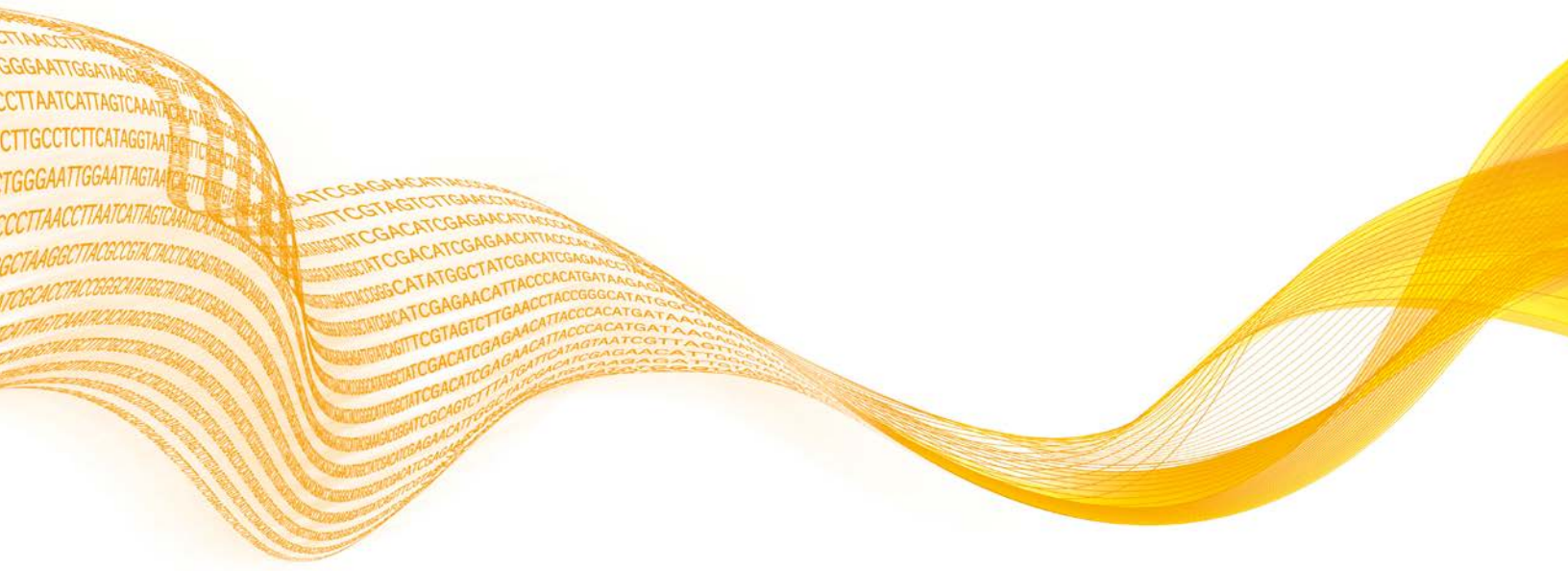
illumina®

Quality Expectations for Suppliers



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Our Mission

At Illumina, we are unlocking the power of genome to improve human health. We do this by delivering against our brand promise and living our values. Suppliers are our partners in this initiative and their commitment is vital to achieving our goals.

About Illumina

A global genomics leader, Illumina provides 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., 2015.

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 Guide

The purpose of the Quality Expectations Guide for Suppliers is to communicate clearly the Illumina quality vision and expectations as they apply to potential and existing suppliers.

This guide applies to all potential and existing Illumina suppliers of materials and services, including both Original Equipment Manufacturer and contract manufacturers.

This guide 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 into between you and Illumina.

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

1. Agreements (Quality, Supply, Purchase Order etc.)
2. Specification Requirements
3. Product Specific Quality Agreement (PSQA) or similar document, if any
4. Quality Expectations Guide for Suppliers

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
- *Relentless…* by using data to drive improvements proactively
- *Moving fast and embracing change…* by sharing real-time data with suppliers
- *Deep collaboration…* by engaging early on in the product development cycle
- *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 guide, you will help achieve this vision and live the values.

Letter from Quality Leadership

Illumina continues to fuel groundbreaking advancements to affect human health. Successful partnerships with our suppliers will promote and strengthen our mission of improving human health by unlocking the power of the genome. The intent of this guide 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.

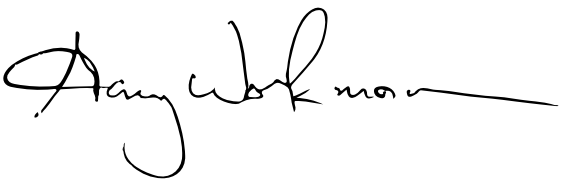
Our *Quality Expectations Guide for Suppliers* comprises best practices used by Illumina and some of the most successful medical device companies globally. The standards in this guide have been established in accordance with the purchasing controls regulations directed by FDA and other regulatory agencies such as International Organization for Standardization and European Union.

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 guide.

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.

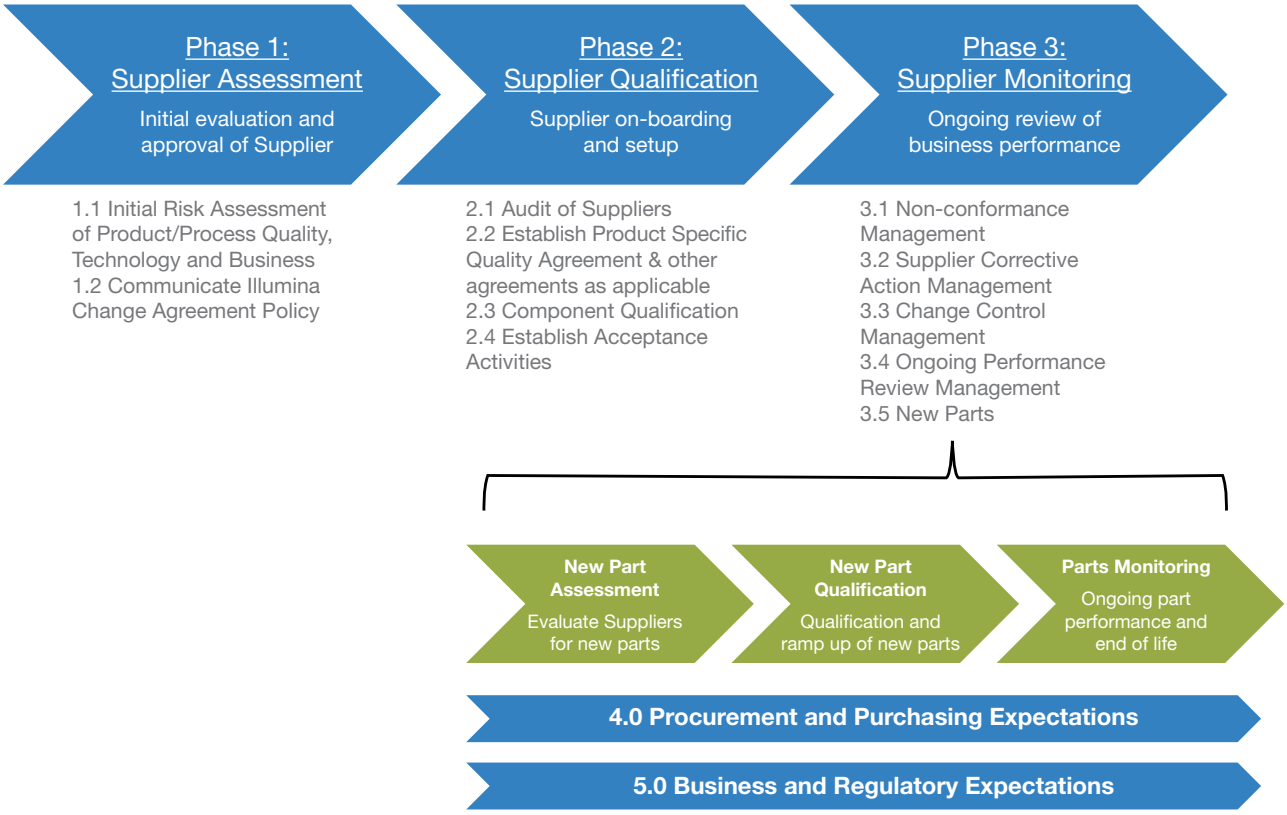
Department	Role	Description
Supply Chain	Supplier Development	This group works early in the supplier relationship to assess and improve matters related to supply chain and business risk. They implement solutions that include risk mitigation and alternative sourcing strategies. Working with the Illumina 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 quality systems and process control.

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 requirements. Specific tools and processes are associated with each phase.

Figure 1. ***Supplier Quality Management Life Cycle Diagram***



Phase 1: Supplier Assessment

Phase 1.1 Initial Risk Assessment

Illumina teams engage with suppliers early in the design and development cycle. During the initial assessment, we identify risks to mitigate or eliminate before qualification and production. The risk assessment is conducted in 2 stages:

1. Product/Service & Quality Systems Risk
2. Technology and Business Risk

The risk assessment investigation will cover the following areas:

- Systems/processes
- Documented procedures supporting the systems/processes
- Regular internal checks to ensure the effectiveness of the system
- Personnel training on the system and associated procedures

Phase 1.1.1 Product/Service & Quality Systems Risk

The product/service risk assessment considers the following elements:

- Custom or off-the-shelf product
- Part complexity
- Part criticality
- Risk management planning
- Long-term serviceability and support

The quality-system risk assessment considers the following elements:

- Does supplier currently manufacture parts or provide service for the regulated medical device industry?
- Does supplier currently have a quality system in place? If so, what type?
- How does supplier control and monitor these elements:
  - Management responsibility and quality objective
  - Design controls
  - Document controls
  - Supplier and material controls
  - Production and process controls
  - Calibration and equipment controls
  - Facilities
  - CAPA
  - Change controls
  - Complaint handling

Phase 1.1.2 Technology and Business Risk

The technology and business risk assessment considers the following elements:

- Financial viability and stability
- Capacity via detailed studies against demand projections (near and long term)
- Sustainability concerns, including regulatory initiatives such as ROHS, REACH, and 3TG
- Dependence on third-party licensing, facility leases, and labor agreements (FTO)
- Planning and replenishment processes
- Systems to notify customer of changes in accordance with change agreement policy
- Disaster recovery programs
- Ability to support Illumina regulatory filing requirements

Phase 1.2 Illumina Change Notification Policy and Agreement

Illumina defines change as “any changes to the design, manufacturing, material or method of the product or service that may affect the performance, intended use, safety, material, labeling, 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 (including moves)
- End-of-life/availability status
- Facilities (address changes)
- Packaging, labeling, storage-condition change
- Changes to supplier base including subcontractors, sub-assembly suppliers, direct material suppliers. etc.

Any other change that may affect the design, manufacturing, or material of the product as agreed upon in any specifications, PO terms and conditions or other agreements that may be in place.

Suppliers are required to notify Illumina and request approval of any change that meets our change definition, at least 6 months ahead of the proposed change.

All Illumina suppliers are expected to sign and comply with a quality agreement that incorporates the Illumina change requirements, or for some suppliers, a standalone change notification agreement.

Phase 2: Supplier Qualification

During the qualification phase, Illumina works with approved suppliers to qualify the part or service they have been selected to provide. Illumina suppliers are expected to meet all part/service qualification requirements, which may consist of one or more of the following:

- Audit or onsite visit to evaluate the supplier quality system and process controls
- Product-specific quality agreement and other agreements as applicable
- Component qualification
- Acceptance activities

Phase 2.1 Supplier Audits

Suppliers are expected to accommodate onsite audits conducted by Illumina as part of the qualification process.

After the supply relationship is established, Illumina might conduct periodic audits of the supplier. We expect our suppliers to cooperate with audits/inspections done by external regulatory or other governing bodies. Audits/inspections by external bodies might be unannounced. In other cases, Illumina will notify suppliers of an onsite audit within a mutually agreed-upon timeframe.

As part of its onsite supplier qualification audits, Illumina reviews the following:

- Compliance with the the supplier quality management system and other regulatory requirements
- Production and process controls for conformance to the Illumina product/service specification and elements of the product-specific quality agreement
- History of compliance with quality requirements

To facilitate the audit, suppliers are expected to provide subject matter experts, requested data, records and procedures, and other objective evidence of compliance.

Phase 2.2 Product-Specific and Other Quality Agreements

Illumina may implement a product-specific quality agreement with suppliers. A Product-Specific Quality Agreement (PSQA) is a detailed statement of quality objectives and requirements that both the supplier and Illumina agree to meet to ensure continuous quality improvement. A PSQA outlines quality system and process control requirements specific to a supplier.

As part of a PSQA, suppliers are expected to:

- Engage in risk management plan activities, such as generating a Process Failure Mode Effects Analysis (FMEA) or pFMEA to identify high-risk characteristics
- Create a process-capability index to understand the part or process variability

Unless otherwise specified, all Illumina suppliers are expected to meet the following criteria for critical parts and processes.

Description	Process Capability Index (Cpk) Value
Operational Range	Cpk ≥ 1.33
Probational Range	1.00 ≤ Cpk ≤ 1.32
Unacceptable Range	Cpk ≤ 0.99

- Gauge repeatability and reproducibility to make sure that the specification tolerance is within the acceptable range of < 10%
- Other part/process qualification, quality assurance, and acceptance activities defined in the PSQA

After qualification occurs, Illumina may implement one or more of the following agreements with suppliers:

- Supply agreement
- Quality agreement

Phase 2.3 Component Qualification

Component qualification requirements are established in the PSQA. Illumina suppliers must submit the component qualification package agreed to in any applicable PSQA.

The following elements are typically part of the component qualification package:

- Risk Management Plan (FMEA and/or DFMEA)
- Measurement System Analysis (Gage RandR, Equipment Installation Qualification, Operational Qualification Protocols, and Reports)
- List of tools, equipment, and gauges
- Process capability studies (performance qualification and Process Capability Index studies)
- Control Plans (including process flowcharts and work instructions)
- Material certifications
- Packaging and labeling specifications
- First-article inspection samples and reports
- Other elements

Phase 2.4 Acceptance Activities

During the acceptance phase, suppliers are expected to:

- Meet the first-article and other lot acceptance requirements stated in the specification
- Identify ongoing controls and metrics for critical dimensions identified on the specification
- Submit inspection data for critical dimensions as part of acceptance activities, if necessary
- Meet purchase order requirements

Other elements that suppliers are expected to control and monitor as part of acceptance activities include:

- Customer order management
- Manufacturing batch records traceability
- Packaging and labeling
- Product release activities
- Customer complaint resolution

Phase 3: 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 expects suppliers to focus on defect prevention rather than correction. Suppliers should implement statistically sound process controls and establish key process indicators to monitor all processes effectively.

Illumina uses the following systems to monitor supplier performance:

- Nonconformance management
- Supplier corrective action management
- Change control management
- Ongoing performance management including:
  - Quarterly business reviews
  - Supplier scorecard programs
  - Risk-based audits

Phase 3.1 Non-Conformance Management

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

- Supply Agreement
- Quality Agreement
- PO Terms and Conditions

Supplier-related nonconformance trends will be monitored on a monthly basis. Continuous-improvement actions will be taken on negative trends, such as issuing Corrective and Preventive Actions (CAPA) and/or conducting onsite audits.

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

Phase 3.2 Supplier Corrective Management

Illumina follows a risk-based approach to determine when to issue a Supplier Corrective Action Request (SCAR).

As a supplier, your timely and effective response to a SCAR is critical for product performance and our overall business relationship. Illumina suppliers are expected to acknowledge and respond to a SCAR in accordance with the following guidelines:

- Acknowledge the SCAR and segregate or separate all affected material within the defined timeframe
- Conduct root-cause investigation and provide short- and long-term corrective action plans, with responsible owners and estimated date of completion, by the date requested by Illumina
- Execute the corrective action plan after Illumina approves it
- Verify effectiveness of corrective actions
- Provide objective evidence of completion and effectiveness of corrective actions

Suppliers are expected to establish an internal CAPA program in accordance with the above guidelines and periodically audit the program for effectiveness and conformance. SCAR trends will be monitored on a monthly basis for number of CAPAs, past-due CAPAs, ineffective CAPAs, etc.

Phase 3.3 Change Control Management

Illumina change control requirements hold suppliers responsible for notifying Illumina in accordance with the change agreement policy listed in section 1.2

At Illumina, your buyer is the first point of contact for all change notifications. Buyer then routes the change notification for evaluation.

The Illumina Supplier Evaluation Team, consisting of Quality, Manufacturing, Design (if applicable), and Supply Chain, will review the change notification and determine next steps. The team might request supporting data and additional details about the proposed change.

After evaluation, Illumina will provide a signed approval or rejection of the change notice along with any appropriate explanation of the decision. Suppliers are expected to comply with the final decision regarding the proposed change notification.

Phase 3.4 Ongoing Performance Review Management

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

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

Feedback about trends and data is shared with suppliers through quarterly business reviews and supplier scorecard reviews. Any negative trends in performance metrics can 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.

Phase 3.4.1 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.

The Illumina Supply Chain group reviews 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 customer-facing team and management team participate in and support all business reviews.

Phase 3.4.1 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.

Phase 3.4.3 Risk-Based Audits

Risk-based audits typically result from a downward trend in supplier performance or a critical-part failure, but can be initiated for any reason that Illumina believes warrants a more detailed review of the supplier operations.

The supplier process controls, quality systems, and business processes may be audited for conformance to applicable agreements and requirements. Any major nonconformance identified will result in a request for a supplier CAPA. Illumina defines a major nonconformance as either (1) a total breakdown of a system, control, or procedure; or (2) an unacceptably high number of minor nonconformances related to the same area or topic.

Phase 3.5 New Parts

As part of ongoing business, current suppliers might be asked to provide, or might express interest in providing, additional parts or services to Illumina. Expanding business to our suppliers on our Approved Supplier List is managed within the Supplier Monitoring phase. It includes:

- New part assessment
- New part qualification
- Parts monitoring

Phase 3.5.1 New Parts Assessment

New parts will be evaluated according to the process described in *Phase 1.1 Initial Risk Assessment*. Existing suppliers may be assessed along with other potential suppliers for new parts.

Phase 3.5.2 New Parts Qualification

New parts will be qualified according to the process described in *Phase 2.3 Component Qualification*.

Phase 3.5.3 New Parts Monitoring

Parts or services added to a supplier portfolio with Illumina will be managed as part of the supplier monitoring processes outlined in *Phase 3: Supplier Monitoring*.

4.0 Procurement and Purchasing

Suppliers must agree to:

- Never provide goods or services without an authorized purchase order.
- Support Illumina requests for information that is necessary for compliance purposes, and grant access to conduct audits.
- Implement appropriate controls and processes for subtier suppliers and incoming materials.

5.0 Business and Regulatory

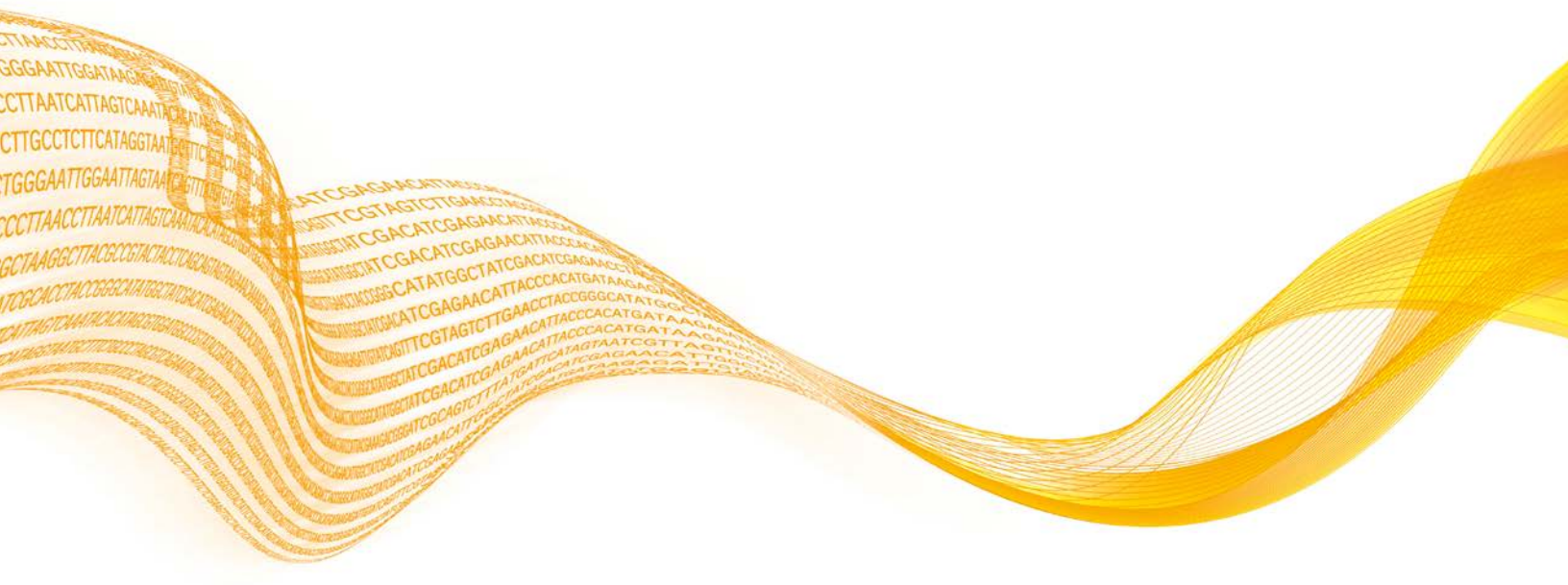
All suppliers are expected to comply fully with all local, regional, national, and industry laws, regulations, codes, ordinances, and guidelines that have the force and effect of law.

Illumina may request evidence routinely to demonstrate legal compliance. We also may request evidence or assurances showing that supply lines practice ethical sourcing. These include but are not limited to proof that our supply chain does not involve indentured or child labor, and that materials are free of content sourced from conflict areas.

Illumina respects the human rights of workers within its direct supply chain. Illumina efforts in this area include:

- Contract provisions with Illumina direct suppliers requiring their compliance with applicable labor laws and barring those suppliers from the use of child, slave, or forced labor
- Inquiries about the use of child, slave, or forced labor and compliance with labor laws during prearranged audits by Illumina
- Requests that new direct suppliers certify their compliance with applicable labor laws, including that they do not use child, slave, or forced labor
- Training for employees working with direct suppliers to bring attention to this law and the issue of human trafficking and slavery
- Training for employees working with direct suppliers about the contract

Access to our markets depends on your efforts, and ours, to comply with RoHS, REACH, WEEE, and other industry programs.



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*Data calculations on file. Illumina, Inc., 2015.

For any questions, please contact your Illumina Buyer.
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