Edwards Lifesciences Supplier Guidebook

Building Trusted Partnerships

Edwards

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A Message From Joe Nuzzolese

CVP, GSC and Quality

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At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease. The strength of these solutions and the ability to serve patients lie in large part on our partnerships with suppliers. We know that the trusted relationships we have with you are vital to help us improve patient lives.

This guidebook and the Edwards Supplier Portal serve as a guide to our expectations and resources for suppliers. We are proud of our reputation for integrity and expect all suppliers with whom we work to follow the same high standards.

Open and effective communication is key to a successful partnership. If you have any questions or suggestions, please don't hesitate to contact a member of our Supplier Management Team. We want to foster a collaborative environment and help drive success for both of our organizations.

Thank you for your commitment to our shared goals. Together we will continue to transform patient lives with innovative medical technologies.

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Our Credo

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At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Through our actions, we will become trusted partners with customers, colleagues and patients – creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

We will celebrate our successes, thrive on discovery and continually expand our boundaries. We will act boldly, decisively and with determination on behalf of people fighting cardiovascular disease.

Helping patients is our life's work, and

life is now

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Introduction

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Edwards Lifesciences is a global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians, stakeholders, and suppliers across the global healthcare landscape.

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Please note that the guidance within this manual is provided to supplement – not replace – terms or conditions within established agreements, drawings, or specifications. In the event of conflicting interpretations, please apply the following order of precedence unless otherwise noted contractually:

1 | Agreements (quality, supply, etc.)

↓

2 | Specification Requirements

↓

3 | Edwards Purchase Orders

↓

4 | The Supplier Guidebook

We understand that our suppliers directly impact our ability to deliver reliable, high-quality products, and we know how important you are to our success in a global, highly innovative marketplace. This guidebook is intended to serve as a helpful resource regarding the requirements and expectations for doing business with Edwards and maintaining a successful partnership during the development, manufacturing, and delivery of high-quality materials, products, and services.

This guidebook is a helpful resource for you regarding the requirements and expectations for doing business with Edwards and maintaining a successful partnership.

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About Edwards Lifesciences and Our Supplier Management Team

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Our Product and Technology Offerings

Transcatheter Heart Valves (THV)

We are the global leader in transcatheter heart valve replacement technologies designed for the minimally invasive replacement of aortic heart valves.

The Edwards SAPIEN family of valves and their respective delivery systems are used to treat heart valve disease using catheter-based approaches for patients who have severe symptomatic aortic stenosis and certain patients with congenital heart disease. Delivered while the heart is beating, these valves can enable patients to return to their normal activities sooner than patients receiving traditional surgical therapies.

The proven SAPIEN 3 system is commercially available for the treatment of symptomatic severe aortic stenosis in over 75 countries and is now an approved treatment option for patients at low risk for surgery in Europe, the U.S., Japan, and other countries around the world based on the superiority of outcomes demonstrated in the PARTNER 3 Trial.

Alterra adaptive prestent and **SAPIEN 3** transcatheter heart valve

Edwards SAPIEN 3 Ultra transcatheter heart valve

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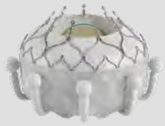
Transcatheter Mitral and Tricuspid Therapies (TMTT)

Our focused investment in structural heart initiatives has resulted in the development of multiple innovative therapies for patients suffering from mitral and tricuspid disease.

PASCAL Precision system

Our PASCAL repair platform delivers differentiated transcatheter leaflet repair for patients with mitral and tricuspid regurgitation. Through continuous innovation coupled with our high-touch procedural and imaging support, the PASCAL system enables our physician partners to optimize clinical outcomes for their patients.

The EVOQUE tricuspid replacement system expands our treatment options for patients with tricuspid valve disease, providing a new transcatheter therapy for patients with limited options. SAPIEN M3 and



Edwards EVOQUE tricuspid replacement system

other mitral valve replacement systems are designed to treat patients with mitral valve disease. We are advancing our clinical experience with these mitral and tricuspid replacement therapies through continued enrollment in pivotal trials and clinical studies.

SAPIEN M3 system

The SAPIEN M3 transcatheter mitral valve replacement system is the world's first approved transcatheter valve replacement therapy using a transfemoral approach to treat mitral valve disease. Leveraging the company's SAPIEN technology, the SAPIEN M3 system substantially reduces mitral regurgitation and improves quality of life.

For more information about Edwards Products and the patients we serve, please visit https://www.edwards.com.

*Investigational device. Limited to investigational use only.

**CE Mark in EU. Investigational device and not available for sale in the U.S.

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Surgical Structural Heart (SURG)

We have a proven commitment to ongoing innovation in surgical structural heart solutions to advance the state of the art and put better outcomes within reach. Our RESILIA tissue is helping us redefine tissue durability standards.

INSPIRIS RESILIA aortic valve

The INSPIRIS RESILIA aortic valve features RESILIA tissue, a bovine pericardial tissue with advanced anti-calcification properties and proprietary VFit technology, which is designed for potential future valve-in-valve procedures.

MITRIS RESILIA mitral valve

The MITRIS RESILIA mitral valve is built on the trusted Carpentier-Edwards PERIMOUNT valve platform with RESILIA tissue and an enhanced delivery experience. This valve is designed to handle the pressure of the mitral position and was developed with patients' quality of life in mind.

KONECT RESILIA aortic valved conduit is part of our class of resilient bovine pericardial valves, or RESILIA valves. This ready-to-implant* aortic valved conduit helps patients maintain their active lifestyles and streamlines bio-Bentall procedures.

* Consult instructions for use for device preparation instructions.

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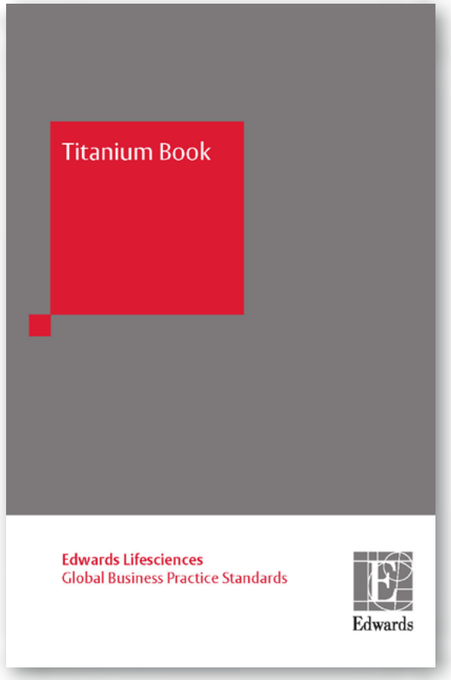
Our Global Business Practice Standards

We take pride in conducting our business with honesty, openness, and fairness, and in accordance with legal standards and the highest ethical principles because it is the right thing to do. Our Global Business Practice Standards (our "Titanium Book") help explain the universal principles governing our business, provide clarity about expectations, and identify resources that support these standards. These standards apply globally to all of Edwards' businesses and subsidiaries and to all employees, members of the Board of Directors, and Agents of Edwards. They are a practical guide to help us with issues we face as an innovative, growing company. Our actions taken with integrity will allow us to live our Credo and help more patients around the world.



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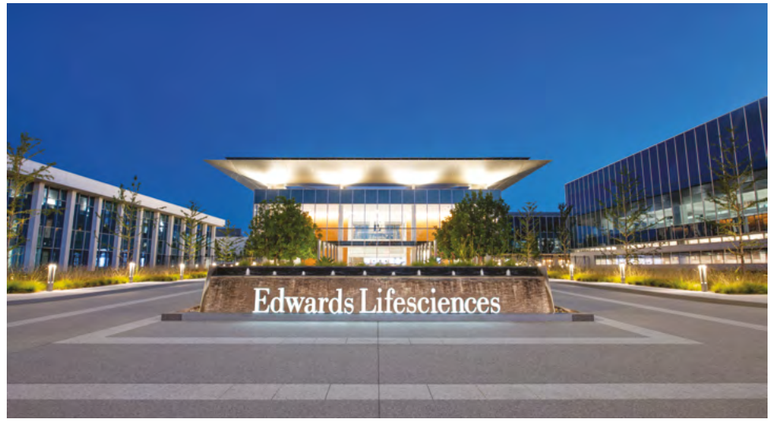
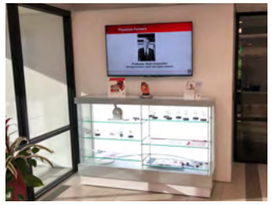
Our Manufacturing Locations





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Our Supplier Management Team

Supporting each of our sites and all of our suppliers is the Edwards Supplier Management Team. Our mission is to provide innovative, cost effective, and reliable solutions to improve product development processes and deliver quality components for outstanding product performance.

We partner with our suppliers to ensure they have the systems, processes, and technical capabilities to meet our quality, delivery, cost, and innovation needs.

The primary responsibilities of our team include:

- Providing Design for Manufacturability (DFM) input to R&D during component design and development
- Acting as the primary technical point of contact for suppliers
- Completing supplier process characterizations (Design of Experiments [DOEs], range cliff studies)
- Developing supplier/Edwards workmanship standards
- Completing component qualification (First Article Inspection [FAI], Part Qualification Plan [PQP], etc.)
- Completing supplier equipment and process validations
- Conducting capacity assessments and improvements
- Facilitating and supporting a Notification of Change (NOC)

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The responsibilities of our suppliers in working with our Supplier Management Team include:

- Optimizing designs for manufacturability
- Developing and optimizing processes to improve manufacturability and increase yield, thus reducing cost over time
- Increasing productivity through improved inspection processes

Communicating With Our Supplier Management Team

The Edwards Supplier Portal is designed to facilitate communication with our supplier partners. The portal:

- Helps suppliers manage their day-to-day business with Edwards
- Offers resources (e.g., policies, procedures, reports) for suppliers
- Provides performance updates through a supplier scorecard
- Allows prospective suppliers to apply to become an Edwards partner

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A Responsible and Sustainable Supply Chain

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We have an enduring commitment to conduct business according to the highest standards of ethics and integrity. We hold our suppliers to the same high standards and will only maintain relationships with third parties that demonstrate a commitment to:

Compliance with Laws and Regulations
- World Trade Compliance
- Business Integrity and Corruptions
- Regulatory Compliance

Ethical Business Practices
- Workplace Free of Harassment
- Fair Employment Practices
- Non-discrimination

Human Rights
- No Practice of Human Trafficking and Modern Slavery
- Fair Wages and Benefits

A Safe and Healthy Workplace
- Occupational Safety
- Emergency Preparedness
- Equipment Safeguards
- System Training Procedures

Environmental Responsibility
- Operational Efficiencies
- Managing Carbon Emissions
- Water and Waste Reduction Controls

We regularly perform a variety of actions and activities to ensure that our suppliers meet these expectations.

To learn more about how we operate as a business and the expectations we have for our third-party partners, please review these documents:

- Responsible Supply Chain
- Third Party Code of Conduct
- Conflict Minerals Policy
- Conflict Minerals Report
- ISO Certificate

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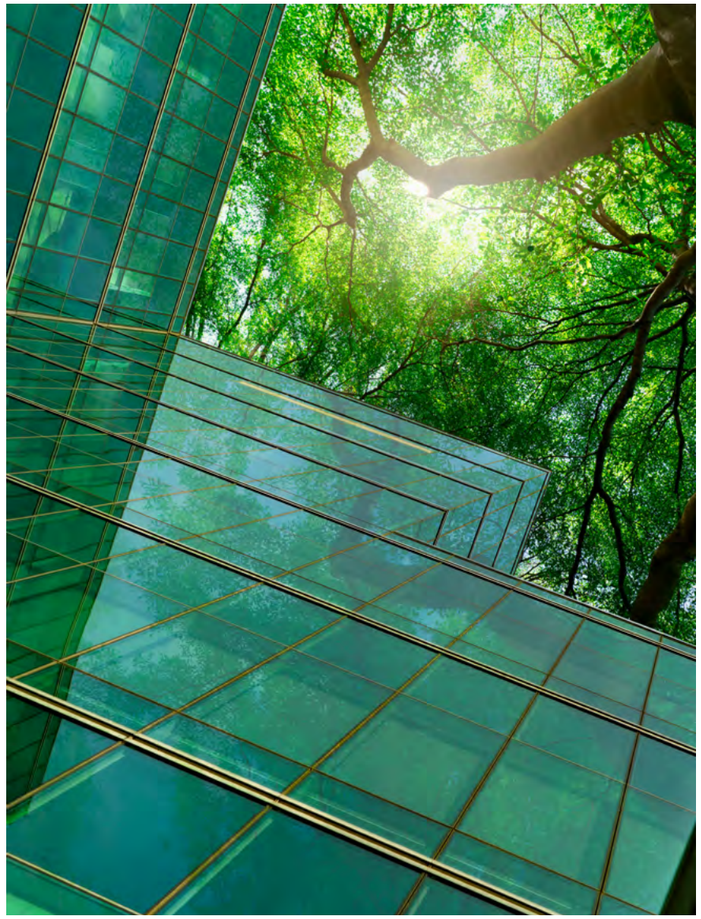
Supplier Environmental Responsibilities

We understand the importance of addressing climate change and we are committed to driving a meaningful reduction in our greenhouse gas (GHG) emissions. This includes a science-based target to reduce Scope 3 GHG emissions from our value chain, most notably from purchased goods and services. It's imperative that our suppliers share this vision and align their strategies to meet Edwards' expectations.

Four Climate Expectations for Suppliers

1. Quantify greenhouse gas emissions from their direct operations
2. Establish a carbon reduction target
3. Identify and execute opportunities to reduce greenhouse gas emissions
4. Report their progress annually to the public



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Supplier Diversity

We recognize that having a diverse and inclusive procurement process helps us meet the needs of patients globally. Hence, we are committed to incorporating diversity in our supply base by building communities of trust with certified and qualified businesses that meet our supplier requirements within historically marginalized groups, including but not limited to, women, minorities, veterans, service-disabled veterans, LGBT+s, persons with disabilities, and small businesses, to enable continuous growth and meet the needs of our increasingly multicultural, multilingual, and multidimensional patients.

We encourage and recognize the memberships in the following organizations (membership is not required to do business with us):

- National Minority Supplier Development Council
- National LGBT Chamber of Commerce
- National Veteran Business Development Council
- Women's Business Enterprise National Council
- Disability:IN

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Supplier Management Overview

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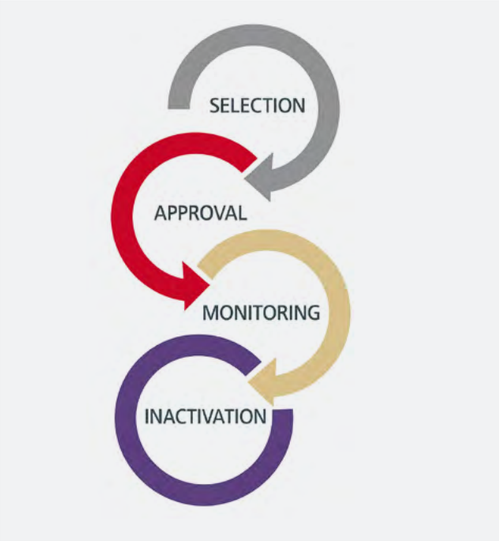
Supply Chain Supplier Management Process

Our Supply Chain Supplier Management Process helps ensure that suppliers are aligned with best practices when sourcing raw materials, components, or services for incorporation into our finished medical devices. The process also helps identify potential risk in order to mitigate major supply chain disruption to production.



Process steps include:

SELECTION

- Specifying what we need from a supplier
- Identifying and evaluating potential suppliers
- Selecting the supplier based on their strategic fit for Edwards' requirements

APPROVAL

- Qualifying and approving the supplier, materials, or services provided

MONITORING

- Providing oversight to ensure the supplier continues to meet Edwards' expectations. This includes:
  - Direct monitoring through management reviews, supplier score cards, and/or onsite assessments
  - Implementing change management and systems to address and resolve issues linked to supplier's services and/or materials, such as Non-Conformance Reports (NCRs) and Supplier Corrective Action Requests (SCARs)

INACTIVATION

- Discontinuing business with a supplier, either company-wide or at an individual site to respond to changing business needs and/or addressing performance issues over time

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Medical Device Industry Focus

We put a priority on partnering with suppliers who have prior knowledge and experience working with medical device customers. Suppliers with an ISO 13485 certification, significant revenue from the medical device industry, and cleanroom manufacturing capability (as required), are preferred.

Supplier Selection

Quality Audits

Quality audits of vendors can be performed by Edwards and regulatory authorities. We conduct periodic audits (e.g., verifications, factory audits) to review vendor procedures and processes for supplying manufacturing materials and services. These audits are typically pre-planned events that verify a supplier's compliance with written agreements and quality system requirements.

Suppliers identified as critical to our operations may experience unannounced audits by regulatory authorities for products that are sold worldwide. Suppliers are expected to:

- Allow auditors unimpeded access to information and facilities
- Ensure that provisions are in place for hosting unannounced audits, including staff being properly trained and aware of audit requirements and responsibilities
- Address all issues arising from audits
- Ensure that actions taken to address audit findings do not adversely impact materials or services supplied to Edwards

Technical Assessments

We conduct technical assessments to understand the strengths and opportunities of our suppliers' technical capability in the areas of:

- Quality Excellence
- Operational Excellence
- Product and Process Development
- Culture
- Enterprise Alignment
- Technology

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Our maturity rating scores for the technical assessment include:

1 Immature

What It Looks Like:

Individuals choose what tools to use when there are minimally documented processes

Results are based on individuals' efforts and abilities

How It Performs:

Metrics are nonexistent, inconsistent, or not sustained

2 Developing

What It Looks Like:

There are established procedures that individuals are following with some use of the right tools

Results have variation with little predictability

How It Performs:

Metrics exist in some areas; they are reactionary and lagging, with little to no trending

3 Stable/Capable

What It Looks Like:

Well-established procedures are consistently applied using a standard set of tools

Results are predictable and show some improvement over time

How It Performs:

Metrics are widely understood

There's a combination of leading and lagging indicators, which are monitored and reacted to in a timely manner

4 Robust

What It Looks Like:

Processes drive individuals to use standardized, best-known methods and tools to perform their duties and drive continuous improvement

Results are predictably improving over time

How It Performs:

Metrics are leading and have improvement targets

Metrics are monitored and reacted to in a standard manner

5 Best in Class

What It Looks Like:

Processes drive individuals and teams to use standardized best-known methods and tools to perform not only their duties, but also the supporting processes

Results are continually improving over time and working toward attainment of "benchmarked world-class" standards

How It Performs:

Metrics are leading and show year-over-year continuous improvement

They are monitored and reacted to by everyone every day

We may use the results of a technical assessment to drive decisions regarding prospective key and strategic supplier partnerships. Suppliers are expected to drive improvement activities based on opportunity areas identified in assessment results.

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Information Security Third Party Risk Management Service (IS-TPRM)

The IS-TPRM aims to reduce the risk of a cyber incident materializing due to our supply chain. By protecting the confidentiality, integrity and availability of Edwards systems, assets and data, IS-TPRM focuses on managing risks within Edwards' risk appetite.

Edwards evaluates a supplier based on their risk profile and assess the security posture and practices to ensure they do not introduce unacceptable risks to Edwards.

Why is Information Security Important for Suppliers?

- Prevents Security Incidents
- Protects Sensitive Information
- Maintains Trust and Compliance

Financial Stability

We seek to establish long-term partnerships with each of our approved suppliers. Along with the quality and business performance metrics that form the pillars of that partnership, we also assess the business viability of suppliers to ensure supply chain stability. We may ask suppliers to assist in this evaluation by providing documentation such as audited financial reports that demonstrate an accurate picture of their past and current financial well-being and business prospects.

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Supplier Approval

Supplier Classification

Suppliers are designated as "Approved" based on their business, quality and delivery performance with us. The expectations set forth in this Supplier Guidebook provide the framework for suppliers who would like to grow their business with Edwards Lifesciences. Suppliers not meeting Edwards' expectations would be in a "Restricted" status, and this restricts the development of new business.

Quality Agreements

We expect suppliers to document their commitment to a specific scope of quality management activities during the duration of their relationships with us in a Quality Agreement. This agreement corresponds to the product or service being provided.

Depending on the supplier's scope of work and risk level, a basic agreement may cover any of the following:

- Scope/Definitions
- Manufacturing
- Storage, Packaging, and Shipping
- Inspection and Testing
- Non-Conforming Products
- Supplier Change Control Management
- Drawing/Specification Changes
- Changes in Registration Status
- Device History Record and Record Retention
- Complaints/Recall/Field Corrective Actions
- Audits by Federal, State, or Local Regulatory Agencies/Edwards Quality Audits
- Terms, Confidentiality, and Ownership or Rights
- Hazardous Substances Regulations

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Supplier Monitoring

Supplier Corrective Action Request (SCAR)

A Supplier Corrective Action Request (SCAR) is a written request for a supplier to identify the root cause(s) of a non-conformance and document steps taken to eliminate the cause(s) and prevent recurrence. A SCAR may also be initiated due to other supplier-related issues such as failure to comply with an Edwards requirement as outlined in the Quality Agreement.

Our risk-based decision-making process for supplier issues, known as the Supplier Nonconformance Event Determination (SNED), works in tandem with the SCAR classification system to ensure appropriate and proportional responses.

Each supplier issue is classified based on severity, the outcome of an incident review, and its direct material impact. This ensures that SCAR actions are properly scaled to the level of risk.

Risk-Based SCAR Classification:

SCARs will be classified into 2 levels (1 and 2) based on assessed risk to Edwards and in alignment with the severity/compliance risk levels of the Edwards CAPA process.

Level 1 SCAR	Level 2 SCAR
Deemed higher risk to Edwards. Targets a 45 day turnaround on investigation. Requires management approval for investigation and closure.	More flexible with the investigation timeline and requires management approval for closure.

Supplier Notification of Nonconformance (SNN)

In the event a SCAR is not initiated the supplier may receive a Supplier Notification of Nonconformance (SNN) indicating Edwards has nonconforming material that is determined to be supplier caused. Suppliers are expected to investigate and initiate actions to prevent additional occurrence.

Quality Metrics

Two of the most important quality metrics that we track among suppliers are the Supplier Corrective Action Request (SCAR) rate and the Lot Acceptance Rate (the percentage of lots that pass receiving inspection).

Suppliers are expected to work toward:

- SCAR-free rate of >98%
- Lot acceptance rate of >95%

Suppliers are encouraged to maintain an audit-ready status (zero to minimal potential for critical findings).

Performance Scores

On an annual basis, we select key strategic suppliers to go through a review process. This may include a business review, in which elements such as quality, delivery, cost, business continuity, and innovation are assessed to determine the Supplier Operational Excellence Maturity Index, either Bronze, Silver, or Gold.

Bronze:	Silver:	Gold:
≥ 60%	≥ 75%	≥ 90%

Promoting Supplier Excellence

We want to elevate our level of engagement with suppliers to focus on increasing quality and business expectations as well as develop supplier capabilities in anticipation of future Edwards needs. When evaluating whether to elevate our level of engagement, we consider the following elements:

- **Quality and Compliance:** The capability to consistently manufacture products that meet or exceed specifications and quality requirements, along with management commitment to quality, intellectual property protection and a culture of continuous improvement
- **Technology:** The possession of core technical competencies and leadership in the development of new technical capabilities
- **Innovation:** The ability to provide engineering and secure business solutions to help drive Edwards innovation
- **Partnership:** A mutually beneficial relationship that will help both Edwards and our suppliers aid more patients
- **Value:** A zeal to provide competitive pricing, excellent service, lead time reduction, inventory management, and subject matter expertise

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Expectations for Suppliers

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Quality Management System

Alignment with Edwards' standards for quality management lies at the heart of our quality and compliance expectations of suppliers. We consider and prefer supplier certification with ISO 13485 (direct material and service suppliers), as this indicates a supplier has a robust Quality Management System (QMS) within their organization. The ISO 13485 standards provide a shared foundation for Edwards and suppliers to effectively work together in the following areas:

- Process Validation (including inspection)
- Change Control
- Complaints Investigation
- Control of Non-Conforming Product
- Record Retention
- Receiving Inspection
- Sterilization Control (for sterile products)
- Packaging and Labeling
- Training

We also encourage suppliers to seek certification with other industry standards (e.g., ISO 9001, ISO 17025) that apply to the specific supplier processes that interface with Edwards.

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Record Retention

We expect suppliers to adhere to the requirements below for record retention.

Type of Product/Item	Record Retention Requirement
Non-implantable Finished Device	10 years past the last date of manufacturing
Implantable Finished Device	15 years past the last date of manufacturing
Sourced customer parts that are part of a product Bill of Material (BOM) (Example: a component that is part of an Edwards finished device)	Minimum of 7 years
Off-the-Shelf (OTS) item	Record retention requirements are **not** applicable
Something consumed during the manufacturing process (indirect)	

Regulatory Registration and Compliance

We expect suppliers to be aware of and compliant with regulations around the world that impact their interface with Edwards. These regulations are set by government agencies, health ministries, and notified bodies in geographic areas where Edwards' products are being marketed. As such, these include requirements with cross-border impact such as FDA site registrations for contract manufacturers within and outside the U.S. and compliance with the UDI (Unique Device Identifier) regulations for exported products in the U.S.

We expect suppliers to provide or disclose required information to support site registration, Good Manufacturing Practice (GMP) certification, product registration, and product license maintenance.

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Trade Compliance

Suppliers, their agents, and their representatives are responsible for complying with import and export restrictions imposed by the laws and regulations of the countries in which Edwards does business, including restrictions set on member states by international organizations such as the United Nations, the World Trade Organization, and the European Union. Appropriate measures must be taken to ensure goods, services, and technology are not improperly imported, exported, re-exported, or diverted.

Intellectual Property and Supply Chain Security

We are committed to the protection of intellectual property relating to our company and our supplier base. Safeguarding business information is critical from the time a potential supplier is considered through the duration of the business relationship with us. A confidentiality agreement is required when confidential information must be disclosed as part of formulating a supplier proposal. We respect a supplier's right to protect their own confidential information but expect supplier compliance with external or Edwards-driven mandates for identifiability and traceability.

Our business security requirements include the protection of Edwards' data. We evaluate the security practices of suppliers, particularly those that support critical operations and materials, during the supplier selection and onboarding process, and suppliers may be subject to frequent monitoring. We recommend disclosing these security practices as needed.

We also expect suppliers to take proactive action to address security vulnerabilities that might compromise the software, hardware, or raw materials they provide to us. Suppliers must also disclose all critical risks to Edwards, provide contingency plans to counteract and mitigate these risks, and notify us of any security breach. Supplier-side safeguards must be in place to ensure that information and materials are available only to individuals on a need-to-know basis.

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Product Stewardship

Edwards is committed to responsible sourcing, and our suppliers are a critical link in those efforts. We require that suppliers align with Edwards in adhering to laws and regulations governing the origin, content, packaging, and labeling of products, components, or substances. These standards include the following, but are not limited to:

- **REACH** (Registration, Evaluation, Authorisation and Restriction of Chemicals): EU law which protects human health and the environment from the risks that can be posted by chemicals
- **RoHS** (Restriction of Hazardous Substances): A directive which limits the amount of hazardous chemicals in electronics
- **WEEE** (Waste from Electrical and Electronic Equipment): EU directive on waste from electrical and electronic equipment
- **POP** (Persistent Organic Pollutants): Restricts the use of persistent organic pollutants
- **EU MDR** (European Union Medical Device Regulation): Hazardous material regulations
- **Cal** (California) **Prop 65**: Requirements to protect drinking water sources from being contaminated with chemicals
- **TSCA** (Toxic Substances Control Act): Addresses the production, importation, use, and disposal of specific chemicals
- **BPA** (Bisphenol A): Products should be free of BPA

Because new substances of very high concern are added to REACH every six months, we expect suppliers to actively partner with us in monitoring these changes. They must also be aware of and willing to comply with other materials regulation standards that are specific to their geographic regions.

For conflict minerals, we adopt the definition set forth by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act and implement a sourcing policy and procedure based on the OECD (Organisation for Economic Co-operation and Development) Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas. Please refer to our Conflict Minerals Policy Statement.

We take steps to confirm suppliers are sourcing, where possible, from conflict-free smelters. We expect them to undertake reasonable efforts to provide timely and relevant information and participate in other initiatives to support our compliance efforts.

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Manufacturing Capabilities and Growth Potential

As we reach new heights in market demand and expand our product portfolio, we expect suppliers to keep up with the momentum, ensuring adequate current capacity and growing manufacturing capabilities to meet our future demands. Suppliers and sub-tier suppliers should invest in future capacity based on an assessment with Edwards. Typically, we set the minimum requirements for the manufacturing capacity to be greater than 30% than the expected demand.

Facilities and Control Systems

We expect suppliers to provide cleanroom and associated controlled environments that are commensurate with the requirements we set for the material, component, service, or product being provided. Our requirements for controlled environments used for the manufacture of sterile devices are aligned with key international standards for product contamination and particulate control that apply to air, water, surfaces, and personnel. These standards include the classification of controlled areas based on manufacturing and supporting activities and correspond to limits for the maximum particulates and microbial contamination allowed for these activities.

For manufacturing facilities, suppliers must provide adequate equipment and testing instruments, expertise, and resources to execute qualification, validation, and maintenance activities to a level that ensures compliance with current FDA and other government regulations pertinent to the product.

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Materials and Asset Control

We require suppliers to have the processes and facilities for the proper control, inventory, and storage of raw materials, components, and products, as defined by Edwards' and regulatory requirements. These processes and facilities should take into account procedures for receiving and documentation, product identification and traceability, setup and maintenance of supporting equipment, personnel and work environment, and the disposition of returned, discarded, and non-conforming products. Suppliers are responsible for the traceability of products provided to us.

Edwards-owned assets that are maintained by a supplier (e.g., tooling and molding apparatus) must be covered by a bailment agreement.

Specifically, for the injection molding category, molds must be properly loaded in the Coast Asset Management Software. Coast software proactively evaluates mold conditions during the product lifecycle in order to kick off timely refurbishment and replacement projects, which ensures continuity of quality supply.

For additional information, please contact your Edwards sourcing partner.

Consignment Capacity or Vendor-Managed Inventory (VMI)

Because our product distribution model relies heavily on the consignment of products to medical institutions, we expect suppliers to develop a logistics capability to participate in our components consignment programs. When suppliers make their inventory available to us prior to payment and actual use on the production floor, it enables a more agile response to market demands.

Vendor-managed inventory enables:

- Production efficiency
- Inventory efficiency
- Transport efficiency

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Business Continuity Planning

When natural and man-made disasters threaten, we rely on affected suppliers to have a comprehensive framework for mitigating the impacts on key stakeholders and Edwards assets. A supplier's Disaster Recovery Plan must incorporate the elements below, be reviewed by Edwards at least once a year, and account for, as applicable, the activities of sub-tier suppliers:

- Emergency response activities
- Incident management information
- Back-up strategy for information technology (IT) systems
- Operational continuity strategy

Suppliers must:

- Provide an overview of their updated business continuity plans annually for Edwards to review
- Cooperate with the company's due diligence activities related to property insurance
- Address gaps in the capital- and behavior-driven aspects of the supplier's business continuity planning

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Change Management: Notification of Change (NOC)

Change control is essential for maintaining the quality of our products. To communicate and address changes in a timely and efficient manner, suppliers must have a change control process in place that proactively interfaces with Edwards. This process must be commensurate with the risk level and complexity of the outsourced material, component, service, or product. Suppliers must also communicate any changes they make after Design Verification and Validation/Edwards Quality Laboratory (DV&V/EQL) builds have been executed for Edwards.

We require that suppliers are fully capable of meeting our change notification and control requirements for the following scenarios:

- Actions or situations that may change a supplier's regulatory compliance status. These include:
  - Significant complaints
  - Regulatory or notified body inspection findings
  - Manufacturing malfunctions or deterioration of product performance
  - Change of address
  - Change of notified body
  - Change of manufacturer name
  - Significant changes in building and facilities such as an expansion and/or refurbishment of a controlled environment
- Actions that would trigger a Notification of Change. These include:
  - Proposed alteration in the form, fit, or function of a supplied product or component. Examples include design, composition, or source of any raw materials; method of producing, processing, or testing; change in sub-contractors for producing, processing, or testing, site of manufacture, and labeling.
  - Proposed changes to drawings and other documents that constitute the Device Master Record (DMR).

All changes initiated by suppliers affecting parts, services, and contractors are managed within the Edwards Supplier Quality Management System (SQMS). To initiate a Notification of Change, an email with details of the change and the products affected should be sent to Supplier_Quality_Irvine@edwards.com.

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The Product Development Process (PDP) describes how Edwards complies with all requirements related to the design, development, and commercialization of medical devices. The process integrates design controls and quality system requirements with business deliverables in order to develop product that:

- Is safe and effective for its intended use
- Meets the needs of the user and the patient
- Meets specified requirements

Notification Requirements During the Product Development Process (PDP)

For additional details/information about the product phases, please refer to the Product Development Process section of this guidebook.

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NOC/Change Management Table

	NOC Is Not Required	NOC Is Required
Manufacturing Process-Related Changes	• Decrease in handling duration/contact with material/component • Sample size increased for lot acceptance inspection(s) • Manufacturing process, settings, method, flow: – Similar to established temperature/duration of energy sources (e.g. laser welding, cutting). • Manufacturing environment: – Does not affect the certification of the current cleanroom/controlled environment.	• Increase in handling duration/contact with material/component • Sample size decreased for lot acceptance inspection(s) • Inspection method for lot acceptance • Water source requiring validation • Manufacturing process, settings, method, flow: – Changes to established temperature/Duration of energy sources for patient contacting surfaces (to be verified with Edwards) – Something that affects material surface, geometry, or shape (to be verified with Edwards) – Something that affects a critical feature or a validated process – Sequence of manufacturing process flow impacting validation and/or a critical feature • Manufacturing environment: – Different cleanroom/controlled environment – Something that impacts the certification of the current cleanroom/controlled environment

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NOC/Change Management Table *continued*

	NOC Is Not Required	NOC Is Required
Manufacturing Equipment-/ Tooling-/ Fixturing-Related Changes	• Tooling or fixturing – Manufacturing aid with no impact to form, fit, function, and uses Edwards EQL approved parts (e.g. materials) (to be verified with Edwards) • Duplicate equipment/tooling/fixture/software: – Not affecting equipment software – Affecting equipment but not impacting established parameters nor validated state – Equipment is the same make, similar model, etc. – Equipment is located in the same room – There is no change to the supplier • Molding Process: – Repaired Mold that does not impact supplier validation or PQTM capability with no impact to form, fit, function – Alternative process that requires no parameter changes	• Equipment type or model • Tooling or fixturing – Not a manufacturing aid – Manufacturing aid with impact to form, fit, function (to be verified with Edwards) – Manufacuturing aid with no impact to form, fit, function, and does not use Edwards EQL approved parts (e.g. materials) (to be verified with Edwards) • Duplicate equipment/tooling/fixture/software: – Changes to established parameters or existing validations. – Requires PQTM capability (e.g. new mold, new equipment make/model, etc.) • Molding Process: – New Mold – New Press requiring parameter changes

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NOC/Change Management Table *continued*

	NOC Is Not Required	NOC Is Required
Component Changes		• Primary or secondary packaging • Location: – Part (e.g. component, material) manufacturer – Sub-tier supplier – Critical outsourced process supplier • Raw materials, chemicals, or processing agents: – Formulation – New chemical/raw material added – Brand – Colorants – Cleaning process – Water source

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NOC/Change Management Table *continued*

	NOC Is Not Required	NOC Is Required
Non-Manufacturing Process-Related Changes		• Supplier acquisition • Administrative location • Notified body/FDA registration status • Supplier management structure • Part nomenclature/numbering • Supplier name change • Warning letter notification

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Requirements for Sub-Tier Suppliers

We expect suppliers to manage their own (sub-tier) suppliers with controls commensurate with risk. This means ensuring that products manufactured by sub-tier suppliers use only authentic, conforming, and specified materials, as stipulated in the specifications.

Suppliers must also have formal purchasing and supplier control processes to manage sub-tier suppliers. These controls must include, but are not limited to:

- Supplier selection, evaluation, and approval
- Product qualification
- Procurement
- Product acceptance
- Performance measurement and monitoring, including auditing programs
- Nonconforming product and Corrective and Preventive Action (CAPA) processes
- Change control
- Change management (Notification of Change [NOC])
- Quality Agreements

Suppliers must also ensure and control the quality of all components and raw materials used to manufacture product for Edwards.

Note: Prior to making any changes to sub-tier suppliers, suppliers must get approval from Edwards.

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Expectations for Finished Goods Manufacturers/Contract Manufacturing Organizations (CMOs)

To facilitate effective communication and help build relationships between Edwards and our finished goods suppliers and/or CMOs, we expect the following meetings to occur during the duration of our partnership:

Meeting Type	Cadence	Topics Addressed	
Quality Data Reviews (QDRs)	As needed	• Project discussions • Upcoming Notifications of Change (NOCs) • Quality escalations	• Ongoing successes and lessons learned • Inventory • Sterilization Requalifications
Business Reviews	As needed	• Yields • Non-Conformance Reports (NCRs) • In-process test results • Complaints • Field Corrective Actions (FCAs) • Product Risk Assessment (PRA) • Supplier Corrective Action Requests (SCARs) • Supplier capacity • Supplier scope • Capabilities • Payment status • New products/projects • Spend • Organizational charts • Forecasting by item number	• Internal audits • External audits • Notifications of Change (NOCs) • Inventory • On-time delivery • Planned vs. actual • Business Continuity Plan (BCP) • Sustainability • Contract review • Innovation • Regulatory status • Quality Metrics Review (QMR) (high level)

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Developing New Products in Partnership with Edwards

6

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In design and development, our goal is for Edwards' suppliers to develop robust, scalable, and capable manufacturing processes or services. This includes the development of innovative technologies and processes to achieve the design output. A streamlined approach from product development to manufacturing makes for a nimble supply chain response to Edwards' product development requirements.

This section outlines our process for suppliers developing products in conjunction with Edwards. For additional details and requirements about these processes, please contact your Edwards sourcing partner.

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Product Development Process (PDP)

1 2 3 4 5

	PHASE 1 Concept Selection	PHASE 2 Design Freeze	PHASE 3 Design Verification & Validation	PHASE 4 Process Validation, Transfer, & Launch	PHASE 5 Post Commercialization
Description/Steps	• Fully assess the market opportunity and clearly define the product • Assess Edwards' and supplier's capability to develop and manufacture the product • Plan the project	• Finalize the product design • Develop effective manufacturing processes	• Challenge the design and manufacturing processes to demonstrate that the design output meets the design input (Design Verification) • Ensure that the final product output meets the user needs, intended uses, and is safe and effective (Design Validation)	• Ensure that the device design is correctly translated into product specifications • Demonstrate that the product has been successfully transferred to production and can be repeatedly and reliably produced to meet specifications and process capabilities	• Ensure successful product performance through post-launch feedback and proper integration into sustaining engineering
Deliverables	• Feasibility Parts per Drawing	• **Initial Drawing Release (X-release)** • **Initial Supplier Selection** • Design for Excellence (DF(x)) Assessment • Inspection Plan Strategy • **Part Qualification Trace Matrix (PQTM) Draft*** • Supplier/Edwards Program Overview • Development Agreements (SOWs) • Test Method Development • Measurement Plan Draft - Essential Design Output (EDO) • Process Development and Characterization • Pre-Design Verification/Edwards Quality Labs (DV/EQL) Feasibility Parts Build • First Article Inspection (FAI) • Initial Capability Assessment • Process Failure Mode and Effects Analysis (pFMEA)	• Measurement Plan - Essential Design Output (EDO) • Test Method Validation/Measurement System Analysis (TMV/MSA) – Essential Design Output (EDO)** • Supplier Process Survey Form (Form 1731) • Design Verification/Edwards Quality Labs (DV/EQL) Builds • Supplier Builds Review • **Part Qualification Trace Matrix (PQTM) Plan Release*** • Equipment Installation Qualifications (IQs) • **Human Use Device Master Record (DMR) Release (D-Release)** • Human Use Parts Build (if applicable) • Process Freeze (Note: After the process freeze, any changes require a Notification of Change [NOC]) • Process Failure Mode and Effects Analysis (pFMEA)	• Test Method Validation/Measurement System Analysis (TMV/MSA) – Non-Essential Design Output (EDO)** • Supplier Builds Review • Operational Qualification/Performance Qualification (OQ/PQ) • Quality Agreement • Critical Control Point (CCP) Implementation • Receive on Certification (ROC) or Reduced Inspection • **Part Qualification Trace Matrix (PQTM) Closure*** • Supply Agreement • **Device Master Record (DMR) Commercial Release (P-release)** • Process Failure Mode and Effects Analysis (pFMEA)	• Production Monitoring (Critical Control Points [CCPs] and Inspections) • Process Improvements

Bold = Edwards' responsibility
Red = Minimum requirements (other deliverables may be deferred to subsequent phases)

Roll your cursor over Deliverables for links to additional information.

*PQTM completion may not be required in all instances. Please concur with your project core team.
**TMV completion may be required in earlier phase based on project need.

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Design for Excellence (DF(x)) Assessment

For this assessment, suppliers and Edwards review the applicability of the design, tolerances, and the manufacturing/assembly process to ascertain their viability. We provide feedback on the Design for Manufacturability (DFM) or the Design for Assembly (DFA) prior to Phase 2 closure:

- Review drawing (Edwards and supplier)
- Complete DF(x) assessment (Edwards and supplier)
- Provide feedback on assessment (Edwards)
- Update drawing to reflect feedback and provide a revised quote to Edwards (supplier)

2

Inspection Plans

We require that suppliers use a statistically valid sampling plan for lot acceptance testing. Sampling plans may be contingent on the development lifecycle and the risk associated with the feature.

Edwards' preferred sampling plans for capable and non-capable processes are AQL 0.25% (c=0) and AQL 1.0% (c=0), respectively.

Additional sampling plans that may be considered with Edwards consultation include ANSI Z1.4, ANSI Z1.9, ASQ H1331, LTPD based sampling, double sampling, AQL sampling, or Binomial/ Hypergeometric plans at 95% confidence.

Inspection plans are included as part of the Part Qualification Trace Matrix (PQTM).

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Part Qualification Trace Matrix (PQTM)

PQTM is a trace matrix generated by Edwards to designate component qualification requirements and their results over the product development lifecycle per the Part Qualification Plan (PQP). The following information is provided in the PQTM:

FEATURE INFORMATION		FEATURE CATEGORY				EDWARDS RECEIVING INSPECTION		
1	2	3	4	5	6	7	8	9
DRAWING DIMENSION/ GENERAL NOTE	FEATURE DESCRIPTION	FEATURE VERIFICATION	FEATURE TYPE	CATEGORY 1 OR 2	SEVERITY 5	EDWARDS RI SAMPLING PLAN	TMV	EDWARDS RI INSPECTION METHOD

MINIMUM SUPPLIER QUALIFICATION REQUIREMENTS						SUPPLIER INSPECTION		ADDITIONAL INFORMATION	
10	11	12	13	14	15	16	17	18	19
			CAPABILITY / PROCESS VALIDATION						
PFMEA	PROCESS VALIDATION	TMV	CAPABILITY	SAMPLE SIZE (N)	ACCEPTANCE CRITERIA	SUPPLIER SAMPLING PLAN	SUPPLIER INSPECTION METHOD	PRIMARY QUALITY GATE/ DOWNSTREAM MITIGATIONS/ CCP	COMMENTS

Columns 1 to 6 – Features from the drawing with their Essential Design Output (EDO) designations based on Edwards' design documentation

Columns 7 to 9 – Inspection sampling methods, test methods required, and their validation plan requirements at Edwards

Columns 10 to 15 – Capability, process validations, pFMEA, and the acceptance criteria required (supplier provides evidence of completion)

Columns 16 to 17 – Inspection sampling methods, test methods required, and their validation plan requirements (supplier provides information)

Column 18 – Primary lot inspection location along with Critical Control Point (CCP) designations

Column 19 – Comments or notes pertaining to qualification requirements

PQTM Activities in the Product Development Process (PDP)

PHASE 1 Concept Selection
No activities during concept selection

»

PHASE 2 Design Freeze
Draft plan with inspection plans available

»

PHASE 3 Design Verification & Validation
Part Qualification Trace Matrix (PQTM) plan released

»

PHASE 4 Process Validation, Transfer, & Launch
Qualifications activities completed
•
PQTM report released

»

PHASE 5 Post Commercialization
PQTM updated per improvement activities

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Receive on Certification (ROC) Program

We developed the Receive on Certification (ROC) program to support suppliers owning the quality of the products they deliver to us. Its intent is to avoid duplication of or repeating receiving inspection activities at Edwards.

As part of this program, we work with our suppliers to establish a robust and capable supply chain to mitigate risk of product returns and the need to hold excessive inventory. Achieving high maturity levels reduces manufacturing variability and lowers scrap costs at the supplier and at Edwards.

Suppliers must monitor and act on performance trends of each and every lot produced (Refer to the Control Plan and Critical Control Point [CCP] sections of this guidebook) to support improved product and patient outcomes. Critical Control Point monitoring is not a requirement for parts to qualify for the ROC program.

Review the chart below for requirements to be considered for the ROC program.

Supplier Enrollment Criteria	Part Performance Criteria	Part Qualification Criteria
• Acceptable audit results • Signed Quality Agreement • Acceptable response timeliness for Non-Conformance Reports (NCRs), Supplier Corrective Action Requests (SCARs), and/or audit findings • Not on 'restricted' status with Edwards and currently listed as an active supplier	• Existing commercial parts: Zero (0) non-conformance issues at Edwards due to supplier fault for up to 12 months	• Completed Part Qualification Process (PQP) for inspection feature being certified • Custom component to Edwards

Parts enrolled in the ROC program will require summary data to be included with the Certificate of Conformance (CoC). We will work with our suppliers to align on the CoC content. The Edwards CoC summary data template or an equivalent format may be used.

Planning for completion of PQP and supplier qualification deliverables in earlier phases will enable successful ROC enrollment in Phase 4.

Once a supplier is participating in the ROC program, the following events can lead to disqualification:

- Field Corrective Action (FCA)
- Supplier Corrective Action Request (SCAR)
- Critical audit finding
- Refusal to respond to a SCAR and/or an audit finding and/or supplier is past due for greater than 3 months
- Supplier moved to restricted status
- Failure to comply with Quality Agreement expectations

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2 3 4

Supplier/Edwards Program or Build Overview

Communication through the phases of the Product Development Process (PDP) is key to a successful process and product development cycle. Supplier/Edwards build reviews should follow all major project milestones with the intent of aligning on build deliverables, results, and feedback from testing/inspection. Specific considerations for supplier build reviews during the PDP phases include:

Phase 1	Phase 2
No overview recommended	Initial discussions or program kickoff: • Initial program timeline/milestones • Budget quoting process • Supplier deliverables by phases Post builds review: • Initial supplier review content (as needed) • Previous build review action items • Project timelines and milestones • Detailed process flow • Input/Output mapping • Critical Station Identification • Critical Fixture Review • Initial Capacity Assessment • Design for Manufacturability (DFM) scorecard • Part Qualification Trace Matrix (PQTM) drafts • Program risks • Action items and follow-up

Phase 3	Phase 4	Phase 5
Pre-build review: • Previous build review action items • Project timelines and milestones • Validation status (if needed) • Open Orders Report • Plan vs. actual build plan • PQTM drafts • Notification of Change (NOC) summary (past, open, and planned) • Quality (yield metrics, defect pareto, etc.) • Capacity and ramp plan • Program risks • Action items and follow-up	Pre-build review: • Previous build review action items • Open Orders Report • Plan vs. actual build plan • NOC summary (past, open, and planned) • Capacity expansion and support (if needed) • PQTM progress • Program risks • Action items and follow-up	No overview recommended

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2

Development Agreements

Complex development projects with suppliers may warrant a Statement of Work (SOW) agreement. An SOW agreement defines in detail the work to be performed, obligations, and responsibilities (including project costs and payment terms) of each party (Edwards and supplier). The agreement may also encompass project milestones, deliverables, quality objectives, and requirements. SOWs stay in effect through the course of product development and eventually transition to commercial agreements (e.g., quality and/or supply agreements) as appropriate.

2

Process Characterization

Process characterization helps ensure consistent product quality. Our suppliers must demonstrate that the manufacturing process is robust using appropriate statistical and engineering techniques. A typical process development and characterization cycle is shown at right.

Process Characterization Cycle (typical)

1. Identify all potential process steps
2. Determine critical characteristic or component features from specification document
3. Complete an initial assessment of tools/manufacturing process for key process variables
4. Complete prototype tooling and component builds
5. Conduct tooling or manufacturing optimization studies
6. Conduct Design of Experiments (DOEs) to find the optimized processing window and identify the key effects of the inputs to the process
7. Determine edge of failure and worst-case operating range
8. Perform evaluation runs through process capability studies

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2

First Article Inspection (FAI)

We require that a First Article Inspection (FAI) be performed once the Product Development Process is determined to be stable and capable. First Article submissions must include:

- Bubble numbered drawing
- B/P Zone, including page numbers for multiple page drawings (i.e., 1-C3, designating page 1, zone C3)
- Nominal dimension including units
- Tolerance and lower and upper specification limits
- Actual inspection measurements for all features and notes on drawing
- Any measurements out-of-specification
- Any variable gaging (wherever possible, the same methods should be used as those for production)
- Geometric Dimensioning and Tolerances (GD&T) features (This should be reported as variable data, not attribute data)
- Raw material certification(s), including any secondary processing induced mechanical properties also listed on the specification (i.e., heat treatment, passivation, deflashing, etc.)
- Part/tooling/fixture number
- Serial number and/or lot number
- Inspector
- Date
- Mold number and cavity number (for molded components only)
- Measuring equipment used for inspection (detailed description, asset ID#, calibration date/due date, and resolution)
- Signature of person authorizing the report and date

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Process Validations

Features that are not fully verifiable require process validations such as Installation, Operational, and Performance Qualifications (IQ/OQ/PQ) with OQ/PQ requiring protocol and report approvals by Edwards. All other inspection features listed on the drawing must meet the minimum capability requirements prior to moving to acceptance sampling methods. The statistical acceptance criteria and the required qualification per feature are identified on the Part Qualification Trace Matrix (PQTM).

Sample Collection for Capability Studies

Parts must be run on production tooling/fixtures under expected normal production conditions. After process characterization and control plans are completed, capability studies must also be performed on all applicable features as shown on the drawing.

Samples must be collected from a stable running process and sequentially for each group. All conforming qualification components from the qualification lot may be saleable once successfully qualified and the final completion report is approved.

Process Capability Assessment

Measurements must be taken and recorded for the dimensions listed in the drawing/specification document using qualified (30%, maximum gage error P/T) gaging.

All features listed in the drawing must demonstrate capability and control for a minimum of two lots, with a statistical acceptance criteria similar to OQ/PQ.

Process Validation Phases

- The Installation Qualification (IQ) establishes by objective evidence that:
  - The equipment and ancillary systems comply with manufacturers' specifications, are installed correctly, and operate in a stable manner within specified limits and tolerances
  - All equipment safety features are functional
  - Ongoing equipment controls have been established, including calibration requirements and preventive maintenance procedures
- The Operational Qualification (OQ) establishes by objective evidence that the process:
  - Will produce acceptable product under worst-case conditions and at the limits of the operating window
  - Exhibits short-term capability to meet predetermined requirements
- The Performance Qualification (PQ) establishes by objective evidence that the process:
  - Will consistently produce acceptable product under normal operation conditions
  - Exhibits long-term stability and capability to meet predetermined requirements

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Sample Size and Acceptance Criteria

Sample sizes and their acceptance criteria for process capability and validations are indicated below with minimum required criterion.

Severity	Reliability at 95% Confidence	EDO/ Non-EDO	Minimum Sample Size for Attribute Features	Minimum Sample Size for Variable Features	Minimum Lot or Runs for Capability Assessment	Minimum Lot or Runs for PQ Assessment	Acceptance Criteria	
							Variable	Attribute
5	99.5%	EDO	598	15*	2 (EDO) 1 (Non-EDO)	3	Ppk ≥1.33 (EDO) Ppk ≥1.00 (non-EDO)	No Failures
4	99.0%		299					
3	97.0%	EDO or Non-EDO	99					
2	95.0%		59					
1	90.0%		29					

*30 is recommended

Process Validation Activities in the Product Development Process (PDP)

PHASE 1 Concept Selection — Process identified

»

PHASE 2 Design Freeze — Process map developed • Process ranges & capability assessed

»

PHASE 3 Design Verification & Validation — IQ completed • OQ/PQ with released pFMEA (if applicable)

»

PHASE 4 Process Validation, Transfer, & Launch — OQ/PQ completed

»

PHASE 5 Post Commercialization — Process monitoring, trending, & improvements

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2 3 4 5

Process Failure Mode and Effects Analysis (pFMEA)

We require that suppliers initiate and release a pFMEA for quality features as required through the Part Qualification Trace Matrix (PQTM). Supplier pFMEAs must comply with the requirements of ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices.

We review supplier pFMEAs for release in the supplier's respective Quality Management System (QMS) prior to any validations.

2 3

Measurement Plan

Edwards creates measurements plans for all parts with Essential Design Output (EDO) features that cannot be inspected with simple hand tools (e.g. calipers or micrometer). Edwards utilizes the measurement plan to aid test method development, align test methods with our suppliers as much as possible, and document test method implementation. The measurement plan includes:

- Feature Description: Definition of inspection feature with design intent and functional purpose
- Method Type: General method type (e.g. vision system)
- Inspection Strategy: Rationale for method type with implementation strategy (e.g. feature datum and edge selection, lighting conditions, fixturing, and data collection)
- Inspection Summary: Details on final inspection (e.g. procedures, equipment, fixtures, and software)

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Measurement System Analysis (MSA)

In general, Measurement System Analysis (MSA) is a group of studies to determine the fitness of a gaging system or test method for its intended purpose. MSA elements confirm the suitability of the use of test methods for specific Edwards test equipment and inspections. The Gage R&R element of MSA is essentially a preliminary version of Test Method Validation. For purposes of test method development, MSA serves as a checklist of readiness for formal validation (which occurs in phases 3 and 4 of our Product Development Process) or an objective determination of suitability and capability for a specific test setup utilizing a test method.

MSA Components Are Broken Down Into the Following Sub-Categories:

CALIBRATION (LINEARITY)

- This can include a verification of linearity of the method across the range of interest. It is a formal process governed by the local business unit calibration procedures and can involve significant lead times if gages and sensors have to be sent out to a contract lab or if a contract service technician has to visit to conduct calibration in a supplier's test lab.
- The test method developer should review the calibration record for each included gage type to verify that the gage has sufficient calibrated sensitivity and appropriate range for its intended use. A common error is to use a properly calibrated gage for measurement below its sensitivity.

GAGE REPEATABILITY AND ACCURACY

- Suppliers should conduct a Type 1 Gage Study. Because this type of study involves one operator measuring one part, it doesn't provide the reproducibility found in a full Gage R&R study. The Type 1 Gage Study is a quick and easy way to see if the test method is ready for a Gage R&R study or if it needs additional development work. It is also intended (for the Edwards Test Method Validation [TMV] process) to provide objective evidence that test setups utilizing compendial methods are suitable and capable.

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2 3 4

Test Method Validation (TMV)

TMVs (and compatibility studies, if required) must be performed on measurement methods for any inspection features indicated in the drawing or specification document.

Our suppliers are responsible for:

- The design and build of all gaging required to adequately inspect the component, both from a qualification and production standpoint
- Calibration of all fixtures and gages they produce and/or use
- Performing the Measurement System Analysis (MSA) to ensure that all gages are repeatable and reproducible (Note: Where multiple gage systems exist for same product, gage compatibility assessment must be performed.)

For Features Measured as Variable Outputs:

Use the Analysis of Variance (ANOVA) method for analysis using Minitab or a similar statistical analysis software.

Variable Test Method Validation (VTMV) Acceptance Criteria:

Feature Type	Analysis Technique	Sample Plan Determinations	Acceptance Criteria	Gage R&R Study Variation
Destructive	Nested Gage R&R	Minimum of 48 determinations with minimum of 6 test samples	**2-sided Spec.:** % Tol ≤ 30% **1-sided Spec.:** % Tol ≤ 30%: or % SV ≤ 30% **No Tolerance:** % SV ≤ 30%	Six Sigma
Non-Destructive	Crossed Gage R&R			

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2 3 4

Test Method Validation (TMV) *Continued*

For Features Measured as Attribute Outputs:

Attribute TMV gage studies assess agreement among operators using Kappa (Fleiss coefficient between each operator and the standard) and estimate the probability of misclassifying a REJECT part as ACCEPT (Pmiss) and the probability of misclassifying an ACCEPT part as REJECT (Pfa).

ATTRIBUTE TMV (ATMV) ACCEPTANCE CRITERIA:

Sampling Plan Determinations	Acceptance Criteria
50 Pmiss 50 Pfa Minimum of 2 appraisers and 2 trials with appropriate test sample size to satisfy Pmiss and Pfa criteria	Pmiss ≤ 2%, Pfa ≤ 5%, and Kappa ≥ 0.80

Test Method Validation Activities in the Product Development Process (PDP)

- **PHASE 1 Concept Selection** – Test or inspection methods identified
- **PHASE 2 Design Freeze** – Test methods developed; Mesurement plans drafted for Essential Design Output(EDO) features
- **PHASE 3 Design Verification & Validation** – Measurement Plan, MSA and TMV completed for Essential Design Output (EDO) features
- **PHASE 4 Process Validation, Transfer, & Launch** – MSA and TMV completed for Non-Essential Design Output (EDO) features
- **PHASE 5 Post Commercialization** – Process monitoring and trending

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Device Master Record (DMR) Release Levels

We use different engineering release levels for the specification documents through our product lifecycles. These levels are not visible on requirement documents, so please ask your project core team for this information when you receive your purchase order.

Engineering Release Level	Description
Draft – Concept, Non-human Use (not released)	Experimental products, prototypes, lab equipment, animal studies or similar applications, marketing samples
X – Prototype, Non-human Use	
D – Pre-production, Human Use	Human use in a clinical trial or controlled market trial
P – Production	Full-scale production

Suppliers will access drawings for Production parts (P-release) through the Edwards Supplier Portal. Drawings for parts at earlier Engineering Release Levels (X and D) will be provided by the Edwards project teams.

Typical Release Levels by Phases

- **PHASE 1 Concept Selection** – Draft or X
- **PHASE 2 Design Freeze** – Draft or X
- **PHASE 3 Design Verification & Validation** – X or D
- **PHASE 4 Process Validation, Transfer, & Launch** – D or P
- **PHASE 5 Post Commercialization** – P

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3

Supplier Process Survey Form

We require that suppliers document their process controls and contact materials through the Supplier Process Survey Form (Form 1731). It may include any of the following information, as applicable:

- List of polymers contained within the part, including additives and colorants
- List of chemicals that contact the part during the manufacturing, assembly, or packaging processes
- List of outsourced processes and suppliers
- Water processes that meet the parts and endotoxin controls
- Confirmation of animal derivative materials contained in the part
- Confirmation of medicinal substances contained in the part
- Confirmation of sterilization processes
- Confirmation of controlled environments and their controls
- Confirmation of the use of natural rubber during packaging

Supplier Process Survey Form (Form 1731) Activities in the Product Development Process (PDP)

PHASE 1 Concept Selection	PHASE 2 Design Freeze	PHASE 3 Design Verification & Validation	PHASE 4 Process Validation, Transfer, & Launch	PHASE 5 Post Commercialization
Process determination with maps	Draft form surveying manufacturing processes and sub-tier supplier processes	Form 1731 completed	Updates to form as needed; consider Notification of Change (NOC)	Updates to form as needed; consider NOC

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Medical devices designed and manufactured for Edwards require cleanliness controls. The following cleanliness controls should be maintained as documented on Form 1731 (Note: This is not an all-inclusive list):

- Cleanroom controls (Class 7 or 8) with viable and non-viable monitoring
- If water used
  - Sterile water containing ≤ 2EU/ml, or
  - Heat exposure of components
    - ≥482ºF (250ºC) for 1.5 minutes or
    - ≥392ºF (200ºC) for 60 minutes or
    - ≥437ºF (225ºC) for 4 minutes
- Validated part cleaning for removal of manufacturing processing residuals
  - Cleanliness controls through the assembly, inspection, and packaging processes for the supplier and their sub-tier suppliers

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Critical Control Point (CCP)

CCP is a point in the manufacturing process where something Critical to Quality (CTQ) or its associated essential design outputs, as well as the resulting hazard, is controlled and there is no risk of introducing subsequent hazards.

There are five elements that comprise a "Great" CCP:

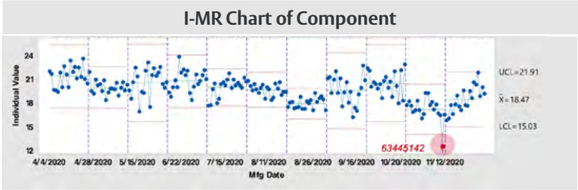
- Linked to CTQ
- Mistake-proof
- Adequate measurement system
- Robust sampling plan
- Statistical process control

CCPs provide the following benefits for our suppliers:

- Detection at the source, preventing downstream quality issues
- Enables high process capability and quality control
- Pathway to Receive on Certification (ROC)

Why CCP?

Customers will notice the effect of process variation…



The implementation and sustainment of CCP practices requires a change in mindset. The typical mindset is "Accept to Specification." To be successful, this needs to change to "Reacting to Process Variation." This mindset shift needs to happen at each level of the organization. CCP Guidance Documents are available to Edwards' suppliers for support on CCP implementation.

Supply Agreements

A Supply Agreement may not be required for selective commodities, as an Edwards Purchase Order (PO) is a contract and contains the necessary terms and conditions to manage the transaction defined in the PO. A Supply Agreement may be considered to ensure continued access to critical purchased items.

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Control Plan

Process monitoring for manufacturing control points requires the use of a plan to list the control points monitored and action plans triggered when the process exceeds the trigger plans. We require that suppliers maintain a control plan which addresses the following:

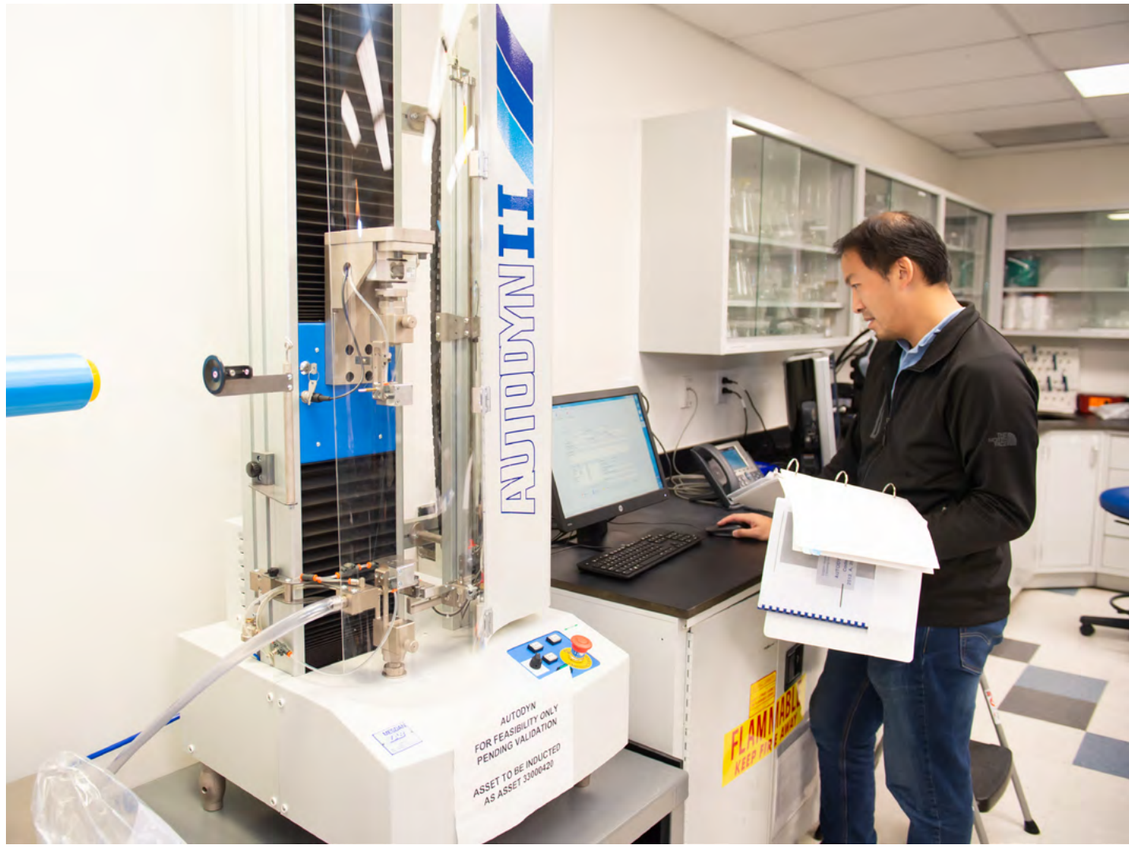
- List of the critical features of the product (delta dimensions and general notes)
- Type of inspection plan associated with each feature
- The entire product process, from receipt of raw material through delivery to Edwards
- Control points (identified through Process Failure Mode and Effects Analysis [pFMEA])

Features identified by Edwards as Critical Control Points (CCP) require Statistical Process Control (SPC). Suppliers must use statistical methods to show the real-time stability of the specific feature. Those methods must be reviewed and approved by Edwards and documented in the control plan, including executable reaction plans for out-of-control or out-of-specification product.

Suppliers must also maintain appropriate internal quality policies which govern out-of-control conditions and appropriate reaction plans.

Control Plan Activities in the Product Development Process (PDP)

PHASE 1 Concept Selection	PHASE 2 Design Freeze	PHASE 3 Design Verification & Validation	PHASE 4 Process Validation, Transfer, & Launch	PHASE 5 Post Commercialization
No activities during concept selection	Process identified & process map developed CTQs identified	Inspection plans established	Control plans established	Process monitoring, trending, & improvements



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Acronyms/ Terms and Definitions

7

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Acronyms

aFMEA	Application Failure Mode and Effects Analysis
ANOVA	Analysis of Variance
ANSI	American National Standards Institution
AQL	Acceptable Quality Limit
ASL	Approved Supplier List
ASQ	American Society for Quality
ATMV	Attribute Test Method Validation
BCP	Business Continuity Plan
BPA	Bisphenol A
BSA	Biological Safety Assessment
CAPA	Corrective and Preventive Action
CCP	Critical Control Point
CE	Conformite Europeenne
CMO	Contract Manufacturing Organization
CoA	Certificate of Analysis
CoC	Certificate of Compliance / Certification of Compliance
COE	Center of Excellence
CTQ	Critical to Quality
DA	Design Assurance
DDQ	Due Diligence Questionnaire
DFA	Design for Assembly
DEHP	Di (2-ethylhexl) phthalate
DF(x)	Design for Excellence
DFM	Design for Manufacturability
dFMEA	Design Failure Mode and Effects Analysis
DHR	Device History Record
DMR	Device Master Record
DOE	Design of Experiment
DV&V	Design Verification and Validation
EDO	Essential Design Output
EFS	Early Feasibility Studies
EH&S	Environmental Health and Safety
EHU	Early Human Use
EQL	Edwards Quality Labs
EU	European Union
EU MDR	European Union Medical Device Regulation
FAI	First Article Inspection
FCA	Field Corrective Action
FDA	Food and Drug Administration
FHU	First Human Use
FIH	First In Human
FMEA	Failure Mode and Effects Analysis
GD&T	Geometric Dimensioning and Tolerances
GHG	Greenhouse Gas
GMP	Good Manufacturing Practices
GSC	Global Supply Chain
GSM	Global Supplier Management
HPI	Hypotension Prediction Index
HUBZone	Historically Underutilized Business Zone Small Business
IQ	Installation Qualification

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ISO	International Organization for Standardization
IS-TPRM	Information Security Third Party Risk Management Service
IT	Information and Technology
LTPD	Lot Tolerance Percent Defective
MBE	Minority Business Enterprise
MSA	Measurement System Analysis
NCR	Non-Conformance Report
NDA	Non-Disclosure Agreement
NIST	National Institute of Standards and Technology
NOC	Notification of Change
NPD	New Product Development
NPI	New Product Introduction
ODS	Ozone Depleting Substances
OECD	Organisation for Economic Co-operation and Development
OQ	Operational Qualification
OTS	Off-the-Shelf
PDP	Product Development Process
pFMEA	Process Failure Mode and Effects Analysis
PM	Project Management
POP	Persistent Organic Pollutants
Ppk	Process Capability Index
PQ	Performance Qualification
PQP	Part Qualification Plan
PQTM	Part Qualification Trace Matrix

PRA	Product Risk Assessment
P/T	Percent Tolerance
QBR	Quarterly Business Review
QCP	Quality Control Plan
QMR	Quality Metrics Review
QMS	Quality Management System
R&D	Research and Development
R&R	Repeatability and Reproducibility
RA	Regulatory Affairs
REACH	Registration, Evaluation, Authorisation and Restriction of Others
RFQ	Request for Quotation
RI	Receiving and Inspection
RIMS	Regulated Indirect Material Supplier
RL	Risk Level
ROC	Receive on Certification
RoHS	Restriction of Hazardous Substances
SB	Small Business
SBA	Small Business Administration
SCAR	Supplier Corrective Action Request
SDB	Small Disadvantaged Business
SDE	Supplier Development Engineer
SDVOSB	Service Disabled Veteran Owned Small Business
SME	Subject Matter Expert
SNED	Supplier Nonconformance Event Determination
SNN	Supplier Notification of Nonconformance

SOW	Statement of Work
SPC	Statistical Process Control
SQE	Supplier Quality Engineering
SQMS	Supplier Quality Management System
TA	Technical Assessment
TAVR	Transcatheter Aortic Valve Replacement
THV	Transcatheter Heart Valve
TMTT	Transcatheter Mitral and Tricuspid Therapies
TMV	Test Method Validation
TSCA	Toxic Substances Control Act of 1976
UDI	Unique Device Identifier
UN	United Nations
VMI	Vendor-Managed Inventory
VOSB	Veteran-Owned Small Business
VTMV	Variable Test Method Validation
WBE	Women Business Enterprise
WEEE	Waste From Electrical and Electronic Equipment
WOSB	Woman-Owned Small Business
WTO	World Trade Organization

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Terms and Definitions

Approved Supplier:
Supplier who has been successfully evaluated and whose approval has been documented on the Approved Supplier List for the purpose of supplying specific goods and services to Edwards Lifesciences.

Certificate of Analysis (CoA):
A document providing evidence that a particular product satisfies the test requirements defined in the applicable specifications.

Certificate of Conformance (CoC):
A document attesting that a particular product is manufactured or serviced in accordance with applicable Quality Management System requirements, specifications, or the Quality Agreement. This may also be referred to as a Certification of Compliance.

Contract Manufacturing Organization (CMO):
An organization that manufactures a finished device to another company's specifications.

Critical Control Point (CCP):
A point(s) in a process where a Critical to Quality (CTQ) (or its associated essential design outputs) and the resulting hazard is controlled and there is no risk of subsequent hazard introduction.

Control Point:
Any point, step, or procedure at which a variable, parameter, or quality factor(s) can be controlled within established specifications. All processing steps are control points. Only some control points may be Critical Control Points (CCPs).

Critical to Quality (CTQ):
A concept used in quality management and Six Sigma methodologies which refers to a product or process characteristic that is critical to the customer and therefore, critical to the overall quality of a product or process.

Design Validation:
Establishing by objective evidence that device specifications conform with user needs and intended use(s).

Design Verification:
Confirmation by examination and provision of objective evidence that specified design requirements have been fulfilled.

Direct Supplier:
A supplier providing a part that is listed in the Bill of Material of an Edwards finished device.

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Essential Design Output (EDO):
A design output (i.e. part specification) that is essential to the function defined by a CTQ design input (i.e. finished device requirement).

Edwards Quality Laboratory (EQL):
Includes the Microbiology, Biology, and Chemistry laboratories at Edwards Lifesciences. This group is responsible for product BSA, product sterilization, and product cleanliness.

Field Corrective Action (FCA):
An action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. It may involve recalling, repairing, modifying, or replacing the medical device.

Regulated Indirect Material Supplier (RIMS):
A supplier providing a part or service that is not listed in the Bill of Material of an Edwards finished device that is deemed by Edwards to have a performance or regulatory impact on a finished device.

Supplier Corrective Action Request (SCAR):
A record used to document and resolve a supplier nonconformity or potential nonconformity that does not meet the CAPA (Corrective and Preventive Action) criteria, but warrants an investigation and some level of supplier action.

Tier 1 Supplier:
A supplier that provides materials, components, assemblies, services, or finished goods directly to Edwards Lifesciences.

Tier 2 Supplier:
A supplier that provides materials, components, assemblies, services, or finished goods directly to a Tier 1 Supplier.

Validation:
Confirmation by examination and provision of objective evidence that the applicable requirements can consistently be fulfilled.

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