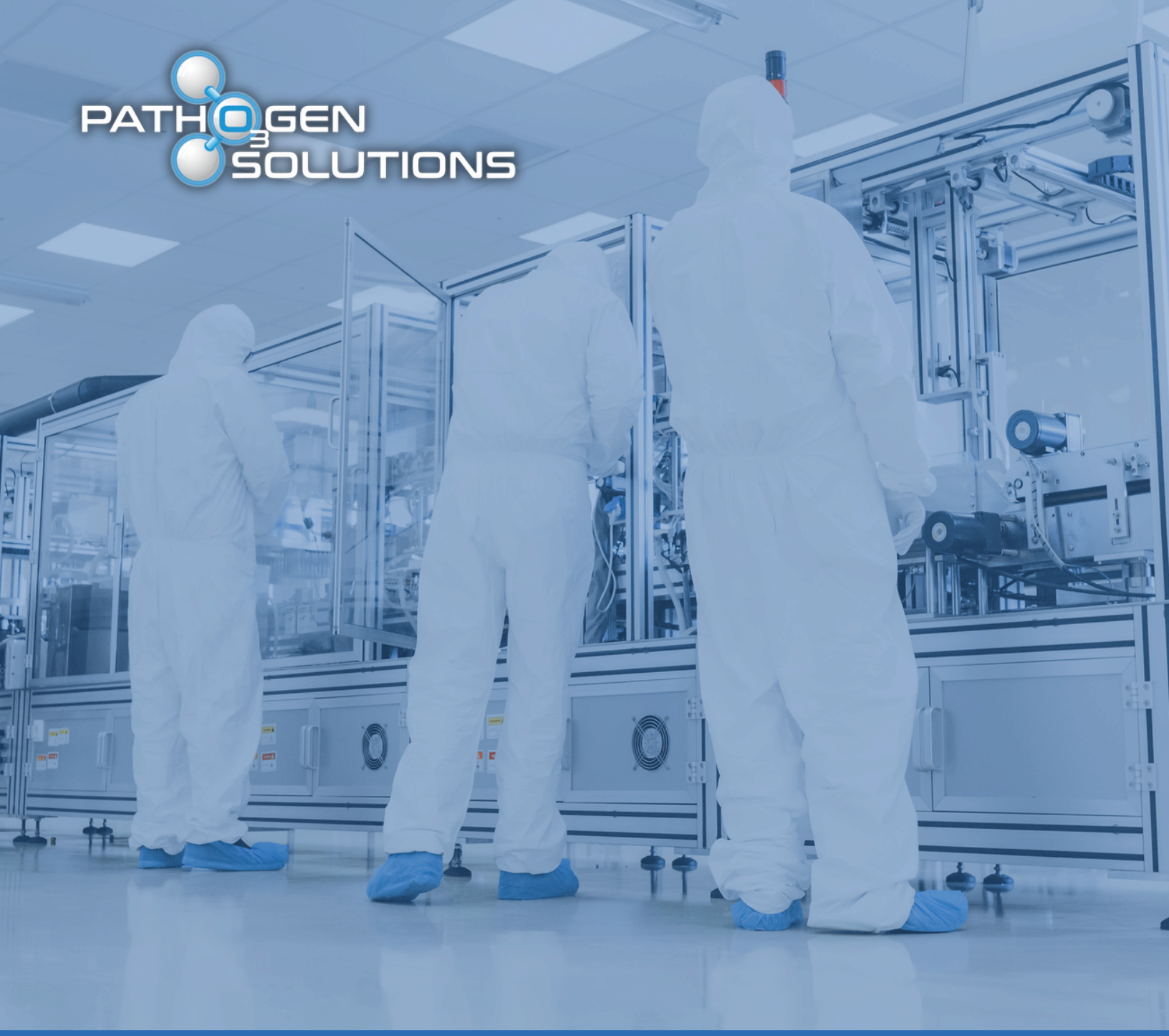
PATHOGEN SOLUTIONS



Floor & Entryway Contamination

RISK ASSESSMENT CHECKLIST

Internal self-assessment for personnel entry, footwear control, and contamination prevention in pharmaceutical manufacturing facilities

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RISK ASSESSMENT CHECKLIST

Internal self-assessment for personnel entry, footwear control, and contamination prevention

HOW TO USE THIS CHECKLIST

This self-assessment tool is intended for quality, operations, and compliance teams in pharmaceutical manufacturing and related controlled environments. It reviews facility entry, footwear control, traffic flow, and environmental monitoring practices in relation to applicable FDA, EU GMP, and ISO cleanroom expectations.

Complete each section by indicating whether each control is implemented, documented, and verifiable. Points may be assigned based on the level of implementation and evidence available. If supporting evidence is not available, the control should be treated as not sufficiently demonstrated for this assessment.

Total possible score: 100 points | **Completion time:** 20–30 minutes
Recommended frequency: Quarterly, or before any regulatory inspection.

This Risk Assessment Checklist is provided for general informational purposes only and is not intended as regulatory, legal, or compliance advice.

SECTION 1: FACILITY ENTRY PROTOCOL & FOOTWEAR CONTROLS

26 Points Possible

✔	Control Item	Pts	Notes / Evidence
	A current SOP exists for personnel entry procedures for classified manufacturing areas	+4	
	The SOP addresses footwear hygiene, sanitization, or changeover requirements at relevant entry points, where applicable *Regulatory ref: 21 CFR §211.28, EU GMP Annex 1 §7.13–7.16*	+4	
	Where footwear sanitization is used, the method is qualified or validated as appropriate to the process and risk assessment	+5	
	Footwear sanitization equipment, if used, is qualified, maintained, and included in the preventive maintenance program as applicable	+5	
	Entry sanitization steps are included in personnel training curriculum	+3	
	Gowning and footwear change procedures are visually posted at entry gowning areas	+2	
	Footwear and gowning requirements are applied consistently to personnel, contractors, visitors, and other authorized entrants, as applicable. *Common 483 gap: visitor/contractor exemptions*	+3	
	Section Total:		/ 26

If a UV-based or other sanitization technology is used, supporting performance data should be available to demonstrate that the method is suitable for its intended use. Acceptance criteria should be defined in advance and justified by risk assessment.

SECTION 2: CONTAMINATION PATHWAY MAPPING & RISK ASSESSMENT

24 Points Possible

✔	Control Item	Pts	Notes / Evidence
	A documented contamination risk assessment addresses floor-based contamination pathways and is reviewed periodically	**+5**	
	Personnel and material flow paths between classified and non-classified areas are documented where relevant to contamination control	**+4**	
	High-traffic areas such as entry points, gowning areas, and nearby support spaces are evaluated for contamination risk where they may affect controlled areas	**+3**	
	Environmental monitoring (EM) locations, including any floor or surface points near transitions or entry areas, are selected based on risk and documented in the monitoring program *EU Annex 1 §9 requires EM sampling locations and frequencies to be risk-justified and documented*	**+5**	
	Contamination events, including those potentially associated with personnel or footwear, are investigated according to written procedures	**+4**	
	Cross-contamination risk is considered in facility layout and traffic flow design, and the basis for the design is documented in appropriate site records	**+3**	
	Section Total:	**/ 24**	

SECTION 3: ENVIRONMENTAL MONITORING & TRENDING

18 Points Possible

✔	Control Item	Pts	Notes / Evidence
	The environmental monitoring program is written, approved, current, and reviewed periodically	**+4**	
	Environmental monitoring results are trended and reviewed at a frequency defined by procedure and risk *Look for adverse trends near entry points — leading indicator of footwear contamination*	**+4**	
	Alert and action limits, where applicable, are established and documented in the environmental monitoring program	**+3**	
	Out-of-limit or adverse environmental results trigger investigation in accordance with written procedures	**+4**	
	Environmental monitoring data is reviewed as part of the applicable product quality or periodic quality review process	**+3**	
	Section Total:	**/ 18**	

SECTION 4: DOCUMENTATION, TRAINING & CHANGE CONTROL

17 Points Possible

✔	Control Item	Pts	Notes / Evidence
	All contamination control SOPs are version-controlled and reflect current practice	**+3**	
	Personnel training on gowning and entry procedures is documented and current (within 12 months for all staff)	**+4**	
	Any change to footwear sanitization technology or vendor are processed through formal Change Control *Change control should assess GMP impact including contamination risk*	**+4**	
	Deviations related to footwear/entry protocol violations are documented and investigated	**+3**	
	CAPA effectiveness checks are performed and documented for any contamination-related corrective actions, where required	**+3**	
	Section Total:	**/ 17**	

SECTION 5: AUDIT READINESS & REGULATORY ALIGNMENT

15 Points Possible

✔	Control Item	Pts	Notes / Evidence
	A contamination control strategy document exists and addresses relevant contamination risks including personnel and traffic flow *EU Annex 1 (2022) now requires a formal CCS — this is a frequent observation gap*	**+4**	
	Supporting documentation for footwear sanitization equipment qualification or performance is readily available, where applicable	**+4**	
	Recent inspection readiness or mock audit activities included evaluation of personnel entry and footwear controls	**+3**	
	Previous inspection observations related to contamination control have been addressed through documented remediation and CAPA, where applicable	**+4**	
	Section Total:	**/ 15**	

Assessment Conducted By: : _____ Date of Assessment: _____

SECTON 1	SECTON 2	SECTON 3	SECTON 4	SECTON 5
SCORING: _____ / 100 points				

SCORE INTERPRETATION GUIDE

Score	Risk Level	Audit Posture	Recommended Action
85–100	**LOW RISK**	Audit-ready. Controls well-documented and implemented.	Maintain program; conduct quarterly reviews.
65–84	**MODERATE RISK**	Most controls in place; gaps exist in documentation or consistency.	Close documentation gaps within 30 days.
40–64	**ELEVATED RISK**	Significant control deficiencies. Vulnerable to 483 observations.	Corrective action plan required immediately.
0–39	**HIGH RISK**	Critical gaps. Contamination event or regulatory citation likely.	Escalate to QA leadership and COO. Immediate remediation.

WHAT FDA AND EU INSPECTORS ARE LOOKING FOR

Regulation	What Inspectors Specifically Examine Related to Personnel & Footwear
21 CFR § 211.28	Personnel hygiene, clean clothing, protective apparel, sanitation, and access control.
21 CFR § 211.42(c)	Facility design and defined areas must prevent contamination and mixups.
EU GMP Annex 1 §7.3, 7.13–7.16 (2022)	Personnel gowning and qualification, plus a site-wide CCS in §2.3.
EU GMP Annex 1 §9	Environmental monitoring with defined locations, limits, and investigations.
ISO 14644-1/-2	Cleanroom classification and monitoring, with traffic control handled as part of contamination risk management.

TOP 5 FOOTWEAR CONTAMINATION GAPS CITED IN FDA 483s AND WARNING LETTERS

1. Visitor & contractor exemptions. Entry protocols applied inconsistently — inspectors observe executives and visitors bypassing gowning and footwear controls that regular staff follow. This directly undermines the control.

2. Unvalidated sanitization devices. Facilities use footwear mats or devices without documented efficacy data. A sanitizing station must demonstrate a measurable, reproducible reduction in microbial load to be defensible.

3. No formal Contamination Control Strategy. Post-2022 EU Annex 1 revision, the absence of a written CCS — or a CCS that doesn't explicitly address footwear — is among the most common new observations.

4. Training records not current. Procedures exist on paper but annual retraining is overdue, or records cannot be produced during inspection. A common discovery during unannounced visits.

5. Lack of environmental data from entry zones. Environmental monitoring programs that sample only core production areas and miss entry transition points leave a blind spot that inspectors specifically probe.

NEXT STEPS

01

Share Your Score

Use this assessment in your next QA leadership or operations review.

A shared risk score creates alignment on priorities across QA, operations, and the C-suite.

02

Close the Gaps

For each unchecked item, assign an owner and a 30/60/90-day deadline.

Priority items: CCS document, validation data for sanitization devices, and visitor/contractor training.

03

Benchmark & Improve

Reassess quarterly. Track your score over time.

A score trending upward is evidence of a maturing quality culture — and a defensible compliance posture.

ABOUT UVZONE® SHOE SANITIZING STATION

The UVZone Shoe Sanitizing Station is the leading validated UV-C + ozone footwear decontamination solution for pharmaceutical manufacturing, biotech cleanrooms, and life sciences facilities.

Deployed at facility entry points, UVZone delivers a documented, hands-free, 6-, 8-, and 10-second sanitization cycle that reduces microbial contamination on footwear surfaces providing a defensible, auditable contamination control at the first point of entry.

To learn how UVZone supports your contamination control strategy, visit: **patho3gen.com**