



PHARMACEUTICAL

UV-C

STERILE MANUFACTURING

GMP ANNEX 1

HVAC

CASE STUDY

UV-C TECHNOLOGY IN THE PHARMACEUTICAL INDUSTRY

Contamination Control from Incoming Materials to Finished Product

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Contamination control in sterile pharmaceutical manufacturing **is not a one-off intervention: it is a strategy**. Every step along the production chain — from incoming materials to sealed product — represents a **potential microbial entry vector**. This article documents **six real installations of germicidal UV-C technology** at pharmaceutical manufacturing sites and in vitro diagnostic device producers, each addressing a different critical zone: incoming materials, RTU components, equipment transfer, gowning areas, recirculated air, and the product itself. All systems were **dose-designed**, verified with **on-site radiometric measurements**, and developed in alignment with the Contamination Control Strategy framework of EU GMP Annex 1.

A Regulated Challenge: Contamination in Sterile Manufacturing

EU GMP Annex 1, revised in 2022, places the Contamination Control Strategy (CCS) at the centre of compliance for sterile manufacturing. The CCS requires manufacturers to **identify, assess, and mitigate all contamination risks** throughout the entire production pathway — from logistics and warehousing through to the filling point.

Physical decontamination methods, including **germicidal UV-C technology**, fit naturally within this framework: the technology acts on microbial DNA and RNA inhibiting replication, **leaves no chemical residues**, does not induce resistance in microorganisms, and — a decisive factor in the

regulatory context — delivers a **dose that is calculable, measurable with a calibrated radiometer, and fully documentable** in the qualification dossier.

These characteristics make UV-C technology particularly suited to a sector in which **traceability and documentability are not optional**. From a GMP perspective, a treatment whose efficacy is expressed as **delivered energy (mJ/cm^2)**, independently measurable and periodically requalifiable, is **far more defensible at inspection** than a protocol whose outcome depends entirely on chemical concentration, contact time, or the variability of manual application.

Light Progress **designs, develops, and manufactures UV-C solutions since 1987**. We have developed and installed solutions covering the **six principal contamination entry points** identified in **sterile pharmaceutical manufacturing** and **in vitro diagnostic** environments. The six case studies presented below concern the sterile injectables department of a primary pharmaceutical manufacturer, a second pharmaceutical site, and a producer of in vitro diagnostic devices. Every system was dimensioned on the **target microorganism** and the **exposure time actually available**, measured in the field at the **worst-case point**, and qualified or requalified against **documented dose criteria**.

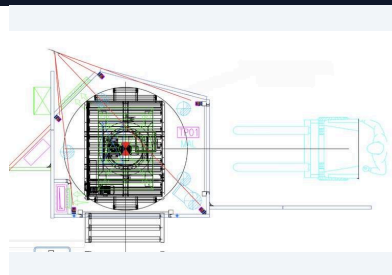


Six Critical Points, Six Installed Solutions

The contamination pathway in a sterile manufacturing facility **proceeds from outside to inside**: through goods receipt, component transfer, equipment pass boxes, personnel gowning areas, HVAC circuits, and ultimately the product assembly line.

Case Study 1 — UV-C in the Goods Freight Elevator: Incoming Materials

Facility: pharmaceutical company, sterile injectables department



△ PROBLEM

Bags, drums, and palletised loads arriving from the external warehouse must reach the sterile production floor without introducing **surface bioburden**. The goods freight elevator is the mandatory bottleneck of this transit: any decontamination treatment must take place inside the cabin, across variable load geometries, and **without requiring any additional manual operations** by personnel.

⚙️ SOLUTION

Light Progress **UV-STICK vertical lamps** were installed in **all four corners of the elevator cabin**. The positioning ensures simultaneous UV-C treatment across multiple lateral surfaces and across the full height of the load. Lamp positions were engineered in plan to **minimise shadow zones** caused by the structural frame and by the geometric variability of the loads. The treatment is physical and **leaves no chemical residues** on bags, drums, plastic films, or external packaging.

✓ RESULT



GMP QUALIFICATION

Dose verified with a calibrated radiometer under a formal qualification protocol

0

OPERATIONAL CHANGES

No changes to personnel procedures — transparent integration into the logistics flow

24/7

CONTINUOUS OPERATION

Automatic cycle on every elevator transit, without dedicated supervision

✓ Established application in current use

✓ Dose tracked per cycle

Case Study 2 — UV-C Tunnel for RTU Pharmaceutical Components

Facility: primary pharmaceutical manufacturer, injectable products



△ PROBLEM

RTU (**Ready-to-Use**) nests and plastic components intended for sterile filling present critical surfaces that must be decontaminated before entering the cleanroom. The geometry of nests — with cavities, edges, and internal walls — inevitably creates **shadow zones difficult to reach** with conventional treatments. The client defined a target reduction of **3 log of *Bacillus subtilis* spores** on critical surfaces, selecting this microorganism as the reference challenge species for its high resistance to UV-C germicidal technology.

⚙️ SOLUTION

A **UV-C tunnel** was installed above the conveyor belt leading nests towards the sterile chamber. UV-C lamps fitted with **mirror reflectors** are positioned on all sides of the belt, maximising surface coverage and ensuring an exposure time of **146 seconds**. The design included analysis of shadow zones as a function of nest geometry; the measurement point was identified at the **geometrically worst-case position** — inside the nest itself — and verified with a calibrated radiometer during **three separate measurement campaigns**.

✓ RESULT

196

MJ/CM² MEASURED

Minimum dose at the geometrically worst-case point inside the nest

>4×

SAFETY MARGIN

vs. 46 mJ/cm² required for 3-log reduction of spores

3 log

GUARANTEED REDUCTION

Confirmed dosimetrically even under worst-case conditions

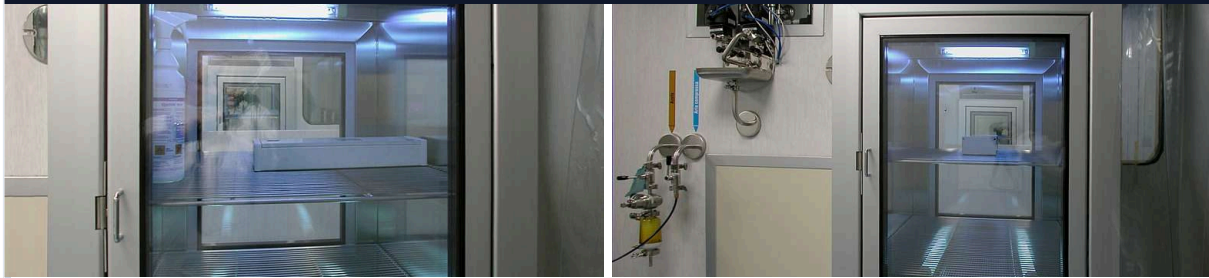
✓ Dosimetric qualification completed

✓ Margin >4× at end of lamp life

The measured dose **exceeds the biological requirement by more than four times**, even at the worst-case point. Verification is dosimetric (on-site radiometric measurement); a microbiological challenge test was not required at this stage by the client protocol.

Case Study 3 — UV-C Pass Box for Equipment Transfer

Facility: sterile pharmaceutical manufacturing



△ PROBLEM

Tools, spare parts, and maintenance materials must transit into the sterile area without acting as a contamination vector. Conventional chemical methods (alcohol, peroxide) **require contact times, may leave residues**, and depend on correct application by the operator. A **fixed, repeatable, and documentable** system was required to make the treatment independent of operational variability and to structurally prevent untreated materials from entering.

⚙️ SOLUTION

A **UV-C pass box with interlocked doors** was installed. UV-C lamps are mounted **both above and below the stainless steel mesh shelf**, treating the load from both directions. The interlock system **physically prevents the door** to the sterile zone from opening until the treatment cycle is complete, eliminating both the risk of partially treated ingress and the risk of accidental personnel exposure to UV-C radiation. Irradiance at the centre of the shelf is **measured annually** as part of the requalification programme.

✓ RESULT

~25
SECONDS

To reach the 3-log target dose at the centre of the shelf — the point furthest from the source

100%
TRACEABILITY

Every cycle logged by the interlock: opening impossible before cycle completion

≥1/yr
RADIOMETRIC CHECK

Documented measurement at the worst-case point for the qualification dossier

✓ Measurement data 2010 and 2011

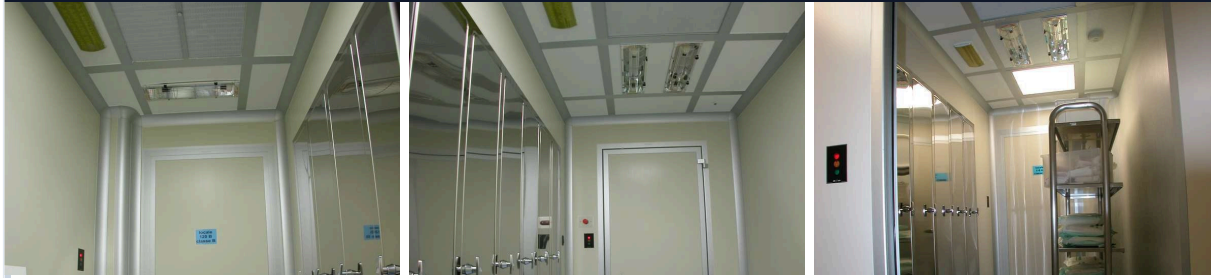
✓ Complex tools included in qualification

The protocol is fully documentable: **every cycle is logged by the interlock** and the dose at the worst-case point is verified by annual radiometric measurement. Measurement data were obtained in 2010 and 2011.

Geometrically complex tools present shadow zones on surfaces not directly exposed to the lamps. Correct load orientation — with critical surfaces facing the UV-C field — is specified in the operating procedure.

Case Study 4 — UV-C in Changing Rooms and Gowning Areas

Facility: sterile pharmaceutical manufacturing



△ PROBLEM

Changing rooms and gowning areas represent one of the **most frequently underestimated contamination vectors** in sterile manufacturing facilities: personnel introduce environmental bioburden **at every shift change**, depositing it on benches, shelving, floors, and walls. Surfaces receive no treatment between shifts, and manual cleaning is not always scheduled with the frequency needed to control cumulative microbial load.

⚙️ SOLUTION

Light Progress installed **recessed UV-C fixtures** in the suspended ceilings above the gowning zones. The decontamination cycle starts automatically for **12 minutes after the last operator has left**, triggered by the door interlock, without any manual action required. A visual warning signal — compliant with **Directive 2006/25/EC on worker safety** for artificial optical radiation — prevents re-entry during the treatment. Irradiance was measured at floor level in **four separate changing rooms**, identifying the minimum irradiance point in each as the basis for worst-case performance assessment.

✓ RESULT

9–17

MJ/CM² PER CYCLE

Measured dose range across the four treated rooms

>3 log

Reduction at the minimum irradiance point — calculated using a linear inactivation model

0

CHEMICAL DISINFECTANTS

Fully automatic end-of-shift cycle, with no additional burden on personnel

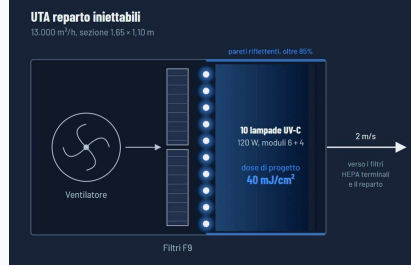
✓ Automatic at every shift end

✓ Periodic radiometric verification

Treatment occurs automatically at every shift end, **without any chemical disinfectant consumption** and without additional burden on personnel activities. The dose per cycle is periodically re-verified by radiometric measurement.

Case Study 5 — UV-C in the Air Handling Unit

Facility: pharmaceutical manufacturer, sterile injectables department



△ PROBLEM

Recirculated air in the HVAC system of a sterile injectables department may carry **viable microbial particles** that, even in small quantities, contribute to the cleanroom environmental bioburden. Terminal HEPA filters **retain particles but do not inactivate them**: bioburden accumulating on the filter surface can, under certain conditions, represent an additional risk. The client required a **continuous germicidal barrier** in the airstream, active 24 hours a day, without interrupting production and **without modifying the structure of the existing HVAC system**.

⚙️ SOLUTION

Light Progress designed and installed **two UV-C modules** in the AHU duct section (cross-section 1.65×1.10 m), positioned **downstream of pre-filters and upstream of the terminal HEPA bank**. Each module is equipped with **10 lamps of 120 W** each, for a total airflow of **13,000 m³/h**. The interior of the duct is lined with **high-reflectance UV-C aluminium panels** (>85%): radiation reflected from the walls re-enters the airstream, increasing the effective dose per pass without additional lamps. Each lamp is **individually monitored** with fault signalling to the control room.

✓ RESULT

40

MJ/CM² DESIGN DOSE

Maintained throughout the entire lamp service life (up to 5,000 operating hours)

+17%

INSTALLED POWER MARGIN

Installed power vs. calculated requirement — compensates for source output decay

ISO 15714

COMPLIANCE

In-duct radiometric verification compliant with the international standard for UV-C HVAC systems

✓ No interruption for the full lamp life

✓ ISO 15714 compliant

The design dose is verified by in-duct radiometric measurement **in compliance with ISO 15714**. The +17% power margin ensures that the dose remains within specification for the entire lamp service life, with no treatment interruptions or precautionary early replacements. The **air treatment calculation software is validated by the DIEF Department, University of Florence**. This is an established application in current use.

Case Study 6 — Inline UV-C on Product: Containers and Caps for In Vitro Diagnostics

Facility: in vitro diagnostic device manufacturer



△ PROBLEM

Biological sample containers and caps for in vitro diagnostics must reach the assembly stage with a **documented and controlled surface bioburden**. The line operates at **100 pieces per minute**: treatment must be inline, must not interrupt the production flow, and must deliver a reproducible dose to every single piece. The product is **heat-sensitive** and incompatible with residual chemical treatments, making UV-C germicidal technology the only feasible option. The process, classifiable as a critical step under **EN ISO 13485**, required a formal validation with a **microbiological challenge test**.

⚙️ SOLUTION

Light Progress developed an **inline UV-C system** that separately treats container bodies and caps immediately before assembly. UV-C lamps are positioned and oriented to ensure uniform coverage of the **internal and external surfaces** of parts passing at production speed. The system was dimensioned to deliver the required dose to each piece within the time interval corresponding to its passage under the lamps, **without reducing line speed**.

✓ RESULT

770

CFU INOCULUM

spores —
more than 100x the
routine environmental
bioburden of the facility

0

COLONIES
RECOVERED

After UV-C treatment:
no colonies detected in
any microbiological
challenge test

>2.7

LOG REDUCTION

Confirmed by challenge
testing under worst-
case conditions across
multiple batches

0 ★

CONTAMINATION
EVENTS

Sterility tests on
production batches
since 2009: zero
contamination events
recorded

✓ Challenge test passed (10^3 spores)

✓ Statistically robust results

✓ Validated EN ISO 13485 · In production since 2009

The Light Progress Method: Design, Measure, Requalify

In all six applications, the engineering approach follows a **three-phase methodology** that aligns directly with the qualification and requalification requirements of EU GMP Annex 15.

- 1

Design

The UV-C dose is calculated as a function of the **target microorganism (species, required log reduction)** and the exposure time actually available — belt speed, cycle duration, airflow velocity in the AHU. **Three-dimensional shadow analysis** of the load geometry identifies the worst-case point before the system is built.
- 2

Measure

A **calibrated radiometer** is positioned at the worst-case point identified during the design phase. System acceptance is based **on the dose measured at that specific point**, not on the nominal emission specifications of the lamp. This approach produces a **defensible qualification record** that is directly traceable.
- 3

Requalify

Periodic measurement campaigns — annual or at defined intervals — generate a **documented lamp decay curve**. A replacement criterion **based on delivered dose**, rather than calendar time, ensures that performance remains within specification throughout the entire lamp service life.

Regulatory References

STANDARD / REGULATION	RELEVANCE FOR UV-C APPLICATIONS IN PHARMACEUTICAL MANUFACTURING
EU GMP Annex 1 (2022)	Contamination Control Strategy: material transfer, personnel, HVAC
EU GMP Annex 15 (2015)	Qualification and requalification protocols with measured dose
EN ISO 13485:2016	Process validation for medical device and IVD manufacturers
Directive 2006/25/EC	Worker safety for artificial optical radiation: interlocks, delays, warning signals
ISO 15714	Method for estimating germicidal UV-C dose in air and water treatment systems

Who This Is For

QA managers and validation specialists responsible for CCS documentation and process qualification dossiers will find in this technology a **physically verifiable decontamination method** — with documented and traceable dose — that integrates directly into the qualification protocols required by EU GMP Annex 1 and Annex 15. Radiometric records provide dated, traceable evidence for **AIFA, EMA or FDA inspections**.

HVAC engineers designing or upgrading AHU systems for cleanrooms can incorporate UV-C modules in the duct as a **complementary bioburden control layer** upstream of terminal HEPA filtration, using a dimensioning methodology based on ISO 15714 and verified in the field.

Production and operations managers at sterile injectable facilities or diagnostic device manufacturers who need **reliable, residue-free decontamination** at material transfer points, pass boxes, personnel areas, and product assembly lines.

Regulatory Affairs departments preparing technical dossiers for medical device or pharmaceutical product registrations will find in UV-C processes validated under EN ISO 13485 a **structured, internationally recognised framework** for process control documentation.

UV-C germicidal technology addresses contamination control in sterile pharmaceutical manufacturing **at every point along the production pathway**: from the first contact with incoming materials to the last moment before container closure. The six installations documented in this article demonstrate that **a single physical principle**, engineered to the specific constraints of each context and verified through on-site measurement, can form the backbone of a **dose-documented, inspection-ready Contamination Control Strategy**.

Every system was dimensioned to a dose, measured at the worst-case point, and qualified under GMP Annex 15 or validated under EN ISO 13485. **None of the performance data** reported in this article is a theoretical extrapolation: they are **results measured at facilities in production**.

A Proposal Takes Five Pieces of Information

1 What to treat

incoming materials, equipment, rooms, air or product

2 Size or flow rate

piece dimensions, room size, m³/h

3 Available exposure time

line speed or cycle duration

4 Requirement

expected log reduction, target microorganism, area classification

5 Constraints

space, UV-sensitive materials, operator presence during operation

FEASIBILITY STUDY AND
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Disclaimer: this article is intended for general information and technical reference purposes. The case studies described are based on real installations and field measurement data reported by Light Progress S.r.l. Performance data refer to specific operating conditions and cannot be extrapolated to other configurations without an independent feasibility assessment. This article does not constitute regulatory or legal advice and does not replace qualification, validation and risk assessment obligations required by GMP regulations and applicable standards.

SOURCES

- EU GMP Annex 1 — Manufacture of Sterile Medicinal Products (EMA, 2022)
- EU GMP Annex 15 — Qualification and Validation (EMA, 2015)
- EN ISO 13485:2016 — Medical Devices: Quality Management Systems
- Directive 2006/25/EC — Artificial Optical Radiation at Work
- ISO 15714 — Method of Estimating the Germicidal Dose of UV Radiation