

IDEXX Supplier Quality Manual

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Introduction

*Together we are inspired to enable best-in-class value-chain
partnerships to the delight of our customers*

IDEXX recognizes the very important role that suppliers have in our success. Our suppliers are an extension of our own operations and we rely on them to provide material, products, and services that meet all IDEXX requirements. This will be realized with our suppliers through collaboration, clearly defined expectations, and maintaining open lines of communication.

Our vision is for all IDEXX suppliers to implement and maintain a quality management system that is compliant with industry standards and which allows them to produce and deliver globally competitive products and services that are superior in performance and value. Our suppliers are expected to conduct business with a high degree of integrity and in an ethical manner, which includes the suppliers' responsibility for ensuring compliance to all contracts and IDEXX specifications. This also includes compliance to local and national laws and regulations.

Purpose and Scope of This Manual

The purpose of this manual is to communicate IDEXX quality and reliability expectations and requirements to all potential and existing suppliers to IDEXX. These expectations and requirements are influenced by IDEXX quality, regulatory, product, process, and customer requirements. This manual provides further explanation and guidance for requirements set forth in existing agreements, purchase orders, drawings, and specifications. It does not replace or alter any of those other requirements.

Supplier Management

Overview

Fundamental to the partnership between IDEXX and suppliers is a willingness to collaborate and communicate effectively at all levels. Open and direct access to personnel and facilities is expected. Information exchange will include the following areas:

- Quality data—Traceability and other processing data available to IDEXX when addressing quality or compliance concerns.
- Manufacturing systems process controls—FMEAs, control plans, measurement systems analysis, corrective actions, continuous improvements, and other information that provides confidence in the supplier's ability to deliver products that consistently meet IDEXX requirements.
- Product qualification and change control—Specification/drawing development and review, verification and validation, measurement systems analysis, change notifications, first article inspections, change effect assessments, and other efforts to approve new or modified products and processes.
- Sustainability initiatives—Sustainability projects/initiatives, process/product improvement projects, and IDEXX/supplier process cross-training, planned or underway.

Supplier Planning, Selection, and Qualification

Supplier Planning and Selection

Supplier planning and selection activities ensure that selected suppliers are aligned with IDEXX's quality and technology. The supplier selection process is also used to assess potential risks in the supply chain, so those risks can be mitigated or eliminated prior to production.

Supplier Selection

When selecting a supplier, key areas that are evaluated include:

- Collaboration—Agreeable to working with IDEXX personnel in an open and cooperative manner, such as sharing of data and information.
- Quality—The ability to consistently produce product which meets or exceeds the technical and quality requirements of IDEXX.
- Technology—Technical capability and commitment to advancing process technologies in support of IDEXX's strategic direction.
- Service—Capability to meet IDEXX's production, delivery, and service requirements with a high level of support and responsiveness.
- Corporate responsibility—Commitment to responsible business practices.

Qualification

IDEXX's qualification process is based on an underlying philosophy of defect prevention, process control, and continuous improvement, rather than product acceptance testing or defect detection. The strategy is to achieve, maintain, and improve stable and capable production processes.

Quality Management System

Suppliers are expected to have a quality management system in place that fulfills IDEXX requirements and aligns with applicable governing standards and regulations such as ISO 9001 or ISO 13485. For suppliers who are not yet certified to one of these types of industry standards, it is preferred that they have a plan in place to become certified.

Quality Assessments

Quality system assessments are an integral part of IDEXX's supplier selection process. IDEXX prefers to perform on-site assessments at the supplier's manufacturing facilities, which requires that representatives be allowed to visit supplier facilities, including unexpected visits, in order to:

- Assess the supplier's quality systems, production facilities, and process controls to determine their potential impact on IDEXX's manufacturing process.
- Gauge potential product risks.
- Verify the quality of outgoing shipments.
- Assist suppliers in evaluating and upgrading their quality system.
- Review past inspection and test records.

IDEXX may request corrective action for observed issues and may make recommendations for improvement to better align the supplier's processes with IDEXX expectations. Suppliers are expected to cooperate with IDEXX on any such requests or recommendations and are encouraged to make their own recommendations to improve IDEXX's processes.

Although on-site assessments are preferred, there may be situations, such as travel restrictions, that prevent a planned on-site assessment. In such situations, the supplier is expected to work with IDEXX on alternate methods to achieve the assessment objectives. This may include a virtual/video assessment, sharing of process specifications and data, or exchange of supplier's audit results.

First Article Samples—Custom or Semi-custom Products

Suppliers shall conduct a validation run and produce parts for first article samples utilizing normal production equipment, materials, tooling, and processes that would be used in mass production.

Suppliers shall make every attempt to implement corrective action for any "out of spec" condition prior to submittal to IDEXX.

All specified parameters shall be validated by the suppliers and the resulting data shared with IDEXX.

First Article Samples—Standard or Commercially Available Products

When requested, suppliers shall provide first article samples that utilize normal production equipment, materials, tooling, and processes that would be used in mass production.

No first article parts or materials should be submitted to IDEXX if any specified parameters do not meet IDEXX specifications without prior review and authorization by the IDEXX SQE to do so.

IDEXX reserves the right to perform additional validation testing to verify the supplier's results. If the testing indicates the product does not meet IDEXX's requirements, the supplier is expected to work cooperatively with IDEXX to make improvements that eliminate the observed test results.

Verification and Validation

Verification and validation of systems, processes, and products are critical to a supplier's ability to provide consistent products or services. As such, IDEXX expects its suppliers to utilize effective methods to test and confirm the capabilities of all manufacturing equipment, processes, and controls used to produce products that are supplied to IDEXX.

Additionally, suppliers are expected to conduct process control or product acceptance testing during production. Sample sizes and test frequencies utilized for production testing should be consistent with expected process variation, thereby ensuring that all agreed upon specifications are met. When requested, suppliers must ensure in-process product is controlled until required tests or approvals are performed to demonstrate compliance to IDEXX specifications. The supplier must document and retain all such test results.

Production and Process Controls

Each supplier must develop, control, and monitor production processes to ensure parts are manufactured in conformance to IDEXX specifications. This includes documented instructions that define the production activities, approval of processes, and equipment validation.

Control of critical process parameters and component or device characteristics during production must be maintained. Suppliers will participate with IDEXX, when requested, on qualification and validation efforts, including special studies, such as Measurement Systems Analysis (MSA), sample size calculations, and designed experiments.

Any software used to control, monitor, or test critical processes must be evaluated to ensure that it conforms to its intended use. Written procedures must be established to define how changes to the software are implemented and controlled documentation is maintained. The supplier must maintain a record of the dates when change comes into effect. Only the most recent revision of any control software must be available for use at the time of production.

Process Qualification

Process qualification includes several activities that are used to confirm that the supplier's processes have the capability to produce product that meets all IDEXX requirements during volume production. At the successful completion of process qualification, approval is given to the supplier to begin production shipments.

The requirements for successful process qualification are provided below. IDEXX will collaborate with suppliers and develop an appropriate qualification plan that will include some combination of these activities and may, when requested, include other actions.

- Define the manufacturing process flow—The manufacturing process should be defined in a flow chart, process diagram, or even as product-specific production routings in a manufacturing control software system. The supplier must have a means of identifying and documenting all changes to the process flow after completion of process qualification.
- A completed Process Failure Mode and Effects Analysis (PFMEA)—With the exception of a small number of processes that are simple enough that they may not benefit from their use, IDEXX prefers that suppliers utilize FMEAs to understand and prevent process weaknesses whenever possible. Potential failures with high severity and occurrence values, or with a high overall risk priority number (RPN), must have appropriate controls in place to prevent such failures during production.
- Process control plans are defined—Suppliers should utilize process control plans to define, at a minimum, process monitors and production acceptance testing to be performed, the required sample size and frequency of the testing, and the methods used for testing.

The content of the control plan is more important than the format and suppliers are encouraged to utilize formats that work best for them, as long as a copy with clear content can be readily provided to IDEXX when requested.

A copy of the supplier's process control plan may be requested during process qualification and suppliers are expected to work cooperatively with IDEXX on any such requests. It is further expected that process control plans are to be revision controlled and suppliers will have an effective process in place to maintain all established process control plans.

- The manufacturing line layout should be completed for new production or line capacity verified for existing production. Suppliers are expected to maintain layout flow charts, diagrams, or photos as documentation of the line layout. IDEXX may request photos of non-proprietary operations during on-site quality assessments. Suppliers are expected to support such requests whenever possible.
- All fixtures, jigs, and tooling required for production or process monitoring must be fabricated, validated, and ready for implementation. IDEXX may request a list of all tools and fixtures used during the manufacturing process.
- Custom test and control systems are installed and operational. IDEXX may require that specialized IDEXX-defined test equipment be included as part of the supplier's manufacturing process. If requested, IDEXX expects suppliers to work collaboratively with IDEXX on the installation, use, calibration, and maintenance of such equipment. Review of this equipment, and the controls for it, will be included in on-site quality assessments.

- All standard operating procedures, work instructions, or set-up documentation for the process, equipment, and associated systems must be approved and released in the supplier's document management system. IDEXX expects suppliers to support requests for a listing of all documentation related to the qualified manufacturing process. Suppliers are expected to provide process documentation for processes that are deemed critical, when requested by IDEXX.
- All manufacturing staff and support personnel must be properly trained for the functions they perform, and training documentation must be available upon request. The supplier should also have verifiable controls in place to prevent staff from performing operations for which they are not properly trained.
- A data collection system for all agreed upon IDEXX-identified parameters must be established and proven fully functional. IDEXX will request copies of such data as necessary to verify process control or from time to time to support problem solving efforts.
- There may be IDEXX-specified product parameters that, due to technical limitations, cannot be tested during the production process. IDEXX expects suppliers to work cooperatively in such situations to identify alternative methods that may be used to provide confidence in conformance to all IDEXX-defined specifications.

Measurement Systems Analysis and Correlation Studies

Specifications for new IDEXX products are developed and validated based on measurements made by IDEXX. Because of this, it is critical that supplier's measurement systems are correlated to the systems and methods utilized by IDEXX. For correlation studies to be effective, suppliers must agree to participate and openly collaborate with IDEXX on a plan that includes activities such as alignment of measurement equipment, agreement on measurement method and joint measurement of common samples.

In addition to correlating the measurement systems and methods, it is equally important to assess the adequacy of the supplier's measurement system. A Measurement Systems Analysis (MSA) may be requested to assess the adequacy of the measurement system for parameters that are identified as critical to quality. A capable measurement system is one that has been shown to add a minimal amount of variation to the total measurement range. IDEXX expects suppliers to participate in such analyses and, if necessary, work with IDEXX to find alternate methods of measurement if a system proves to be incapable of stable and sufficient measurement resolution.

Shipping and Logistics

Traceability

Suppliers are expected to maintain forward and backward traceability for all products, when requested. Backward traceability allows the supplier to look back at lot or process history based on the identification of a suspect product. Forward traceability allows the supplier to identify other shipments that may include a problem that is related to a confirmed product failure.

Traceability may take the form of an assigned serial number for each product, or it may be an assigned lot number for each production batch. The required level of traceability is dependent on assumed risk to IDEXX. Some products require traceability for every component, material, and subassembly. Other products only require traceability for critical components or subassemblies. Some very low-risk products require little or no traceability. IDEXX will inform the supplier of traceability requirements before materials are purchased.

Labeling

Product and package labeling must be easily readable and provide the information required to clearly identify the material and associated IDEXX purchase order. IDEXX maintains labeling documents that include details for different types of products. These documents will be provided upon request.

Packaging

Suppliers are expected to use packaging and shipment methods that prevent product damage or degradation. Suppliers are expected to work with subcontractors or freight forwarders that they utilize to resolve any IDEXX-identified problems.

In cases where there are known risks, IDEXX may request custom packaging to prevent product damage or degradation during shipment. Suppliers are expected to work cooperatively with IDEXX on any such solutions.

Sustaining Product Quality

Change Control

Suppliers are expected to understand and validate the impact of any changes they make to their manufacturing processes and/or the products. As suppliers do not often possess the information necessary to assess the impact of changes to IDEXX's products or customers, it should not be assumed that there are minor changes that do not need to be reported to IDEXX. Instead, ALL changes that are planned for any aspect of a process or product which IDEXX has qualified and approved must be reported to the appropriate IDEXX Supplier Quality Engineer.

Once notified of a change, IDEXX's change control process includes the following steps:

- Assessment of all reported changes.

IDEXX evaluates all supplier reported changes. Those changes that IDEXX determines to have the potential to impact final product or customers are further assessed with an FMEA-like Change Effect Assessment (CEA) process.

IDEXX may request the supplier's change validation test report or additional data as part of the change assessment process. In addition, suppliers are expected to collaborate with IDEXX on the CEA process when requested.

- Validation and verification (V&V) testing based on the potential risks is identified.

The scope of testing will be dependent on the magnitude of the perceived risk. IDEXX may require samples incorporating all aspects of the change and suppliers are expected to fully cooperate with any such requests. Suppliers may also be requested to support IDEXX's evaluation of reported changes through participation in V&V testing.

IDEXX will generate a final V&V report. This report may be shared with the supplier upon request.

- Review and approval by IDEXX's Product Quality Change Review board (PQCR).

The final V&V report must be reviewed and approved by the PQCR. Supplier changes cannot be accepted by IDEXX without PQCR approval.

Notification of supplier changes should be completed at least six months prior to the planned implementation date as the CEA/PQCR process takes time and some critical materials may require significant validation plans to mitigate identified risks.

Nonconforming Material

Nonconforming material may be identified upon receipt at IDEXX, after shipment to the final customer or anywhere in between. No matter where the nonconformance is identified, the supplier can expect to be notified by IDEXX of the problem.

Nonconforming material may be managed via a business-related process wherein a credit is requested, or material is returned to the supplier for rework, repair, or replacement. Corrective actions are rarely requested in such cases.

Nonconforming material may also be managed by a process that is based on common quality management system methods. In those cases, the responsible Supplier Quality Engineer will communicate the need to investigate nonconformances, implement containment actions, identify

and eliminate the root cause of the nonconformance, and eliminate the risk of similar problems occurring with other materials supplied to IDEXX.

Corrective Actions

The supplier should establish and maintain procedures for implementing a corrective action system in compliance with industry standards and quality management system requirements. IDEXX prefers the 8-Discipline (8D) process, but suppliers may use any documented problem-solving process that provides the same critical information as the 8D process.

Suppliers are expected to collaborate with IDEXX if a Supplier Corrective Action Request (SCAR) is issued for nonconformances. IDEXX and the supplier will work together to determine the division of responsibility for implementation of corrective and preventive actions, depending upon the nature of the quality problem and the resolution. The supplier's commitment to timely acknowledgement of issues and implementation of solutions is critical to the business relationship. The supplier must collaborate with IDEXX to determine the best support for the return of defective and questionable material, performance of problem analysis, and implementation of actions to prevent recurrence.

If a SCAR is generated, the supplier is expected to provide the following documentation within 2 business days:

- Problem/defect description
- Interim containment actions to prevent the shipment of additional nonconforming material
- Initial investigation status
- Contact information of employees addressing SCAR

Within 30 days, the supplier will provide an action plan which includes:

- Corrections, corrective actions, and/or preventive actions defined, including responsible owners and estimated date of completion for each action
- Proposed effectiveness criteria for corrective and preventive actions

Supplier Feedback

Structured reviews with suppliers may be held on a recurring basis. These reviews will address current activities, performance metrics, upcoming events, and action items. It is also an opportunity for suppliers to present changes, new initiatives, or other key information.

Supplier feedback consists of a combination of sources of information and summarizes the result of the supplier's performance to IDEXX requirements. The information reviewed may vary over time but may include items such as:

- Quality performance of products or materials
- Incoming quality acceptance rate
- Integration acceptance rate
- Delivery performance
- Qualitative performance measurements of cost, account support, technical support and innovation, and risk and compliance

