AirSpace Machinery
Power On, Worry Off

HIGH-PERFORMANCE INDUSTRIAL AIR COMPRESSION SYSTEMS

REGULATORY WHITE PAPER

Pharma Compliance Guide

ISO 8573-1 Class 0 for GMP Compressed Air Systems

2026 EDITION

- EU GMP Annex 1 (2022) Compliance
- IQ / OQ / PQ Validation Checklist
- FDA, PIC/S, USP <793> & WHO TRS 1044
- ISO 8573-1 Class 0 Explained
- 35% Energy Delta ROI Model
- 10-Point Supplier Audit Questionnaire

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"Power On, Worry Off"

Document Version: 2026.07 — CE & ISO 9001 Certified

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1 Executive Summary

This guide provides pharmaceutical facility managers, QA/QC teams, and procurement engineers with a regulatory blueprint for specifying, validating, and maintaining ISO 8573-1 Class 0 compressed air systems in GMP-compliant environments.

KEY TAKEAWAYS

- EU GMP Annex 1 (2022) mandates **native oil-free generation** for product-contact air
- ISO 8573-1 **Class 0** is the only acceptable purity standard for sterile manufacturing
- The 2026 **USP <793>** standard adds new compliance requirements for US-market facilities
- Proper validation documentation (**IQ/OQ/PQ**) is as critical as the hardware itself
- The **35% Energy Delta** from PMV technology makes compliance a net-positive ROI decision

Compressed air is no longer a background utility in pharmaceutical manufacturing — it is a **Critical Utility** under every major regulatory framework. The 2022 revision of EU GMP Annex 1, the arrival of USP <793> in 2026, and the global harmonisation led by PIC/S have collectively transformed how compressed air must be generated, validated, and monitored throughout a facility's lifecycle.

This white paper consolidates the regulatory expectations across six standards, demystifies the frequently misunderstood ISO 8573-1 Class 0 designation, and provides a practical IQ/OQ/PQ documentation framework that audit teams can adopt directly. It concludes with a transparent financial model demonstrating that compliance and economics are no longer in conflict.

2 Regulatory Landscape

Pharmaceutical compressed air is governed by an overlapping matrix of regional and international standards. The sections below summarise the obligations that most directly impact compressor specification, system design, and ongoing validation.

2.1 EU GMP Annex 1 (2022 Revision)

The 2022 revision of EU GMP Annex 1, "Manufacture of Sterile Medicinal Products," significantly raised the bar for compressed gases used in aseptic processing.

KEY REQUIREMENTS

- Compressed air is classified as a "Critical Utility" when it contacts product or primary packaging
- "Compressed air used in direct contact with the product should be oil-free by design"
- Formal qualification (IQ/OQ/PQ) of the generation and distribution system is mandatory
- Terminal filtration at point of use (0.22µm sterile-grade filters) is required
- Continuous or high-frequency monitoring with defined alert and action limits
- Risk-based Contamination Control Strategy (CCS) must include compressed air

2.2 FDA 21 CFR Part 211

While the FDA does not explicitly cite ISO 8573-1, its expectations under 21 CFR 211.63 and 211.65 are uncompromising.

KEY REQUIREMENTS

- Utilities must not introduce contamination or react with the drug product
- FDA inspectors look for "State of the Art" controls
- Oil-lubricated compressors with add-on filtration are increasingly flagged as high-risk
- 21 CFR Part 11 compliance for electronic records and data integrity

2.3 PIC/S PE 009-17

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) ensures consistent inspections across 50+ countries.

KEY REQUIREMENTS

- Aligned with EU GMP standards
- Compressed air system is part of the Contamination Control Strategy (CCS)
- Pressure fluctuations from fixed-speed compressors are a risk factor for filter integrity
- Documentation of "Unload Tax" risk assessment is expected

2.4 USP <793> (Effective 2026)

The first dedicated United States Pharmacopeia standard for compressed air in compounding and manufacturing.

KEY REQUIREMENTS

- Focus on moisture control (Dew Point) to prevent microbial growth
- Pressure Dew Point (PDP) of -40°C (Class 2) or -70°C (Class 1) for most applications
- Requires high-performance desiccant dryers
- Alignment with ISO 8573-1 classification system

2.5 VDI 2083 (Germany / DACH Region)

For facilities operating in German-speaking markets, VDI 2083 is the gold standard for cleanroom technology.

KEY REQUIREMENTS

- VDI 2083 Part 13 treats compressed air as a "Clean Medium"
- Air purity must match or exceed the cleanroom classification it enters
- Grade A (ISO 5) cleanrooms require ISO 8573-1 Class 1 or 0
- Prevents "Cleaning Robbery" — frequent decontaminations due to poor air quality

2.6 WHO TRS 1044

WHO GMP guidelines for pharmaceutical manufacturing.

KEY REQUIREMENTS

- Compressed air is a critical utility in sterile manufacturing
- Requires documented quality specifications
- Validation of generation and distribution systems

3 ISO 8573-1 Class 0 Explained

3.1 What Class 0 Actually Means

COMMON MISCONCEPTION

Class 0 means "absolute zero" oil contamination.

REALITY

ISO 8573-1 Class 0 is a user-defined purity standard that must be more stringent than Class 1.

Class	Total Oil (mg/m³)	Notes
Class 0	**User-defined (< 0.01)**	**Must be agreed between manufacturer and user**
Class 1	≤ 0.01	Measurable limit
Class 2	≤ 0.1	10× higher than Class 1
Class 3	≤ 1.0	General industrial
Class 4	≤ 5.0	Not suitable for pharma

3.2 Verification Requirements

- **ISO 8573-2:** Test method for oil aerosols
- **ISO 8573-5:** Test method for oil vapor
- Third-party (DAkkS-accredited) laboratory certification required
- Documentation must cover the entire unit, not just the air end

3.3 AirSpace Class 0 Integrity

AirSpace Machinery Guarantees

- **0.00 mg/m³** total oil content (aerosol, liquid, and vapor)
- Independent third-party certified
- Full documentation package including FAT reports and test certificates

4 Validation Documentation Checklist

Validation is not optional. The three qualification phases below form the backbone of any GMP-compliant compressed air system. Each item must be documented, traceable, and audit-ready.

4.1 Installation Qualification (IQ)

- [ ] P&ID diagrams showing all filters, dryers, and piping
- [ ] Calibration certificates for dew point sensors and pressure transducers
- [ ] Material certificates for all product-contact surfaces (304SS / 316L)
- [ ] CE Declaration of Conformity
- [ ] ISO 9001:2015 certificate
- [ ] Factory Acceptance Test (FAT) report

4.2 Operational Qualification (OQ)

- [ ] Purity testing at "Worst Case" (maximum flow)
- [ ] Verification of alarms (High Dew Point, Oil Vapor detected)
- [ ] Pressure stability testing (±0.1 bar)
- [ ] Filter integrity testing
- [ ] Dryer performance verification

4.3 Performance Qualification (PQ)

- [ ] Consecutive days of purity sampling at various points of use
- [ ] Microbiological sampling (CFU counts)
- [ ] 21 CFR Part 11 compliant data logs
- [ ] Trending analysis over 30 / 90 / 365 days

5 Common Audit Findings & Remediation

The recurring deficiencies below are drawn from real GMP inspections across EU, FDA, and PIC/S jurisdictions. Each is paired with its root cause and a direct remediation path.

Finding	Root Cause	Remediation
Missing oil vapor test data	Only tested for oil liquid, not vapor	Use native oil-free compressor; test per **ISO 8573-5**
Expired sensor calibration	No maintenance schedule for sensors	Annual calibration with easy-access ports
"Technically oil-free" claims	Oil in gearbox claimed as "oil-free"	Demand full-unit Class 0 certification
No Contamination Control Strategy	Compressed air not in CCS	Include air system in risk assessment
Inadequate dew point monitoring	No real-time PDP measurement	Install continuous dew point monitoring
Pressure fluctuations > ±0.3 bar	Fixed-speed compressor cycling	Upgrade to **PMV VSD** (±0.1 bar stability)

6 The Financial Case: 35% Energy Delta

Compliance and cost-efficiency are not opposing forces. The PMV (Permanent Magnet Variable-speed) platform delivers Class 0 oil-free air while consuming up to 35% less energy than legacy fixed-speed oil-injected systems — turning a regulatory necessity into a net-positive ROI decision.

6.1 Annual Cost Comparison (75kW System, 6,000 hrs/yr)

Cost Component	Legacy Fixed-Speed (Oil-Injected)	AirSpace PMV (Oil-Free)	Annual Savings
Electricity ($0.12/kWh)	$64,800	$42,120	**$22,680**
Filter Replacements	$4,200	$1,100	**$3,100**
Condensate Disposal	$2,500	$0	**$2,500**
Risk Contingency	$15,000	$0	**$15,000**
Total Annual Cost	**$86,500**	**$43,220**	**$43,280**

6.2 10-Year TCO Comparison

System	10-Year TCO	Savings vs Legacy
Legacy Fixed-Speed (Oil-Injected)	$865,000	—
AirSpace PMV Oil-Free	**$432,200**	**$432,800**

ROI INSIGHT

Over a 10-year lifecycle, the AirSpace PMV oil-free system saves **$432,800** versus a legacy fixed-speed oil-injected equivalent — a figure that exceeds the entire acquisition cost of the compliant system, while simultaneously eliminating the regulatory risk of oil carryover.

7 10 Questions for Your Supplier

Before purchasing a pharma-grade compressor, demand clear, documented answers to the following questions. Evasion or ambiguity on any point is itself a compliance risk signal.

1. Can you provide a Class 0 certificate that includes oil vapor, not just aerosols?
2. Does the unit use PMV technology to maintain ±0.1 bar pressure stability?
3. Are internal cooling tubes and piping made of 304 or 316L Stainless Steel?
4. What is the guaranteed Pressure Dew Point under max summer humidity?
5. Is there a "Service Prison" — or can my local team perform basic maintenance?
6. Can the controller export 21 CFR Part 11 compliant data logs?
7. What is the "Unload Tax" (idle power) of this specific model?
8. Do you provide a full IQ/OQ template for this machine?
9. Is the motor rated for IE4 or IE5 efficiency?
10. How do you handle the "Humidity Tax" in tropical or high-moisture environments?

8 About AirSpace Machinery

AirSpace Machinery Co., Ltd. designs and manufactures CE- and ISO 9001-certified PMV oil-free screw compressors engineered for the pharmaceutical, food, and electronics sectors. With two decades of engineering excellence and 100+ global pharma installations, the company delivers factory-direct Class 0 systems on a 35-day lead time.

Company	**AirSpace Machinery Co., Ltd.**
Heritage	20 years of engineering excellence
Certifications	CE and ISO 9001 certified
Facility	4,000 m² manufacturing facility
Specialty	PMV oil-free screw compressors
Delivery	35-day factory-direct delivery
Pharma Track	100+ global pharma installations

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Document Version: 2026.07 — For reference only. Consult your local regulatory authority for applicability.