

CULTURAL AUDITS: WHAT ARE THEY AND WHY ARE THEY ESSENTIAL?

Everyone in the medical device industry is familiar with quality audits. They're an essential part of determining whether a supplier is capable of meeting – and continues to meet – the expectations of the purchaser. Objective metrics are a central component of the audit process. They do not allow much room for interpretation. Nor should they.

But identifying the key to a mutually beneficial relationship requires more than what mere data can portray. A case in point: just think about all the professional sports transactions that look reasonable based on a player's statistics yet fail for reasons that are not a function of the player's demonstrated capability. Commentators inevitably point to intangibles like team chemistry or motivation as the cause.

Where quality audits supply objective documentation of a potential partner's suitability, we advocate a practice we call a cultural audit. A cultural audit looks beyond the data and systems. It evaluates compatibility of the two companies on a multitude of levels – everything from broad corporate mission to an individual contact's personal objectives. Embracing the concept of a cultural audit instills a level of formality to an action that usually happens informally as a relationship matures. And in many instances, it prompts exceedingly healthy discussions about the purpose, expectations and boundaries of the interaction.

CULTURAL AUDIT COMPONENTS

Obviously, informal cultural audits begin the minute you begin interacting with someone. What's your first impression? Do you immediately feel a sense of trust? Does the other person care about you as much as he or she cares about himself or herself?

The cultural audit takes the process several steps further by compelling you to evaluate a host of criteria that would likely portend a successful or unsuccessful relationship.

Because cultural audits are not overseen by any regulatory body, there are no established formats or benchmarks for success. They can be as structured or as loose as a company wants. In fact, the thoroughness of a cultural audit is partially a function of the other company's openness to it. Some are more willing to be forthcoming than others (which in itself is worth noting in the audit).

Here are the most important things we look at when conducting cultural audits of our suppliers.



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CORPORATE MISSIONS

Start at the top: it's important to determine how well the companies' missions are aligned. Do they use similar language in their mission and vision statements? Do they have similar core values? Just as importantly, are there inconsistencies between companies and where they strategically allocate their resources? Furthermore, it's essential to evaluate how companies are upholding their missions. Research recent news stories for positive and negative evidence of their adherence to missions. Ask customers and other suppliers. Check to see if they have won industry awards or acclaim.

COMPANY HERITAGE

Similarly, spend time evaluating a company's history and heritage. Is there anything in a company's DNA that might underpin its practices and how it approaches the market? Or are there differences that could stand in the way? Perhaps a company has been purchased recently. You will want to assess how much influence the new parent company will assert over time. In addition, the nationality of the company can impact how it operates. Cultural idiosyncrasies usually affect everything from strategic decisions to day-to-day activities. Make sure you look for evidence that confirms or contradicts anticipated cultural influences.

FINANCIAL STABILITY AND MANAGEMENT OBJECTIVES

When you enter into a supplier-customer relationship, you are investing a potentially significant amount of time and money in one another. (In many ways, it's more profound than investing in a company's stock because the investment of resources is not liquid.) So it is essential to conduct a financial analysis of the other company to determine its soundness and practices. If it's a public company, you can check financials online; a private company would require a third-party report. Does it exhibit steady financial performance, or are results all over the board? Does it have the cash and resources to respond to issues, or is it debt-laden and strained? How are its accounts receivable and accounts payable trending?

In terms of management practices, there are a number of areas to investigate. How has the company dealt with problems with the FDA or the public? Does it exhibit responsibility and pursue a remedy, or is it confrontational and unresponsive?

While each situation is different, determining how a company reacts to a negative situation could shed light on how it may interact with you if a problem occurs. Risk tolerance is another issue to inquire about. Some companies are naturally risk-averse, whereas others push the envelope. Certainly, everyone follows the same FDA/ISO guidelines, but there is room for interpretation. Does the company favor a strict interpretation, or does it view the regulations more aggressively? The same holds true for environmental practices. Do the companies wear the same shade of green?

Finally, it's useful to know the customer's corporate directives. Why is it entering into the relationship? Is it looking to curtail headcount? Focus on fewer vendors? Remove noncore capacities? Limit capital expenditures? Drive down costs to go head to head with an aggressive competitor? Knowing a company's motivation can help the contract manufacturer identify product or process improvements that will be congruent with the customer's long-term objectives.

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INNOVATION AND TECHNOLOGY

Almost all companies claim to be innovative and advanced, especially in the medical device business. But how truly innovative are they? Are they product technology leaders or followers? How advanced are their quality practices? How about the software and tools that they use? A wide difference between levels of innovation can cause frustration on both sides of the equation. Perhaps the contract manufacturer has ideas on how to improve a product design. A customer unwilling to consider improvements or collaborate because of its deficiencies could fuel friction and misunderstanding between the parties.

COMPATIBILITY AT PARALLEL LEVELS OF THE ORGANIZATION

The contract manufacturing relationship works best when professional counterparts at each company communicate openly and completely. Engineers should talk with engineers; quality managers should talk with quality managers. It allows information to be disseminated among each party's project team members to better articulate and understand expectations and issues. It is imperative to look for problems within an organization that might impair communication between two companies. Maybe it is an individual who disrupts or bottlenecks information flow. Or it could be an inadequacy in one company's area of expertise that might cause uncertainty. The contract manufacturing arrangement succeeds with transparency and openness. Treating one another as equal colleagues can eliminate contention and conflict.

PERSONAL OBJECTIVES

One can't forget that people are at the heart of any supplier-purchaser relationship. Each of us brings personal objectives to the table. It can be helpful to ask what specific goals the individual has for his or her department or personal career. Will successful completion of a project lead to someone's promotion? Is an individual awarded a bonus based on his or her ability to control costs?

Knowing personal motivations upon entering a relationship can help you prepare for and address expectations that will never appear in the specifications or supplier agreement. And by helping someone realize his or her personal objectives, you can forge a stronger long-term relationship based on trust.

CONCLUSION

Subjective matters will always play an important role beyond the objective measures of quality audits. Cultural audits provide a framework for establishing parameters and expectations of the relationship. Early on, cultural audits force both parties to address potentially contentious issues as well as identify areas where they can collaborate more readily and efficiently. They give you a measure of assurance about how a company and its representatives will react to problems and opportunities.

Cultural audits compel participants to deal with the human aspect of the relationship – something that is an unavoidable fact of business. They help assess the competence, dedication and passion that each party brings to the table. Just because these qualities aren't measurable doesn't mean they're irrelevant. In many ways, they're every bit as crucial.

How B. Braun OEM Division can be a resource

As a major medical device manufacturer, B. Braun has extensive resources throughout the organization – experts in engineering, materials, project management, packaging, quality systems, regulatory support and more. The B. Braun OEM Division can apply the organization's wide-ranging expertise to your contract manufacturing projects.

Because we're a full-service outsourcing partner, B. Braun OEM Division approaches projects with the same standards and quality that we apply to end-products that carry the B. Braun logo. By fostering strong, mutually beneficial relationships, we are capable of managing a variety of intricate projects including device and kit assembly.

Contact us at (610) 691-6785 or visit bbraunoem.com to learn more about our capabilities and schedule an introductory discussion about an upcoming project.

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