Alceon
MONTHLY NEWSLETTER

Jun 2020

Dear Readers,

Welcome to the first issue of our newsletter. We have introduced this newsletter to share with you news and content relevant to your field of business. In this copy we are looking at two areas - one related to supplier management and the other on requirements on packaging as per the new EU Medical Device Regulations.

Risk-based supplier management is a concept discussed in the ISO13485:2016 standard and other regulatory standards and guidance documents. With increasing regulatory focus on manufacturers, a risk-based process to manage suppliers can help to optimally use resources. We discuss here methods that you can use to classify suppliers and also to monitor and manage them based on the risk level.

The second topic we are discussing concerns the packaging requirements on sterile packs as per the new EU Medical Device Regulations. There are new definitions and requirements in the regulation and we find a close alignment with the ISO11607 standard.

We hope that these articles will be of interest to you. We look forward to any questions that you might have on medical device regulations and will try our best to answer you as soon as possible. Questions which are of general interest will be published in the newsletter for all to benefit.

IN THIS ISSUE

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RISK-BASED SUPPLIER MANAGEMENT 01

In this global era of disruptive innovation and increased out-sourcing trends, irrespective of the company size and product type, managing quality deliverables has become a far more complex and challenging endeavour for medical device companies. As supply chain and customer satisfaction are intertwined, it is imperative to have a resilient and effective supply chain management in place.

Supplier management is a process that encompasses the entire life-cycle of your product.

There are several ISO standards, regulations and guidelines like the ISO 13485:2016, 21 CFR parts 820, GHTFSG3/N17:2008 which lay the foundation to implement and maintain a sustainable supplier management system. All these documents require the organization to establish criteria for the selection, monitoring and re-evaluation of suppliers based on the type of product or service supplied and its impact on the quality of finished product.

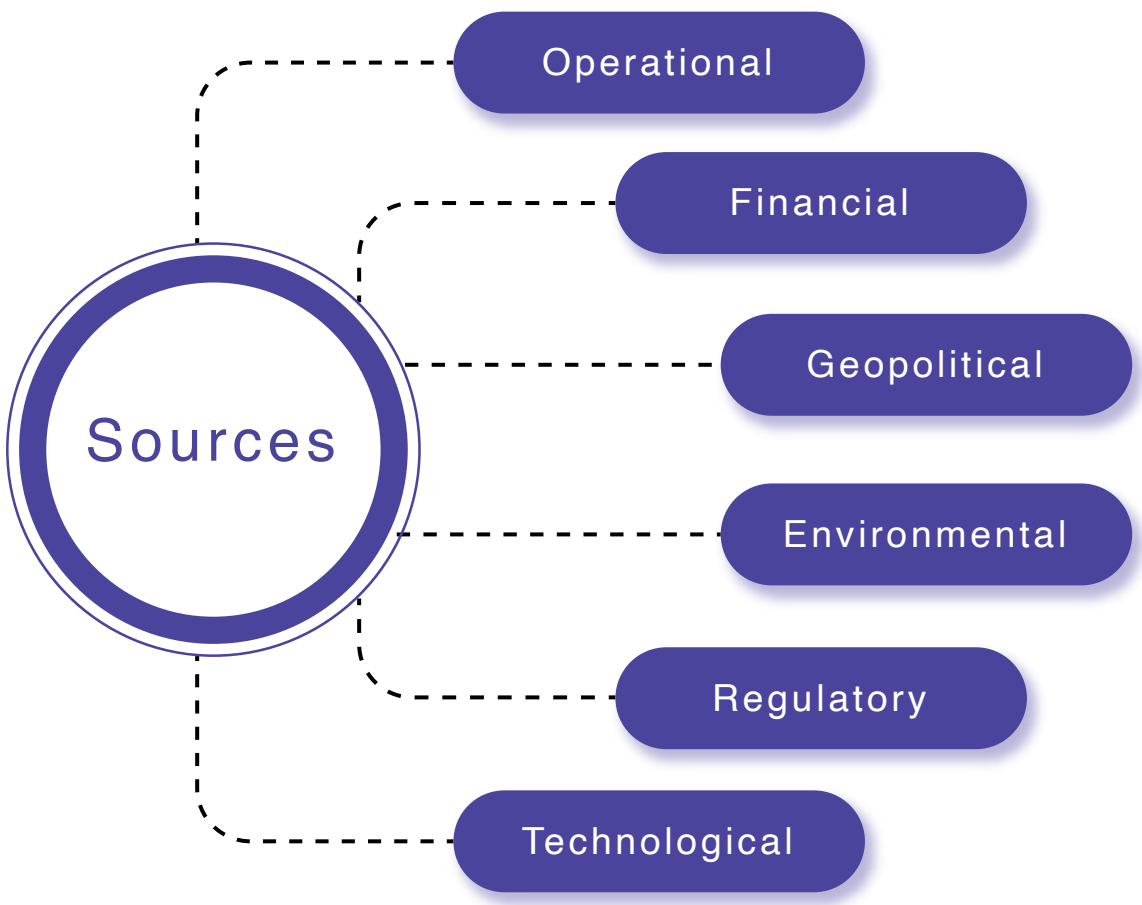
The common theme is to use a risk-based approach for supplier management.

Base your selection and monitoring of suppliers on a risk classification.

This risk-based approach in managing suppliers begins at the supplier selection stage and is an ongoing process through selection, monitoring and re-qualification.

It is befitting for companies to categorize suppliers based upon an assessment of the relative risk of the material or service they provide that can affect the final product quality and/or safety. Such a categorization can help organizations to prioritize its finite resources to what is most important.

There can be several sources of supplier related risks.



While one can define his own risk matrix, below is an example one can use to classify suppliers.

Type of Supplier	Risk Profile
Single source supplier of raw material or packing material, or Critical raw material, packing material, consumable that can impact the safety or performance of the product or Critical service providers like moulding, welding, sterilization that does outsourcing activities	High
Non-critical materials suppliers or service providers which directly do not impact the product safety or performance like labels, consumables, pest control, maintenance	Medium
Low risk materials and services like off the shelf commercial items, office supplies, general housekeeping services	Low

A differentiated approach to evaluate (select and approve) and then monitor each type of supplier can be followed.

For example, for a high-risk supplier, it may help to do a site audit and not depend only a QMS certificate provided by the supplier. After selection, quality agreements need to be established. Such quality agreements clearly outline expectations between the two parties and set the benchmark for quality of products and services supplied. Other methods can include a score card which rates the supplier on various criteria like rejections in goods supplied and timeliness of supplies.
For a medium risk supplier, the supplier may not need to be QMS certified and you can rely on your own assessment of their quality system.
For low risk suppliers an incoming goods inspection may be enough.

HIGH

- Audit
- QMS certification
- Trial Orders
- Score Card
- Quality Agreements
- Change Notification

MEDIUM

- Desktop review of QMS
- Trial Orders
- Score Card

LOW

- Incoming Testing

In conclusion;

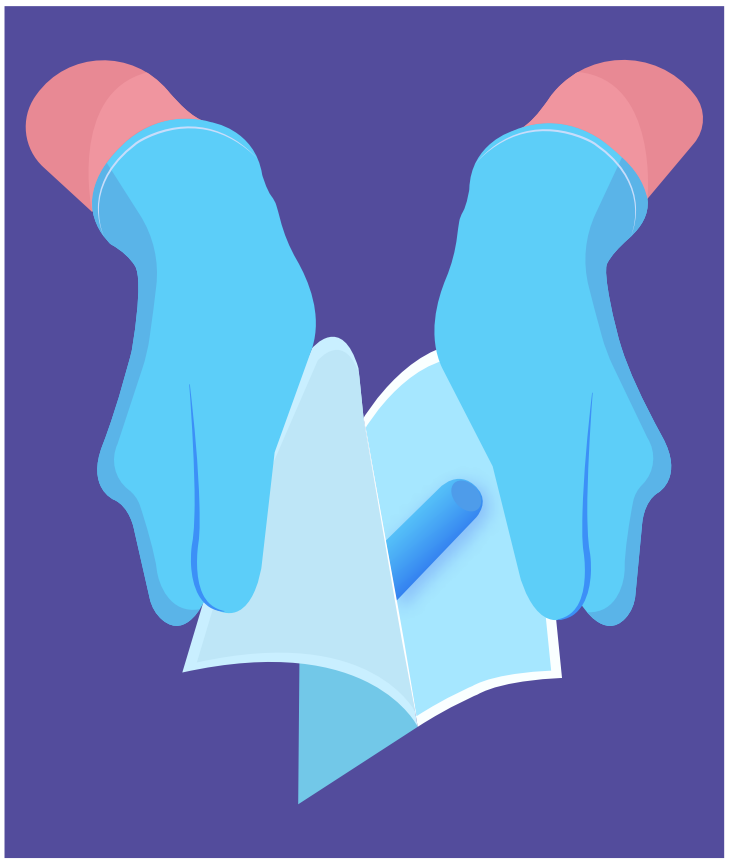
The state of regulated industries is continuously changing due to regulatory changes, economic and technological pressures and globalization. The suppliers play a vital role if manufacturers have to achieve the desired results as well as reduce the risks in their business. Suppliers need to be constantly monitored so that there is no slip in the quality, safety and efficacy of the products and services. With limited resources at their disposal, organizations cannot focus with the same vigour with all suppliers. It therefore makes sense to follow a risk-based approach and separate the critical from the sundry.

STERILE PACKAGING REQUIREMENTS IN THE EU MDR 02

The EU MDR had put focus on medical device packaging and several new requirements for the packaging and labelling have been introduced.

Packaging for sterile devices must comply to the ISO11607 standard. Both parts 1 and 2 of the standard have now been revised and are considered as state-of-art. The new editions of the standards are more closely aligned to the requirements of the MDR, even though they are still not the harmonized standards. There are also requirements in the harmonized standard ISO13485:2016 for appropriate controls during packaging. Let's look at the requirements one by one.

Usability Evaluation of Aseptic Presentation



MDR Annex I, Chapter 2, section 11 addresses infection and microbial contamination and has some new and enhanced requirements for packaging. For example, the devices and manufacturing processes “should be designed to eliminate or reduce as far as possible, the risk of infection to the patient,” and the design should “allow easy handling” and “minimize contamination.” These elements can be addressed using materials with high microbial barrier properties and designs that allow for effective aseptic presentation. One way of generating quantitative data for aseptic presentation is through usability testing. Interestingly, usability evaluation of aseptic presentation is also required by ISO11607-1, thus making the standard more aligned to the MDR.

Packaging Integrity Evaluation at Point of Use

Another requirement comes from MDR Annex I, section 11.4:

"*Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer,* ***until that packaging is opened at the point of use****. It shall be ensured that the integrity of that packaging is* ***clearly evident*** *to the final user.*"

The key statements here are "point of use" and "clearly evident". The term “clearly evident” seems ambiguous, leaving room for interpretation. At this point, the intent or interpretation is not fully understood. In its simplest sense it may mean that the integrity of the sterile barrier has to appear intact to an unaided eye.

The point of use is also subject to interpretation. Since devices are generally handled inside a hospital or end-use location without the protective covering (usually called the secondary packaging), it may appear that manufacturers must test the sterile barrier for integrity under simulated conditions without the secondary packaging and shipping container.

Transportation Studies

The MDR Annex 1, chapter 1 section 7 requires that the packaging will not be adversely affected during transportation and storage. This is not a new requirement and was there in the MDD as well. However, the MDR gives an example of possible conditions such as fluctuations in temperature and humidity which can affect the packaging. This may involve conducting tests for the packaging in testing chambers where temperature and humidity variations are induced, controlled, monitored and

evaluated. These tests will be additional to performance tests that are generally conducted on shipping containers like burst, drop and vibration.

The ASTM D4169 or ISO4180 standard can be an appropriate starting point to conduct these tests.

Labelling Requirements on Device Packaging

There are three categories of labelling mentioned in the MDR:

- Requirements for labelling on the sterile barrier system
- Requirements applying to general labelling of the product (like the carton label)
- Requirements included in the instructions for use (IFU)

EU MDR Annex I, Chapter III, section 23.3 and states that sterile packaging must include “an indication permitting the sterile packaging to be recognized as such”. Whether these indications shall be in the form of symbols or any other means is not clear from the MDR text. The European Commission has not come up with any new harmonized symbol for this requirement so far. The intention is that such indications will help healthcare professionals understand which parts of the package are sterile so they can aseptically present devices into the sterile field.

The sterile packaging must also have “a declaration that the device is in sterile condition” (Annex I, Chapter III, 23.3 (b)). This is different than the current symbols for sterilization method. Additionally, there must be “an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use” (Annex I, Chapter III, 23.3 (j)).

In the instructions for use, the MDR states that, if the device is supplied sterile, packaging must include “instructions in the event of the sterile packaging being damaged or unintentionally opened before use” (Annex I, Chapter III, 23.4 (l)).

The Commission has not yet provided a harmonized symbol to instruct users to check the IFU.

Another addition to the general labeling or carton labeling requirement is to have “an indication that the device is a medical device” (Annex I, Chapter III, 23.3 (q)). Currently there is no harmonized symbol used for a medical device but below is a proposed symbol to be included in the revised ISO15223-1:

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