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CLEANROOM TECHNOLOGY

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One of the manufacturing lines built to cGMP requirements

BUILDING QUALITY INTO CONTAMINATION CONTROL PRODUCTS

To be fit for purpose contamination control products must be manufactured to the strictest of standards. ***Ecolab Contamination Control*** *describes how investment at its high-tech facilities is ensuring it can more than meet these requirements*

The preparation and manufacture of contamination control products for use in cleanrooms is a critical process, with no room for error. Processes need to adhere to the most stringent standards and remove any doubt about the validity of products or compromise existing procedures and protocols, all within an environment that is fit for purpose.

Early in 2014, Ecolab Contamination Control, part of the global Ecolab group, committed to creating a new mark of assurance that would highlight to customers that its manufacturing facility adheres to the same industry guidelines that they do.

After 15 years in high quality cleanroom manufacture, it broke industry ground by introducing this new assurance mark, which it calls Process Match.

'Process Match shows that we are totally confident in our own manufacturing processes which take place in cleanrooms and are directly comparable to those of our customers, giving them complete peace of mind,' said James Tucker, Marketing Director at Ecolab Contamination Control. 'When customers see the assurance mark they will know immediately that the way we manufacture products is as carefully monitored as their own.

'We have had many companies audit our manufacturing facility and we welcome this interaction with all our customers.'

Ecolab Contamination Control is a leading provider of premier contamination control solutions for life science cleanrooms worldwide. Its fully validated range of both sterile and non-sterile products is produced in a purpose-built facility in Baglan, South Wales to the requirements of cGMP, using automated processes which reduce product variability.

The bespoke facility emulates the critical manufacturing standards of the pharmaceutical industry and with its reputation for highly innovative manufacture is the benchmark for the contamination control industry.

The 'Centre of Excellence for Contamination Control' was developed and launched in 2008, with the objective of replicating the requirements of external pharmaceutical and medical cleanrooms. At nearly 50,000ft² (4,645m²), with a 16,000ft² (1,486m²) production facility, it is four times that of its predecessor and is

Centre of Excellence for Contamination Control

- **Facility size 4,645 m²**
- **Production facility 1,486 m²**
- **Fifteen cleanrooms**
- **Grade A laminar airflow is utilised at point of aseptic fill**
- **Grade B, C and D providing 40, 25 and 15 air changes respectively, per hour, across the operational cleanroom network**
- **Advanced intercom system**
- **400,000 litre sprinkler system incorporating discreetly located sprinklers in the cleanroom ceilings**

MADE IN CLEANROOMS PROCESS MATCH FOR CLEANROOMS

housed on a site with ample space for future expansion. The facility also includes laboratory areas for product testing.

It is now home to more than 100 staff, together with some of the most innovative technology in the industry. It has ISO 9001 and ISO 13485 accreditation and Medical Device Directive 93/42/EEC for the manufacture and distribution of sterile and non-sterile cleanroom products.

In total there are 15 cleanrooms within the facility, five of which form the main production areas with the remainder allocated to preparation and changing rooms. Grade A laminar airflow is utilised at point of aseptic fill with Grade B, C and D providing 40, 25 and 15 air changes per hour respectively across the operational cleanroom network.

Other innovative features include an advanced intercom system to enable two-way conversations from both sides of the cleanroom, helping to minimise risk of contamination and improve quality.

The change areas and preparation rooms also feature a high specification and use different coloured flooring to highlight clean and dirty areas, based on the '5S System', which provides a methodology for organising, cleaning, developing and sustaining a productive work environment. A 400,000 litre sprinkler system incorporating discreetly located sprinklers in the cleanroom ceilings ensures a compliant level of cleanliness is sustained. The sprinkler system also serves the warehouse, office suites and corridors.

Cellular production layout

Production has been segregated into cellular manufacture, encompassing U-shaped workflow designs, while dedicated resource and equipment maximises working efficiencies and delivers best practice.

Automated equipment commissioned in the facility includes multi-head automatic liquid filling, torque tightening, labelling and conveyance for both Sterile Fill and Terminally Sterilised products. Many of the handling features are also automated, including transfer conveying, loading systems, vacuum-lift palletisers, pallet shrink wrappers and bagging systems.

The blending suite is furnished with two 5,000 litre stainless steel vessels and two 5,000 litre PVC vessels and three 1,000-litre stainless steel blending tanks. The facility can also now produce 800 litres per hour of Water-For-Injection (WFI), manufactured via distillation at

Right: The bottling line. Below: New external tanks at the Baglan plant give increased storage capacity for IPA and Denatured Ethanol

the highest standard, in line with the European Medicines Agency Reflection Paper on WFI. It also has provision to store water once produced in a 10,000 litre tank. The annual three shift production capacity for compounds is 5,500 tons and equipment at 28,000 cases.

Next year will see major investment in the latest automation processes as Ecolab Contamination Control grows to meet its global expansion through a strategy of lean manufacturing and continuous improvement.

As part of its focus on delivering best practice, Ecolab Contamination Control is also firmly committed to ensuring full compliance with the latest regulations affecting both its customers and its own manufacturing processes. This is supported by an investment to date of more than US$1m and a dedicated in-house team of regulatory experts.

This strategic approach comes at a time when recently introduced and future EU guidelines put manufacturers under greater scrutiny than ever before and raise the stakes for the consequences of non compliance.

These include the need to pre register all chemicals under REACH (the Registration, Evaluation, Authorisation and Restriction of Chemicals). REACH requires products to be registered with the European Chemicals Agency (ECHA).

Any product registered with the Biocidal Product Regulations (BPR) is assumed to be compliant with REACH and is therefore part of the authorised list of active substances, acceptable for use in biocides from the BPR. The BPR is the successor to the Biocidal Products Directive and it ensures that companies register their products for authorisation by the ECHA. The aim is to ensure a high level of protection for human health and the environment as well as simplification and harmonisation of biocidal products registration across the EU.

Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. This also applies to the purchase of raw materials with the intention of using them to biocidal effect, in-house.

Tucker concludes: 'In an industry which is traditionally risk averse it is vital that all companies review their procedures and supplier arrangements like never before.

'With the expertise of our team, investment in regulatory compliance and the manufacturing capabilities at our disposal, Ecolab Contamination Control is already ahead of the game as regards new regulatory guidance.

'This means we are able to give our customers the peace of mind that they are not going to fall foul of the regulators, while delivering contamination control, without compromise.'

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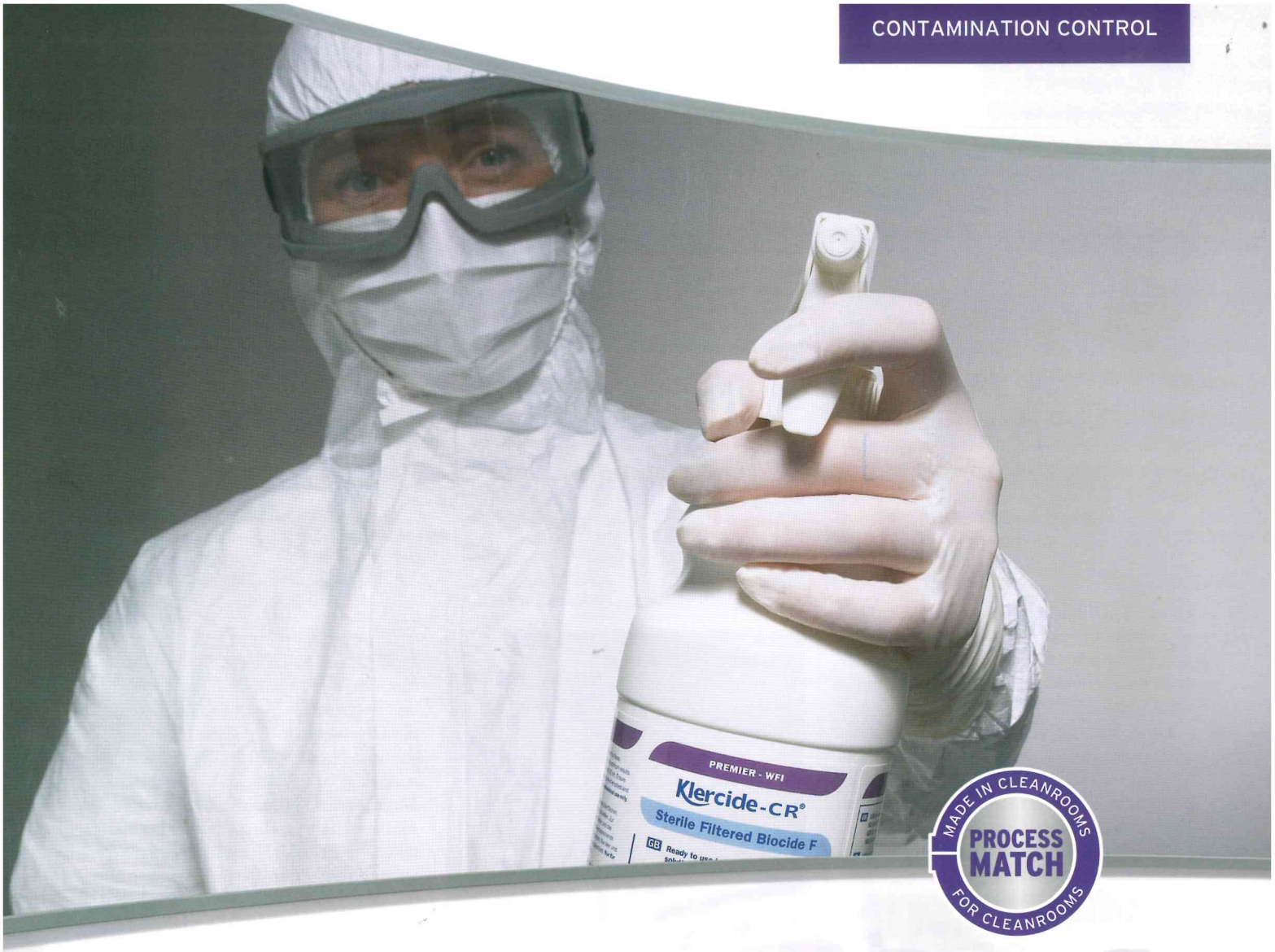


Hands Up If You're Ready!

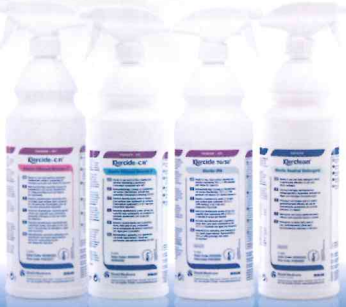
Uncompromising. That sums up the new regulations and guidelines coming into force, requiring pharmaceutical manufacturers to have an implementation strategy in place.

A number of recent guidelines from the MHRA and the Pharmaceutical Inspection Cooperation Scheme, along with proposed changes to EU guidelines for GMP, represent a shift in regulatory expectations for cleanroom facilities.

The new recommendations include adding a sporicidal agent to current 'spraying in'[1] procedures, and support the use both of endotoxin tested products and a closed dispensing system[2] for disinfectants in cleanrooms to minimise risk.

Fortunately, Ecolab's expert team won't compromise on contamination control either and can use all their expertise to help your facility prepare with a full range of products and services that directly addresses these requirements. Aside from a fully validated product range, Ecolab offer SiteCheck - the free, no obligation site review service - and the DDE system - to establish disinfection best practice.

So with Ecolab, you're always ready.



Our unrivalled range of alcohol & biocide sprays all feature our unique SteriShield Delivery System (SDS).

As the only fully validated trigger spray system compliant with the new MHRA guidelines, the SDS can further reduce the possibility of risk. Visit ecolabcc.com for more details.

TO FIND OUT HOW WE CAN HELP CONTROL CONTAMINATION IN YOUR FACILITY, PLEASE CONTACT YOUR ECOLAB CONTAMINATION CONTROL EXPERT, EMAIL US AT INFOCC@ECOLAB.COM OR CALL +44 (0)2920 854 390

CONTAMINATION CONTROL WITHOUT COMPROMISE

USE BIOCIDES SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

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New regulations are not just affecting you but they are also coming into force for your cleanroom products supplier.

At Ecolab Contamination Control, we are ready... is your supplier?

ECOLAB®
Everywhere It Matters.™

1. PI 007-6 PIC/S 2. MHRA Guidance for MS Holders Version 1, App 2, Sec 3. 5.20