

# External Provider Quality Manual

**REVISED APRIL 2024** 





### **Table of Contents**

Product/Product Safety	Error! Bookmark not defined
Production Part Approval Process (PPAP)	
Process Approval	
Measurement System Analysis (MSA)	
Special Characteristics	
Pass-Through Characteristics	8
Advanced Product Quality Planning (APQP) for Direct Material	
Safety Data Sheet	
Review of Statutory and Regulatory Requirements	
Advanced Verification Process	
Customer-Specific Requirements	
Audits	
External Provider Qualification Process	6
External Provider Qualification Process	6
Review of Design Records	
Request for Quote	5
Request for Quote (RFQ)	5
Confidentiality Agreement	5
Environmental Management System	5
Quality System Certification	
External Provider Management System Requirements	
Customer Focus and Continual Cost Improvement	
"Zero Defect" Policy	
Social and Environmental Responsibility	
Expectations	
Scope	
Anovion Quality Policy	
Introduction	
	_

### External Provider Quality Manual





Capacity Assessments	9
Safe Launch	10
Change Management	10
Change Management	10
Unauthorized Changes	10
Communication and Risk Management	11
Communication	11
Maintaining Knowledge Base	11
Disaster Recovery and Business Continuity Plan	11
Supply Chain Requirements	12
Communication	12
Packaging and Freight	12
Inventory Management and Lot Traceability	13
Containment and External Provider Rejection Processes	13
External Provider Rejection Process	13
Controlled Shipping	14
External Provider Rejection: Financial Responsibilities	15
External Provider Performance	15
External Provider Monitoring	15
Delivery Performance	15
Quality PPM	15
Responsiveness	15
Scorecard	16
Low Performing External Providers	16
Low Performing Supplier (LPS Notification)	16
Record Requirements	17



#### Introduction

Anovion is committed to developing long-term relationships built on mutual trust and collaboration with our External Providers. Anovion values its providers as strategic partners in achieving our business objectives. By working together, we strive to deliver high-quality materials to our customers while driving efficiency, innovation, and sustainability throughout our supply chain.

This manual serves as a comprehensive guide for External Providers who provide materials or services to our organization. It outlines our expectations and requirements, ensuring a mutually beneficial and successful business relationship with respect to social responsibility, environmental responsibility, continual cost improvement, and customer focus.

#### **Anovion Quality Policy**

Anovion supports the electrified future by providing safe, reliable, competitive, and cutting-edge advanced materials. We strive for continuous improvement in technology, quality, service, and product safety.

Our Quality Policy can be articulated through the acronym CAPACITY:



#### Scope

This External Provider Quality Manual has been developed to communicate the operating principles, general expectations, and requirements of our External Providers. It applies to all external suppliers of materials, goods, and services. Specific requirements of providers of direct materials or processes related to production are defined with the term "direct provider" for clarity.

This manual is provided as a supplement to, and does not replace or alter, any purchase agreement and general purchase conditions or requirements included in applicable engineering drawings, specifications,



and other contractual documents. Acceptance of any and/or all purchase orders constitutes acceptance and commitment on behalf of the recipient to comply with this manual's content.

### **Expectations**

#### Social and Environmental Responsibility

Anovion mandates that External Providers comply with all local, federal, and internationally acceptable fair and safe labor practices.

Anovion mandates that External Providers comply with all local, federal, and international environmental standards. Anovion seeks to reduce, improve, and eliminate emissions and waste in the overall supply chain. Anovion will cease all business activities with External Providers failing to comply with acceptable fair and safe labor practices and environmental laws.

### "Zero Defect" Policy

In order to supply safe, reliable, and state-of-the-art battery material products, it is necessary that all functions within Anovion and our direct providers operate with a "Zero Defect" policy. We strive for a fundamental quality management system that ensures customer satisfaction in quality, cost, and delivery and encourages continuous improvement. Emphasis should be on defect prevention, the reduction of variation, and the elimination of waste (including emissions) in all areas of the supply chain.

#### **Customer Focus and Continual Cost Improvement**

It is expected that the entire External Provider organization will give their full support to the relationship that exists between our organizations and will demonstrate flexibility and creativity in supporting Anovion to meet all market and customer requirements.

Anovion strives to maintain competitiveness through continuous improvement in processes and costs. The External Provider is expected to review its products and processes on an ongoing basis for cost-improvement opportunities along the entire value stream.

## **External Provider Management System Requirements**

### **Quality System Certification**

Direct material External Providers are expected to demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA member, (International Accreditation Forum "IAF" Multilateral Recognition Arrangements "MLA") and where the accreditation body's main scope includes management system certification to ISO/IEC 17021.

#### External Provider Quality Manual

Revised April 2024



External Providers are strongly encouraged to implement an IATF 16949 Automotive Quality Management System.

Non-certified External Providers may be exempted from certification requirements if approved in writing by Anovion and, if applicable, by our customers.

The External Provider is responsible for sending copies of its quality certification(s) to Anovion within 2 weeks of receipt. Loss of certification for any reason requires immediate notification to Anovion. Failure to update certification on time or the loss of certification may cause the External Provider to be placed on blocked status and may result in an immediate order stop.

#### **Environmental Management System**

External Providers are expected to adopt a responsible environmental approach which satisfies all applicable legal requirements and includes processes/procedures to reduce overall impact.

For External Providers certified to ISO 14001 Environmental Management standard, Anovion may request a copy of the certification body audit report and/or a copy of the corrective actions approved by the certification body when such requirement may be imposed by a customer of Anovion.

# **Confidentiality Agreement**

Anovion considers discussions between External Providers and prospective External Providers as private matters between two parties. Anovion keeps these discussions confidential and expects our External Providers and potential External Providers to abide by the same principle. This requirement must be passed down throughout their supply chain.

Interactions involving our customers and External Providers shall only take place with Anovion authorized representation and only as it relates to Anovion business matters. As appropriate, a Non-Disclosure Agreement will be initiated.

Use of the **Anovion** name and/or trademarks is strictly forbidden in key messaging channels such as, but not limited to marketing, advertising, social media, brochures and/or presentations without written authorization in advance. Furthermore, if permission is granted, adherence to the brand guidelines will be required.

### Request for Quote (RFQ)

### Request for Quote

When receiving a request for quotation (RFQ), the External Provider is responsible for reviewing all elements of the request as applicable.

These include but are not limited to design records, technical specifications, capacity requirements, delivery schedules, and all applicable Anovion/Customer specifications and requirements.



The RFQ (quotation and contract) elements shall be reviewed and, where possible, done so in accordance with the respective provider's quality management system.

The External Provider may be required to provide a capacity assessment to confirm that it has the necessary capacity to fulfill the quoted Anovion demand.

#### Review of Design Records

Upon award of business, the External Provider will be responsible for reviewing all documentation and specifications provided. It is the responsibility of the External Provider to notify Anovion if they have not received sufficient specifications noted in the design records.

It is the responsibility of the External Provider to notify Anovion if any technical standards (OEM, ASTM, SAE, etc.) are unattainable for any reason and provide corresponding alternate standard for approval.

### **External Provider Qualification Process**

#### **External Provider Qualification Process**

Anovion's supply base shall consist of organizations supporting our business and strategic requirements. Disciplined methods are utilized through which External Providers are evaluated, selected, monitored, and developed.

Prospective External Providers may be requested to complete and submit a self-audit or participate in an Anovion audit, which may be evaluated based on the potential risk assessment performed by Anovion.

#### Audits

Anovion reserves the right to verify the materials and manufacturing processes, including the related systems and interactions either at the External Provider's premises or remotely via the Supplier Self-Audit Questionnaire, and throughout their supply chain using different classifications of audits.

Unless otherwise specified, Anovion uses the VDA 6.3 Process Audit Tool by VDA QMC for Second Party Audits. Utilization of this tool, however, does not necessarily mandate full compliance with VDA Requirements exceeding other requirements already herein specified. This requirement is not limited to the External Provider selection process and may be implemented at any time.

# **Customer-Specific Requirements**

Customer-specific requirements (CSRs) include those of Anovion and its end customer CSRs. It is the responsibility of the External Provider to evaluate all relevant manuals and customer-specific requirements.



#### **Advanced Verification Process**

The External Provider may be required to submit an advanced verification document, such as a Certificate of Analysis (CoA), before the product leaves the External Provider's control/ facility.

The External Provider may have a similar process requirement defined in their quality management system for all sub-tier External Providers.

The External Provider of direct materials shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination.

#### Review of Statutory and Regulatory Requirements

The External Provider is responsible for complying with and satisfying all federal, state, local, and international requirements on all materials used in product manufacturing.

#### Safety Data Sheet

A safety data sheet in accordance with the Globally Harmonized System (GHS) guideline must be sent and approved by the receiving Anovion site before delivery of any materials or substance used in production processes is allowed.

The GHS is an international approach to hazardous communication, providing agreed criteria for the classification of chemical hazards, and a standardized approach to label elements and safety data sheets. For more information go to: https://www.osha.gov/dsg/hazcom/ghsguideoct05.pdf

Anovion participates in the International Material Data System (IMDS). Accordingly, External Providers should be prepared to create safety data sheets within IMDS for their materials and components. IMDS must be submitted and approved at or before PPAP submittal, as required, articulated by Anovion Quality.

For products used in the European markets, the use of lead, mercury, cadmium, and hexavalent chromium are prohibited for use in products supplied to Anovion. Certain exemptions are published in The End-of-Life Vehicle Directive, 2000/53/EC, Annex II. When requested, the External Providers must complete and submit a Declaration of Compliance (ELV).

# Advanced Product Quality Planning (APQP)

Anovion encourages External Providers of direct material to utilize Advanced Product Quality Planning (APQP) to produce a product quality plan which ensures the quality and reliability of products throughout the development and production stages.

Each External Provider shall define an associate as a point of contact who shall be responsible for the organization and communication of Anovion project goals and objectives within their organization.



Project management is encouraged to utilize the principles outlined in the latest AIAG Advance Product Quality Process (APQP) manual.

Anovion encourages External Providers of direct materials to maintain and supply Process Failure Mode and Effects Analysis (PFMEA) for products and services in the supply chain. The PFMEA shall describe the risks to the production process and/or materials produced and identify actions taken to mitigate risks, such as process controls. PFMEA inputs must include warranty issues, customer concerns and lessons learned, and address past concerns/ corrective actions. Refer to the AIAG FMEA manual for additional guidance.

#### Pass-Through Characteristics

Pass-Through Characteristics are product characteristics that are not controlled or functionally tested downstream in the supply chain, are ultimately supplied to an Anovion customer (e.g. it will "pass through") and may have a significant impact on customer satisfaction and/or warranty. A PTC may or may not be a Special Characteristic.

#### **Special Characteristics**

Anovion defines the pass-through characteristics using the definitions below:

- Pass-Through Characteristics (complete pass through) = PFMEA Detection 10. A characteristic that will not be detected at any point prior to being delivered to Anovion's plant.
- Weak Detection (WD) (may pass through) = PFMEA Detection 6-9. A characteristic that does not have robust detection and might not be detected at any point prior to being delivered.
- Potential PTC A characteristic which has no detection within the manufacturing External Provider (PFMEA Detection of 10) and has not yet been reviewed to check if it passes through the supply chain.
- Potential WD A characteristic which does not have robust detection within the manufacturing External Provider (PFMEA Detection of 6-9) and has not yet been reviewed to see if it passes through subsequent tiers of the supply chain.

The External Provider working with Anovion must ensure controls are in place for the PTC/WD. The External Provider and Anovion must reach an agreement on the proper method of control for the identified PTC. PTC symbol "P" must be noted on PFMEA and Control Plan when such are used.

The appropriate symbol (CC, SC, <>, etc.) must be included on all related documents (including control plans, FMEAs, work instructions, and process control documents) for the operations that produce special characteristics.

External Providers must ensure their associates understand the significance of special characteristics, what the special characteristic(s) in their operation means, the part function, and the impact of failure.

Designated critical characteristics shall be subject to continuous ongoing Statistical Process Control in accordance with the latest edition of the AIAG SPC Manual. The External Provider must employ competent associates knowledgeable in measurement systems analysis and statistical methods.



If Anovion has not defined special characteristics for External Provider part(s), it is the External Provider's responsibility to identify any critical/significant characteristics needed as a result of the External Provider's DFMEA and PFMEA or other risk assessment activity.

The External Provider must maintain capability data for all customers or External Provider-designated special characteristics and make capability information available.

#### Measurement System Analysis (MSA)

Measurement systems used for evaluation or qualification of Anovion product must be calibrated or verified, or both, prior to use and at specified intervals against measurement standards traceable to international or national measurement standards. Variability should be acceptable in accordance with the AIAG Measurement System Analysis (MSA) manual. These requirements extend to outsourced processes and external labs.

# **Process Approval**

#### Production Part Approval Process (PPAP)

Anovion may require External Providers of direct materials and their sub-tier External Providers to follow AIAG Production Part Approval Process (PPAP) requirements when submitting PPAPs. When required, and unless otherwise specified by Anovion Quality, the default is a level 3 PPAP with all requested documentation. Samples are to be submitted to Anovion on or before the agreed due date.

Process changes may require PPAP re-submission. The control plan and PFMEA must be updated as control methods and measurement systems are changed and improved and be audited periodically as part of the External Provider's internal audit process to ensure continued effectiveness. Unless otherwise exempted, External Providers are expected to use the control plan format in the AIAG APQP manual.

### **Capacity Assessments**

Capacity Assessments support Anovion to understand its External Providers' processes and secure capacity. It identifies bottleneck processes at External Provider operations that could impact supply and allows them to be addressed so that customer demands can be met. This section can apply to both direct and indirect vendors as circumstances warrant.

#### The External Provider must:

- Perform and submit a capacity self-assessment upon request.
- Define and complete an action plan to close any performance gaps.
- Manage its tooling, equipment, and facilities such that:
  - Average production weekly capacity requirements are to be met by operating on a 5day work week.
  - The remaining time during the week is reserved for completing the required tooling, equipment, and facility maintenance.



Anovion reserves the right to perform a Capacity Audit on the External Provider's premises and processes at any time.

#### Safe Launch

When required, Anovion may require the External Provider to implement a safe launch plan. Where applicable, the External Provider can apply for an Interim Approval if unable to conform to all specified requirements. The External Provider should apply for this as soon as they see that they cannot present a complete PPAP on the agreed date. The Interim Approval request should specify which requirement the provider cannot fulfill and an action plan to meet requirements in a defined time period. An interim approval may be granted for a set product volume or time period.

Anovion reserves the right to inspect samples for conformance and will return a signed Warrant indicating whether it is approved to produce parts for production purposes. Shipping of production material is only allowed with an approved PSW (Part Submission Warrant) or a signed Interim Approval by Anovion.

# **Change Management**

#### Change Management

Changes to an established product, process, or site with the External Provider or that of its sub-tier External Provider(s) require written advanced notification to Anovion. This notification shall occur a minimum of 12 weeks prior to change unless unforeseen circumstances drive the need for an emergency approval. Reference section 3 of the AIAG PPAP manual for more detail on when notification is required.

External Providers must complete and submit an External Provider Product/ Process Change Request and secure written approval from Anovion prior to initiating change.

The External Provider must provide traceability of changeover, date of first shipment, and Anovion-approved labeling of changeover lots.

#### **Unauthorized Changes**

External Providers must never ship a deviated product/process before obtaining written Anovion approval. Anovion may approve, reject, or apply conditions of approval on the change request (e.g.: level 3 PPAP required after the change is implemented).

In cases where an External Provider has implemented an unauthorized change and Anovion and/or its customers have been negatively impacted, the External Provider may be responsible for compensating Anovion for all associated costs and may be required to submit documentation of corrective action.

Anovion will not give approval to any deviation that may negatively impact safety and/or regulatory requirements.



Any External Provider unable to meet the requirements of this section must submit a request in writing and receive approval.

### Communication and Risk Management

#### Communication

The External Provider is required to identify, maintain, and communicate via a primary contact person and a proxy who serve as a coordinator within the External Provider organization and supports Anovion in resolving quality questions, concerns or discrepancies.

Changes in the External Provider's management structure shall be communicated within 3 business days of such change.

Changes in the provider's ability to meet delivery and quality commitments must be communicated within 24 hours of discovery of such a situation. This notification must be submitted in writing to Anovion's quality and purchasing contacts.

#### Maintaining Knowledge Base

External Providers are required to ensure competency in its workforce at all levels of the organization. The External Provider shall ensure that it maintains continuity of knowledge if key associates leave the company or that any other event occurs that could impact the knowledge level of the organization. The External Provider will ensure that sufficient training is provided to all personnel involved in the product safety and manufacturing process.

A contingency plan must be made and reviewed on a regular basis as part of the management review process or as conditions warrant.

If Anovion determines through objective evidence that the External Provider is lacking in these or other core areas, Anovion may require the External Provider to acquire the necessary training/capabilities.

### Disaster Recovery and Business Continuity Plan

The External Provider shall prepare contingency plans for continuity of supply in the event of any of the following: fluctuation in business (up or down); key equipment failures; interruption from externally provided products, processes, and services; natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions.

For direct material, these contingency plans shall:

- Include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations.
- Periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate), and maintain records of the test for a minimum of five years.



- Conduct contingency plan reviews (minimum annually) using a multidisciplinary team including top management, update as required, and maintain records of reviews for a minimum of five years.
- Document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).
- Include protection against cyber-security attacks which could result in either loss of information, downtime, or breach of protected data.

The contingency plans shall include provisions to validate that the manufactured product continues to meet Anovion's and/or its customers' specifications after the re-start of production following an emergency in which production was stopped and the regular shutdown processes were not followed.

Any change to the External Provider's business that may affect their ability to supply products to meet Anovion's requirements must be communicated.

External Providers must notify Anovion of labor contract expiration dates no later than six months before the expiration. External Providers must have a documented risk mitigation plan in the event of labor disruption/ logistics disruptions.

# **Supply Chain Requirements**

Anovion strives for a reliable, efficient, and lean supply chain which consistently delivers a product to the customer with the least amount of waste. Anovion and External Provider must work together to achieve supply chain stability while ensuring flexibility, and to minimize waste while maximizing value creation.

#### Communication

External Provider must communicate, at minimum, the following in written or electronic form:

- Order acknowledgment, including confirmation of delivery date, quantity, and terms.
- Any expected delivery deviations to order placed.
- Receipt and shipment of Anovion returnable packaging.
- Advanced shipment notification.

#### Packaging and Freight

External Providers are responsible for packaging the material in a manner that protects the material during storage and transportation and allows the product to be handled safely. External Providers must follow the packaging and label requirements defined by Anovion and any customer-specific requirements, if applicable. Materials with defined shelf life must be clearly marked with expiration dates and lot information shared with Anovion for each delivery.



The External Provider shall ensure and maintain documented procedures for the control, verification, storage, and maintenance of returnable packaging or other Anovion-owned property, where applicable.

Incidences of premium freight assigned to the External Provider for quality or delivery issues may be reported on the External Provider's scorecard and may be charged back to the External Provider. The target is to have zero incidences of premium freight.

#### Inventory Management and Lot Traceability

The External Provider shall ensure materials to Anovion are delivered using First-In-First-Out (FIFO) inventory lot management principles. Deviations to FIFO may require Anovion approval in advance.

The External Providers shall have an effective lot definition and traceability procedure based on risk analysis and compliance with government, Anovion, and customer-specific requirements or product-specific requirements.

Delivered product should be traceable back to:

- Finished product
- Raw material
- Production history of the processes applied to the product
- Rework operation, if applicable
- Product and process special characteristics
- All test records as defined in the control plan
- All External Providers in the supply chain

### Containment and External Provider Rejection Processes

### **External Provider Rejection Process**

If a nonconforming product or material is delivered to Anovion, the External Provider must proactively inform Anovion, or Anovion will notify the External Provider of the nonconformance. External Provider is required to complete a thorough analysis of the defective product and returns from Anovion and/or its customers.

The External Provider must immediately address the issue with the appropriate containment, root cause, and corrective action in the timeframe specified and submit a corrective action using the 8 Disciplines of Problem-Solving (8D) methodology. Anovion may supply a format or approve an alternate format prior to submission.

The expected timeframe of the 8D process is as follows unless otherwise agreed:

- Initial Response: 24 hours
- **D1-3:** Within **48 hours** provide notice of the suspect issue to Anovion, including the definition of the problem. Immediately begin data-driven containment activity, including sorting



throughout the supply chain. Results of containment activities shall be made available upon request by Anovion.

- **D4-D5:** Within **10 days** after notification (or as specified by Anovion), a thorough root cause analysis must be completed for both occurrence and non-detection, and permanent corrective action defined.
- **D6-D8:** Within **30 Days** (or as dictated by Anovion) implement and validate permanent corrective actions. The effectiveness of permanent corrective action must be verified, and recurrence prevented.
- **Closure:** Anovion Quality reviews the submittal and determines if the corrective action is effective in addressing the nonconformance to decide if problem resolution is acceptable.

Any charges assessed against Anovion by its customers due to External Provider issues will be communicated and passed on to the External Provider for reimbursement. The External Provider will be responsible for all costs, including but not limited to freight costs, containment services, and administration costs which are related to the nonconformance or field failures.

Upon request, and where applicable, the External Provider shall provide an immediate replacement product at the Anovion facilities to ensure no stoppage of production.

#### **Controlled Shipping**

If quality issues or risks occur repeatedly, Anovion may require Controlled Shipping Levels (CSL) from External Provider.

Controlled Shipping Level 1 (CS1) requires that the External Provider put in place a redundant inspection process at the supplying location to inspect and sort for a specific and specified nonconformance to protect Anovion and/or its customer from the receipt of nonconforming parts/material. The redundant inspection shall be executed by the External Provider and must be in addition to the normal production process controls. Exit from Level 1 requires written approval from Anovion. All products and/or containers are to be labeled and identified as CS1.

If the CS1 criteria is not executed properly and Anovion continues to receive nonconforming material, Anovion may require Controlled Shipping Level 2 (CS2).

CS2 includes the same processes as CS1, with an additional inspection process executed by a third party representing Anovion's interests specific to the containment activity. The third party is selected by the External Provider, approved by Anovion, and organized and paid for by the External Provider. Exit from Level 2 requires written approval from Anovion. All products and/or containers are to be labeled and identified as CS2.

If the External Provider requests the defective parts to be returned, they must arrange and pay for transportation to their location.



# External Provider Rejection: Financial Responsibilities

The External Provider is responsible for the quality, on-time delivery, and reliability of the product it supplies. The product must meet the drawings, specifications, and/or customer-specific requirements of Anovion and downstream customers.

The External Provider accepts financial responsibility for the consequences of nonconforming product and/or services including but not limited to: costs incurred for containment, sorting, premium freight, additional administrative efforts, rework, value add processing, replacement of defective material, resulting overtime, and productivity loss incurred by Anovion or customers.

#### **External Provider Performance**

#### **External Provider Monitoring**

External Provider delivery and quality performance will be continuously monitored using Key Performance Indicators (KPIs). These KPIs will be communicated at a defined frequency using scorecards, reviewed with the External Provider and will be considered in making sourcing decisions.

#### **Delivery Performance**

Delivery performance is measured as the percentage of on-time delivered volume compared to total ordered volume. There is no tolerance for early or late deliveries unless agreed in advance with Anovion.

Anovion expects External Providers to target >95% on-time delivery performance (OTD), unless otherwise stated by Anovion.

### Quality PPM

Quality performance is measured in the volume or number of External Provider parts per million (PPM) rejected by Anovion due to External Provider quality issues.

PPM data is used by Anovion to assess the performance of the Supply Chain relevant to Quality.

PPM requirements are specifically articulated via the PPM Target Agreement and PPM Counting Rules shared with the External Provider.

### Responsiveness

Anovion will measure each External Provider's responsiveness for items including timely completion of corrective actions, quote responses, and PPAP submission.



#### Scorecard

Anovion provides regular feedback to critical External Providers in the form of an External Provider Scorecard. The Scorecard is intended to encourage excellence in terms of quality (PPM and Problem Reports), delivery performance, and responsiveness to Anovion requests.

If the External Provider's performance consistently falls below expectations, the External Provider may be placed in an External Provider improvement program, placed on new business hold, or removed from the supply base.

# **Low Performing External Providers**

Anovion monitors External Provider performance and capabilities on a regular basis. When any of the monitored parameters indicate a negative performance trend or significant abnormality, the External Provider is considered for placement into an External Provider improvement program.

Areas evaluated may include, as applicable:

- Product launch capabilities/performance
- Issues related to critical and special characteristics
- Responsiveness
- Non-compliance with statutory and regulatory requirements
- Safety-related concerns
- Quality performance
- Delivery performance
- Warranty performance and premium freight
- External Provider's financial health
- Compliance with customer-specific requirements
- Other areas deemed applicable

External Providers may be notified of the potential inclusion in any External Provider improvement program by a Low Performing External Provider warning letter sent to the External Provider's management representative.

### Low Performing Supplier (LPS Notification)

There are three stages of Low Performing Supplier: LPS1 (initial stage), LPS2 (mid-level stage), and LPS3 (advanced stage).

Each time the External Provider is elevated to a higher stage, the actions required will include those of all previous stages, plus the additional actions required by the new stage.

At the LPS1 stage, the External Provider will receive notification in the form of a warning letter. The External Provider shall take necessary action to address the concerns noted in the notification and report the action taken to the initiator of the LPS1.

Revised April 2024



Considerations may include, but are not limited to:

- Safe Launch Plan, as applicable
- Control Plan(s) audit.
- Update LPA's
- CS1 containment, as defined by Anovion
- Safety audits, as defined by Anovion
- MSA Reviews
- External Provider notification of NBH to the External Provider's certification body
- Weekly review with Anovion representatives (at Anovion site as warranted)

If the actions are deemed timely and effective, Anovion will issue a closure statement. If the actions are not deemed timely or effective, Anovion may escalate the LPS1 to an LPS2 level.

At LPS2, the External Provider is placed on New Business Hold (NBH) status. Upon receipt of the LPS2 notification, the External Provider's management team must take an active leadership position in defining and addressing the root causes of the concerns. The action items shall be monitored and reported to the Anovion SQ representative on a weekly basis.

If the actions are deemed timely and effective, Anovion will issue a closure statement. If the actions are not deemed timely or effective, Anovion may escalate to an LPS3 level. The External Provider is kept on New Business Hold during this phase.

At LPS3, the External Providers' executive management team is required to compile and report on actions taken to address the concerns. This team will be required to present the current and planned actions in person to an Anovion Executive Management Team at an agreed-upon date.

In the event that the improvements are not realized, Anovion may elect to develop an exit strategy with the External Provider. The External Provider is required to support the exit strategy.

# **Record Requirements**

The External Provider shall ensure that the records comply with all applicable legal, governmental, Anovion, and its customers' requirements. The minimum retention of records shall be 20 years unless otherwise specified and authorized. External Providers must understand, and document all record retention requirements.