OLYMPUS

Olympus Corporation

Version 1.0 | January 2026

Global Supplier Handbook

HOW TO UTILIZE OUR SUPPLIER HANDBOOK

Dear Supplier,

This handbook provides high-level guidance on Olympus' Supplier Lifecycle, outlining the essential policies, processes, and procedures suppliers are expected to follow to meet Olympus' expectations in areas such as procurement, quality management and compliance with regulatory and legal requirements. It is designed to ensure successful collaboration by aligning suppliers with standards like ISO 9001 and ISO 13485, medical device laws, market requirements across regions, and Olympus' Code of Conduct as well as internal quality standards.

Intended for suppliers whose products or services directly or indirectly impact the safety, quality, and efficacy of medical devices and Olympus' Quality Management System (QMS), this handbook serves as a framework for partnership. We encourage suppliers to review these guidelines carefully and discuss any questions with their Olympus point of contact. We deeply appreciate the dedication of suppliers who consistently meet our quality criteria, and we are grateful for your ongoing commitment to our shared success.

Michael Groth
Vice President Supplier Quality, Global

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Vice President; Acting Global Head of Procurement

SUPPLIER LIFECYCLE MANAGEMENT

01 Supplier Identification

Supplier identification involves finding suitable onboarded partners or new suppliers for products or services.

During the identification phase, we screen suppliers based on their ability to meet Olympus' requirements. This process includes gathering relevant information from both current and potential new suppliers. Suppliers should be prepared to provide necessary documentation and complete forms sent by Olympus upon request. A Non-Disclosure Agreement (NDA) may be required before critical information is exchanged.

02 Supplier Evaluation and Selection

Supplier Evaluation and Selection involves comparing shortlisted suppliers identified during the supplier identification process based on specific criteria. This process applies to both existing and new suppliers.

The entire supplier lifecycle at Olympus Corporation depends on the contracts and documents established with suppliers. Suppliers may be asked to review and, if necessary, align and sign additional documents to support specific requirements.

03 Supplier Approval

The Supplier Approval Process ensures that suppliers meet all regulatory and legislative requirements, maintaining compliance and quality throughout the supply chain.

Requirements vary by supplier and the associated product or service. Deviations may lead to approval limitations or withdrawal. The approval process may include Quality Assurance Agreement (QAA), Supplier Purchase Agreement (SPA), and/or audits.

04 External Product Qualification

The External Product Qualification (EPQ) assesses the technical aspects of the manufacturing process in order to approve the parts or products for serial production. The method follows the Production Part Approval Process (PPAP) approach. This ensures that future orders meet all specifications and that suppliers can consistently maintain these standards. Olympus approval is mandatory before the first regular delivery of production parts. This process applies to both new products and existing products with changes.

Suppliers will receive a Product Qualification Plan outlining all mandatory deliverables, which vary based on the product type or the nature of the changes being qualified. This may include deliverables such as Process Failure Mode and Effects Analysis (PFMEA), Process Validation, Control Plans or Measurement System Analysis (MSA).

Before manufacturing for Olympus, suppliers must ensure all processes meet quality and functional standards through verification or validation.

Change Management

Suppliers may undergo internal changes affecting processes, production, and/or other areas. Olympus must be informed of any changes impacting products or services to assess potential risks. These include business, regulatory, product-specific, or process-related changes. Suppliers must maintain a documented change management process.

SUPPLIER CHANGE NOTIFICATION

A Supplier Change Notification (SCN) is a formal process for reporting changes that may impact products, services, processes, business details, or regulatory compliance. It ensures quality, compliance, and transparency by documenting and assessing potential effects. Olympus provides a standardized form, though equivalent documents may be accepted if they meet the required details.

Suppliers must notify Olympus within the QAA-defined timelines for any changes affecting product quality, regulatory compliance, or delivery reliability. They must provide accurate details on the change, including scope, rationale, and impact, allowing Olympus to assess risks and take necessary actions. Additional documentation may be requested during the review process.

05 Supplier Performance and Risk Control

Monitoring & Re-Evaluation

To ensure a sustainable, long-term partnership, Olympus closely monitors supplier performance and risks. Continuous evaluation helps maintain quality standards and meet expectations.

SUPPLIER MONITORING

Supplier monitoring involves a systematic recurring assessment based on defined quality, logistics, and procurement KPIs. It assesses factors such as Part Failure Rate, On-Time In-Full, etc. to ensure alignment with Olympus' standards. The results are compiled into a performance score, identifying strengths and areas for improvement.

SUPPLIER RE-EVALUATION

Supplier re-evaluation at Olympus reassesses risks to ensure ongoing compliance with high standards. The process generates a risk score based on KPIs and other factors, guiding further actions if needed.

Suppliers with a satisfactory status require no action, while those needing development undergo targeted improvements. In some cases, surveillance audits may be conducted to verify compliance and performance. Olympus may take additional action in the event that a supplier does not meet targeted improvements or audit expectations.

Non-conformities

Nonconformance (NC) refers to deviations from established requirements in products, services, or processes, including materials, equipment, and documentation. NCs are managed through complaints and reports, requiring supplier confirmation. The process involves identifying, investigating, and resolving issues to ensure compliance and prevent recurrence.

A Supplier Notification Only (SNO) is issued by Olympus to inform suppliers of nonconformances (NC) and requires acknowledgment and immediate corrective actions to ensure quality improvement. In contrast, a Supplier Corrective Action Request (SCAR) addresses more critical nonconformances, requiring formal resolution through containment, root cause analysis, and corrective/preventive actions with evidence. SCARs follow the eight disciplines (8D) Method, with submissions reviewed and revised if incomplete, ensuring effective resolution and preventing recurrence. Both processes aim to uphold Olympus' quality standards and drive continuous improvement.

06 Supplier Development

The Supplier Risk Improvement Program mitigates supplier risks while enhancing performance. A committed approach strengthens collaboration, ensures compliance, and drives continuous improvement to meet Olympus' standards.

Suppliers enter the program if they show insufficient progress, pose risks, or fail to meet expectations. Based on their progress, they are either accepted, required to continue improvements, or phased out.

07 Supplier Phase-Out

The supplier phase-out process formally concludes the supplier lifecycle with a structured approach. Transparent communication and planning ensure a smooth transition, minimizing risks and supply chain disruptions. All actions are documented for compliance and operational stability.

Disclaimer: This Handbook is intended as a reference guide outlining general expectations, quality requirements, and compliance obligations for suppliers working with Olympus. It does not constitute a legally binding agreement and may be updated periodically without prior notice. It does not supersede or replace any formal purchasing agreements, supplier quality agreements, or contractual obligations. If there is a conflict between this Handbook and a signed agreement, the terms of the signed agreement shall apply.