illumina®

Supplier Quality Manual

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Introduction

Supplier Quality Management

Who We Are

At Illumina, we are unlocking the power of genome to transform health care and beyond. We do this by living our vision and core values. Suppliers are our partners in this initiative and their commitment is vital to achieving our goals.

Our Vision

Illumina is a global company with the vision to be the leading provider of integrated solutions that advance the understanding of genetics and health. Our goal is to improve human health by enabling our customers to accelerate the collection, analysis, and application of biological information.

Our Values

- Innovation is in our DNA
- We are relentless in the creation of great products
- We move fast and embrace change
- We collaborate deeply
- We are open


Innovation is in our DNA. We
empower scientists to expand the
possibilities in their daily research.

Purpose and Scope of this Manual

The purpose of the Supplier Quality Manual is to communicate clearly the Illumina quality vision and expectations as they apply to potential and existing Suppliers.

This manual applies to all potential and existing Illumina Suppliers of materials and Services, including both OEM and Contract Manufacturers.

This manual is a supplement to, but not a replacement or modification of the terms or conditions in any agreements or specifications that may be separately entered between Illumina and its Supplier.

If a conflict arises between this manual and any other relevant document, the following order of precedence applies unless otherwise agreed contractually:

1. Agreements (Quality, Supply, PO etc.)
2. Specification Requirements
3. Supplier Quality Manual

Supplier Quality Vision and Values

The Illumina Supplier Quality vision is to build and foster a leading Supplier base that ensures safe and conforming products every time. We will achieve this by building a strong partnership with our Suppliers and a foundation of continual improvement of quality systems and process controls.

The values of our Supplier Quality Organization directly support Illumina core values.

- *Innovation… by partnering with suppliers on technology development*
- *Deep collaboration… by engaging early on in the product development cycle*
- *Moving fast and embracing change… by sharing real-time data with suppliers*
- *Relentless… by using data to drive improvements proactively*
- *Open… by engaging supplier feedback for product and process improvements*

Illumina suppliers are an integral part of our vision and values. By meeting the expectations set forth in this manual, you will help achieve this vision and live the values.

Letter from Quality Leadership

Illumina continues to provide innovative solutions to fuel groundbreaking advancements to human health. Successful partnerships with our Suppliers will promote and strengthen our vision of transforming health care by unlocking the power of the genome. The intent of this manual is to provide an effective, standard process that our Suppliers can follow to meet Illumina requirements and expectations.

The essence of the Illumina quality philosophy is that all employees, both at Illumina and at our Suppliers, have the responsibility and discipline to ensure the quality of their own work before passing it on to the next step in the process. We strive to build quality into our products and processes starting early in the development cycle to ensure that we meet customer expectations. We expect the same from our suppliers, demonstrated by meeting our specifications on each shipment.

Our Supplier Quality Manual comprises best practices used by Illumina as well as those of the most successful medical device companies globally. The standards in this manual have been established in accordance with the purchasing controls regulations directed by FDA and other regulatory agencies such as ISO and EU.

You are an integral part of the Illumina Supply Chain and a partner in our vision of transforming health care and beyond through preventive and precision medicine. Our mutual success depends on your adherence to the standards and expectations laid out in this manual.

I look forward to a successful partnership with your Organization in achieving our mission of transforming health care and beyond.

With utmost commitment,

Gary Workman

Vice President, Global Quality

Partnering with Illumina

When you become part of the Illumina Supply Chain, you become part of a team of dedicated Supply-Chain professionals who are committed to delivering world-class products to our Customers.

The Illumina Strategic Sourcing Manager will be your first point of contact for all business-related matters. This includes contracts, new product development, specification review, agreements, costs and pricing, and relationship management. Your Strategic Sourcing Manager will be consistent across projects.

During different phases of the project life cycle, you might also interact with the following roles within Illumina.

Department	Role	Description
Supply Chain	Purchasing Process Excellence	This group works early in the Supplier relationship to assess and improve matters related to Supply Chain and business risk. They implement solutions that include risk mitigation and alternative sourcing strategies. Working with the Illumina Supplier Quality and Strategic Sourcing groups, this team generates performance metrics for Illumina Suppliers, such as scorecards, documentation packages, and QBRs.
	Strategic Sourcing Managers	This person is your first point of contact for all business-related matters such as contracts, agreements, cost, and relationship management.
	Buyer	This is your contact for all purchasing-related matters, such as delivery, purchase orders, and forecasts.
Development	Design	The design group is the technical partner and point of contact for all questions related to product design and specifications.
Quality	Supplier Quality	This group collaborates with suppliers to make sure that the product/service meets Illumina requirements for quality, performance, safety, and intended use. They are your point of contact for all questions related to product quality, quality systems and process controls.

We collaborate deeply. We seek the inspiration and expertise from thought leaders in many fields to break barriers to human health.

Supplier Quality Management Life Cycle

The Supplier Quality Management life cycle sets clear expectations for each phase, to make sure that the quality of products and services meets Illumina requirements. Specific tools and processes are associated with each phase.

Phase 1: Supplier Selection and Evaluation

Phase 1.1 Supplier Selection

Illumina is committed to provide world class genome solutions to our customers by diligently selecting suppliers for Materials, Finished Medical Devices and Services.

Illumina Supplier selection process takes into consideration design, technical capabilities, business, quality and manufacturing capabilities. The Supplier selection process is also used to identify potential risks in the Supply Chain, so risks can be mitigated or eliminated prior to production.

Phase 1.2 Supplier Evaluation

All selected Suppliers will be assessed for risk associated to product/process quality upon registering in the Illumina Supplier Onboarding Portal. Suppliers are required to complete a Questionnaire and Change Notification Agreement. All suppliers are expected to comply fully with every local, regional, national, and industry laws, regulations, codes, ordinances, and guidelines that have the force and effect of law by acknowledging the Supplier Code of Conduct.

Depending on the type of product or service provided to Illumina, there may be other quality documentation requested (e.g. ISO certification, Quality Agreement, etc.). Suppliers providing Finished Medical Devices or In-Vitro Diagnostic products are expected to have a QMS in place that complies with the requirements of ISO9001, ISO13485, FDA 21 CFR Part 820 and/or other comparable standard or regulation. All other Suppliers are expected to have a QMS in place that is aligned with or similar to ISO9001, ISO13485, FDA 21 CFR Part 820 or other comparable standard or regulation.

Phase 2: Supplier Qualification

A Supplier Qualification Plan is established for every Supplier based on classification and criticality of the products and/or services provided to Illumina in order for the Supplier to be fully qualified and included in the Illumina Approved Supplier List (ASL). The Qualification Plan may include items such as Change Notification Agreement, Quality Agreement or Qualification audit.

Phase 2.1 Change Notification Agreement

Illumina defines changes as “any change to the design, manufacturing, material, processing, testing, labeling, packaging, or method of delivering a product or service impacting the performance, intended use, safety, material, labeling, packaging or technology.”

Below are some examples of changes that require notification:

- Company ownership or name change
- Design or specification change
- Manufacturing material, process, equipment, tooling or service change
- End-of-life availability status
- Facilities (address change)
- Packaging, labeling, storage-condition change
- Changes to supplier base including subcontractors, sub-assembly suppliers, direct material suppliers, etc.

Suppliers are required to notify Illumina and obtain approval of any change meeting our change definition at least 6 months ahead of the proposed change where possible. Suppliers are expected to submit a Supplier Change Notification Form in a Cloud based Supplier portal using the link **rcp-illumina-prod.etq.com/prod/reliance** and provide details of intended change, material impact and evaluation. The proposed change request will be reviewed by the Illumina internal team. Suppliers may be requested for additional validation or test reports to support the proposed change request. Illumina shall reply to the Supplier requested changes within 30 days of its receipt and shall not unreasonably withhold approval of any such requested change. Suppliers can monitor the approval status from portal and may receive automatic notifications on the status of change request submitted.

Phase 2.2 Quality Agreement

As included in the terms and conditions of Illumina Purchase Orders, acceptance of Illumina purchase order constitutes acceptance of requirements of the purchase order terms and conditions.

In addition to the requirements contained in the purchase order terms and conditions, Illumina may execute a Supply agreement and/or Quality Agreement with some Suppliers based on criticality and type of products or services provided. A Supply Agreement is a specific type of contract which defines terms and conditions under which Illumina will conduct business with a Supplier, which may include responsibilities for quality. A Quality Agreement is an agreement which defines Supplier's quality responsibilities under which Illumina will conduct business with a Supplier. Suppliers are expected to discuss and understand the specific applicability of these requirements with the appropriate Illumina representative in order to make effective business decisions. Refer to the Illumina Purchase Order for the Illumina Standard Terms and Conditions of Purchase that can be accessed from the link **www.illumina.com/company/contact-us/suppliers.html**.

Phase 2.3 Qualification Audit

A Qualification Audit is performed while onboarding a Supplier as a part of the Supplier qualification process. The audit performed may be onsite or desktop, which is decided at Illumina discretion. In addition to its suppliers, Illumina may also audit its sub-tier suppliers.

During onsite Supplier qualification audit, Illumina reviews the following:

- Compliance with Quality Management System and other regulatory requirements
- Production and process controls that conforms to Illumina product/service specification
- Elements agreed upon regarding product-specific Quality Agreement

Audit reports are sent to Suppliers within 30 days of audit completion. Suppliers are expected to review and sign off the report if no concerns were raised with the contents of audit report. SCARS may be issued for any major non-compliance identified during the audit and minor findings may be tracked until closure of corrective action. Suppliers are expected to provide a written response for all Illumina audit findings in a timely manner.

Phase 3: Component Qualification

All custom materials purchased by Illumina are required to be qualified before production use. Suppliers are expected to meet the component qualification deliverables as agreed upon between Supplier and Illumina. Deliverables could be assigned based on material classification and design criticality. Below are some of the qualification deliverables requested from Supplier and Illumina expectations on those deliverables.

Phase 3.1 First Article Inspection

Dimensions and tolerances (First Article Inspection Report) provided by the Supplier should correlate with the Engineering drawing (including annotation). The parts used for dimensional data must be from production tooling and randomly sampled from a run at production rate.

Material performance and test data may be included by the Supplier on a format that allows for clear interpretation of the results. For example, material results can be addressed using a material composition report or a certificate of analysis (COA) from an accredited lab that confirms that the material content meets a known standard or COC signed by vendor.

Sample parts may be requested which must be the actual samples measured in the report. Sample requirements shall be determined and aligned between Supplier Quality and Supplier during the Component Qualification Review meetings.

Phase 3.2 Measurement System Analysis/Gage R&R

Illumina may possibly request capability analysis of all measurement tools identified in the Control Plan (in process and offline gages) by performing a Gage R&R study using Total Tolerance on each measurement tool. The percentage R&R should be at 10% or less. A Gage Repeatability and Reproducibility (GR&R) Study is used to ensure that measurements used in the manufacturing process are reasonably consistent regardless of how many times they are performed, or by who they are performed. GR&R studies can be useful to Suppliers in that they can identify equipment that needs service, or operators who may need additional training on the equipment.

The minimum requirement for suppliers below may vary at the discretion of Supplier Quality:
A Gage R&R study using Total Tolerance on each measurement tool

- % R&R should be at 10% or less for CTQs
- Marginal gages (between 10% and 30%) may be acceptable based on applications and at Illumina discretion
- Gages with R&R at 30% or more cannot be used

Phase 3.3 Process Capability

Illumina expects Suppliers to develop and maintain highly capable processes to produce quality Products and Services. We recommend the use of Statistical Process Control (SPC) for special part and process characteristics. SPC is expected for certain critical drawing characteristics (unless otherwise specified). SPC data may be requested by Illumina as part of failure investigation, monitoring or qualification. Acceptable capability will be agreed upon by Illumina and Supplier prior to performing a process capability study.

Phase 3.4 Process Failure Mode and Effect Analysis (PFMEA)

A PFMEA may be requested for every part, piece of equipment or process involved in manufacturing irrespective of commodity classification. Suppliers are expected to review PFMEA with Illumina Supplier Quality prior to build and shipment of first article inspection samples. Cutoff for potential failure items with high RPN ranking where action is needed to address the potential failure mode may be determined collaboratively by Illumina and the supplier.

Phase 3.5 Control Plan

Control Plan describes the action required at each step in the process to assure that all process outputs will be in a state of control. Each control plan describes the actions that are required at each phase of the process including receiving, in-process, outgoing, and periodic requirements. Control Plan methodology is expected to be fully integrated into the Supplier's QMS.

Phase 3.6 Sub-Tier Supplier Control

Suppliers are expected to manage sub-tier Suppliers with controls in place mitigating any potential risks foreseen. Suppliers are responsible to ensure that Product(s) manufactured utilize only reliable, conforming and specified material as stated in the specification.

The Illumina expectation is that the Supplier has a formal Purchasing and Supplier control processes to manage sub-tiers. These controls are expected to include:

- Selection, evaluation and approval
- Product qualification
- Procurement
- Product acceptance
- Performance measurement and monitoring, including sub tier auditing programs
- Nonconforming Product and CAPA processes
- Change control

We are open. We are dreamers, innovators and seekers, working in a culture fueled by inspiration and hope.

Suppliers are responsible for ensuring and controlling the quality of all components and raw materials purchased by Illumina.

Please Note: Prior to implementing sub-tier Supplier changes, Suppliers are expected to seek Illumina approval per Change notification agreement in Phase 2.1.

Phase 4 Supplier Monitoring

To strengthen our partnership, Illumina monitors the performance of Suppliers on an ongoing basis to ensure:

- Conformance to specifications, processes, and procedures
- Compliance with regulatory requirements and agreements
- Continuous improvement

Illumina expect Suppliers to focus on defect prevention rather than correction. Suppliers are expected to implement statistically sound process controls and establish key process indicators to monitor all processes effectively.

Phase 4.1 Non-conformance Management

If Illumina identifies a supplier-related nonconformance (NC), the team will generate a non-conformance report and notify the Supplier. Illumina Suppliers are expected to handle non-conformances as agreed upon in PO terms and conditions, supply agreement, and/or quality agreement. If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

1. Supply Agreement
2. Quality Agreement
3. PO Terms and Conditions

Supplier-related non-conformance trends will be monitored on a monthly basis. Continuous-improvement actions will be taken on negative trends, such as issuing Supplier Corrective Action Request and/or conducting onsite audits.

Phase 4.2 Supplier Corrective Action Requests (SCARs)

Supplier Corrective Action Request may be issued to Suppliers on below scenarios:

a. Major Noncompliance from Supplier audit
b. Customer complaints verified to be Supplier fault
c. Regulatory and/or compliance related issue verified to be Supplier fault
d. Failure to provide Change Notification for critical IVD Components

SCARs may also be issued at the discretion of Supplier Quality based on Supplier performance. SCARs are monitored for timely and effective completion to the stated completion date.

Expected SCAR response timeline from Supplier:

- Acknowledgment – 2 business days from the receipt
- Investigation and action plan – 30 business days of the request
- SCAR closure – aligned between Illumina and Supplier based on corrective action plan and timeline to implement. Supplier Quality shall approve the SCAR information provided by the Supplier if satisfactory and approve the content and execution of SCARs

Phase 4.3 Ongoing Performance Review Management

At Illumina, Supplier performance is monitored on an ongoing basis to prevent defects. Trends in these performance metrics are reviewed such as:

- Nonconformance data
- Corrective action data
- Responsiveness (past due, on-time response, etc.)
- Key process indicators

Feedback on trends and data is shared with Suppliers through quarterly business reviews and Supplier scorecard reviews. Any negative trends in performance metrics may trigger an onsite audit of the Supplier process and quality system. Illumina reserves the right to audit for any reason at any time, as provided for in agreements between Illumina and the Supplier. Re-evaluation audits are performed on key Suppliers every 2years based on Supplier performance and scoring.

Phase 4.4 Business Reviews

Illumina conducts business reviews with most Suppliers as part of ongoing business, or when performance or other criteria lead Illumina to conclude that a review is needed.
Illumina may discuss the following information during business reviews, often quarterly:

- Quarterly performance data—Nonconformances, SCARs/CAPAs, audit findings, etc.
- Quarterly service data—On-time delivery, fulfillment accuracy, etc.
- Business data—Costs, new projects, etc.
- Technology reviews—Current and future

It is important that the Supplier's Customer-facing team and management team participate in and support all business reviews.

Phase 4.5 Scorecard

Illumina has a Supplier scorecard program that can be used to monitor supplier performance. The purpose of the scorecard is to assess current performance and identify opportunities for increased operating efficiencies, improved quality, and reduced risk. The following areas are measured on the scorecard:

- Quality
- Service
- Business
- Technology

Illumina Suppliers are expected to meet or exceed the set target on the scorecard. Scores below the set target may lead to an onsite audit, CAPA, or an improvement project.

Environmental and Regulatory

Illumina and its Suppliers are required to comply with all relevant environmental and medical device regulations relating to materials within products. This may be achieved by restricting, labeling, or controlling materials and/or by implementing collection and waste reduction programs. Failure to comply with geography-specific laws may prohibit sales of a device in that geography. Regulations that restrict the use of certain materials include, but are not limited to, the Medical Device Directive, the RoHS Directive, the REACH Regulation, and rules concerning materials safety and materials of animal origin. Therefore, suppliers shall have knowledge of, and inform Illumina of, restricted and regulated materials that are used to manufacture, process, or package products for Illumina. For applicable materials, as part of RoHS compliance suppliers will be asked to provide certificate of compliance. Access to our markets depends on your efforts, and ours, to comply with RoHS and other industry programs.

Glossary of Terms

ASL (Approved Supplier List)- A list of suppliers that meet the criteria for using the supplier.

CAPA (Corrective and preventive action)- Consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

COC (Certificate of Compliance)- A document certified by a competent authority that the supplied good or service meets the required specifications. Also called certificate of conformance or certificate of conformity.

CTQ (Critical to Quality)- A physical, chemical, biological or microbiological property or characteristic that needs to be controlled (directly or indirectly) to ensure product quality. These may be stated as specifications or requirements. It is not only important to consider the identity of a Critical to Quality Attribute, but also the frequency of occurrence (% reliability) needed for the attribute.

FMD (Finished Medical Device)- A device or accessory to a device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Gage R&R- Gage R&R, which stands for gage repeatability and reproducibility, is a statistical tool that measures the amount of variation in the measurement system arising from the measurement device and the people taking the measurement.

IVD (In-Vitro diagnostic)- In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

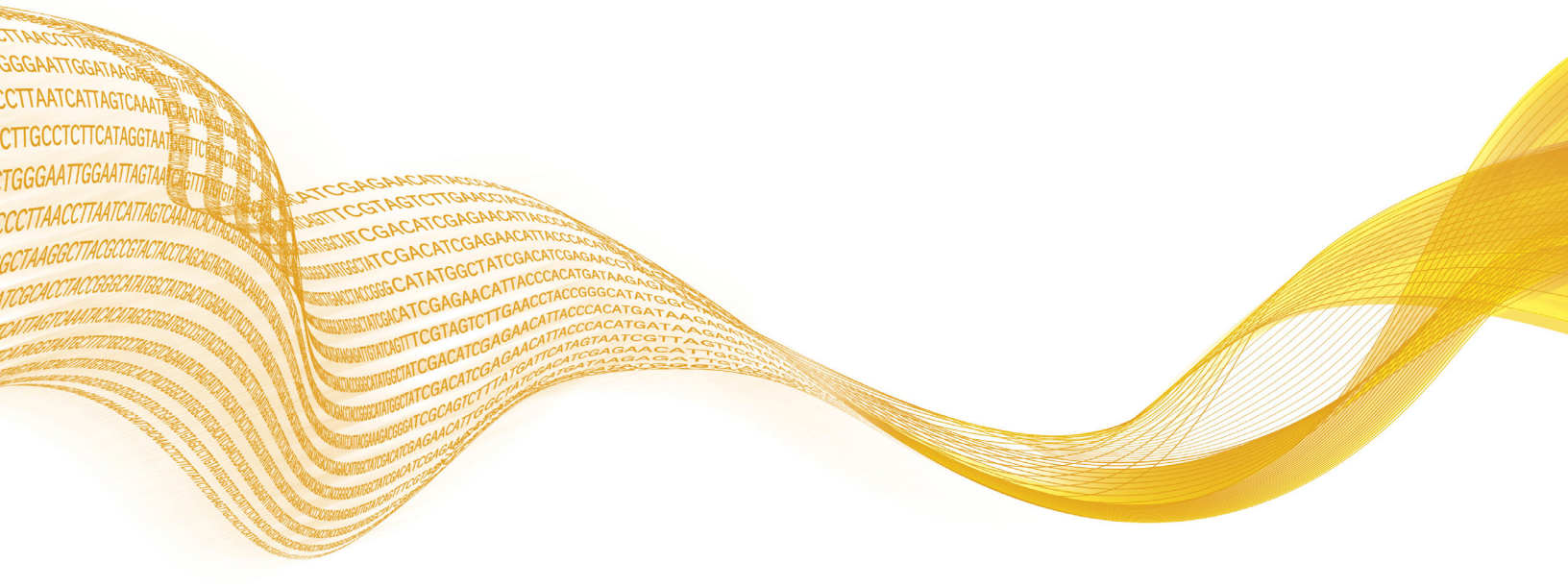
OEM (Original equipment manufacturer)- A company whose goods are used as components in the products of another company, which then sells the finished item to users.

QMS (Quality Management System)- Management system to direct and control an organization with regard to quality.

RoHS (Restriction of Hazardous materials)- The RoHS directive aims to restrict certain dangerous substances commonly used in electronic and electronic equipment. Any RoHS compliant component is tested for the presence of Lead (Pb), Cadmium (Cd), Mercury (Hg), Hexavalent chromium (Hex-Cr), Polybrominated biphenyls (PBB), and Polybrominated diphenyl ethers (PBDE).

RPN (Risk priority number)- The Risk Priority Number, or RPN, is a numeric assessment of risk assigned to a process, or steps in a process, as part of Failure Modes and Effects Analysis (FMEA).

SCAR (Supplier Corrective Action Report)- Request to a supplier for corrective action.



A global genomics leader, Illumina delivers complete next-generation sequencing workflow solutions to the basic and translational research communities. Illumina technology is responsible for generating more than 90% of the world's sequencing data.* Through collaborative innovation, Illumina is fueling groundbreaking advancements in the fields of oncology, reproductive health, genetic disease, microbiology, agriculture, and forensic science.

*Data calculations on file. Illumina, Inc., 2017.

For any questions, please contact your Illumina Buyer.
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