International Journal of Pharmaceutics 701 (2026) 127179

Contents lists available at ScienceDirect

International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

Review

Pulsed light technology for surface decontamination in pharmaceutical environments: mechanisms, validation strategies, and regulatory considerations

Edith Filaire [a,b,*], Anais Georgeault [a], Christophe Riedel [c], Christian Poinsot [d]

[a] Groupe ICARE, Rue Emile Duclaux 63360 Saint Beauzire, France
[b] ECREIN Team, UMR 1019 INRAE-UCA, UNH (Human Nutrition Unit), University Clermont Auvergne, 63000 Clermont-Ferrand, France
[c] Claranor, 862 rue André-Jean Boudoy, 84140 Avignon, France
[d] Bora, 63450 Tallende, France

ARTICLE INFO

Keywords:
Pulsed light
Surface decontamination
Pharmaceutical manufacturing
EU-GMP Annex 1
Biological indicators
Process validation

ABSTRACT

The recent revision of EU-GMP Annex 1 has intensified the demand for robust and reproducible surface decontamination technologies in pharmaceutical environments. Pulsed Light (PL) technology has emerged as a disruptive, chemical-free approach based on high-intensity, short-duration polychromatic pulses (200–1100 nm). Unlike conventional continuous UV treatments, PL-induced microbial inactivation results from a synergistic combination of photochemical, photophysical, and photothermal mechanisms, leading to irreversible damage to nucleic acids and cellular structures.

Originally matured in the food industry, PL is increasingly attracting interest in aseptic processing as a sustainable alternative to chemical disinfectants and ionizing radiation. PL typically achieves Log Reduction Values of 4 to 6 without generating chemical residues. Its compact footprint and rapid cycle times make it particularly suitable for the flexible, small-batch manufacturing lines required for modern biopharmaceutical production.

This review provides a critical overview of PL principles, inactivation kinetics, and industrial implementation. Emphasis is placed on the transition from time-based to energy-based validation strategies, introducing the $D_{fluence}$ value as a key metric for process qualification. The critical role of biological indicators is discussed, addressing specific challenges such as shadowing effects, spore clumping, and the selection of worst-case surrogates.

Beyond reviewing current knowledge, this work proposes a novel validation paradigm for photonic decontamination processes, integrating energy-based metrics, biological indicators, and Quality Risk Management principles to support regulatory qualification. Furthermore, it highlights the need for dedicated standardization pathways, including future ISO standards for photonic biological indicators and validation methodologies, to facilitate the broader regulatory acceptance of PL in pharmaceutical manufacturing.

1. Introduction

The recent revision of the European Union's Good Manufacturing Practices (EU-GMP) Annex 1 (Sandle, 2022) has intensified the demand for robust, reproducible, and residue-free surface decontamination technologies. Maintaining aseptic conditions throughout pharmaceutical manufacturing processes remains a critical challenge, as surface microbial contamination is a persistent and ongoing problem across healthcare (Abreu et al., 2013). In these highly regulated settings, decontamination refers to processes or treatments that render medical devices, instruments, and environmental surfaces safe to handle.

Conventional surface decontamination approaches, including chemical agents such as hydrogen peroxide, peracetic acid, and isopropyl alcohol, as well as E-beam, are widely used but present significant limitations. These methods often require long contact times, generate chemical residues, raise occupational safety concerns, and lack the flexibility needed for modern biopharmaceutical production. This is particularly true for low-speed, small-batch, and highly adaptable manufacturing lines which are increasingly prevalent. In this context, Pulsed Light (PL) technology has emerged as a disruptive

* Corresponding author at: Rue Emile Duclaux 63360 Saint Beauzire, France.
E-mail address: edith.filaire@groupeicare.com (E. Filaire).

https://doi.org/10.1016/j.ijpharm.2026.127179
Received 9 January 2026; Received in revised form 19 June 2026; Accepted 10 July 2026
Available online 14 July 2026
0378-5173/© 2026 Elsevier B.V. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

photonic surface decontamination process.

Originally developed for food-contact applications, PL delivers high-intensity, broad-spectrum light pulses over extremely short durations, enabling rapid microbial inactivation on exposed surfaces without the use of chemicals or elevated temperatures. Unlike conventional sterilization technologies, PL is specifically suited for non-porous and semi-porous surfaces, achieving reproducible microbial reductions typically ranging from 4 to 6 log within milliseconds, while preserving material integrity and production throughput.

This review evaluates the adoption of PL technology in pharmaceutical environments, with a particular focus on its application as a surface decontamination tool. The underlying photochemical, photophysical, and photothermal mechanisms contributing to microbial inactivation are discussed, along with the key technological and regulatory challenges associated with process validation. Special emphasis is placed on the use of standardized biological indicators (BIs) as a critical component for demonstrating reproducible performance and facilitating the regulatory acceptance of photonic decontamination processes.

Beyond providing an overview of pulsed light technology, this review introduces a novel validation framework specifically tailored to photonic surface decontamination processes in pharmaceutical environments. Unlike conventional sterilization approaches based primarily on time-dependent lethality, we propose an energy-driven validation paradigm integrating photonic parameters, BIs, and Quality Risk Management principles. This perspective further highlights the need for dedicated standards for photonic biological indicators and provides a roadmap for the future regulatory adoption of pulsed light technologies in pharmaceutical manufacturing.

2. An overview of pulsed light technology

PL decontamination technology has been around for many years, but its transfer to industrial applications is recent. It is a non-thermal method using pulse energy technology, used as an alternative to the traditional thermal treatment and can kill many pathogenic and spoilage microorganisms, including bacteria, yeasts, molds and viruses (Filaire et al., 2025). It delivers a polychromatic spectrum of white light comprising UV wavelengths from 200 to 400 nm (UV-C: 200–280 nm, UV-B: 280–315 nm, UV-A: 315–400 nm), visible spectrum wavelengths from 400 to 700 nm, and near-infrared region (IR) wavelengths from 700 to 1100 nm (Mandal et al., 2022), with flash durations ranging from hundreds of microseconds to milliseconds. It is generally considered as a surface decontamination technology for spoilage and pathogen microorganisms and its effectiveness is greatly dependent on several parameters such as 1) physical factors (amount of UV content, pulse fluence…), 2) biological factors (type of microbial strains, spore, vegetative cells), 3) environmental factors (quality of surface) (Levy et al., 2012).

Although PL equipment varies from system to system, the way it works remains the same. In fact, PL equipment contains flash lamps (xenon lamps), a high voltage power supply and a storage capacitor. PL is produced by a lamp that converts electricity into pulses of light with a broad, intense spectrum (Levy et al., 2012). Several PL equipments have been developed for the food and pharmaceutical industries. These include the PureBright™ system (PurePulse Technologies, Inc., San Diego, CA, USA) designed for biopharmaceutical manufacturers, the Robotic Pulsed Light Sterilizer (RPLS1) and Robotic Tub Decontamination System (RTDS2) utilizing pulsed light technology from CLARANOR (France) for the pharmaceutical sector, Claranor Pulsed Light Sterilization Systems (CLARANOR, France) for industrial applications in various fields (food, pharmaceutical, cosmetics), and the SteriPulse™ XLR Pulsed Light Systems (Xenon Corp., Wilmington, USA), available in different series (S-, RC-, Z-, X-), primarily for disinfection in the food industry. Although these devices differ in various factors such as radiant energy density per pulse, pulse characteristics, pulse rate, pulse width, in general the pulses are released rapidly to achieve a peak power which is the specificity of PL. Light bulbs emitting PL are usually filled with inert gases, such as xenon and krypton, because these gases efficiently convert electrical energy into optical energy. When a high-energy pulsed electrical current passes through these bulbs, the gases are ionized into plasma, producing intense light. The resulting light emission is short but of high intensity, reaching approximately twenty thousand times the intensity of sunlight at sea level (Wekhof et al., 2001). Approximately 25% of the wavelengths of this light fall within the UV spectrum, 45% within the visible spectrum, and 30% within the infrared spectrum. The dose received by the product is generally described by the fluence ($J.cm^{-2}$), which represents the energy received per unit area of the target per flash (a unit also used in the case of continuous UV treatments), knowing that the fluence is considered a crucial factor in PL treatments (Perez-Lavalle et al., 2020). However, the efficiency of PL is related to the voltage applied to the lamp terminals, which not only affects the fluence (the higher the voltage, the higher the flash fluence), but also the quality of the emitted spectrum (% UV). In addition, the number, duration and frequency of flashes emitted, the distance between the light source and the sample, the treatment time and the peak illuminance ($W.cm^{-2}$), which represents the maximum power on 1 cm^2 of surface for the duration of a flash, all influence the efficacy of the PL treatment. Product area, thickness, color, opacity, and type of microorganism are also factors to be considered to obtain the highest effectiveness of the PL treatment (Levy et al., 2012).

2.1. Pulsed light inactivation mechanism

PL decontamination process is essentially a surface-mediated phenomenon that occurs within an extremely brief exposure period. Unlike continuous UVC irradiation, the germicidal efficacy of PL is a multimodal phenomenon. The photochemical effect remains the primary driver, characterized by the induction of *cyclo*-butane pyrimidine dimers (CPDs) that halt DNA replication. However, the high-peak power of PL (reaching up to 20,000 times the intensity of terrestrial sunlight) introduces a photothermal component where rapid energy absorption leads to localized transient heating (50 to 150°C) of the microbial cell wall. Furthermore, the photophysical effect, unique to high-intensity pulses, induces structural mechanical stress, leading to membrane rupture and cytoplasmic leakage (Hwang et al., 2021; Jaiswal and Srivastava, 2024). It is important to note that Dorbani et al. (2025) noted that the effectiveness of these mechanisms is modulated by the delivered fluence ($J.cm^{-2}$) and the specific morpho-type of the target organisms.

To elucidate the complexity of this synergy, the following sections detail each individual mechanism, beginning with the photochemical pathway, which is widely recognized as the fundamental driver of lethal damage.

2.1.1. Photochemical mechanism

PL inactivation primarily involves photochemical reactions inducing irreversible damage to DNA, RNA, and proteins (Dorbani et al., 2025). Specifically, the UV-C fraction (200–280 nm) triggers the formation of CPDs (e.g., thymine dimers) in the genomic sequence. These dimers inhibit the formation of new DNA strands during replication, effectively preventing microbial proliferation (Mandal et al., 2022). Unlike conventional low-pressure UV treatment, the high energy density of PL often overcomes or impairs cellular DNA repair systems (such as photolyases), rendering the damage irreversible (Elmnasser et al., 2007).

PL additionally promotes the generation of reactive oxygen species (ROS), such as hydroxyl radicals and superoxide anions, which exert broad-spectrum biochemical damage by oxidizing nucleic acids, proteins, and membrane lipids. ROS formation is predominantly driven by the UV-A fraction and represents a significant indirect contributor to microbial inactivation (Heinrich et al., 2016). Microbial resistance to PL is governed by several factors, including the efficiency of cellular repair pathways, cell-wall thickness/composition, and the presence of

protective pigments (e.g., melanin) capable of dissipating specific wavelengths (Setlow and Christie, 2023).

Photo-sensitization is an additional characteristic often associated with the photochemical effect (Lukšiene, 2005). It involves the administration of a photoactive compound (photosensitizer) that accumulates within the target cells, followed by light pulses that trigger localized oxidative stress.

2.1.2. Photothermal mechanism

The inactivation can also be attributed to transient thermal effects. At visible and infrared wavelengths, PL exposure causes a rapid increase in the surface temperature, typically reaching 50 to 150 °C (Chen et al., 2015). According to Heinrich et al. (2016), when the rate of energy absorption exceeds the rate of cellular cooling, localized overheating occurs. This leads to the formation of intracellular microbubbles due to rapid water evaporation, resulting in internal pressure build-up, membrane rupture, and the eventual "melting" of microbial structures. These effects are most pronounced under high-fluence conditions and minimal lamp-to-target distances.

Crucially for pharmaceutical applications, this heating is restricted to the extreme surface (approx. 10 μm depth), preserving the integrity of the bulk material or product (Elmnasser et al., 2007).

2.1.3. Photophysical mechanism

The photophysical mechanism involves direct mechanical disruption of cellular structures. Exposure to high-intensity pulses causes substantial morphological alterations, including vacuolar enlargement and deformation of the cell wall (Takeshita et al., 2003). Wekhof et al., (2001) reported that these pulses lead to spore deformation in *Bacillus subtilis* and *Aspergillus brasiliensis*, while vegetative cells like *Escherichia coli* exhibit severe cytoplasmic damage.

Generally, microbial susceptibility follows the trend: Gram-negative bacteria > Gram-positive bacteria > fungal spores (Mandal et al., 2022). However, exceptions exist due to specialized repair systems (photoreactivation, dark repair) or spore-specific protective tunics.

2.1.4. Enzymatic inactivation

Beyond genomic damage, PL disrupts the secondary and tertiary structures of proteins, leading to enzymatic inactivation. This occurs through protein unfolding, aggregation, and peptide backbone cleavage. Photo-oxidation also promotes cross-linking among amino acid residues (Manzocco et al., 2013). The UV component plays a dominant role here, as the absorption of high-intensity light modifies active sites through amino-acid ionization and the cleavage of disulfide bonds. Residues such as tryptophan, tyrosine, and cysteine are particularly vulnerable, leading to the total loss of enzymatic function (Pellicer et al., 2020).

3. Microbial decontamination by PL

3.1. Pharmaceutical industry

The scientific literature surrounding PL technology has seen substantial growth over the last two decades. This is evidenced by a significant increase in PubMed-indexed publications, rising to 61 citations between 2004 and 2025, with over 30% of these appearing in the last three years alone. While the technology was initially matured within the food industry, it has increasingly established itself as a robust solution for clinical settings. In the production of sterile injectable drugs, maintaining the integrity of the aseptic chain is paramount. The entire manufacturing sequence must ensure and maintain sterility, necessitating the use of validated technologies. The revised Annex 1 of the EU-GMP (EU Commission, 2022) mandates a more robust, science-based approach to contamination control, emphasizing the need for validated and reproducible processes. The process typically involves several critical stages: unpacking sterile packaging in a grade-controlled area, preparing and filling sterile medicines, and sealing the final container. Surface decontamination is often applied during the transfer of materials between different grades (e.g., from Grade C to Grade B/A). Traditionally, the method for handling nested sterile packaging involves decontaminating the surface of the protective bags before removal.

Currently, several methods are employed for surface treatment, each with distinct limitations (Table 1).

While chemical methods are the most widely used, they face increasing scrutiny due to their environmental impact, occupational safety concerns, and lack of process reproducibility.

3.2. The shift toward flexible manufacturing

The emergence of biotechnological drugs and Advanced Therapy Medicinal Products (ATMPs) has catalyzed a paradigm shift toward low-speed, highly flexible production lines (Filaire et al., 2025). Unlike traditional large-scale manufacturing, these modern facilities prioritize rapid format changes and smaller batches, often rendered difficult by E-beam systems or by time-consuming chemical cycles. In this context, PL has emerged as a disruptive alternative for surface treatment (Filaire et al., 2025). Its integration offers a unique combination of advantages specifically aligned with the Quality by Design approach:

- Speed: Inactivation is achieved in milliseconds, facilitating high-frequency transfers without the bottlenecks associated with chemical contact times (Levy et al., 2012).
- Process Control: PL critical parameters, namely fluence ($J.cm^{-2}$), voltage, and pulse frequency, are fully automated and monitorable. This ensures the reproducibility required by the latest Annex 1 principles regarding the validation of automated decontamination.
- Sustainability and Safety: By eliminating chemical residues and providing a non-ionizing alternative to E-beam, PL enhances operator safety and reduces the environmental footprint of the decontamination cycle.

However, the precision of physical monitoring (fluence and pulse duration) is only one facet of process reliability. To establish a robust contamination control strategy, the physical energy delivered must be correlated with its actual microbial reduction efficiency. This necessitates a transition from physical measurement to biological proof, using specialized challenge tools to quantify the Log Reduction Value across various target surfaces.

4. Biological indicators for pulsed light validation

The validation of surface decontamination processes in pharmaceutical manufacturing relies on the use of BIs to demonstrate reproducible microbial reduction under defined and worst-case conditions. According to EU-GMP Annex 1 and FDA guidance on aseptic processing, BIs must be representative of relevant microorganisms, exhibit a well-characterized and reproducible resistance, and be suitable for the intended decontamination mechanism. While BIs are well established for thermal processes, their qualification for PL technology introduces

Table 1
Comparative analysis of current technologies.

Technology	Mechanism	Major Limitations
Manual Wiping	Chemical (IPA 70%)	Lack of reproducibility, human error risk (Voorn et al., 2026)
Spraying	Chemical (Peracetic acid, Alcohol)	Residues, long drying times, operator exposure risk (Kchaou et al., 2020)
H_2O_2 Airlocks	Vapor/Gas (VHP)	Long cycle times (20–120 min), complex aeration, potential product interaction (Agalocco and Akers, 2013)
E-beam	Ionizing Radiation (Electrons)	High cost, massive shielding (>10 tons), complexity, only for high-speed lines (Sadat and Malcom, 2005).

specific scientific and regulatory challenges, particularly due to the shift from time-based lethality to energy-based microbial inactivation. In this context, the efficacy of a PL decontamination cycle is typically described by the $D_{fluence}$ value, defined as the radiant exposure ($J \cdot cm^{-2}$) required to achieve a 90% (1-log) reduction of the target population (Schottroff et al., 2018). The reliability of a BI for PL validation depends on several key criteria. First, the microbial resistance must be standardized and calibrated specifically for the spectral output and peak power characteristics of the PL system. Unlike continuous UV-C sources, xenon-based PL emits a broad spectrum with extremely high peak irradiance, which can significantly alter microbial susceptibility and DNA repair responses. As a result, a BI validated for conventional UV treatment may exhibit markedly different $D_{fluence}$ values when exposed to PL (Perez-Lavalle, 2020).

Secondly, the carrier substrate plays a critical role in PL efficacy. Surface material, roughness, reflectivity, and topography directly influence light distribution and micro-shadowing phenomena, which are recognized as major sources of variability in surface decontamination processes (Hwang et al., 2021). BI carriers should therefore be representative of pharmaceutical-grade materials such as stainless steel, glass, and polymer-based components commonly used in aseptic environments.

Thirdly, the BI must maintain its integrity throughout preparation, transport, and storage, particularly with respect to microbial adhesion, spatial distribution, and clustering on the surface. Non-uniform inoculum distribution has been shown to artificially increase apparent resistance and compromise the reproducibility of validation studies, a key concern for regulatory acceptance of photonic decontamination technologies (Dorbani, et al., 2025). While *Geobacillus stearothermophilus* spores remain the reference standard for many decontamination processes, alternative microorganisms such as *Bacillus atrophaeus* and *Bacillus pumilus*, as well as pigmented fungi such as *Aspergillus brasiliensis*, which possesses UV-absorbing melanin, have been proposed as conservative worst-case challenges for light-based technologies (Setlow and Christie, 2023). The selection of an appropriate BI for PL validation should therefore follow a risk-based approach integrating microbial resistance, surface characteristics, and PL-specific photonic parameters.

Fig. 1 illustrated that PL surface decontamination efficacy results from the combined interaction between photonic process parameters, surface characteristics, and BI properties, which together govern local fluence distribution and microbial inactivation outcomes.

5. Physical limitations: shadowing and clumping effects

PL is inherently non-penetrative technology. Unlike gamma radiation or gaseous processes that can penetrate porous materials or reach hidden crevices through diffusion, the germicidal efficacy of PL is strictly limited to surfaces directly exposed to photonic flux. This physical constraint introduces two major phenomena that can compromise decontamination reliability: microbial clumping and surface-induced shadowing.

5.1. Microbial clumping and the shielding effect

The preparation of BIs often involves the deposition of high-concentration microbial suspensions (10^4 to 10^6 spores per carrier). If the inoculation process is not strictly controlled, spores tend to aggregate, forming multi-layered clusters. In these structures, the outermost layers of spores act as a biological shield, absorbing and scattering the incident UV photons. Consequently, the underlying microorganisms are protected from the lethal dose, leading to a significant decrease in the apparent inactivation rate. This phenomenon results in non-linear inactivation kinetics characterized by a "tailing effect", where the survival curve flattens regardless of the increase in delivered fluence ($J.cm^{-2}$). To ensure a reproducible $D_{fluence}$ value, validation protocols must guarantee a monolayer deposition of the challenge organism on the carrier.

5.2. Surface topography and micro-shadowing

The microscopic landscape of the target surface plays a decisive role in PL efficacy. Even materials considered smooth in pharmaceutical environments, such as 316 L stainless steel, exhibit a specific surface roughness (Ra).

- Micro-cavities: Spores (typically 0.5 to 1.5 μm in size) can become lodged within micro-crevices or pits of the substrate. If the depth of these cavities exceeds the spore diameter, the light pulses, especially at acute angles, may fail to reach the microorganisms, creating shadow zones.

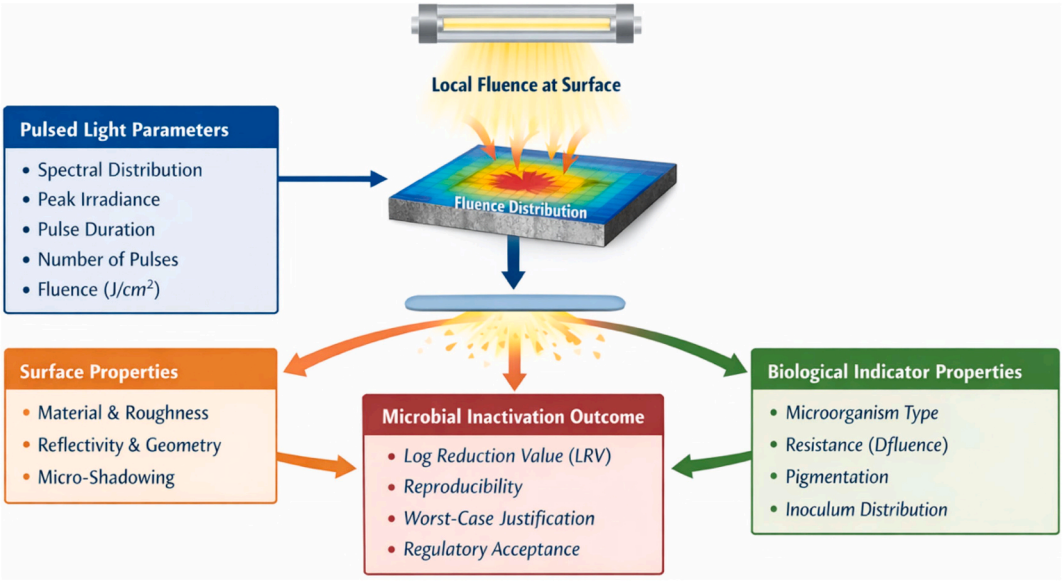


Fig. 1. Integrated conceptual framework for Pulsed Light surface decontamination validation in pharmaceutical environments, illustrating the interplay between photonic process parameters, surface characteristics, and biological indicator properties.

- Reflectivity: Conversely, highly reflective surfaces (e.g., polished aluminum or certain polymers) can enhance the local fluence through backscattering, potentially increasing the inactivation rate compared to absorbent materials.

5.3. Implications for validation and risk management

To translate these physical constraints into a compliant validation strategy, a multi-parametric "worst-case" approach is required. As mandated by the Quality Risk Management principles of the revised EU-GMP Annex 1, validation must move beyond simple surface exposure to address three critical pillars:

- Carrier Substrate Matrix: It is insufficient to validate PL on a single surface. The validation matrix must include all representative materials used in the aseptic chain, such as 316 L stainless steel, borosilicate glass, and various polymers (e.g., PE, PET, or Tyvek®). Each material must be characterized by its specific roughness (Ra) and reflectivity to account for micro-shadowing or backscattering variability.
- Geometric Challenge Mapping: Beyond surface texture, the spatial orientation of the target is paramount. Validation protocols must identify "cold spots" where the incident light intensity is minimized due to complex shapes or acute angles.
- Biological Challenge Standardization: To avoid "tailing effects" caused by artificial resistance, the BI preparation methodology (e.g., spray-coating vs. micro-pipetting) must be qualified to ensure a consistent monolayer deposition. This ensures that the observed $D_{fluence}$ value reflects the true sensitivity of the microorganism rather than a physical shielding effect.

In the absence of a dedicated ISO standard for PL biological indicators (equivalent to ISO 11138–1, 2017), manufacturers must provide robust internal qualification data. This includes a rigorous correlation between physical fluence mapping and biological performance to define a reliable worst-case scenario within the decontamination chamber.

6. Future perspectives and standardization roadmap

PL technology holds strong potential as a next-generation surface decontamination process. However, its broader industrial adoption requires a transition from experimental implementation to a standardized regulatory framework.

- Digitalization and Real-time Monitoring: A major perspective lies in the integration of PL into Industry 4.0aseptic environments. Advances in optical sensors monitoring may allow for the continuous assessment of lamp aging.
- Surface-centered Modeling: Future research should focus on predictive modeling of light-surface interactions. By combining computational fluid dynamics with photonic ray-tracing, manufacturers could simulate "shadow zones" in complex geometries before physical validation, significantly strengthening Quality Risk Management.
- Evolution of Biological Standards: There is a clear need for an international consensus (e.g., a dedicated ISO standard) specifically for photonic BIs. This roadmap must include standardized protocols for monolayer deposition to eliminate artificial resistance caused by clumping, and the characterization of "worst-case" surrogates.
- Expanded Clinical Applications: Beyond cleanroom transfers, PL offers promising perspectives for point-of-use decontamination in hospital pharmacies, medical device reprocessing, and the rapid treatment of high-touch surfaces in clinical environments to prevent healthcare-associated infections.

7. Conclusion

PL represents a paradigm shift in surface decontamination, offering a disruptive, chemical-free, and high-speed alternative to conventional technologies. By bridging the gap between its maturity in the food industry and the stringent requirements of pharmaceutical and healthcare environments, PL provides a robust response to the revised EU-GMP Annex 1 expectations for automated, reproducible, and science-based contamination control strategies. While physical limitations such as micro-shadowing and spore clumping remain inherent to photonic processes, these challenges can be effectively managed through a risk-based approach combining surface characterization, fluence mapping, and calibrated BIs.

Beyond its technological advantages, this review highlights that the implementation of PL in pharmaceutical manufacturing requires a fundamental shift from conventional time-based lethality approaches toward an energy-driven validation paradigm. In this context, $D_{fluence}$ emerges as a key metric for process qualification, while dedicated photonic biological indicators and Quality Risk Management principles become central elements for demonstrating process robustness and reproducibility.

The broader adoption of PL will ultimately depend on the establishment of harmonized regulatory and standardization frameworks, including the development of dedicated ISO standards for photonic biological indicators and validation methodologies. By integrating speed, sustainability, automation, and regulatory compliance, PL has the potential to become a key enabling technology for next-generation aseptic manufacturing and contamination control.

A.I

A.I. was used to generate Fig. 1.

CRediT authorship contribution statement

Edith Filaire: Writing – original draft, Visualization, Conceptualization. **Anais Georgeault:** Visualization, Validation, Supervision. **Christophe Riedel:** Visualization, Validation, Supervision. **Christian Poinsot:** Writing – original draft, Conceptualization.

Funding

Not applicable.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in this article.

References

Abreu, A.C., Tavares, R.R., Borges, A., Mergulhão, F., Simões, M., 2013. Current and emergent strategies for disinfection of hospital environments. J. Antimicrob. Chemother. 68, 2718–2732.

Agalocco, J., Akers, J., 2013. Overcoming limitations of vapourished hydrogen peroxide. Pharmaceutical Tech. Eur. 25, 54–65.

Chen, B.Y., Lung, H.M., Yang, B.B., Wang, C.Y., 2015. Pulsed light sterilization of packaging materials. Food Pack. Shelf Life. 5, 1–9.

Dorbani, J., Armengaud, F., Carlin, C.D., 2025. UV-C and hydration state drive pulsed light-induced proteome damage in *Bacillus pumilus* spores. Front. Microbiol. 16, 1579161.

Elmnasser, N., Guillou, S., Leroi, F., Orange, N., Bakhrouf, A., Federighi, M., 2007. Pulsed-light system as a novel food decontamination technology: a review. Can. J. Microbiol. 53, 813–821.

Filaire, E., Georgeault, A., Poinsot, C. 2025. Lumière pulsee : une technologie prometteuse pour la sterilisation de DM ? Device Med. 24-26.

Heinrich, V., Zunabovic, M., Varzakas, T., Bergmair, J., Kneifel, W., 2016. Pulsed light treatment of different food types with a special focus on meat: a critical review. Crit. Rev. Food Sci. Nutr. 56, 591–613.

Hwang, H.J., Kim, G.A., Chung, M.S., 2021. Impact of factors affecting the efficacy of intense pulsed light for reducing *Bacillus subtilis* spores. Food Sci. Biotechnol. 30, 1321–1329.

NF EN ISO 11138-1. 2017. Sterilization of health care products. Biological Indicators. Part 1: general requirements. https://www.boutique.afnor.org/en-gb/standard/nf-en-iso-111381/sterilization-of-health-care-products-biological-indicators-part-1-general-/fa188155/78301.

Jaiswal, M., Srivastava, B., 2024. Evaluating the impact of pulsed light treatment on microbial and enzyme inactivation and quality attributes in fresh-cut watermelon. J. Food Process Engineering 47, e14626.

Kchaou, M., Abuhasel, K., Khadr, M., Hosni, F., Alquraish, M., 2020. Surface disinfection to protect against microorganisms: overview of traditional methods and issues of emergent nanotechnologies. Appl. Sci. 10, 6040.

Levy, C., Aubert, X., Lacour, B., Carlin, F., 2012. Relevant factors affecting microbial surface decontamination by pulsed light. Int. J. Food Microbiol. 152, 168–174.

Lukšiene, Z., 2005. New approach to inactivate harmful and pathogenic microorganisms: photosensitization. Food Tech. Biotech. 43, 411–418.

Mandal, R., Mohammadi, X., Wiktor, A., Singh, A., Anubhav, P.S., 2022. Applications of pulsed light decontamination technology in food processing: an overview. Appl. Sci. 10, 3606.

Manzocco, L., Panozzo, A., Nicoli, M.C., 2013. Inactivation of polyphenoloxidase by pulsed light. J. Food Sci. 78.

Pellicer, J., Navarro, A.P., Gomez-Lopez, V.M., 2020. Pectin methylesterase inactivation by pulsed light. Innov. Food Sci. Emerging Technol. 62, 102366.

Perez-Lavalle, L., Carrasco, E., Valero, A., 2020. Strategies for microbial decontamination of fresh blueberries and derived products. Foods 9, 1558.

Sadat, T., Malcom, F., 2005. A new e-beam application in the pharmaceutical industry. Nuclear Instr. Meth. Physic. Res. Section B 240, 100–104.

Sandle, T. 2022. EU Commission. EU-GMP Annex 1. 2022. Manufacture of Sterile Medicinal Products.

Schottroff, F.A., Fröhling, F., Zunabovic-Pichler, M., Krottenthaler, A., Schlüter, O., Jäger, H., 2018. Sublethal injury and viable but non-culturable (VBNC) state in microorganisms during preservation of food and biological materials by non-thermal processes. Front. Microbiol. 20, 2773.

Setlow, P., Christie, G., 2023. New thoughts on an old topic: secrets of bacterial spore resistance slowly being revealed. Microbiol. Mol. Biol. 87, e0008022.

Takeshita, K., Shibato, J., Sameshima, T., Fukunaga, S.Q., Isobe, S., Arihara, K., Itoh, M., 2003. Damage of yeast cells induced by pulsed light irradiation. Int. J. Food Microbiol. 85, 151–158.

Voorn, M.G., Tembo, G.M., Rayney, K.E., Teska, P.J., Oliver, H.F., 2026. Wiping cloth material choice significantly impacts the bactericidal efficacy of select disinfectant chemistries in environmental surface decontamination. Am. J. Infect. Control 54, 44–50.

Wekhof, A., Trompeter, F.J., Franken, O., 2001. Pulsed UV disintegration (PUVD): a new sterilisation mechanism for packaging and broad medical-hospital applications. In: The First International Conference on Ultraviolet Technologies, p. 15.