PathWise

Effective Management of Supplier Corrective Action Requests

Appropriate Supplier Management is a critical piece of managing a successful business. Not only is it an important element of the Quality Management System (QMS), but it directly relates to product quality and On-Time Delivery. If your supplier isn't delivering acceptable quality components, that affects your overall production schedule and ability to deliver the finished device on time.

This White Paper provides a discussion on managing the Supplier Corrective Action Request (SCAR) process effectively, and in accordance with requirements per 21 CFR 820.50 and ISO 13485:2016 § 7.4.

Why is there a need for SCARs?

In order for your product to meet its acceptance criteria, that means the constituent parts (components, materials, subassemblies, etc.), must meet theirs. In a scenario where these constituent parts are provided by a supplier, the quality of those parts becomes critical. In cases where suppliers may be providing parts that don't meet the applicable acceptance criteria, this becomes an opportunity to determine why, and put measures into place to prevent it from happening again.

This level of control is also discussed in the following regulations / standards:

21 CFR 820.50(a)(2) states that each manufacturer shall:

> *Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.*

ISO 13485:2016 § 7.4.1 discusses criteria for the evaluation and selection of suppliers including:

> *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.*

The use of a SCAR Process can be integrated into the QMS. Defining appropriate acceptance criteria allows for the identification of nonconformance. In the event of a supplied product nonconformance, a SCAR can be issued to the supplier.

SCAR Process

A Supplier Corrective Action Request is very similar to a Corrective and Preventive Action (CAPA) that is initiated by the supplier; however, it allows for visibility and appropriate communication with the Customer.

A strong SCAR process includes the following:

- Containment – How will the supplier prevent future shipments of materials containing this same nonconformance?
- Correction – How will the supplier address the current shipment of nonconforming product?
- Root Cause – How did the current nonconformance arise and how was it allowed to enter distribution?
- Corrective Action – How will the supplier appropriately address the Root Cause to prevent the nonconformance from recurring?
- Preventive Action – This isn't always applied; however, there may be instances where it's appropriate for the supplier to look right and look left to determine if there are similar areas of potential nonconformance that they can also address to prevent nonconformance occurrence.
- Supplier Quality Approval demonstrating commitment to the defined actions, including timelines and responsibilities for any pending actions.

Timely receipt of appropriate content for the above bullets, allows for closure of the SCAR. Often times; however, suppliers struggle to provide the required content in a timely manner. In that scenario, what are some helpful approaches?

SCAR Approach

In order for the supplier to appropriately complete the SCAR, in a timely manner, it is important to provide them with all of the information they need up-front. This may include the following information related to the nonconformance:

1. Date
2. Part Number
3. Lot / Serial Number
4. Product / Material Description
5. Detailed Nonconformance Description
6. Samples / Photographs of the Nonconforming Material
7. Purchase Order Number (or other applicable linkage to the shipment)

It is also helpful to clearly define what is required in their response. This may be achieved by providing them with a SCAR Form to complete. This SCAR Form should include detail of the SCAR requirements including the applicable items identified in the SCAR Process above (Containment, Correction, Root Cause, Corrective Action, Preventive Action, Supplier Quality Approval / Commitments) along with a Due Date.

SCAR Challenges

At times, there may be challenges encountered in the SCAR Process. Some examples are discussed below, along with some suggestions for handling each challenge.

Supplier Doesn't Provide Timely Response

- Prior to sending the SCAR, ensure that the correct Supplier Contact Information is available. This is generally Quality Management, who can coordinate further with the supplier team internally.
- Ensure that the SCAR communications include clearly defined expectations and due dates.
- Incorporate the use of reminders / follow-ups leading up to the due dates defined. This will help to ensure that the issue remains on the supplier's radar.
- A hold can be placed on orders with the supplier until the issues are resolved. While not ideal, there may be times where responsiveness can be triggered by financial impact.

Supplier Doesn't Provide Appropriate Information

- The use of SCAR Form (as discussed in the SCAR Approach Section above) can aid in ensuring the supplier is providing appropriate information.
- In some cases, suppliers may return a SCAR Form without filling it out completely / correctly. In these circumstances, it may be beneficial to have continued communications with the supplier. This may help them to understand the expectation for what each field should include to enable SCAR closure.
- In circumstances where the SCAR Form provided by the supplier is complete, but could benefit from additional background information, this can be supplemented by a Memo written internally to add depth to the details and provide background that the supplier hasn't clearly described. In this situation, it's important to retain the original information provided by the supplier, while using the internal Memo for clarification / supplemental purposes to strengthen the response and further support SCAR closure.

Of course, one main consideration is that the Supplier is appropriately qualified initially. This can include a Quality Agreement that defines the supplier's responsibilities, including their

responsiveness to SCARs. This Quality Agreement can also include a clause for holding the supplier accountable financially, for quality defects.

Summary

Appropriate Supplier Management is critical not only to compliance, but also to running a successful business. Nonconforming materials received from the supplier can impact product quality, create delays in manufacturing schedules and impact delivery timelines to the end user. For these reasons, it's important to have a functional SCAR Program integrated into your Quality Management System. Incorporating appropriate SCAR Process and Approach elements can aid in ensuring the supplier has established effective long-term corrective actions to prevent defect recurrence.

About the Author: Nola Benstog is a diversified professional with a thorough knowledge of Quality Management Systems. She has over sixteen years of experience in the areas of Quality Assurance, Quality Control, Regulatory Affairs, Validation and Sterilization in both industry and consulting roles. She has worked in the medical device, pharmaceutical, combination product and nutritional supplement industries with experience ranging from start-ups to Fortune 100 and 500 companies. She began her career as a Technician in a Microbiology Lab and has held various positions up to the Executive Management level throughout her career. Nola received a Bachelor of Science in Microbiology from Weber State University and a Master of Business Administration from Utah State University. She has been an American Society for Quality (ASQ) Certified Quality Auditor (CQA) since 2007.