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IRELAND PHARMA CLEANROOM SERVICES

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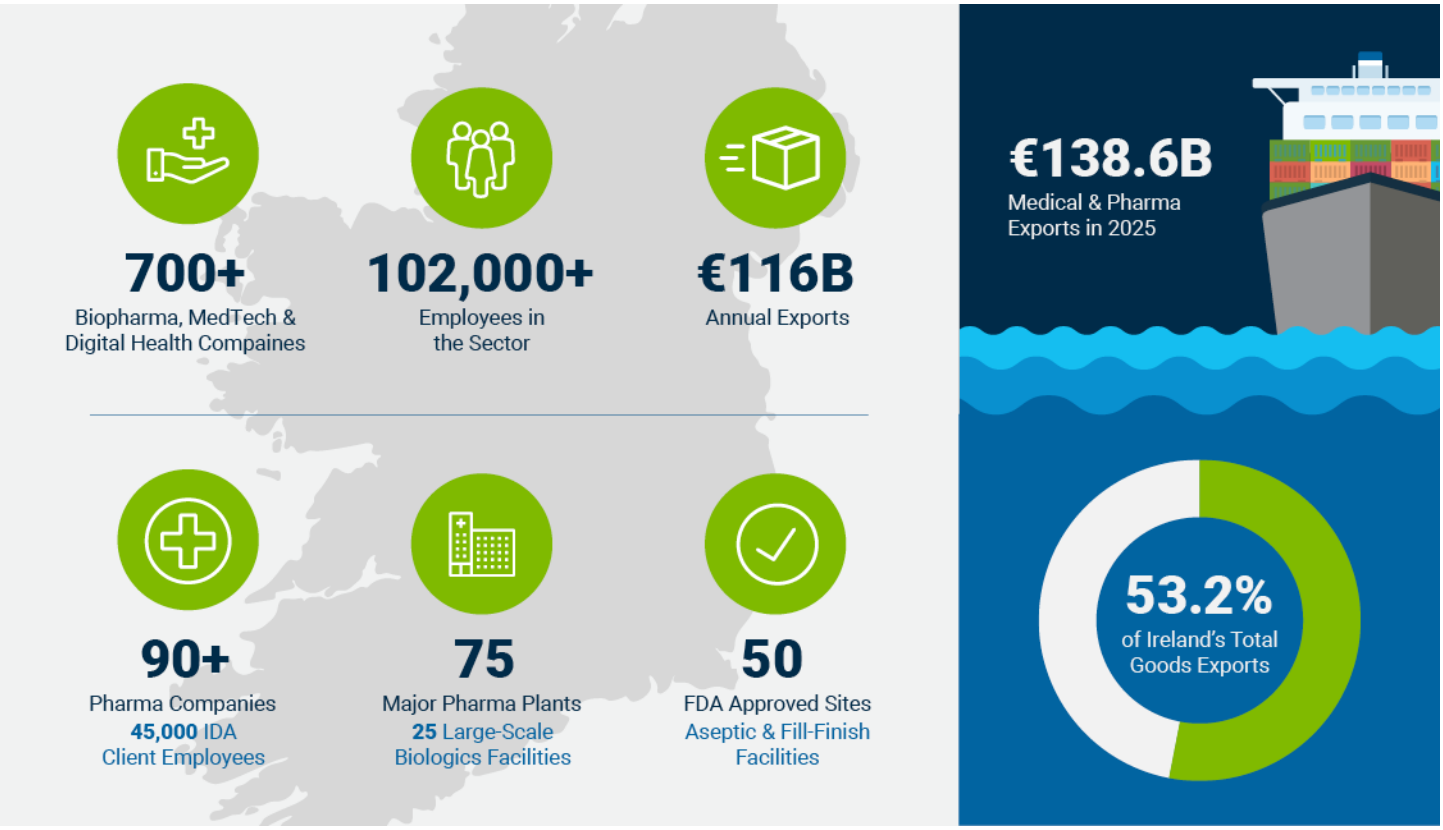
Ireland has established one of Europe's most significant life sciences manufacturing bases, with a highly concentrated footprint across pharmaceuticals, biologics, and other regulated production environments. The demand for contamination-controlled operations, validated cleaning procedures, and expert support that meet strict regulatory and quality standards is expected to propel the cleanroom services market in Ireland.



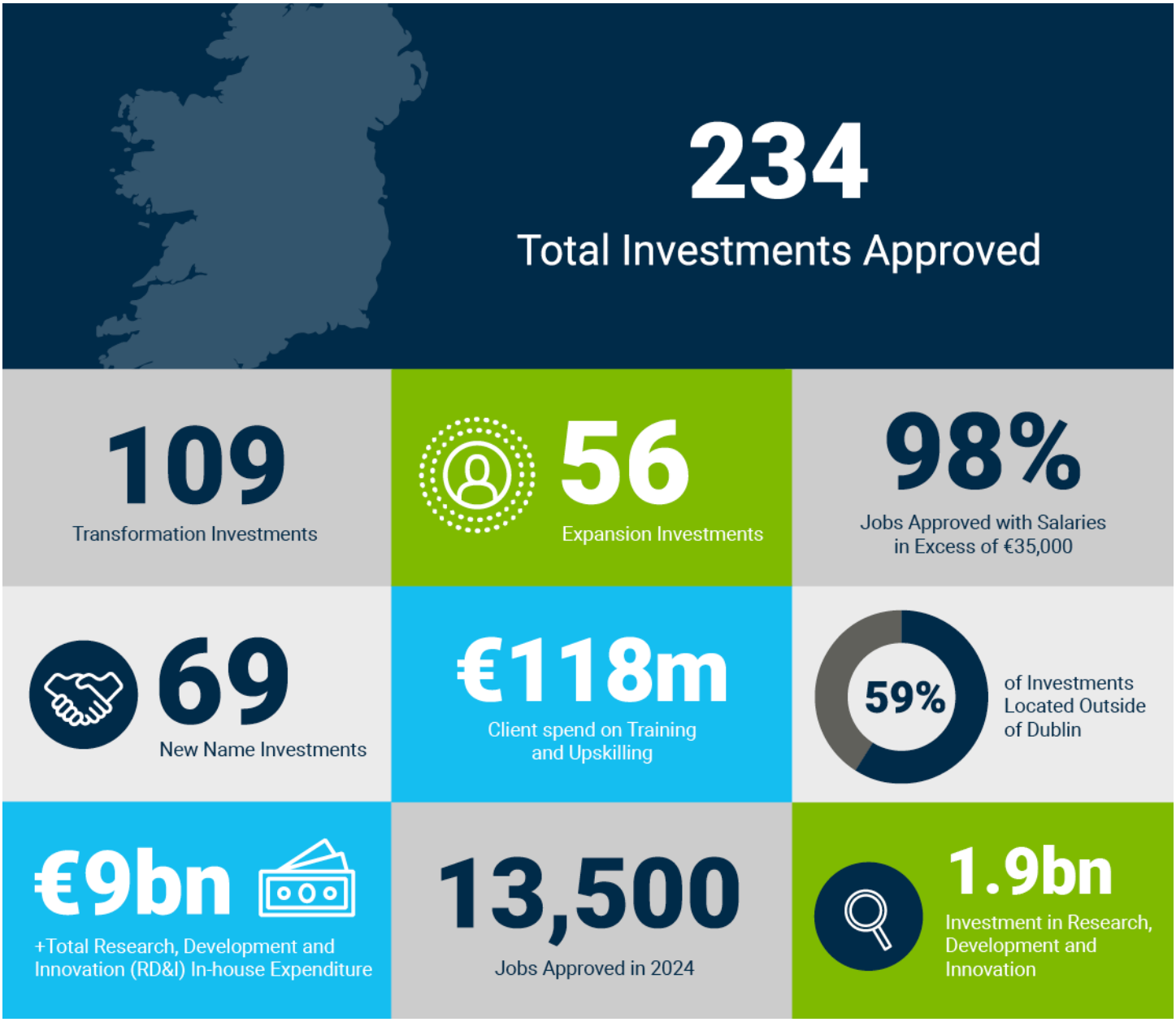
Medical devices are an important adjacent segment in Ireland's controlled-environment market. The sector broadens the country's installed base of cleanroom-linked production space, specialized operating conditions, and experienced cleanroom labor. IDA Ireland states that Ireland is home to:

> 300 medical technology companies, including 14 of the top 15 global medtech firms, with sector employment exceeding 50,000 and annual exports above €14.9 billion.

The scale of this footprint strengthens Ireland's overall controlled manufacturing base and supports sustained demand for specialist cleaning and contamination-control capabilities.

Recent Investments Expanding Ireland's Controlled-Environment Capacity

Recent investments indicate that Ireland's controlled-environment footprint is continuing to expand across biologics, vaccines, packaging, injectable drug-delivery systems, filtration, and Medtech. This reinforces demand for specialist cleanroom services, as new and expanded facilities increase requirements for validated cleaning, contamination control, and audit-ready operations.



Company	Location	Investment / Expansion	Controlled-Environment Relevance
Eli Lilly	Limerick and Kinsale	$1.8 billion total, including $800 million in Kinsale	Expands biologic active ingredient and broader manufacturing capacity, increasing demand for controlled production environments
MSD (Merck)	Dundalk	Acquisition of existing facility	Adds a 15,520 m² vaccine manufacturing site with drug substance, drug product, and QC laboratory capabilities
PCI Pharma Services	Ireland	An additional 82,000 sq ft facility beside the existing 45,000 sq ft site	Expands commercial pharmaceutical packaging capacity in contamination-controlled settings
West Pharmaceutical Services	Dublin	165,000 sq ft expansion and 330 additional roles	Supports injectable drug-delivery manufacturing with high-quality control requirements
Merck	Cork	€150 million investment	Opened a 3,000 m² cleanroom filtration facility
Sanmina	Fermoy	Facility expansion	Includes a new ISO 8 cleanroom for Medtech manufacturing

Key Trends Driving Industry Growth

CONTAMINATION CONTROL SYSTEMIZATION:

The market is transitioning from stand-alone cleaning provision toward more systemized contamination-control support. Annex 1's contamination control strategy framework, explicit disinfection requirements, and monitoring logic, together with Annex 15 validation expectations and Chapter 7 controls over outsourced GMP activities, are increasing the level of discipline expected from specialist providers. In practice, this means buyers are placing more weight on service partners that can support documented procedures, traceability, deviation handling, and validated methods, rather than simply supplying labor to perform routine cleaning tasks. For the pharma cleanroom services market, the implication is that specialist cleaning is increasingly being assessed as part of site control infrastructure rather than a peripheral hygiene activity.

BROADER CONTROLLED-SPACE DEMAND:

Annex 1 explicitly states that some of its principles, including contamination-control strategy, cleanroom classification, qualification, validation, monitoring, and personnel gowning, may be used to support certain non-sterile products and low-bioburden biological intermediates where contamination reduction matters. The same annex also lists Grade D examples, such as cleaning of equipment and handling of cleaned components after cleaning. This supports a broader market for specialist cleaning in controlled environments that are not highest criticality.

PACKAGING AND HANDLING GROWTH:

Growth in Ireland's life sciences footprint is extending beyond core sterile manufacturing into commercial packaging, final assembly, and drug-handling environments.

PCI's CityNorth expansion is focused on commercial pharmaceutical packaging and adds 82,000 sq ft of new production and services space alongside its existing 45,000-sq-ft Irish facility, which supports oral solid-dose and sterile injectable dosage forms.

West's Dublin expansion adds 165,000 sq ft and broadens the site's role beyond component molding, device assembly, and packaging to include advanced automation and expanded drug-handling capabilities at commercial scale for high-volume injectable therapies.

These investments are significant because they point to rising demand in controlled environments that sit outside the most critical open aseptic intervention zones but remain commercially and operationally important. Such spaces combine GMP scrutiny with materials control, line-clearance discipline, visual cleanliness requirements, and mix-up prevention, particularly where packaging, labeling, final assembly, and product handling are closely tied to commercial supply. For Ireland's pharma cleanroom services market, this broadens the relevance of specialist support beyond sterile cores alone.

Rising Digital Execution:

Digital execution is becoming a more visible feature of Ireland's biopharmaceutical operating environment.

> Industry findings indicate that 54% of manufacturing businesses are adopting AI, compared with a 39% national average, and that two-thirds intend to expand AI activity within the next one to two years.

At the same time, Ireland's biopharma ecosystem is increasingly framing this transition through Biopharma 4.0, with practical focus areas including paperless execution, CAPA, deviation management, and supply chain optimization. For pharma cleanroom services, this does not reduce the need for contamination control. It raises the importance of service delivery that is disciplined, documented, and compatible with more structured GMP operating systems. As site execution becomes more digital and more tightly controlled, cleanroom support is likely to be judged increasingly on traceability, consistency, and fit with broader production routines.

Emerging Sustainability Criteria:

Sustainability is becoming a more visible consideration in Ireland's life sciences facility base, though it remains secondary to GMP compliance and contamination control in cleanroom-related purchasing decisions. Recent investments show that new pharmaceutical and cleanroom-adjacent facilities are increasingly being built with defined environmental features.

> PCI's new Irish pharmaceutical packaging facility is targeting LEED Gold, an A3 BER, and rainwater harvesting. Merck's new Blarney filtration facility is designed for climate-neutral operations, powered by 100% renewable electricity, and built to reuse up to 95% of high-purity water from the manufacturing process.

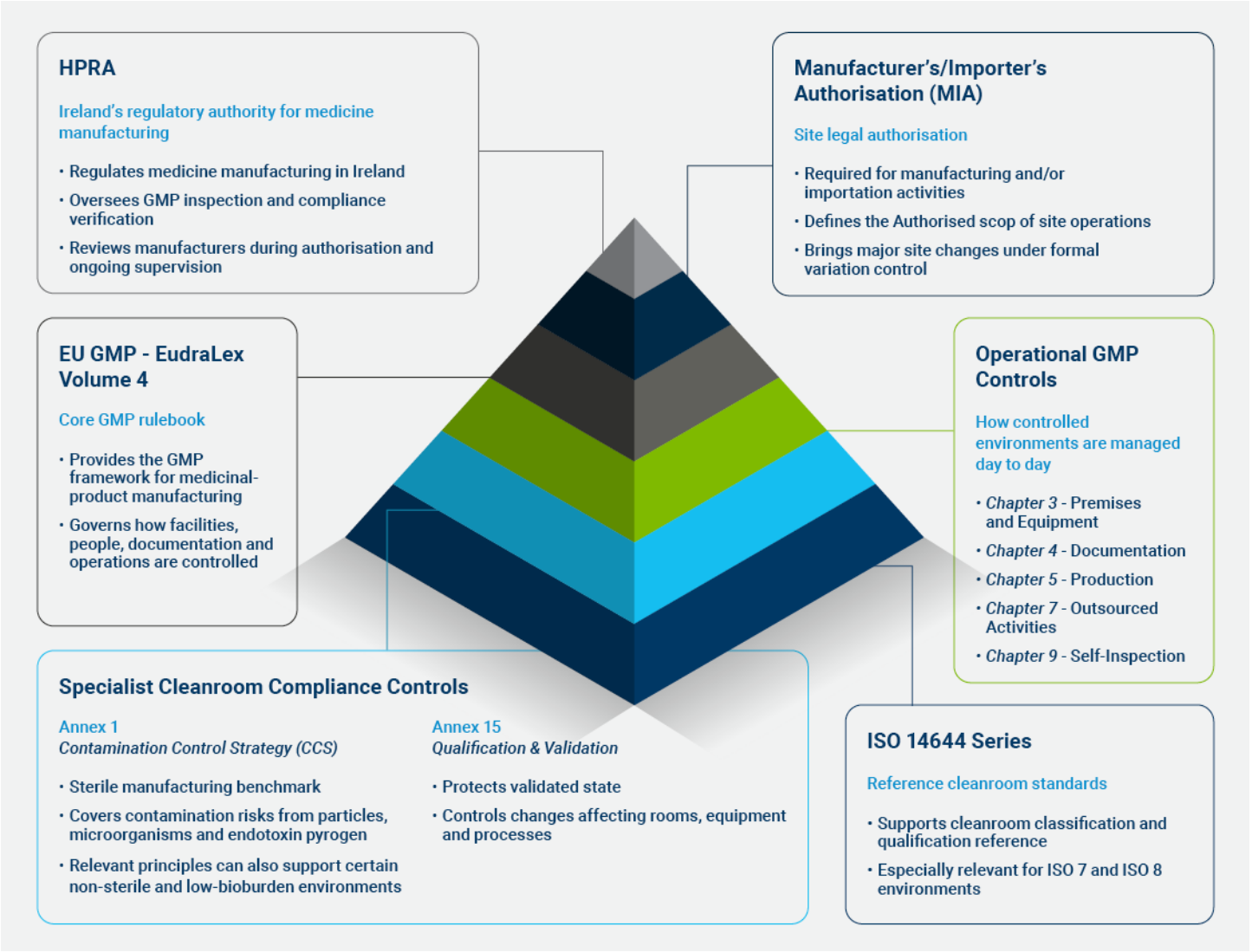
For pharma cleanroom services, this suggests that some buyers will increasingly examine how providers manage water, chemistry, waste, consumables, and operating efficiency. However, these criteria are likely to remain additive. In practice, supplier selection in controlled environments will still be led primarily by contamination control, GMP fit, documented execution, and audit readiness.

Ireland Pharma Cleanroom: Regulations and Standards

Ireland's pharma cleanroom services market is shaped by a layered regulatory framework comprising HPRA oversight, site authorization, EU GMP, and ISO-linked cleanroom standards. As a result, service providers are judged not simply on whether a room appears clean, but on whether they can operate inside the client's GMP system with controlled methods, complete documentation, validated-state awareness, and audit-ready execution. EU GMP Chapter 4 places documentation at the center of compliance, Chapter 5 requires written procedures across production activities, Chapter 7 formalizes the control of outsourced GMP services, and Annex 15 ties execution to qualification, validation, and change control.

Ireland Pharma Cleanroom Services: Regulatory & Standards Hierarchy

FROM HPRA OVERSIGHT TO EU GMP AND ISO-LINKED CLEANROOM CONTROLS



ISO 14644-5 reinforces these expectations by requiring an operational control program spanning personnel, material flows, cleaning, maintenance, and monitoring. For buyers managing ISO Class 6, 7, and 8 cleanrooms, this shifts the service requirement from routine cleaning provision to disciplined contamination-control support.

Key Challenges and Risks

Area	Remarks
Contamination-control failure and environmental excursions	HPRA reported 83 GMP inspections, 906 human-medicine quality defect cases, and 46 human-medicine recalls in 2024. Five recall actions were attributed to particulate contamination. Annex 1 requires a CCS, validated disinfection, and effectiveness monitoring.
Shared equipment and changeover cross-contamination	IDA says many Irish sites now combine drug substance, drug product, and fill-finish. Chapter 5 says contamination can arise from residues on equipment and operators' clothing and requires effective, reproducible cleaning processes.
Packaging, labelling and final-handling control	HPRA includes primary packaging, secondary packaging, relabeling, and serialization in manufacturing. HPRA's 2024 sampling program initiated 319 cases and examined packaging, labeling, and usability. EU GMP requires packaging areas to be free of mix-ups and line-cleared before use.
Gowning, airlocks, and personnel behavior	Annex 1 requires gowning procedures, checks on garment integrity, and, where possible, separation of personnel and material airlocks. ISO 14644-5 includes personnel and material entry/exit in the operations control program. NIBRT states that people are the primary source of contamination in cleanrooms.
Storage, receiving, warehouses, and kitting	Chapter 3 requires storage areas to be clean, dry, and orderly, and receiving areas to allow cleaning of incoming containers where needed. Chapter 5 requires orderly storage and segregation.
Documentation, RCA, and CAPA weakness	Chapter 4 says good documentation is essential to GMP. HPRA's quality-defect guidance requires detailed RCA and CAPA, and links serious defects to recall or abnormal restriction on supply. HPRA also approved 23 CIUNs/DHPCs in 2024, where a recall was not initiated.
Controlled-environment risk in Medtech	Ireland has 300+ Medtech companies and 50,000+ employees. HPRA recorded 403 device market-surveillance cases and 3,672 device-vigilance reports in 2024, though public data do not isolate the root causes of cleanroom incidents.

Case Studies

REGULATORY FAILURES IN CLEANROOM CLEANING AND CONTAMINATION CONTROL

Company	Qianjiang Kingphar Medical Material
Location	China
Environment	Medical devices, ISO 8 packaging, and manufacturing cleanrooms
Issue/ Trigger	During an FDA inspection in June-July 2025, inspectors found dirt and filth accumulation in ISO 8 packaging and woven-gauze cleanrooms, structural deficiencies that prevented effective cleaning, inaccurate cleaning and disinfection logs, and no alert or warning limits or clear breach-handling procedures for environmental monitoring.
Impact	FDA warning letter, repeat observation from a prior FDA inspection, and explicit notice that compliance issues could affect federal contracts and some device approvals.
Company	**ProRx, LLC**
Location	US
Environment	Sterile compounding, ISO 5 biosafety cabinet with ISO 7 anteroom/buffer support
Issue/ Trigger	During an FDA inspection in July-August 2024, FDA found non-sterile wipes in the ISO 5 area, no ISO 5 environmental monitoring, poor gowning practices, cleaning and disinfection deficiencies, and insect presence in the ISO 7 cleanroom.
Impact	FDA warning letter citing insanitary conditions and CGMP violations.

Operational and compliance value created by specialist providers

CLEANING AS PART OF CONTAMINATION CONTROL

In regulated manufacturing environments, specialist cleaning creates value when it is treated as part of the contamination-control framework rather than as a downstream hygiene task. EU GMP Annex 1 requires cleanrooms to be cleaned and disinfected through a written program, with cleaning steps that remove surface contamination effectively, control residues, and support validated disinfection. Annex 1 also ties disinfection choices, including whether agents used in Grade C and D areas need to be sterile, to the site's contamination control strategy. The commercial implication is clear: the value of a specialist provider lies not simply in labor provision, but in controlled execution that aligns with the site's wider contamination-control model.

SUPPORTING DISCIPLINED OPERATIONS IN CONTROLLED SPACES

The operational value of a specialist provider extends beyond the core cleanroom into the spaces and practices that shape day-to-day contamination risk. ISO 14644-5 specifies that cleanroom operations should be managed through an operations control program covering personnel, the entry and exit of people and materials, cleaning, maintenance, and monitoring. Annex 1 similarly places importance on gowning, hand washing, garment checks, and the control of changing rooms and airlocks. In practice, this means specialist providers help clients maintain discipline not only in production rooms, but also in gowning areas, airlocks, material transfer points, and controlled support spaces where weak execution can undermine broader cleanroom performance.

STRENGTHENING AUDIT-READY EXECUTION

EU GMP expects written, controlled, and repeatable practices across GMP operations, and cleanroom cleaning sits within that wider expectation. For buyers, this changes the service requirement: the priority is not a room that merely appears clean, but a cleaning program that is performed to approved methods, in the right sequence, with the right materials, and with evidence that supports internal review, customer audits, and regulatory inspection. This is where specialist providers differentiate themselves from generalist cleaning support by helping regulated operators sustain a more consistent and defensible standard of execution.

ENABLING SAFER CHANGEOVERS AND PACKAGING READINESS

Specialist providers also create practical value during changeovers and pre-start preparation. EU GMP Chapter 5 states that cross-contamination can arise from the uncontrolled release of dust, residues on equipment, and operators' clothing, and that the control strategy should include effective and reproducible cleaning processes. The same chapter requires packaging operations to be managed with physical or procedural segregation as appropriate, clean and line-cleared packaging lines before use, and controls over contamination risks such as glass and metal fragments. In operational terms, specialist cleaning supports cleaner campaign transitions, stronger line-clearance discipline, and better readiness in packaging and final-handling environments, reducing friction at the point where production must move safely from one activity to the next.

Suir Clean Capabilities

Suir Clean is a contract cleaning company established in 1995. The company serves customers across southeast Ireland, with operations in Munster and Leinster. Over nearly three decades, it has developed a regional presence built on long-term customer relationships, staff retention, and internal progression.

Cleanroom cleaning has been a major part of Suir Clean's business activities for more than two decades. The company's technical expertise in this segment focuses on the production environment, where hygiene maintenance, contamination prevention, and reliable service are given the highest priority. This includes the medical devices and pharmaceutical industries, where bioburden control, hidden contamination risks, and stringent room-use guidelines are vital to their operations.

Suir Clean currently operates across Munster and Leinster, two regions that account for an important share of Ireland's pharmaceutical, medical device, and cleanroom-linked manufacturing activity. The company is also considering opportunities to extend its reach into Connacht through future tender activity.

CLEANROOM SERVICE CAPABILITIES

Suir Clean provides cleanroom cleaning services for ISO 7 and ISO 8 environments, with experience across medical device, pharmaceutical-linked, packaging, warehousing, support-area, and project-related cleaning requirements.

The company's delivery model is based on trained cleaning teams, experienced supervision, direct management contact, and practical site-level control. Customers have direct 24/7 access to management. In cleanroom settings, this can be important when contamination concerns, bioburden issues, staffing changes, or urgent operational requirements need prompt coordination.

Suir Clean can move from staff recruitment to training and on-site cleanroom readiness within approximately ten working days. In one recent cleanroom assignment, the company recruited and trained 12 staff for a 24/7 cleanroom cleaning operation that ran for eight months without service disruption. The company can mobilize additional cleanroom teams where a customer requires short-term or project-based support.

Training is supported by managers with more than 20 years of experience in cleanroom cleaning. Supervisors oversee daily service delivery and help maintain cleaning standards, including when staffing changes occur at short notice.

The company also uses digital geofenced timekeeping to monitor attendance, location, and completion within agreed service windows. For customers operating in cleanroom environments, this provides practical control over whether scheduled cleaning activity has occurred at the required time and location.

Project and Episodic Phases: New facility start-ups, line expansions, shutdowns, post-maintenance recovery

Utilities and critical support areas: HVAC adjacent spaces

GMP warehousing and dispensing: Material warehouses, kitting areas

Packaging and secondary operations: Controlled packaging halls, labelling and leaflet areas, final product handling zones

Product and process development: R&D laboratories

Upstream manufacturing: Gowning and Airlocks

Non-sterile drug product manufacturing: Controlled manufacturing rooms

In addition to cleanroom services, the company provides broader cleaning support across industrial, commercial, food and beverage, and government settings. Its service portfolio includes general cleaning, exterior industrial cleaning, industrial floor care, and machine cleaning. The company also highlights a practical sustainability agenda within its operations. The company states that it prioritizes cleaning agents that minimize environmental impact where possible, including products with the EU Ecolabel, and that it monitors monthly chemical usage as a key performance indicator. It has also introduced digital invoicing and timekeeping to reduce paper use and improve operational efficiency.

BROADER CLEANING SERVICES

Alongside cleanroom cleaning, Suir Clean provides cleaning services across industrial, commercial, food and beverage, and government settings. Its wider service portfolio includes general cleaning, exterior industrial cleaning, industrial floor care, machine cleaning, and project-related cleaning.

This broader capability is relevant because site hygiene requirements often extend beyond the cleanroom itself. Warehousing areas, corridors, gowning routes, material movement areas, packaging zones, and support spaces can all affect contamination-control practices. Suir Clean's experience across both cleanroom and wider industrial cleaning allows it to support these adjacent areas within customer sites.

SUSTAINABILITY AND ENVIRONMENTAL PRACTICES

Suir Clean has also introduced several environmental practices across its operations. The company holds ISO 14001 certification and uses lower-impact cleaning agents where possible, including products with the EU Ecolabel. It also monitors monthly chemical usage and has introduced digital invoicing and timekeeping to reduce paper use.

In cleanrooms, Suir Clean uses flat mop systems that carry the EU Ecolabel and are washed for reuse. Chemical selection in cleanrooms is typically governed by customer procedures, validation requirements, and contamination-control protocols. Within these limits, the company's environmental practices contribute to its wider sustainability profile.

Certifications

- ISO 14001 - Environmental Management System
- ISO 45001 - Occupational Health and Safety Management System
- ISO 9001 - Quality Management System

SUMMARY

Suir Clean is an established regional cleaning provider with more than 20 years of experience in cleanroom cleaning. Its work is most closely aligned with ISO 7 and ISO 8 environments, including medical device production, pharmaceutical-linked manufacturing, packaging areas, warehousing, support spaces, and project-related cleaning.

The company's cleanroom model is supported by experienced supervisors, direct management contact, rapid team mobilization, digital timekeeping, and continuity planning for live operating environments. These capabilities position Suir Clean to support customers that require consistent cleanroom cleaning, clear escalation routes, and practical site-level control across regulated manufacturing environments.

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