

## LIFE SCIENCES

### Select Suppliers via Baseline Quality, Then Cement Top-Line Relations

Selecting suppliers and maintaining strong relationships is a constant challenge to all businesses. In the regulated world of the life sciences, establishing successful relationships often includes a personal touch to help these vendors understand the shared value that each party provides to market a safe and effective product.

Current versions of applicable industry regulations and standards include contractors and consultants in these supplier evaluation requirements. This certainly makes sense; anyone affecting the quality management system (QMS) needs to be qualified objectively.

Think about your selection process for personal projects: How many service providers have you chosen strictly out of the phone book or from a list without performing more due diligence? What have the results been if you didn't verify their credentials and abilities before the job began?

#### FIRST STEP Baseline Measures

It's hoped that your company has a supplier management team to assure that everyone is following the same process within the QMS. Certainly, tasks may be delegated to various members of the team, but someone needs to review all data and report to



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the team and senior management (at minimum, during the design control and management review processes). Usually, purchasing and quality share the ownership role of leading the team and meeting the business objectives.

Conducting an initial survey (written or oral) can provide you with much information in a limited timeframe and act as objective evidence for your files. Answers will direct you to appropriate areas for follow-up, particularly if you intend to conduct an onsite audit of the company's facility or facilities.

At minimum, the following should

be included on your team's checklist for review and verification.

- *Financial Viability.* Will they be there when you need them? Start with checking Dun & Bradstreet information.

- *Operational Concerns.* How many years has the supplier been in business? Are there multiple locations? If so, are they within or outside of the U.S., or is it a global enterprise? Where is your component or sub-assembly being made? What types of industries do they serve or support?

For management: Have there been any major changes in last one to two years? Why? What about the political atmosphere in the applicable country of manufacture?

Determine volatility and its potential effect on your business. Other considerations include OSHA compliance and whether it's a union environment (number of employees, shifts, etc.).

- *Quality and Regulatory History.* This is an indicative measurement of QMS effectiveness. If a supplier is a contract manufacturer, verify via records if the company is FDA-registered. Ask for and review any FDA 483 observations or warning letters, or recalls. If applicable, this information should be readily available. Verify that all corrective actions have been closed and that the FDA is satisfied with

these actions.

Check via certification if the company is ISO certified to ISO13485:2003 or ISO9001:2000, as applicable. Are there any issues or outstanding corrective actions with a registrar or notified body? How do they handle customer (i.e., your) complaints? Does their corrective and preventive action (CAPA) system include addressing the root cause of a problem and advising you of potential issues? Is senior management engaged in company operations?

- *Product Development.* Consider the process technology. Is the supplier experienced with materials and processes used in developing and manufacturing your product? Verify that the employees are trained or skilled craftsmen.

## NEXT STEP Need to Audit?

Usually, this depends on the complexity of the product or service that you intend to purchase. What is the potential risk to achieving your business goals if you don't "see things for yourself" and measure their capabilities? Most companies do choose to audit contract manufacturers, at minimum, during the selection process.

"We're ISO certified...you don't need to audit us." This is not a reason to stay at the office. One way to explain your reason for the audit is to inform the potential supplier that it is a requirement of your QMS to perform audits per your procedures. All audits are snapshots in time; for example, someone may have become ISO certified two years ago and the business environment may have changed (see FIRST STEP reference points).

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## COMMUNICATE Now and Later

Many times, suppliers or contract manufacturers are unaware of how their product works or fits in your final product. Initial product development discussions may have only involved senior management or design engineers and not the front line workers.

Providing perspective, particularly in the medical device field, may open many eyes to the important role the supplier has in your process and quality system.

For example, showing a videotape of the product in use (same as may be shown to potential investors) allows the supplier's staff to understand how their actions manifest in the final product. When people consider that this product could be used on a family member or themselves, they become more mindful about

their actions.

This seemingly small gesture of communication can be a large boost to strengthening a partnership/relationship. Include the following when considering your communication needs:

- Proprietary technology,
- Process,
- Material,
- Form, fit, function and
- Change control.

## ONCE SELECTED Develop Relationship

Clear communication and trust are critical elements needed to ensure compliance to your QMS requirements and to deliver business results. Knowing that your supplier will act consistently and alert you to quality or business concerns prior to taking action regarding your product components alleviates potential issues that may result in work stoppage, product recall or unscheduled inspection by the FDA or an international notified body. The FDA and international notified bodies have increased their focus on risk management during their audits and will continue to do so – for example, ISO14971:2000 (application of risk management to medical devices) is recognized by the FDA.

Taking these initial steps and continuing to monitor performance should help you set the foundation to create successful partnerships as you select your suppliers.

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