Test results
Blue light in pharmaceutical manufacturing
September-October 2023

Substantial and persistent reduction of microbial burden in a personnel cut-off room within a pharmaceutical facility following the implementation of automated and continuous Spectral Blue™ disinfection

A leading international pharmaceutical company conducted a comprehensive evaluation of the automatic and continuous Spectral Blue™ disinfection system at one of their manufacturing facilities in the Nordics. The touch-free, UV-free, and chemical-free system uses patented multi-wavelength blue light technology to eradicate airborne and surface-dwelling microbes.

The observed outcomes were unparalleled. The application of Spectral Blue in the cleanroom facility not only **i) substantially diminished contamination but also ii) enhanced the efficacy of the existing cleaning and disinfection protocols.**

1. Summary of results

- Microbial surface contamination, as measured, decreased from over 200 colony-forming units (CFU) per 25 cm^2 to fewer than 20 CFU per 25 cm^2 throughout the testing period.
- A distinct downward trend in microbial contamination was observed during the test period.
- The reduction proved to be persistent, remaining noticeable even after deactivating the blue light system. A plausible explanation is that Spectral Blue eliminated dry biofilms in the room, subsequently enhancing the effectiveness of traditional cleaning methods.

2. Background

The aim of the test was to assess the potential impact of deploying the Spectral Blue system on measured microbial contamination.

The evaluation took place in a frequently utilized personnel cut-off room, designated as class D cleanroom zone. This room is situated between a laboratory area (class F) and a production area (class C).

The company conducted environmental microbial sampling in the room before, during, and after the test. Previous microbial surface samples taken in the room had exhibited occasional spikes and variability, prompting the quality management team to explore new contamination control methods.

3. Test setup and data collection

The room was equipped with two Spectral Blue devices (plug & play series) and a Spectral Blue control module featuring a motion sensor and an hour calculator. The system was configured for continuous disinfection, allowing the control module to activate blue light disinfection automatically whenever the room was unoccupied. The operating hours were recorded on a weekly basis.

For the microbial surface sampling employed as the test method, the company utilized the same approach as part of their regular contamination control practices, with only the sampling frequency increased. Samples were collected and analyzed by the company's own laboratory.

Over a period of 22 calendar days in September-October 2023 (excluding weekends), microbial surface samples were taken from the floor using 25 cm^2 contact plates. The chosen sampling site remained consistent throughout the entire test period.

Throughout the test, the company kept its standard mechanical cleaning and chemical disinfection processes unchanged. The personnel cut-off room continued its normal usage, with a comparable level of foot traffic as during other times. This approach allowed any observable reduction in microbe levels to be attributed specifically to the blue light disinfection.

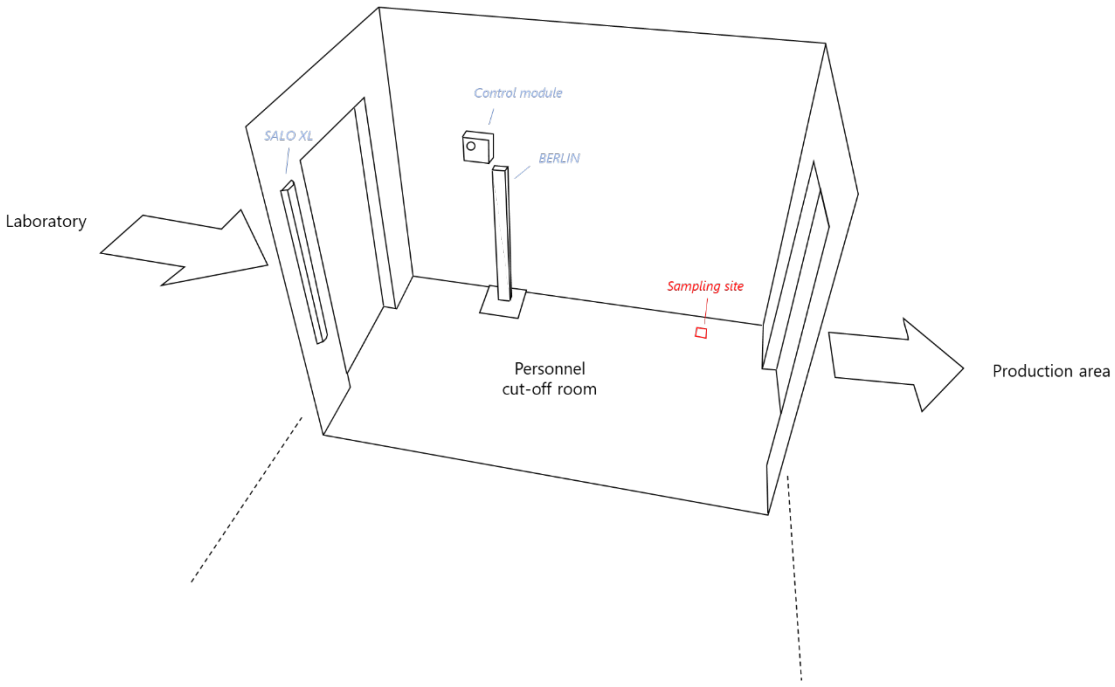

Figure 1: Test setup – a personnel cut-off room equipped with Spectral Blue devices.

4. Results

Over a span of 22 days, there was a substantial reduction in measured colony-forming unit (CFU) counts, decreasing from over 200 CFU per 25 cm^2 to fewer than 20 CFU per 25 cm^2, displaying a distinct downward trend (see figure 2).

The newly attained CFU levels now fall well below the company's alert threshold. Once reaching these lower levels, they consistently remained very low and continued to improve gradually.

These results affirm that continuous disinfection provided by Spectral Blue effectively diminishes contamination, even within ultra-clean environments. The system proves effective against microbes that are challenging to eliminate using traditional methods.

Drawing from other research in the field, a significant portion of contamination identified in cleanrooms can be traced back to personnel cut-off rooms and gowning rooms. The application of Spectral Blue in these areas serves as an effective preventive measure against the risk of contamination entering production areas.

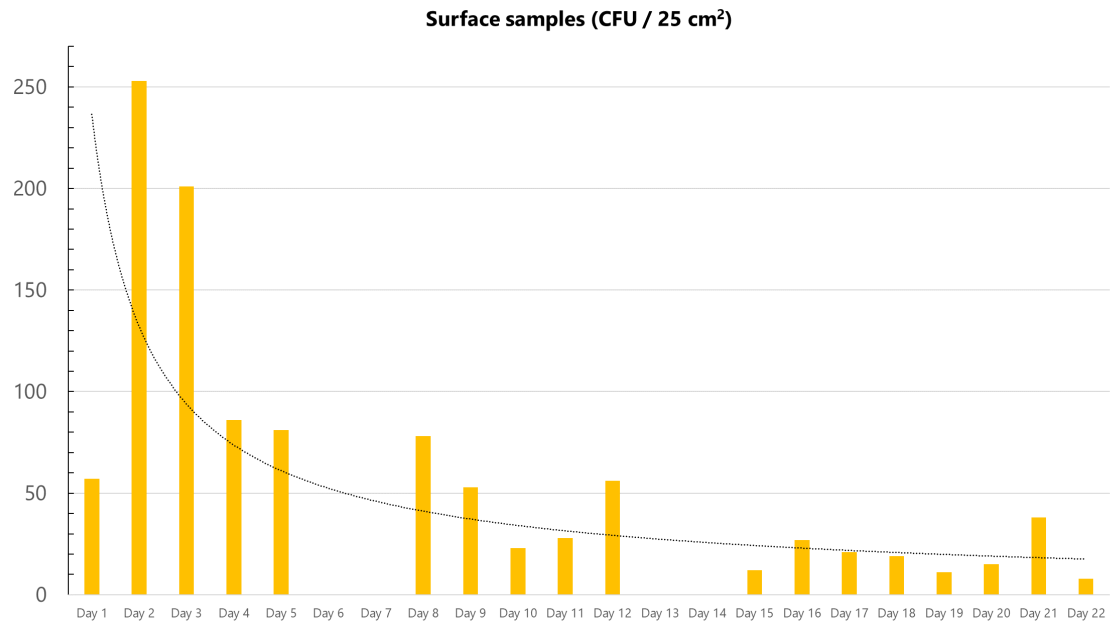

Figure 2: Measured microbial burden in the cut-off room during the active use of Spectral Blue.

5. Persistent effect attributable to elimination of dry biofilms

An additional noteworthy discovery in the test was that, even after deactivating the test system, microbial contamination levels remained remarkably low in subsequent measurements taken 2-3 weeks later.

This persistent effect can be plausibly credited to Spectral Blue's capability to eliminate biofilms from the surfaces in the room. In this case, the biofilms in question can have been so called dry biofilms, that can form for example around chemical residues.

Eliminating the biofilms then enabled the standard cleaning and disinfection practices, which are generally less effective against biofilm, to demonstrate improved performance, maintaining the room at a consistently high level of hygiene.

6. Further remarks and discussion

The results observed in the test suggest the potential for cleanroom operators to reduce reliance on hazardous chemical disinfectants, thanks to automatic Spectral Blue disinfection.

An enhanced contamination control process would involve cleaning surfaces with a detergent and continuously disinfecting using multi-wavelength blue light.

An often-overlooked aspect of chemical usage is the tendency to leave residues on surfaces, creating a growth platform for microorganisms (forming a so-called dry biofilm). When fewer chemicals are used, the impact of dry biofilm becomes less problematic.

Reducing chemical usage not only addresses concerns related to dry biofilm but also enhances the health and safety of the workplace. Chemical vapors are known to be associated with long-term health issues among cleaning and disinfection personnel.

Additionally, the adoption of this approach contributes to the environmental friendliness and sustainability of manufacturing operations by eliminating chemicals from processes. This step aligns with companies' efforts to meet stringent ESG targets.

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