Purchasing Control according to Current requirements
About Ludan - QA & Validation Department

● The Quality Assurance and Validation Department was established as an independent Department in 2005 headed by Dr. Moti Izhar.
● Ludan QA & Validation Department, offers a portfolio of capabilities to deliver measurable results for clients as: design, construct and consult operates GMP compliance facilities for Pharmaceutical and Medical Device manufacturing.
● Preparation of documents: BOD, Layout, flows, and risk assessment for Health authorities – for preconstruction meetings.
● GMP review for new facility and renovation
● Quality Assurance - Consultant, training, document writing, preparation for regulatory inspections, internal and external auditing service
● Validation - Consultant, training, document writing, execution and management of validation for the Pharmaceutical and Medical Device Industries
Main Topics

- Why do we need purchasing controls?
- Requirements and Definitions
- Maintaining Purchasing Controls
- Importers and distributors according to MDR
Why do we need purchasing controls?

Quality of the finished medical device depends on the quality of the components, raw materials and services Poor Quality Can Cause:

– Injuries from the medical device
– Recalls
– Customer dissatisfaction
Purchasing controls-ISO 13485

The ISO 13485 standard represents a Quality Management System base for many regulatory schemes. With the recent publication of the new Medical Device and In Vitro Diagnostic Regulations, the regulatory framework surrounding Medical Devices evolves and re-enforces the control of external parties (Suppliers, Subcontractors).

The newest revision of the ISO 13485 standard published in March 2016 aims in the very same direction.

What is a Supplier?

- There is no specific definition of “Supplier” in the ISO 13485 QMS standard.
- The standard however refers back to the definitions given in ISO 9000:2015.
- According to ISO 9000:2015, a Supplier is “an organization that provides a product or a service”.
- ISO 13485:2016 specifies that a product is the “result of a process” and that it includes “services, software, hardware and processed material”.

In the Medical Device industry, Suppliers include, for example:

- Raw material suppliers
- Sub-assembly suppliers
- Design/Manufacturing Subcontractors
- Consultants
- Any other service providers (Distributors, Calibration etc.)
Purchasing controls-ISO 13485

What are the responsibilities of the Organization/Manufacturer?

• In the **Quality Management System section of the ISO 13485 standard (4.1)**, the following was and is still stated:

> “When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes”.

• **Control of outsourced process is not a new requirement**; precisions were however added in the 2016 revision of the ISO 13485 standard. These precisions are that:

> “the organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements”.

• It clarifies the fact that the organization that subcontracts the activity remains responsible for it. It also formalizes the approach under which controls shall be implemented using a **Risk-based approach**.

• **Section 7.4 of ISO 13485:2016** is then giving more directions for organizations on the Purchasing process, including Suppliers’ control.
Section 7.4 of ISO 13485:2016

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

a) based on the supplier’s ability to provide product that meets the organization’s requirements;
b) based on the performance of the supplier;
c) based on the effect of the purchased product on the quality of the medical device;
d) proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).
Purchasing controls-ISO 13485

Requirements

• The ISO 13485:2003 standard does include requirements for Suppliers control. It is interesting to notice that the 2016 version of the ISO 13485 standard adds on more specific requirement to the process:

• Documentation
  – Precisions have been added for the documentation and the organization shall have:
    • A procedure
    • Records of suppliers evaluation/selection/monitoring,
    • Purchasing information documents and records, including a written agreement as applicable that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements
    • Additional documentation is required to cover the full purchasing process (verification of purchased product).

• The Criteria definition
  – The criteria for the evaluation and selection of Suppliers shall be based on the Supplier’s ability to provide product(s) that meet the organization requirements, on the performance of the supplier and on the effect of the purchased product on the quality of the medical device. The standard also specifies that the evaluation and selection criteria shall be proportionate to the risk associated with the medical device.

• The Risk-based approach
  – Both the above described Criteria and the actions implemented following the non-fulfilment of Purchasing requirements shall follow a risk based approach, proportionate to the risk associated with the purchased product.
The ultimate goals of these changes made in the control of suppliers within the ISO 13485:2016 are:

• to increase the harmonization with existing Quality System Regulatory requirements and ensure consistency between the different texts.

• to increase organizations’ suppliers control in order to meet standards and regulatory requirements.
Purchasing Controls

Sourcing suppliers in the medical device industry is not as simple as going on the internet and finding your material and purchasing it.

As part of a compliant quality management system, purchasing controls must be in place to ensure that quality product and materials are going into your device, and that any service providers that your company uses in the production of your product or within your quality management system are qualified.

ISO 13485 Requirements:

• In light of that, ISO 13485:2016, sections 7.4.1 Purchasing process, 7.4.2 Purchasing information, and section 7.4.3 Verification of purchased product outline the purchasing requirements. The following are requirements for the evaluation and selection of suppliers:

  – The organization must have established criteria for the evaluation and selection of suppliers.
  – The criteria need to evaluate the supplier’s ability to provide product that meet the requirements.
  – It needs to take into consideration the performance of the supplier.
  – It must consider the criticality and the effect that purchased product may have on the quality of the medical device.
  – The level of supplier assessment and monitoring should be proportionate to the level of risk associated with the medical device.
Maintaining Purchasing Controls

• To start, in the most basic sense, purchasing controls involve procedures that ensure you are only purchasing from suppliers who can meet your specifications and requirements. The best way to keep track of your qualified suppliers is to maintain an Approved Supplier List (ASL).

• **You should only purchase product or services that affect your product or quality management system from companies on the ASL** (you would not necessarily need to qualify things like office supplies or legal assistance through purchasing controls).

• When used effectively, the Approved Supplier List can be a great tool to manage the key facets of purchasing control, and keep track of supplier monitoring. Items that you can capture on the ASL include:
  – Supplier Name
  – Scope of Approved Supplies
  – Contact Information
  – Status of Approval (Approved, Pending, Unapproved, etc.)
  – Qualification Criteria
  – Supplier Certification and expiry dates
  – Monitoring Requirements/Activities
    • Date of Last Review
    • Date of Next Review
The first step in your purchasing procedure should involve checking to see if the supplier is under active approved status on the ASL. The second step will be to ensure that you are purchasing an item/service that is within the scope of approval of that supplier. If you have not approved the supplier, or the intended purchase is beyond the scope of that supplier, your purchaser will need to go through the necessary channels to add the supplier to the ASL, or modify their scope on the ASL.

<table>
<thead>
<tr>
<th>Supplier Name</th>
<th>Manufacturing Address</th>
<th>Country</th>
<th>Supplier Risk</th>
<th>Scope of Approved Supplier</th>
<th>Contact Information</th>
<th>Status of Approval</th>
<th>Qualification Criteria</th>
<th>Date of last review</th>
<th>Date of next review</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADS Laminar</td>
<td>Einuk Chernof, Industrial Park, Geshur</td>
<td>Israel</td>
<td>3</td>
<td>Maintenance</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Certification</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Aminolab</td>
<td>Ness Zona, 10-1st, Kinyat Watsman</td>
<td>Israel</td>
<td>1</td>
<td>Test Laboratory</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>On site Audit Certification</td>
<td>27/05/2019</td>
<td></td>
</tr>
<tr>
<td>Bakterlab</td>
<td>Cedarview, Hashata 6, PO Box 1552</td>
<td>Israel</td>
<td>3</td>
<td>Lab Supply</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benin Engineering</td>
<td>Omar, 8 Dizengaf St., 91986</td>
<td>Israel</td>
<td>8</td>
<td>Consultant</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DHL Global Forwarding</td>
<td>Eicheim, 8105 Strasbourg International Airport, Frankfurterstr. 250, 64239</td>
<td>France</td>
<td>3</td>
<td>Transport</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Merck</td>
<td>Darmstadt, Frankfurterstr. 250, 64239</td>
<td>Germany</td>
<td>2</td>
<td>Chemicals</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Questionnaire Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saint-Gobain</td>
<td>100 Warner Boulevard, Taunton, MA</td>
<td>United States</td>
<td>2</td>
<td>Tubing</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>Questionnaire Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synven</td>
<td>Yavne, P.O.B. 214, 81800</td>
<td>Israel</td>
<td>1</td>
<td>Sterilization</td>
<td>Name: E-mail: Phone:</td>
<td>(Approved, Pending, Unapproved, etc.)</td>
<td>On site Audit Certification</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The first step in your purchasing procedure should involve checking to see if the supplier is under active approved status on the ASL. The second step will be to ensure that you are purchasing an item/service that is within the scope of approval of that supplier. If you have not approved the supplier, or the intended purchase is beyond the scope of that supplier, your purchaser will need to go through the necessary channels to add the supplier to the ASL, or modify their scope on the ASL.
Supplier Qualification Criteria

- As required by the FDA, the level of supplier assessment should be proportionate to the level of risk associated with the medical device. The FDA is not prescriptive about the use of specific qualifications or assessments for different types of suppliers, so that is up to your company to determine. This is a somewhat grey area, but there are some general expectations of vendor qualifications that we have observed and would recommend.

- It is good practice to have a form or template that guides your supplier evaluation process. Using input from engineering and QA to first determine the level of risk and the requirements of that supplier, and then base your qualification plan on that information. If you have a higher risk supplier who may be supplying a critical component to your device, or providing a critical service such as sterilization, then your qualification process will be much more involved.

- Here is an example of two different levels of criteria based on the type of supplier (the intent is not for the following items to be rules, and your company is responsible for determining the adequate acceptance criteria for suppliers, but this is a general example of what you may expect).

<table>
<thead>
<tr>
<th>Critical Custom Component Supplier</th>
<th>Non-Critical Consumable Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>- ISO 13485 Certification</td>
<td>- Product available that meets the needs of the company.</td>
</tr>
<tr>
<td>- On-site audit of supplier’s facility</td>
<td>- An associate has previously used by an associate who recommends the supplier.</td>
</tr>
<tr>
<td>- References</td>
<td>- Adequate customer service, returns allowed.</td>
</tr>
<tr>
<td>- Provides Certificates of Analysis (CoA)</td>
<td></td>
</tr>
<tr>
<td>- Written agreement that the supplier will communicate with the company regarding any changes that could affect their ability to meet requirements and specifications.</td>
<td></td>
</tr>
<tr>
<td>- You validate a production sample and it meets requirements</td>
<td></td>
</tr>
</tbody>
</table>

Additional Function of Supplier Evaluation Forms
- The supplier evaluation form can also be used as the plan to assign responsibility and track completion and results during the initial evaluation, and can also include the plan for ongoing monitoring and control of the supplier. This evaluation form should be maintained as a quality record, and auditors will frequently ask to see supplier evaluations.
Are Supplier Audits Required as Purchasing Controls?

• Also valuable, supplier audits may be included as part of an evaluation plan for a new supplier, the change of scope of a supplier, a routine audit as part of ongoing monitoring, or as part of a non-conformity investigation of a high-risk product. While it is not required by ISO 13485, nor does the FDA specify in the CFR that you must audit suppliers, it is a very good idea to audit your critical suppliers. If an auditor or FDA inspector sees evidence that your current purchasing controls are inadequate, performing supplier audits may be forced as a corrective action.

• Beyond that, you can gain so much value, and gather countless clues and important information in an audit that you just cannot get without paying your critical supplier a visit.
  – You can see where they plan to/are making/cleaning/sterilizing/storing your product.
  – Talk to the people on the line, are they competent and trained?
  – Does the company maintain their facility well? How secure is it?
  – Do they maintain adequate records and traceability?
  – Have there been any non-conformities relating to your product that have been detected? Etc.

• Supplier audits should also include evaluation of the procedures, activities, and records of the supplier that could have an impact on the product or service they are providing your company. If it is not the first audit of the company, you should be sure to review the previous audit report findings, and ensure the company has addressed any nonconformities, review supplier performance data, information about any changes that may have occurred at the supplier since your last visit, etc.
Record Maintenance and Ongoing Evaluation of Suppliers

• No matter the method of supplier qualification, it is best practice to maintain supplier files that contain useful information relative to the supplier that may include:
  – The original supplier qualification form
  – Supplier certificates
  – References
  – Audit reports
  – Subsequent performance evaluations
  – Expanded scope qualifications
  – Supplier communications
  – Current contact information
  – Copies of any non-conforming material reports related to the supplier, etc.

• ISO 13485 requires monitoring and re-evaluation of suppliers, and maintaining detailed supplier files will assist in meeting this requirement, and will help in the feedback system to identify and recurring problems or issues with a supplier. On a planned basis, whether that is annually, or every order (dependent on the criticality of the product), your company should conduct a formal supplier evaluation to determine whether the supplier has continued to meet requirements — In general, annual supplier reviews are standard. Additionally, you must specific this frequency in your procedure (auditors will look for what period you specify in your procedure, and then will check your ASL to make sure all of your suppliers have been reviewed within that timeframe).

• During the supplier evaluation, if you find there have been issues, you need to determine and weigh the risks associated with staying with that supplier, and document that in the supplier file. If you determine the supplier should no longer be qualified, then you must also indicate on the ASL that the company no longer approves of the supplier.
Making the Purchase

• When you have verified your supplier is approved on the ASL, you are authorized to purchase product.

• Engineering is usually responsible for identifying the product specifications, requirements for product acceptance, and adequacy of specified purchasing requirements prior to communication to the supplier. The specifications may be in the form of drawings or written specifications.

• Additional information communicated to the supplier should also include, as applicable, an agreement between your company and the supplier that the supplier will notify you prior to the implementation of changes relating to the product that could affect its ability to meet specified purchasing requirements.

• When the first batch of product is received from a particular supplier, it is a good idea to verify that the product performs as intended before entering into production with a new material or component.
Supplier Nonconformity

- From time to time, you may encounter issues with a supplier. **Sources of nonconformity include**
  - incoming inspections
  - production nonconformities
  - final inspection
  - customer complaints

- It is important that you **notify your supplier the nonconformity and record their response and assessment**.

- **Depending on the level of criticality of the vendor,** it is reasonable to require them to perform a **root cause analysis** to determine and alleviate the **cause of failure**. You should also request documentation of an **effectiveness check** to ensure the supplier has taken corrective actions. You should maintain **copies of supplier nonconformity reports** in the supplier file, and discuss nonconformities during ongoing supplier evaluations.

- If the supplier does not cooperate or fails to address the nonconformity in an acceptable manner, or if there is a pattern of nonconformities with the vendor, then you should disqualify the supplier, and indicate that the supplier is “**not approved**” on the ASL.
Supplier Management Process Flow

1. **Planning**
   - Identify the **products or services** to be obtained from suppliers/EMs, along with the quality, technical and business requirements for those products or services.

2. **Selection**
   - Identify possible suppliers/EMs to provide the desired products or services based on their capabilities relative to the quality, technical and business requirements for those products or services.

3. **Quality**
   - Evaluate and **confirm** that the potential suppliers/EMs are capable of meeting the quality, technical and business requirements, with suppliers then being formally approved and added.

4. **Finalization of Controls**
   - Establish the required type and extent of **controls** required over the suppliers/EMs.

5. **Monitoring and Feedback**
   - **Monitor** and maintain control over the suppliers/EMs while they are providing products or Services, Inform the supplier/EM of whether or not expectations are being met through requesting **corrective and preventive actions** where needed and removing suppliers/EMs if necessary.

**Evaluation Form**

- QAG
- SPEC.
- AUDIT
- RECEIVING
- INSPECTION

**ASL**
Example Warning Letter Citation

• Failure to clearly define the type and extent of control to be exercised over suppliers.
  – For example, your Supplier Approval Procedure & Process Map states you will perform ongoing monitoring of Level 1 suppliers. The procedure does not define the frequency and type of monitoring required for these suppliers.

• Failure to evaluate potential contractors.
  – For example, you did not evaluate the company who conducted steam sterilization validation studies for the XYZ Screw System to ensure they could conduct the validation studies in accordance with the specified standard.
• failed to establish and maintain adequate procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR §820.50. —... relies on its PCB supplier to perform a comparison (verification) between electronic design files ... and the manufacturing files ... the requirement that this verification be performed and appropriately documented was not specified in XXX purchasing documentation or supplier agreement. —... relied on the supplier to perform its own First Article Inspection, but failed to established any criteria for the supplier to conduct the verification ... —... continues to have solder flux contamination issues from a supplier even after implementing previous corrective actions. ... has not implemented procedures to adequately control the products from this supplier or to inspect incoming products to detect contamination
Supply Chain Obligations

Becoming **compliant under the MDR and IVDR** requires a close look at the supply chain leading into the EU, and **identification of each entity up to the end user** as one of the economic operators regulated under the regulations: the MAID (Manufacturer, Authorized Representative, Importer and Distributor).

We are used to the **manufacturer having regulatory responsibility** under the directives, but it’s new that the **importer and distributor suddenly have important obligations in the supply chain** and that the role of the authorised representative has changed a lot.
Supply Chain Obligations

• Each link in the supply chain gets the responsibility to check compliance of the previous one.
• Review autonomous general obligations of importers and distributors (articles 11-12 MDR/IVDR). Eg:
  – Verify compliance of the device
  – Inform competent authority of non-compliance of the device
  – Implement corrective action

• Amend contracts accordingly contain all relevant responsibilities
Summary

• Suppliers and Contractors Management is a complex and important process which take place during all product life cycle.

• Purchasing controls pertain to products, components, and services

• Select suppliers based on their capabilities and manufacturing requirements

• Establish adequate supplier control

• Risk based approach is mandatory tool.

• Document is essential in each process step

• Computerized System may be use in order to support manage the process and provide tools to document all process life cycle.
Verify compliance:
- CE +DoC
- AR assigned
- Labeling
- UDI

Manufacturer
- Name on device
- CE +DOC
- GSPR
- UDI
- PRRC

Verify compliance:
- CE +DoC
- IFU present
- Importer details added
- UDI

Importer
- Name on device
- Check Eudamed
- Register of complaints
- Check DoC + cert
- Assist with corr. action.
- Safeguard storage conditions
- Assist authorities
- Not make available if conformity compromised

Distributor
- Forward complaints
- Safeguard storage conditions
- Assist with corr. action.
- Assist authorities
- Not make available if conformity compromised

Authorised Representative
(27) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;

(30) ‘manufacturer’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(32) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer’s behalf in relation to specified tasks with regard to the latter’s obligations under this Regulation;

(33) ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market;

(34) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(35) ‘economic operator’ means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);