the design of equipment for bioprocessing systems. The "time, action, chemistry and temperature" (TACT) concept explains how systems and equipment can be optimised to improve efficiency as well as safety and consistency in the cleaning cycle. A simple test shows how savings of up to 90% can be made on both time, energy and cleaning liquids together with improved cleaning of the system.

Key words: Equipment cleaning, static spray balls, rotary jet heads, equipment cleaning procedures, Time, Action, Chemistry and Temperature (TACT) concept, tank cleaning, dead legs, hygienic design, pharmaceutical cleaning.

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Science and Technology Feature

Suggestions on setting detection limits for new microbiological methods

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Various new microbiological methods have been introduced into the pharmaceutical industry for environmental monitoring. Microbial counts using the new methods can be significantly different from those using conventional growth methods. This article suggests a procedure to set alert and action limits for these new methods. In addition, a graphic format, Control Chart, is proposed to display the microbiological data.

Key words: Microbiological test, alert and action limits, statistical process control.

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Applied membrane air filtration technology for best energy savings and enhanced performance of critical processes

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Strict demands are put on high-efficiency particulate air (HEPA) and ultra-low penetration air (ULPA) filters that are installed as terminal filters in classified cleanroom environments. They need to guarantee that predefined air quality requirements are consistently met so that process efficiency is optimised and product quality is assured. With the increased focus on environmental performance, either stimulated by legislation or as an integral part of the business model, the contribution made by air filtration towards meeting sustainability targets has become much more important. This paper describes how the latest generation of expanded poly-tetra-fluor-ethylene (ePTFE) membrane media supports realising both objectives. It sets out how air filters with ePTFE membrane media provide a significant reduction in energy consumption and it presents the results of a new study on the superior mechanical strength of ePTFE membrane media over traditional fibreglass media. Based on a cycle of four different tests, executed at the ÖP textile testing laboratories in Germany, it is demonstrated that ePTFE membrane media offers a significant improvement in reducing media failure risk for a retained filter integrity. By installing HEPA and ULPA filters with ePTFE membrane media, critical applications working under controlled conditions, such as the pharmaceutical and microelectronics industries, are able to reduce process risk and improve output quality.

Key words: Cleanroom air filtration, ePTFE membrane media, traditional fibreglass media, energy efficiency, mechanical strength, risk reduction, Discrete Particle Counter, Aerosol Photometer.

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Optimal conditions for the recovery of bioburden from pharmaceutical processes: a case study

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Bioburden testing is an important part of pharmaceutical microbiology and provides data in relation to the quality of pharmaceutical products during manufacture. Little guidance is provided in relation to test methodology, culture media and incubation parameters. The quality control laboratory, therefore, needs to establish the most appropriate method. This paper outlines a case study for the selection of incubation parameters for the bioburden assessment of in-process samples using the Total Viable Count technique and pour plate method. While the outcome of the experiment contained within the paper relates to a specific set of processes, the approach taken can be used by other laboratories to compare or to develop their test methods and techniques for bioburden determinations.

Key words: Bioburden, contamination, microorganisms, in-process, total viable aerobic count, pour plate, agar, incubation.

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Science and Technology Feature

How to deliver an aseptic suite on time and to budget

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Twelve NHS aseptic suite projects across the North East and Yorkshire were critically evaluated. Of these, only two were delivered on time and to budget. The analysis was used to develop a successful plan for a new Aseptic Dispensing Unit. Recommendations are made using experience gained to illustrate how diligent planning and design can deliver a successful and satisfactory cleanroom suite avoiding unnecessary confrontation, unanticipated outcomes and subsequent costly delays. A seven-stage plan was developed that can be adopted for any similar future project.

Key words: Plan, new, refurbished, NHS, aseptic suite, project.

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Content and Abstracts

A study of the influence of variables in air velocity measurement in a unidirectional air flow device or environment

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In clean devices and environments, for which the unidirectional air flow (UDAF) is an important factor for contamination control, air velocity and uniformity are parameters to be checked and maintained to ensure containment. This study seeks to show that there are several factors of influence in measurement methods currently used in the field, which are usually neglected in the procedures utilised.

Key words: Uniformity of air velocity, unidirectional air flow, methods for measuring air velocity, UDAF, anemometers, laminar air flow, LAF.

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Results from a Swedish survey – investigations in operating rooms

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A survey is presented with data from 27 operating rooms in four county councils, where air flows, concentration of airborne viable particles and used clothing systems have been given from 111 ongoing surgeries. With the results from the survey, a simple mathematical expression based upon the dilution principle has been established to predict the concentration of airborne viable particles present in the operating room during ongoing surgery. This expression has shown relatively good agreement with reported results from ongoing surgery.

Key words: Airborne viable particles, air flows, clothing systems, ongoing surgery.

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Science and Technology Feature

Pharmaceutical cleanroom technology: forthcoming trends

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Numerous elements will influence the development of pharmaceutical cleanroom technology in the years to come. Regarding the regulatory aspect, the implementation of the International Conference on Harmonization guidelines ICH Q8–Q10 into the world's good manufacturing practice guidelines is first priority. Technically, the increasing relevance of personnel protection, the worldwide breakthrough of isolator and restricted access barrier technologies in aseptic filling as well as the advances in rapid microbiological methods are particularly worthy of note. Prominent attention, however, should also be focused on the optimisation of the energy consumption of contamination control systems.

Key words: Pharmaceutical contamination control systems, quality by design, risk assessment, personnel protection, RABS and isolator systems, isolators for single use, rapid microbiological methods, global warming, optimised energy concepts.

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