BAUSCH & LOMB GLOBAL SUPPLIER QUALITY EXPECTATIONS

SYSTEM EXPECTATION

- Supplier must be ISO 9001:2000 or ISO 13485 registered and have a current certificate available for review. FDA registration and/or CE Mark may also be required, depending on the product supplied.

PERFORMANCE EXPECTATIONS

- Supplier is expected to monitor its product performance and demonstrate continuous improvement measured by First Pass Yield, number of customer complaints, and defects shipped. **THE EXPECTATION IS ZERO CUSTOMER ISSUES AND ZERO DEFECTS SHIPPED.**
- Supplier has financial responsibility for non-conforming materials and their effects, which may include cost recoveries for sorting, re-work, scrap, premium transportation, etc…
- Supplier must have capability to respond to all B&L issued complaints. Initial response must be received within 24 hours and final response within 14 calendar days. Substantiated problems may warrant the supplier being placed in formal product containment, which may include third party inspection, until the problem is contained and irreversible corrective action has been implemented and verified as effective.
- Supplier is responsible for managing performance of their suppliers, including sources directed by B&L.
- Supplier (including sub-suppliers) shall not make **any** changes in specifications, part design, material, manufacturing process, manufacturing location, or registration status without prior written Bausch & Lomb approval.
- The supplier shall ensure 100% on time delivery per Bausch & Lomb's schedule requirements.
- The supplier is responsible for maintaining the tools whether owned by B&L or supplier.

PART EXPECTATIONS

- Must obtain written production part approval from Bausch & Lomb receiving location prior to initial production shipment. This applies to the entire supply chain and may include, but is not limited to:
  - Design Failure Mode and Effects Analysis (DFMEA) for Design Responsible Suppliers
  - Process Failure Mode and Effects Analysis (PFMEA)
  - Dimensional layout results
  - Documented Process Capability
  - Lab Results (Physical and Appearance)
  - Measurement System Analysis (Gage R&Rs)
  - Process Flow Diagram
  - Process Control Plans (Early Production and Production)
  - Significant Production Run / Master Sample Retention
- Production part approval applies to all direct material, components, and devices, including raw material.
- All Critical Features (e.g., customer interfaces, safety critical features) must be properly identified, understood, and controlled by the manufacturing process.
- Apply (Statistical Process Control (SPC) with minimum short-term capability (Cpk) of 1.67 and long term process performance (Ppk) of 1.33, or error-proof / 100% inspect all Critical Features.
- All documents must be submitted in English unless otherwise instructed.
- Must follow requirements of and participate in the advanced quality planning process on all new parts, including feasibility reviews, timing plans, etc. Supplier must participate in production kickoff meetings and plant/process audits.
- Must ensure that subcontracted suppliers participate in the advanced quality planning process on all new parts.
- Must have all performance and material testing performed by a lab approved by an appropriate accrediting body.
- Must have an Early Production Control Plan to ensure flawless product launch.
- Perform/participate in Run at Rate studies as directed by Bausch & Lomb.
- Tool invoices will not be honored until written part approval is given and all applicable Run at Rate studies are complete

PACKAGING, LABELING, AND SHIPPING EXPECTATIONS

- Product must arrive at the B&L designated receiving location undamaged.
- All material must be properly identified with appropriate label information.
- Supplier's labeling system must ensure no mis-identification will occur and allow for complete lot traceability.
- Bar-code labeling is a requirement unless specifically instructed otherwise by B&L purchasing.
- Supplier is responsible for import/export regulations as applicable. For shipments into a B&L U.S. location from a foreign location, only use C-TPAT (Customs-Trade Partnership Against Terrorism) certified transportation providers.

By supplying product to B&L, your company agrees to the expectations outlined above, which shall be deemed to be supply requirements in addition to those outlined in B&L's standard purchase order terms and conditions and/or executed supply agreement, as applicable.