



## Using Spectral Blue disinfection in cleanroom boundary areas reduced contamination in production areas by 90%

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**NextPharma** is a pharmaceutical contract development and manufacturing organization serving worldwide markets. In Winter / Spring 2023 they tested Spectral Blue disinfection devices in their manufacturing facility in Finland. The facility does pharmaceutical development, manufacturing and packaging of ophthalmic products.

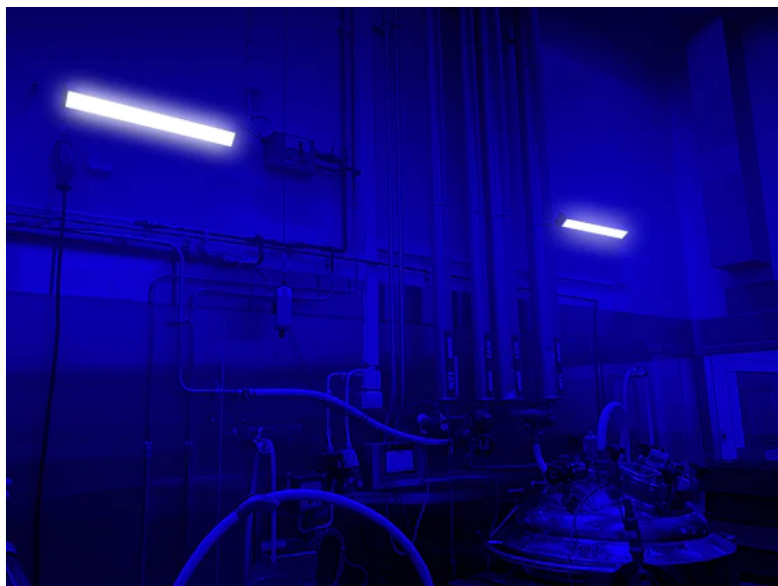
According to the test, **microbial contamination in clean production area was reduced by 90%** when automatic and continuous Spectral Blue disinfection was used in an adjacent airlock and an equipment washing room.

These results verify that installing the UV-free Spectral Blue system in cleanroom boundary areas is an excellent and cost-efficient strategy to reduce the risk of microbial contamination in clean production areas.

"We are very pleased with the test results and look forward to equipping further areas with automatic blue light decontamination" says Sari Autio, Director, manufacturing at NextPharma Oy.

Spectral Blue is an automatic and continuous environmental disinfection system developed by LED Tailor Oy. The system uses patented Multi-Wavelength, High-intensity (MWHI) blue light technology. MWHI blue light is 100% safe for people and materials but eliminates microbes from indoor surfaces and air ([click here to read more about our solutions for cleanrooms](#)).

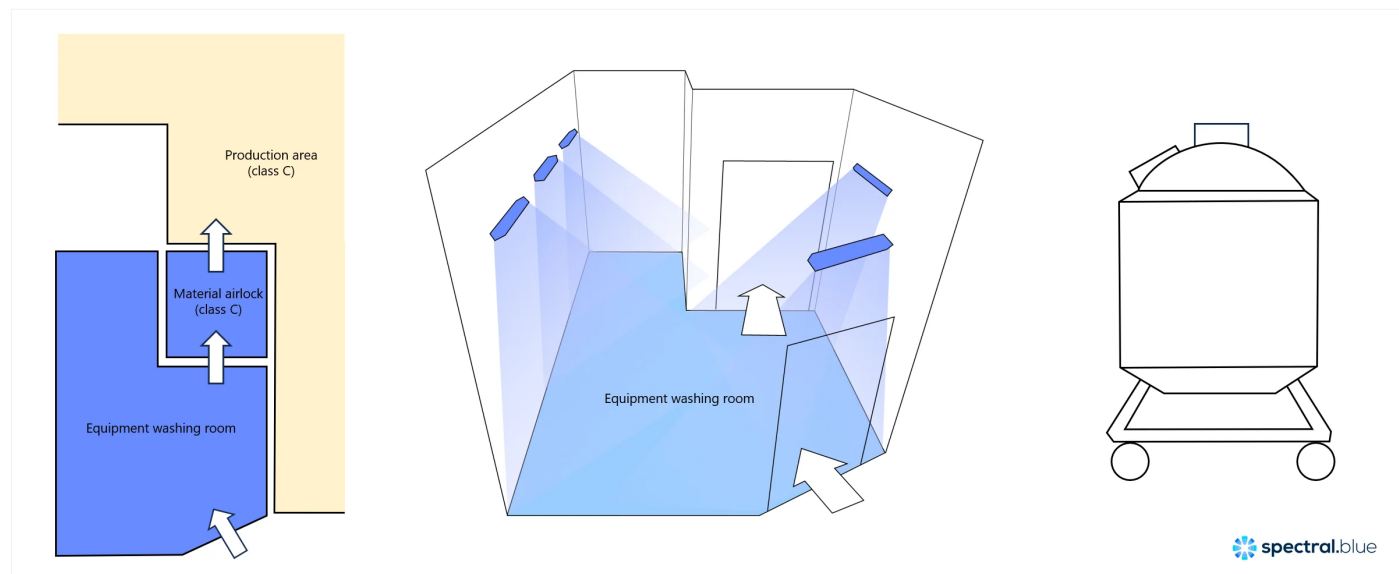
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## Background and test rooms

The purpose of the test was to evaluate the effectiveness of the Spectral Blue disinfection system in NextPharma's cleanroom environment: Would using blue light in boundary areas prevent spore-forming *Bacillus* and other microbes from entering clean production areas?

- Spore-forming *Bacillus* is a common microbe found in cleanrooms and especially difficult to eradicate using regular disinfectants.



Figures: Spectral Blue disinfection devices were installed in two rooms: an equipment washing room and a material airlock. White arrows show the route of pressure vessels from storage to production area. An illustration of a pressure vessel is shown on the right.

The test was performed by taking microbial surface samples from three rooms before and after using Spectral Blue: an equipment washing room, a material airlock (class C) and an adjacent production area (class C). The rooms are shown in the above pictures.

Pressure vessels with wheels are moved between the different areas during the manufacturing process. Some of the vessels also enter a class A production area (not pictured). The pressure vessels' wheels have been identified as a potential carrier of microbial contamination, including spores.

In addition to the pressure vessels, operators move between the different areas wearing cleanroom clothing and cleanroom shoes. The staff's movement and clothing constitute another potential contamination vector that must be controlled.

As a standard practice, the operators enter the cleanroom through a cut-off / gowning room where the change into cleanroom clothing. The cleanroom areas are cleaned and disinfected using chemicals every day before work, and the pressure vessels are thoroughly cleaned and sterilized with hot steam before use.

## Test setup and data collection

- Spectral Blue devices were installed in the equipment washing room and in the adjacent material airlock (class C). When in use, the devices were operated using a motion sensor: blue light switched on whenever the equipment washing room was empty.
- No changes were made to daily cleaning and disinfection practices.
- Microbial samples were collected from each three rooms using contact plates. Sampling was done before (no blue light in use) and after turning on the devices (blue light being used).
- The "before" samples were taken during 10 working days in January – February 2023. The "after" samples were taken in April 2023.
- The samples were taken in so called "worst case" situation, right after work and before daily cleaning.
- The samples were incubated and microbial colonies were counted. *Bacillus* colonies were visually identified.
- Total microbial colony counts and *Bacillus* counts before/after using blue light were compared to assess the effect.
- The test caused no extra risk or work for NextPharma; microbial contamination is regularly measured and controlled as part of their normal quality assurance and contamination control practices.

## Results

Total microbial colony count was reduced by

- 47% in the equipment washing room,
- 37% in the material airlock and
- **90% in the production area.**

While contamination in clean production area is already very low, thanks to rigorous quality and contamination control processes, it was shown that using Spectral Blue in the boundary area significantly reduces contamination entering the production area.

The visually identified *Bacillus* colonies were also reduced, but the starting amounts in each room were so low that statistically meaningful comparison was not possible.

**Based on the study, regular use of Spectral Blue significantly reduces the total microbial burden in cleanroom facilities and has an effect on the presence of *Bacillus* and its spores.**

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