CooperSurgical Supplier Quality Handbook

CooperSurgical®

Healthy women, babies, and families™

Contents

Introduction

CooperSurgical, Inc. customers are increasingly demanding higher quality products, shorter lead-times, and the ability to provide a provision of goods and services across a broader global network. As a result, CooperSurgical, Inc. must continually enhance both the products we manufacture, source and the services we provide.

In this new paradigm, our suppliers must play a key role in helping us achieve our objective of establishing CooperSurgical, Inc. as the highest valued partner in the healthcare of women, babies, and families.

This will be done through a collaborative effort to implement robust quality management systems, ensuring regulatory compliance, leveraging continuous improvement and seamless integration into CooperSurgical business processes.

Therefore, the objective of this SUPPLIER QUALITY HANDBOOK is to serve as a guide for our current and future partners in the collaborative efforts of bringing the highest level of Regulatory Compliance, delight and satisfaction to our customers and key constituents.

Overview of CooperSurgical, Inc.

Quality Policy

We will strive to exceed our customer's expectations by consistently delivering the highest quality products, services, and experience to accelerate every possibility for women, babies, families, and their healthcare providers. We are committed to continually improve the effectiveness of our organization's processes and quality management system to conform to all applicable standards and regulatory requirements. We will continually monitor and work with our suppliers, subcontractors, and distributors to ensure that we deliver products of the highest quality, safety, and reliability

CooperSurgical, Inc.'s portfolio is of high-quality surgical and laparoscopic instruments which was founded on the specialized needs of women's surgery, yet many of our surgical products are found throughout the hospital. Our products include devices for hysterectomy, pelvic surgery, and C-section procedures, as well as surgical retractors and instruments for wound closure and port site management.

We aim to help clinicians strengthen the important relationship between a woman and her OB/Gyn. Our broad portfolio includes products for traditional reproductive medicine, from contraception to fertility and prenatal care, as well as for screening and treatment for urinary incontinence, abnormal uterine bleeding (AUB) and cancer screening. We are proud to be on the forefront of new developments, such as handheld hysteroscopy, that are changing the way OB/Gyns screen, diagnose and treat certain conditions.

Physicians have long depended on our instruments throughout the labor and delivery process. Our portfolio for obstetrical and neonatal care includes devices for vacuum-assisted delivery, fetal monitoring, amniocentesis, PROM testing, infant critical care and C-section.

CooperSurgical Fertility Solutions is the global leader in IVF and reproductive genetics, providing innovative products and services for every step in the ART journey. Our company vision is a world with healthy women, babies, and families. We have a large worldwide presence with direct distribution in 24 countries and a wide network of distributors.

CooperSurgical is a market leader in the development, production, and marketing of medical devices used to advance women's healthcare and minimally invasive surgery. It is an exciting, ever evolving, and significant market that touches all of our lives.

Since forming in 1990, CooperSurgical has grown to over $680 million in annual revenue through organic growth and a series of more than 40 acquisitions with a total of more than 12,000 employees.

We are a company on the move, and our employees are dedicated to keeping the momentum of continuous improvement going. Our team cares enough to want to make a difference – for the communities in which we live and work and in the well-being of women.

CooperSurgical headquarters and primary manufacturing state-of-the-art facilities are located in Trumbull, Connecticut. The company has additional manufacturing locations in the U.S., Costa Rica and Europe, as well as an extensive national and international direct sales team.

Our CooperSurgical Brands

ORIGIO

The company was founded in Denmark in 1987. Its innovative approach quickly positioned it as one of the leaders in the global IVF Media market.

Research Instruments

The company was founded in London in 1962. A global leader in micromanipulation technology, the company moved into the fertility industry in the early 1990s. Working closely with pioneers in the field such as Dr. Simon Fishel, RI refined its products to meet the needs of those perfecting groundbreaking techniques.

K-Systems

K-Systems Kivex Biotec A/S was founded in 1986. Over 30 years they have emerged as a market leader from their premises in Denmark and established a distribution network in more than 60 countries worldwide with the development, manufacturing and sale of innovative and well-designed equipment to professional IVF Clinics. Their innovative range of equipment enables laboratory technicians to perform IVF techniques in safe and ergonomic conditions.

TPC

The Pipette Company (TPC) was established in 1999 by a team of respected practitioners of reproductive medicine. Knowing first-hand the importance of high-quality microtools, the team was dedicated to making the finest quality micropipettes to ensure optimal clinical outcomes.

TPC's market leading reputation is based on an ultraclean environment, precision manufacturing, strict rejection criteria, and comprehensive QC and QA ensure that TPC pipettes have unparalleled levels of cleanliness, consistency, uniformity, and functionality. The Pipette Company offers a standard range of micromanipulation pipettes which have been designed to provide optimal clinical outcomes and minimize oocyte/embryo degeneration rates.

Wallace

Over 35 years ago, Wallace worked with IVF pioneers to design and manufacture the world's first commercially available embryo transfer catheter. This catheter was used in the first successful IVF treatment, resulting in the birth of Louise Brown in 1978, and remains the most popular catheter worldwide. Viewed as the gold standard, the Wallace range is associated with some of the highest pregnancy rates in the United Kingdom.

Building upon the proven design of the Wallace Classic Embryo Transfer Catheter, Wallace created the unique SureView® Ultrasound Visible Catheter and the SurePro® Range Supported Embryo Transfer Catheters that combine the softness of the Classic catheter with the benefits of a supported inner catheter and a pre-formed outer sheath. The SurePro Ultra® range offers an echogenic variant utilizing our patented SureView technology within the inner catheter.

CooperGenomics

Legacy companies Reprogenetics, Recombine, and Genesis Genetics were the pioneers and global leaders of comprehensive reproductive genetic testing. Brought together under the CooperSurgical family, these companies

are now united as CooperGenomics, the premier provider of genetic testing for every step of the family planning journey.

Through expanded carrier screening, PGD, PGS, NIPT, and beyond, our team is committed to advancing the field of reproductive genetics, improving outcomes, and empowering families worldwide.

LifeGlobal

The LifeGlobal Group, headquartered in Guilford, Connecticut, is a privately held company that specializes primarily in IVF media. As the pioneer and leader in “one-step” media for embryo culture, LifeGlobal maintains very strong customer relationships along with product loyalty. The use of one-step media has grown significantly over the years as it reduces handling of embryos and lab requirements to hold multiple formulations of media inventory.

LifeGlobal’s other product categories include other media products as well as IVF laboratory air filtration products and dishware.

CooperSurgical, Inc.,
Roles and Responsibilities

CooperSurgical Supplier Sourcing, Supply Chain, & Supplier Quality Engineer's (SQE's)/Supplier Quality Assurance (SQA's)

CooperSurgical recognizes our business segments are different in nature and in some cases have unique roles and responsibilities to support the functional areas of business, quality, and engineering; however, our supplier network and partners are of paramount and strategic importance to our Mission, Vision and Company objectives. Below are some vital elements which establish common points of contact with our suppliers, sub-suppliers, and supply chain network:

Global Strategic Sourcing:
The representative is responsible for ensuring streamlined and effective communications, facilitating access across the multiple value streams, and supporting the global strategy by driving cross value stream activities, while eliminating non-value added activities and reducing risks to the supply chain process.

Supply Chain Representative:
This is the Supplier's primary contact for value streams and purchasing activities. The representative is responsible for the relationship with the Supplier, including, administering, and sharing the Supplier Quality Scorecard, and actions such as technology roadmap sharing, sustaining engineering efforts, contractual relationship, quality, cost, delivery, non conformance root-cause analysis and resolution, and overall understanding and minimizing any Supplier related risk to CooperSurgical including regulatory agency and notified body visits/audits or inquiries.

Supplier Quality Engineer / Assurance Representative:
Responsible for leadership in executing and addressing non conformance's, complaints, quality issues / concerns / returns / audits, Supplier Corrective Action Request's (SCAR's), Supplier Change Notices (SCN's), supplier development and improvement activities, and potential co-development of New Product Initiatives (NPI).

SUPPLIER ORGANIZATION

CooperSurgical expects our Suppliers to identify a designated contact within their organization to communicate and support decision making with CooperSurgical for each function below:

Customer Representative
The customer representative is the primary contact within the Supplier's organization for any key communications with CooperSurgical, including any regulatory, quality, delivery, or commercial issue resolution.

Quality Management Representative
The Quality Management Representative within the Supplier's organization is responsible for the implementation and maintenance of the Supplier's Quality Management System such as defined by ISO 9001 and/or the ISO 13485 series of standards. The Representative is also responsible for coordinating supplier and sub-supplier audits and resolution management regarding complaints, non conformances (SCAR/CAPA) and responding to complaints in a timely and acceptable fashion.

CooperSurgical, Inc.,
Quality Expectations & Requirements

This handbook outlines the quality elements and fundamentals of the CooperSurgical Supplier Management Program. Our focus shall be driving process discipline and product excellence to deliver quality requirements involving six sigma level quality principles.

We hope that it serves as a valuable tool for you, our supply chain partner, as we work together to establish and maintain the requirements including thriving to achieve process efficiency, service quality and product excellence.

CooperSurgical's expectation and requirements for the different categories of suppliers, based on their ability to meet those requirements and related to the assessed risk classifications, the supplier evaluation and approval process, the ongoing relationship development, and supplier disqualification process.

GENERAL EXPECTATIONS AND REQUIREMENTS

Suppliers are responsible for ensuring that Products or Services meet established CooperSurgical Specifications and Quality requirements. Evaluation by CooperSurgical of supplier's facilities which include audits of supplier's quality system, process controls, acceptance activities, etc., does not absolve the Supplier of the responsibility to provide acceptable Products or Services, nor will it preclude the subsequent rejection of unacceptable Product.

Cooper Companies Suppliers will not discriminate in hiring or employment practices on grounds of race, religion, nationality, social or ethnic origin, sexual orientation, gender, gender identity or expression, marital status, pregnancy, political affiliation, disability, military service (past, present or future), or any other characteristic or class protected by law. This nondiscrimination requirement applies to all partners Cooper Companies does business with, including but not limited to contractors, vendors and suppliers.

Quality Assurance Agreements

In addition to the expectations and requirements contained in this Manual, CooperSurgical shall determine based on internal risk assessment if a Quality Assurance Agreement is needed with our Suppliers.

Quality Assurance Agreements outline the Supplier specific quality requirements and may be in the form of a stand-alone Quality Assurance Agreement or as part of the Purchase Order and/or Material Specification, technical drawings, or authenticated document markups (NPI). Once the need is determined, it is expected that the Supplier shall work with CooperSurgical to execute this agreement.

Non-Disclosure Agreements

Suppliers may be asked to sign a non-disclosure agreement, depending on the level of technology or information disclosed during the course of business. It is our policy to utilize a CooperSurgical standard form that has been created for this purpose.

Information provided to Suppliers involving various intellectual property, trade secrets, designs, materials, and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements, or discoveries, patentable and otherwise.

It is CooperSurgical's policy that Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or advertise the existence of this agreement.

Supplier shall not divulge its terms and conditions or any aspect of the relationship with CooperSurgical without prior written agreement of the other party. Suppliers shall agree not to display or use the CooperSurgical logo, trade secrets, trademark, or Product(s) in any manner without prior written permission from their CooperSurgical Global Strategic Sourcing or Supply Chain Representative.

CooperSurgical values our relationships with our Suppliers and therefore shall protect it through the use of this formal agreement.

Environmental Compliance

Products & Services supplied to CooperSurgical are expected to meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of the following or chemical composition of Products.

Any suspicions that Products supplied to CooperSurgical are not compliant, are expected to be communicated to the appropriate buyer or supply chain representative immediately.

- California Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986
- China RoHS 2, Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products - Order 32
- EU Battery Directive 2006/66/EC and amendments
- EU IVDR - Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- EU MDR - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- EU Packaging Directive 94/62/EC and amendments
- EU Persistent Organic Pollutants (POPs) (EC) 850/2004
- EU REACH Regulation (EC 1907/2006)
- EU RoHS 2 Directive 2011/65/EU
- EU RoHS 3 amendment (EU) 2015/863
- EU WEEE Directive 2012/19/EU
- FDA 21 CFR 801.437 - Natural Rubber Latex
- Democratic Republic of Congo Hazardous Metals (Cobalt)

Declaration of Raw Materials Used

Suppliers of Components and Finished Medical Devices are expected to have information about the composition (e.g., Trade or Chemical name, Color, Grade, etc.) on hand and make this available to CooperSurgical upon request. This detailed information, declaring the raw materials used to manufacture a Product is required to fulfill Regulatory Body requirements for approval for use. If colorants are used, additional details (e.g., Color Description, Trade Name, etc.) for each ingredient or pigment used in the colorant formulation are expected to be known

by the Supplier and made available as needed. Some materials may not be sourced from certain restricted countries (see EPA code of environmental hazards).

Import Compliance

As business becomes increasingly globalized, additional documentation and processes are required. Suppliers who ship Product from outside the United States to a CooperSurgical facility within the United States need to be aware of the following:

- CooperSurgical requires that, unless exempted by law, every article of foreign origin, or its container imported into the U.S. be marked in a conspicuous place as legibly and permanently as possible to indicate the English name of the country of origin to an ultimate purchaser in the U.S.
- A commercial invoice signed by the seller, shipper or associated agent is required for customs entry and is expected to be prepared in accordance with 19 CFR 141.86 of the customs regulations. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased review by import specialists or penalties against the importer.
- Wood packaging material is closely regulated as it pertains to importation of goods into the U.S. The standard calls for wood packaging material to be either heat treated or fumigated with methyl bromide, in accordance with the guidelines, and marked with an approved international mark certifying treatment.

Business Continuity

CooperSurgical expects our Suppliers to complete a formal business Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While contingency plans cannot be expected to cover all potential scenarios, we expect our Suppliers to maintain robust plans to facilitate rapid response and recovery in the event of disruptions. These plans shall be shared with CSI.

CooperSurgical expects its Suppliers to have a thorough crisis management approach to deal with probable disruptions. The approach is expected to include a plan of action to mitigate supply chain interruptions, communication plans, escalation procedures, and roles and responsibilities.

This plan is expected to address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for

equipment, material, supplied components and labor, etc. and be specific to CooperSurgical Products and/or Services provided.

Code of Conduct

CooperSurgical relationships with Suppliers are centered on lawful, ethical, efficient, and fair practices. CooperSurgical requires our Suppliers and contractors to:

- Hold by applicable laws, rules, and regulations of the countries in which they operate
- Uphold the human rights of workers and treat them with dignity and respect
- Ensure a safe and healthy working environment
- Practice social and environmental responsibility
- Demonstrate the highest standards of business ethics
- CooperSurgical reserves the right to discontinue business relationships with Suppliers that fail to conduct business in a legal, responsible, and ethical manner

Supplier Diversity

A diverse base of high-quality Suppliers strengthens our ability to carry out our mission to alleviate pain, restore health, and extend lives. A diverse supply chain, focused on the highest standards of quality, helps us connect with our patients, physicians, and communities as we work to improve lives.

Our United States Supplier Diversity program encompasses the following classifications:

- Small Business (SB)
- Small Disadvantaged Business (SDB)
- Minority Business Enterprise (MBE)
- Women Business Enterprise (WBE)

- Woman-Owned Small Business (WOSB)
- Historically Underutilized Business Zone Small Business (HUBZone)
- Veteran-Owned Small Business (VOSB)
- Service-Disabled Veteran-Owned Small Business (SDVOSB)

Environmental / Social Responsibilities

At CooperSurgical, we expect that our Suppliers:

- Are aware of how their businesses and products impact the environment
- Abide by current global classifications of hazardous substances
- Commit to continuous environmental, safety and health improvements
- Understand and comply with federal, state, and local regulatory requirements
- Alert us of any significant environmental compliance violations
- Supply composition information on parts/components as requested
- Be ISO 14001 certified or have a plan to become certified

Conflict Minerals

CooperSurgical expects Supplier to comply with the U.S. Securities and Exchange Commission (SEC) rules for reporting and disclosure requirements related to Conflict Minerals as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”). CooperSurgical supports the goals and objectives of Section 1502 of the Dodd-Frank Act that requires public companies to determine the sourcing of tin, tungsten, tantalum, and gold used in their Products and to file an annual report disclosing any such use. As part of our commitment to responsible sourcing and human welfare, CooperSurgical and our Supplier are expected to adopt a Conflict Minerals Policy.

C-TPAT

CooperSurgical expects Suppliers to obtain certification with Customs-Trade Partnership Against Terrorism (C-TPAT):

(i) obtain certification under the U.S. C-TPAT program and provide evidence of such certification to CooperSurgical; or (ii) demonstrate to CooperSurgical that it meets the criteria for such certification and has policies and procedures in place that meet C-TPAT requirements.

The U.S. Customs-Trade Partnership Against Terrorism seeks to safeguard the world's vibrant trade industry from terrorists, maintaining the economic health of the U.S. and its neighbors. The partnership develops and adopts measures that add security but do not have a chilling effect on trade. Further information can be found at www.cbp.gov.

Continuous Improvement

CooperSurgical strives for reliability and quality in all of our Products and Services. CooperSurgical recognizes that this cannot be done without the support of a strong supply base committed to meeting the requirements laid out in this manual.

CooperSurgical strives to achieve a world-class supply chain utilizing Lean Sigma methodologies that address the waste and the minimization of variability in processes and supply chain systems. Lean Sigma combines the power of Six Sigma with Lean Manufacturing methodologies, which have become the cornerstone for continuous improvement in our Quality Culture at CSI.

CooperSurgical is dedicated to aligning its continuous improvement strategies with its supply base, namely through the following programs: Supplier Development, Supplier Owned Quality, and Supplier Lean Sigma Training.

Supplier Development

The Supplier Development program engages Suppliers to continuously improve process capability, reduce waste and variability, and other activities and projects. It utilizes tools such as Lean Six Sigma, Kaizen, Rapid Improvement Events, Value Stream Mapping, and training to perform gap analyses, reduce lead times and reduce defects. CooperSurgical trained Supplier Quality Engineers will partner with strategic Suppliers to drive process improvements throughout the value stream that they share.

Both CooperSurgical and our Suppliers can benefit from Supplier Development in the following ways:

- Improved quality and yield by minimizing process variability
- Supplier Owned Quality for Quality at the Source
- Improved production throughput adopted to exact customer demand
- Improved customer responsiveness (on-time delivery; lead time reduction)
- Cost reductions through the elimination of waste (inventory, overtime, labor, and burden/overhead)
- Growth with less capital investment by doing more with less

To achieve these mutual benefits, CooperSurgical partners with Suppliers on specific projects to implement process improvements that have positive outcomes for current and future products and services for our customers and users while minimizing the environmental impact.

Supplier Owned Quality

Supplier Owned Quality (SOQ) is a program developed by CooperSurgical to support the Supplier owning the Product quality of products and services they deliver or provide. Its aim is to avoid duplication or repeat inspection efforts within CooperSurgical. While CooperSurgical continues to own the overall quality of our Product, our Suppliers are expected to own product quality in all the product (including their processes) that they provide. SOQ links the Supplier's Product inspection data results to CooperSurgical, streamlining the acceptance process.

Select Suppliers benefit from engaging in CooperSurgical Supplier Owned Quality (SOQ) initiative by challenging themselves to meet increasing levels of supply maturity to ensure stable and predictable Products. The SOQ program has various maturity levels. Both the Supplier and CooperSurgical can monitor and act on performance trends to support improved Product outcomes.

Suppliers benefit from SOQ by receiving early feedback regarding CooperSurgical Product acceptance thus mitigating the risk of Product returns and the need to hold excessive inventory to support long acceptance lead times. Achieving the highest maturity levels with Statistical Process Control (SPC) reduces manufacturing variability and lowers scrap costs.

Inspection
Supplier Owned Quality Level 1

Supplier can manufacture to requirements with acceptable quality, measurement, and data collection systems. CooperSurgical inspections will remain in effect.

Evaluation
Supplier Owned Quality Level 2

CooperSurgical is accepting per supplier data and sufficient data has demonstrated ability to meet the manufacturing specification limits.

Control
Supplier Owned Quality Level 3

Supplier has systems for defining control limits and is working to achieve sufficient stability to utilize SPC.

Sustainable
Supplier Owned Quality Level 4

Supplier has systems for defining control limits and demonstrated an internal culture for stable and capable manufacturing responding to SPC signals.

Predictable
Supplier Owned Quality Level 5

Supplier demonstrates a continuous culture of manufacturing excellence by controlling inputs to ensure predictable outputs.

Sub-Tier Supplier Control

Suppliers are expected to manage sub-tier Suppliers with controls commensurate with risk. Suppliers are responsible to ensure that Product(s) manufactured utilize only authentic, conforming and specified material as indicated in the specification.

CooperSurgical expectation is that the Supplier has in place 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/SCAR processes
- Change control

Suppliers are responsible for ensuring and controlling the quality of all components and raw materials that are purchased to manufacture Product for CooperSurgical.

Where CooperSurgical requires a Supplier to engage with a specified sub-tier Supplier, relationship management will be established between CooperSurgical and the Supplier.

Please Note: Prior to implementing sub-tier Supplier changes, Suppliers are expected to seek CooperSurgical approval (see section Supplier Change Control for additional details).

Production Part Approval Process (PPAP)

CooperSurgical will require that suppliers support the PPAP process, when required for new or existing parts. Elements of PPAP include MSA, Process Capability, Control Plans, PFEMA’s, First Article Inspections, Flowcharts, etc.

Measurement System Analysis (MSA)

CooperSurgical expects Suppliers to develop and maintain capable, accurate and stable measurement methods and systems.

Measurement System Analysis (MSA) is recommended in determining whether measurement or test equipment has sufficient accuracy, precision, or resolution to adequately provide information about process performance, or the effects of inherent or applied variation of the process under development. One recommended tool is Gage Repeatability and Reproducibility (Gage R&R or GR&R).

Process Capability

CooperSurgical expects Suppliers to develop and maintain highly capable processes to produce quality Products and Services. Use of Statistical Process Control (SPC) for special part and process characteristics is recommended. SPC is expected for all annotated, special, significant, or critical drawing characteristics (unless otherwise specified). SPC data may be required with each shipment at the discretion of the receiving facility. Suppliers are expected to utilize indices such as Cp / Cpk / Pp / Ppk. Special characteristics will be defined in CooperSurgical Specifications, when applicable.

Control Plans

Each CooperSurgical value stream uses risk assessment to identify the need for Supplier Control Plans for purchased Products.

A Control Plan is a documented description of the systems for controlling part and process quality by addressing their key characteristics and engineering requirements. 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. Supplier Control Plans may be used in lieu of CooperSurgical Control Plans as long as the content reflects the requirements as defined by CooperSurgical to ensure ongoing process control.

Process Failure Mode and Effect Analysis

This is a document that states all the possible ways a process or product can demonstrate a manufacturing or product weakness and provides a solution to prevent the potential problem. The document is comprised of two major sections called Risk and Mitigation.

First Article Inspections

This is a design verification, design history file, and a formal method of providing a

reported measurement for each manufactured feature of a part or assembly. Typically, the supplier performs the FAI and the purchaser reviews or approves the report.

Flowcharts
A flowchart is a picture of the separate steps of a process in sequential order. It is a generic tool that can be adapted for a wide variety of purposes, and can be used to describe various processes, such as a manufacturing process, an administrative or service process, or a project plan.

Cost of Poor Quality

CooperSurgical shall notify Suppliers of nonconforming Product. CooperSurgical expects Suppliers to replace nonconforming materials free of charge. Suppliers are expected to cover expenses (including freight and customs clearance, if any) incurred by CooperSurgical in connection with (a) shipment of replacement Product to the same location and (b) shipment of the non conforming Product back to Supplier (if so, requested by Supplier). In the event of a rejection of nonconforming Product, Suppliers are expected to ship replacement Product as soon as practical. Suppliers are expected to provide root cause analysis, containment activities, and corrections for nonconformances.

Labeling

CooperSurgical will require the following minimum labeling requirements for all parts, raw materials, and finished goods received.

- Supplier Name
- Cooper Part Number
- Revision Number
- Batch/Lot Number
- Quantity
- Expiration Date (if applicable)
- Manufacture Date
- P.O. Number

Certificate of Analysis/Conformance

CooperSurgical shall require the minimum for all Certificate of Analysis of Conformance received.

- Certification Statement by the Supplier
- Quantity
- Material Number
- P.O. Number
- Manufacture date and/or shipment date
- Drawing number with correct revision
- Batch number/Lot number

QUALITY SYSTEM EXPECTATIONS AND REQUIREMENTS

Quality System:

Contract Manufacturers of finished devices

- Formal quality system that complies with 21 CFR Part 820, ISO 13485 and/or EUMDR (Required)

Critical-to-function component manufacturers/critical service suppliers

- A formal ISO based quality system (e.g., ISO 13485)
- Independent accreditation/certification for specialized services

Calibration and testing laboratories

- A formal ISO 17025 based quality system (Required)
- Independent 3rd party accreditation/certification

Non-critical suppliers

- Documented quality systems, minimally to ISO 9001

Service Suppliers

- Documented quality systems, minimally to ISO 9001

Delivered Quality:

- Defect free product and services that conforms to all requirements defined in product and performance specifications
- Cost reductions plan forecast
- Parts per millions performance

Delivery:

- 100% on time delivery (expectation)
- 25% incremental capacity upon demand (expectation)
- 100% accuracy on delivered quantity, identification, packaging, and documentation

Customer Service:

- Timely support (within 48 hours) in problem resolution for critical and end user issues
- Compliance/integration with CooperSurgical business processes

Financial:

- A profitable company with a history of capital investment demonstrating both strength and commitment to the future
- Credit standing indicative of good financial management and resources based upon Dunn & Bradstreet

Management:

- Company-wide focus on customer needs and expectations
- Strategic plan in place that is consistent with CooperSurgical business needs

Pricing:

- Competitive total acquisition cost. Capable of working with CooperSurgical to develop and sustain design or process changes leading to cost reductions

The following are key quality system interfaces between CooperSurgical and its suppliers. An overview is given in each of the elements and may be further defined by contract, supply agreement, statement of work, Quality Assurance Agreement, or operational quality management plans. CooperSurgical requires that its suppliers be aware of the requirements and ensure that there is a professional and satisfactory exchange between the two parties on all issues.

Management of Non conforming Material

Non conforming materials are handled and controlled by CooperSurgical in accordance with documented procedures in the following manner:

- Non conforming material is identified and segregated
- The non conformance is documented

- Details are communicated to the supplier and corrective action is requested (SCAR)
- CooperSurgical's Material Review Board has responsibility for the final disposition of the non conforming material
- All dispositions – Return to Supplier, Use As Is, Scrap, Rework/Repair will have supplier involvement

Supplier Corrective Action Request (SCAR)

- Suppliers are required by their contractual agreement and/or quality assurance agreement to respond to requests from CooperSurgical to take risk based corrective and preventive action in relation to product quality problems (such as returns), complaints or quality system deficiencies

- CooperSurgical will utilize SCAR forms to communicate the request for corrective action to suppliers for resolution on systemic/chronic problems, safety issues, supplier audit findings or CooperSurgical customer complaints that have a most probable cause of a supplier product or service

- Response to a SCAR request is required within the timeframe defined by CooperSurgical when the SCAR is first issued. **Suppliers will be measured for their ability to respond with immediate containment in 48 hours from notice.** A plan is required for timely implementation of countermeasures, root cause analysis, corrective and preventive actions

- The SCAR process is administered by CooperSurgical Supplier Quality Assurance/Supplier Quality Engineering and includes:
    - Tracking of all SCAR issues
    - Communication and follow-up with suppliers
    - Monitoring work done on problem identification and verification, root cause analysis, development, and implementation of corrective/preventive actions
    - Verification of effectiveness of actions taken
    - Close-out of SCAR request and related documentation

- Approved suppliers must have documented procedures that specify their process for handling corrective and preventive action as well as establishing countermeasures and containment to mitigate the impact on CooperSurgical. The procedure must include:
    - Communication and tracking of CAPA activities
    - Problem verification with containment/countermeasures
    - Root cause analysis
    - Development/Implementation of appropriate corrective and preventive actions
    - Records of actions and verification of effectiveness
    - Communication of close-out to CooperSurgical
    - Documented TRAINING PROGRAM to ensure compliance of procedures versus practices

Supplier Change Control/ECO or CRCO Process

Changes to supplier product requested by CooperSurgical shall be handled in the following manner:

- Proposed changes are processed through CooperSurgical's Supplier Quality Engineering group
- Supplier Quality shall perform an assessment of the change and Supply Chain will obtain inputs from relevant suppliers to assess the impact of the change on quality, regulatory compliance, schedule, financial impact and inventory
- If the change is approved for implementation, a copy of the Engineering Change Notification is sent to the supplier with the appropriate attachments, including PPAP forms and/or first article, if necessary
- CooperSurgical Supply Chain is responsible for planning and coordinating the supplier's implementation of the approved change

Changes to supplier location, processes, materials and changes that impact the form, fit, or function of the product shall be handled in the following manner:

- Suppliers must formally notify CooperSurgical of proposed changes at least 60 days prior to implementation

- Supplier Quality Assurance/Supplier Quality Engineering will obtain inputs from the supplier utilizing the Supplier Change Notice (SCN) form to assess the feasibility and impact of the change, with support from quality, regulatory, engineering, supply chain and, etc.
- Changes in design, materials or processes that effect form, fit or function of product or device require formal approval
- If the proposed change is permanent, the approval will be approved via an Engineering Change Notification and Supplier Change Notice
- If the change is temporary, a deviation/variance may be initiated
- If the change is approved for implementation, a copy of the completed SCN form is sent to the supplier with the appropriate attachments and properly filed in the Quality Management System
- CooperSurgical Sourcing and Supplier Quality Assurance/Supplier Quality Engineering is responsible for planning and coordinating the supplier's implementation of the approved change

Visits to CooperSurgical or Supplier Facility

Periodic face-to-face contact is a valuable means of general communication and reviewing the business relationship and quality systems evaluations.

- For CooperSurgical onsite visits, Supplier shall require escort unless otherwise arranged

ISO 13485 registration and EUMDR is a key requirement for CooperSurgical, Inc. and in some cases our notified body may exercise its right to audit our OEM, critical suppliers and sub-tier suppliers.

Supplier Selection & Approval

The process of approving a new CooperSurgical Supplier is defined in the quality system. The following is a summary of the key steps:

- When a defined business needs dictates, potential suppliers will be identified, assessed, and evaluated prior to qualification. Supplier Quality Assurance/Supplier Quality Engineering will determine the criteria to be used to

evaluate the potential supplier's quality system and their ability to meet specified CooperSurgical business needs

- Upon selection of a potential supplier, a Non-Disclosure Agreement (NDA) is signed
- A Request for Information (RFI) and a Supplier Survey is transmitted to the potential supplier(s)
- Business and financial analysis of suppliers capabilities are reviewed
- Surveys and quality system assessment may be carried out as part of the supplier selection process. The survey is normally scheduled in advance of a quality systems audit. It may also be used instead of a formal audit. They are also an important element of the on-going business relationship providing improvement opportunities
- Sourcing leads, sourcing process and detailed negotiations with the potential supplier to define the relationship
- The potential supplier(s) then transitions to the part qualification process as a "conditionally" approved supplier and will be added to the approved supplier list

Qualification and Approval

Finished Devices, Direct Materials and Manufacturing Materials

- Supplier Quality Assurance/Supplier Quality Engineering shall review the supplier against the requirements of the Supplier Management policy and determine what controls are appropriate
- Quality Assurance Agreement will be required for Critical, Finished Device, Distribution, and some service suppliers
- The conditionally approved supplier is requested to produce production-ready samples for evaluation per CooperSurgical Supplier Product Part Approval Process (PPAP). Where appropriate the supplier will develop operational quality plans for the process
- The supplier will achieve part or product qualification in accordance with the CooperSurgical new product approval process (e.g., IQ, OQ, PQ)
- Components will be classified to define the extent of quality planning requirements
- All samples submitted for purposes of part qualification must be produced from production ready processes

- First Article Inspection (FAI) will be carried out by the supplier and verified by CooperSurgical against established criteria documented in the incoming acceptance plan
- For critical to function parts, the supplier may be requested to perform a short-term capability analysis using data from the pre-production lot that generated the FAI samples
- For finished device(s) and critical to function parts and critical services a process audit may be carried out by CooperSurgical
- Third party certifications will be verified at this stage if required
- CooperSurgical will develop procedures and acceptance criteria of receiving inspection of the products/components. This will include testing of critical functions, dimensional and cosmetic quality and where appropriate, the establishment of limit standards. In instances where the process or product features cannot be verified, process validation will be completed

Critical Direct Supplier That Provides a Service

- A supplier survey is completed, and an on-site audit of the supplier's quality systems may be performed
- Reference checks are carried out with the potential supplier's major customers to assess the supplier's core competencies and quality of service and delivery of service
- Copies of industry and quality certifications will be obtained. Supplier should be at least ISO 13485 or 9001 certified

The supplier shall be deemed “Approved” on successful completion of the following:

- Achievement of supplier selection activities reviewing Business and Quality Systems per requirements
- As applicable, a statement of work with approved contract/purchase order which include quality requirements
- Signed CooperSurgical Non-Disclosure Agreement, if not included in the contract/purchase order
- A Statement of Work should be created to define scope of work, activities, and expectations. After the formal approval sign-off, the supplier’s status on the Approved Supplier Listing will be updated to indicate approved. Records of the selection process are maintained as part of the supplier quality and purchasing data

MAINTAINING YOUR STATUS AS A SUPPLIER

The performance of approved suppliers is monitored and assessed. This applies to all suppliers of finished devices, critical materials and services and is critical in the overall measurement of CooperSurgical’s own performance in relation to meeting our customer expectations.

Quality Performance:

- A suppliers quality performance will be measured by incoming lot acceptance and sample lot quality predicting defects per million
    - Incoming lot acceptance is calculated as the number of defective lots divided by the number of lots received.
    - The defective parts per million (DPPM) is based on the sampling performed in receiving inspection projecting the sample results against the population received
    - Delivery
    - NCMR’s
- Suppliers’ product performance may also be measured as first pass yield in CooperSurgical factories and/or by analysis of customer complaints and warranty
- While performance is monitored on an on-going basis reporting to the supplier will occur at intervals applicable to the supplier relationship or as required for improvement

SUPPLIER DISQUALIFICATION

The two main causes for disqualification are:

- Continued inability to meet CooperSurgical's requirements for quality system certification
- Continued poor supplier product quality and delivery performance

CooperSurgical will place a supplier on a provisional status and will notify the supplier in writing. CooperSurgical will work with the provisional supplier to document a 90-day get-well plan, which is intended to remedy the situation. If substantial progress is not made in those 90 days CooperSurgical reserves the right to disqualify the supplier if necessary.

Glossary / Definitions

CooperSurgical works in a regulated industry. The definitions used throughout this manual are critical to the understanding of the expectations and requirements.

Corrective and Preventive Action (CAPA) is a process that defines a systematic approach to eliminating the causes of known non conformity in such a manner as to prevent reoccurrence.

CE Mark is a legally required indication on the device that it conforms with the European Union's Medical Devices Regulation.

Complaint Is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly, which is intended to be included as part of the finished, packaged, and labeled device.

Conditional is a status in the Approved Supplier List for suppliers that have successfully gone through the first phase of the supplier evaluation/qualification process and are going through the second phase, which is part/service qualification.

Contract Manufacturer Is an organization that partially or completely manufactures or assembles a branded product or manufactures a finished device using CooperSurgical and its affiliates specifications, also known as private labeling.

Control number means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

Critical to function are parts that directly impact the functionality, safety, efficacy, or reliability of the end medical device. These items are typically identified in a system risk analysis or Design FMEA**.**

Design history file (DHF) means a compilation of records that describe the design history of a finished device.

Design input means the physical and performance requirements of a device that are used as a basis for device design.

Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Device history record (DHR) means a compilation of records containing the production history of a finished device.

Device master record (DMR) means a compilation of records containing the procedures and specifications for a finished device.

Deviation/Variance means a temporary change to a documented procedure, design or process until a permanent change can be accommodated.

Engineering Change Order (ECO) or Change Request/Change Order (CRCO) is the output of the Production Engineering Change Notification process that authorizes a change of design, materials, or process.

EN means European Norm or standard published by the European Standards Committee (CEN).

Establish means define, document (in writing or electronically), and implement.

FDA is the U.S. Food and Drug Administration.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Sourcing/Supply Chain / Buyer means the organization includes sustaining and new product procurement at all CooperSurgical sites.

ISO is the International Standards Organization.

Lot or batch means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Management with executive responsibility means those senior employees of a manufacturer and/or service provider, who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

Manufacturer means any person, who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Manufacturing material means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a by-product constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

Non conformity Is a nonfulfillment of a specified requirement of applicable policies, procedures, standards, or regulations as determined by the auditor. Non conformity may be classified using the MDSAP model from levels 1 to 5.

No Change Agreement is an agreement between supplier and CooperSurgical, in which, the Supplier agrees to notify CooperSurgical of any changes to their QMS which would impact products or services provided to CooperSurgical. (e.g., design changes, manufacturing process changes, equipment and tooling, material(s) or components, product specification, product packaging and/or labeling, storage requirements, locations, etc.).

Non-critical supplier provides direct materials or services that go into the end item or medical device that do not have a direct impact on functionality, safety, efficacy, or reliability.

Operational Quality Plan is comprised of quality planning documents defining the requirements to manage product and process quality throughout the life cycle of a product – development through service.

PPAP is a process for establishing confidence in suppliers and their production processes. The PPAP process is designed to demonstrate that a supplier has developed their design and production process to meet the client's requirements by minimizing the risk of failures.

Product means components, manufacturing materials, in- process devices, finished devices, and returned devices.

Provisional is the rating applied to a supplier that previously was an approved supplier, but whose performance has been unacceptable for a sustained period and is not trending positively. Action plans, which include countermeasures, will be in-place during the period the supplier is designated as provisional.

QSR means Quality System Regulation developed by the FDA.

Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Quality audit means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with

applicable quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

Quality Assurance Agreement means an agreement between the supplier and CooperSurgical on the quality expectations.

Quality policy means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Rework means action taken on a non conforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

SCAR Supplier Corrective Action Request.

Specification means any requirement with which a product, process, service, or other activity must conform.

Statement of Work is a part of a contract that defines the required activities and requirements. For direct materials the applicable engineering specifications referenced on the face of the contractual agreement will serve as a statement of work. In the case of services, the statement of work will include an outline of services to be provided and the deliverables.

Supplier Category is a category assigned to a supplier directly associated with the product or services provided. The categories are finished device, critical to function part, critical to service, non-critical parts or service or manufacturing materials.

Supplier Status includes “active” for suppliers in good standing, “inactive” for suppliers who have not had business activity for a minimum of a three-year period, or “disqualified” for suppliers with poor quality that have failed to maintain compliance to applicable certifications, standards, or other business concerns and who fail to improve performance or address corrective actions in a reasonable timeframe. Conditional for those suppliers who have not completed the approval process. Probation for those suppliers whose quality or other requirements are not meeting CooperSurgical expectations and standards.

UKAS United Kingdom Accreditation Service is the sole national accreditation body recognized by government to assess, against internationally agreed standards, organizations that provide certification services.

Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

IQ, OQ, and PQ are sequential activities that manufacturers carry out to validate their manufacturing processes. IQ stands for Installation Qualification, OQ for Operational Qualification, and PQ for Performance Qualification. The purpose of process validation is to establish documented evidence that the production equipment is correctly installed, operates according to requirements, and performs safely. It is also to demonstrate that the manufacturing process under normal operating conditions will consistently produce conforming products.

Process Validation establishes by objective evidence that a process consistently produces a result or that a product meets its predetermined specifications.

Design Validation establishes by objective evidence that device specifications conform with user needs and intended use(s).

Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Process Verification confirms by examination and provision of objective evidence that specified process requirements have been fulfilled.

Design Verification confirms by examination and provision of objective evidence that specified design requirements have been fulfilled.