

For Life Science Professionals



19 Key Elements to Review for Effective Audits

by Dr. George L. Harris, DBA, CPM, CPCM, President, Calyptus Consulting Group, Inc.

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Background

Manufacturing organizations on a global scale have instituted ways of qualifying suppliers to ensure that their capabilities have been verified. The types of qualification methods used are multifold. Some include quality and business system components that are essential for effective production or service rendering. Others may simply focus on quality characteristics, and still others may only consider production and equipment capabilities. More effective methods, however, include a combination of business, production, service, and quality factors to provide a holistic impression of the supplier's organization. These factors play a critical role in providing excellent customer service.

The problem with many supplier assessment tools is that they only look at what is presently being implemented and can't readily be used to predict future performance. Typically, the buying organization requests copies of quality procedures, defines how suppliers are qualified, reviews how products and services are accepted, evaluates quality and delivery performance data, and reviews process improvement and corrective/preventive action plans. Other activities might include evaluating financial reports, interviewing management staff, and reaching out to customers for references on past performance. A holistic approach is needed. A set of nineteen elements are included in the best practice assessment recommended within this article. In addition, an evaluation process will be described. This type of evaluation process can ensure that assessment work can provide information on both the supplier's present condition and its future ability to meet the buyer's requirements.

Supplier assessment tools that look only at what is being implemented at the present time can't be used to predict future performance.

The Assessment Tool

The tool that will help you assess your suppliers can be categorized into four levels and 19 elements. These elements should be described in full detail. Included in the description should be a definition of each element will be rated. A four-level assessment rating is recommended, based on the following:

Level 1

- The supplier(s) has just begun documenting the key processes and has not formally started tracking performance. There are only anecdotal examples of success and performance

Level 2

- The supplier has documented the process and procedures are in place. The supplier is beginning to track performance and has only a few examples of process improvement.

Level 3

- The supplier has implemented policies and procedures, is tracking progress, and is creating preventive action to improve performance.

Level 4

- The supplier has created a continuous improvement environment and is viewed as a best practice organization for this element.

Some suppliers are ISO-9000 series certified and will have documented procedures. Excellent firms will exhibit Level 3 performance in all of the areas of the assessment. If they don't, buyers should work with the supplier to implement changes to move beyond Level 2.

Organizations pick where they want to focus for excellence, so it is likely that your suppliers will exhibit a range of performance in the levels described. It is a good idea to have the supplier(s) complete a self-assessment and provide the feedback to the buyer for initial evaluation. More on the evaluation process follows later in this article.

The Nineteen Key Elements

The elements aspect of the assessment tool introduced in this article are described below. There may be a need to either revise the descriptions/requirements or eliminate some of the elements based on the nature of your industry, your market, and the types of suppliers that you are assessing.

1. Management	The supplier has documented quality and business policies and objectives and can prove desired results. The organizational structure includes roles and responsibilities needed to implement the policy and achieve stated objectives.	<i>This is important for all suppliers.</i>
2. Quality and Business System	The supplier has documented the quality system used to govern the management of quality and has documented the business system that includes quality and operational performance measures.	<i>This is important for all suppliers.</i>
3. Product and Service Design Control	A formal service and product system is in place to document customer requirements and to assess the ability of products and services to meet these requirements. Suppliers should be an integral part of the system and provide feedback on performance.	<i>This is important when there are ongoing changes to customer requirements and supplier specifications and statements of work.</i>
4. Change Control	The supplier should have a method to manage changes to production drawings, manufacturing methods, and service tasks creating a consistent and accurate process ensuring that only the most recent version is used. Roles and responsibilities must be in place as well as a procedure to be followed for all proposed and approved changes.	<i>This is especially important for manufactured items, and for repetitive services performed in many locations.</i>
5. Supply Management	A supply management plan must be in place to ensure conformance to requirements and process improvement. This includes the ability of the supplier to manage its sub-tier suppliers. There should be a documented supplier improvement program and total costs should be tracked.	<i>This is very important for distributors and suppliers with raw material and complex supply chains.</i>
6. Process Control	The supplier uses control plans and flowcharts to detail the quality planning activities required to ensure conformance to requirements. This includes preventive maintenance, use of statistical control methods, and operator/provider instructions.	<i>This is essential for when there are difficult and complex processes to be followed. Some form of this element should be required for all suppliers.</i>
7. Inspection and Testing	Products and services should be inspected and approved by the staff performing the activities. Adequate tests and assessments are in place to ensure that the supplier is meeting or has met the buyer's requirements. Statistics are used to evaluate performance and to support continuous improvement.	<i>This is important for all suppliers.</i>

8. Control of Test Equipment and Test Methodology	The supplier should have a documented system of ensuring that tests measuring conformance to specifications and statement of work requirements are in place. This includes the calibration of test equipment, the assessment of accurate customer service surveys, and training/evaluation activities that ensure that tests are performed in a consistent and unbiased manner.	<i>This is extremely important for manufacturers.</i>
9. Material and Service Control	In all stages of production and service provision, non-conforming products and services are segregated for review and disposition is made on non-conforming products or services such as rework/re-performance, scrap or taking other similar action.	<i>This applies to all suppliers.</i>
10. Corrective and Preventive Action	There is an effective corrective action system for investigating the root cause of failures and defects and for applying preventive techniques that eliminate recurrence. Continuous improvement goals are set to accelerate implementation of corrective action and to improve system effectiveness.	<i>This is essential for all suppliers.</i>
11. Handling, Storage and Delivery	The supplier has an effective system and process for handling, storing, packaging, and shipping which ensures that shipped products or parts reflect in-process and final product quality. Audits should occur regularly to guarantee that staff and equipment are completing the stated process steps. This includes the supplier's logistics and transportation partner.	<i>This is mostly applicable to manufacturing companies.</i>
12. Training	The supplier has a training process that is effective and addresses the knowledge and skills employees need to meet their objectives as part of the company's quality and operational improvement plans. This includes plans for operator and staff certifications. The supplier should track the success of completed training in creating new and desired behavior and performance.	<i>This is essential for all suppliers.</i>
13. Results	The supplier should have achieved substantial quality and business results in relation to both peer organizations and best-in-class performers. Performance information should be tracked and evaluated. Poor performance should be addressed by effective improvement plans.	<i>This is essential for all suppliers.</i>
14. Sufficient Resources	The organization has identified and committed the necessary human, capital, and budgetary resources to satisfy established quality and business goals. The supplier should evaluate the capacity requirements needed to support customer needs and a process should be in place to monitor and assess whether customers' demands are being met on a real-time basis.	<i>This is essential for all suppliers.</i>
15. Business Stability	The supplier possesses the financial resources, human resources, and investment funding to maintain operations over the long term. Annual goals for direct labor turnover, management staff turnover, current and quick ratio and R&D investment are a few ratios that should be used.	<i>This is essential for all suppliers.</i>
16. Flexibility	The supplier has the capacity, production and service processes, sales system, and inventory methods to provide adequate ordering and flexibility to its customers. Lead time reduction, capacity utilization improvement and inventory stocking should be used when appropriate.	<i>This is essential for all suppliers.</i>

17. Business Capability and Performance	The supplier should have achieved substantial performance in working with its customers and as a company against peers and industry leaders. The supplier should show excellent results in terms of on-time delivery, inventory turns, production and service lead time, profitability, and six sigma quality levels.	<i>This is essential for all suppliers.</i>
18. Strategic Alignment	The supplier has a published short- and long-term strategy that is consistent with the buyer's plans. This includes partnerships, technology and process sharing, R&D targets, and market penetration and growth.	<i>This is essential for all suppliers.</i>
19. Cost Reduction and Value Analysis	Management defines and documents its cost/price reduction objectives and commitments. The system identifies all internal and external costs associated with operations and includes value analysis/engineering ideas. Management should also provide information on closure of successful cost reduction and quality improvement initiatives and exhibit continuous improvement in strategic planning and tactical application.	<i>These are considerable milestones to achieve. If your suppliers consistently reach Level 3 or higher, you will experience world-class performance.</i>

Implementation

You will recognize that aspects of these elements are covered by ISO 9000 standards, Baldrige, and other quality systems criteria. In the event that you require ISO 9000 registration, revise the list to include those elements that are either incremental or are newly composed/revised requirements.

a. Initial Qualification

Use the Level 2 criteria as the base requirement for supplier qualification. Insist that all suppliers achieve this level before being able to supply products or provide services. Communicate the requirements on your company's website and provide a way for the supplier to perform a self-assessment. Request the results of this assessment and follow up with an on-site visit to validate. In the event that the supplier doesn't meet all of the qualification criteria, develop a corrective action plan for them to reach Level 2 status in all areas. You could conditionally qualify the supplier in the event that expected changes and corrective actions only require minor or immaterial adjustments.

b. Certification

Suppliers should reach Level 3 performance in all applicable elements to be certified. The implications of this certification are that the supplier can ship directly to stocking locations, and provide services without surveillance. Data on performance should be tracked in this case, so that performance can be monitored and investigated in the event that results reflect a lower status level in one or more elements.

c. Partnerships

Suppliers reaching Level 4 in the majority of elements should be considered as partner candidates. This would mean that both organizations (the manufacturer and supplier) would share new product and service ideas, cost and supply chain information and end-customer information discussions with the stated interest of mutual gains in the market.

Typical Findings

Having completed scores of supplier assessment using these elements, a number of common findings have been noted for manufacturers, service providers and distributors. When implementing, be ready to address the following areas:

- Work instructions are not available, not adequate, are not being followed, and the accompanying procedures are inadequate.
- Suppliers are not able to effectively evaluate quality due to a lack of skills, poor instructions, and the lack of a current and accurate quality status. The absence of sound quality plans will also create an impact.
- Sub-tier suppliers are not approved or monitored and non-conforming materials or services are not properly evaluated.
- Last but not least, documentation issues such as evidence of unauthorized changes, poor tracking to specifications or work statements, and the inadequate handling of customer-requested changes to standard procedures should also be a part of the checklist.

Regular Assessment and the Keys to a Successful Site Visit

Assessments should be scheduled yearly with existing suppliers in addition to when suppliers are initially qualified. The keys to a successful site visit include:

- Plan effectively before the site visit
- Involve all team members in planning and in task execution
- Control the site visit agenda
- Make necessary mid-course changes in the agenda
- Ensure that essential information is obtained during the visit
- Act as a team during the visit
- Thoroughly document findings during the site visit
- Summarize findings immediately
- Prepare a clear and accurate written report

With a clear set of elements, an effective implementation plan, and a dynamic assessment strategy, a comprehensive assessment of the supplier's capabilities can be made. In addition, the buyer will be able to predict supplier performance based on current conditions, systems in place, and future goals for continuous improvement.

Dr. George L. Harris specializes in the areas of procurement, materials management, and quality management. He has performed supply management studies for private and public sector clients such as Harley Davidson, Motorola, Rio Tinto, United Technologies Corporation, Energizer, Tyco, Texas A&M University, Bright Horizons, GSA, U.S. Army, FTA, U.S. Department of Education, and the State of Oregon Department of Human Services.

Since founding [Calyptus Consulting Group, Inc.](#), Dr. Harris has conducted more than 300 courses related to supplier management and strategic sourcing, and has prepared and implemented action plans for improvement.

Dr. Harris has directed or collaborated in the development and preparation of training materials of over 120 training programs in supply management and quality including the following subject areas:

- Supplier Management Training
- Supplier Evaluation and Selection
- Supplier Identification and Implementation
- Supplier Quality
- Strategic Sourcing
- Cost and Price Analysis
- Contract Negotiations
- Working With International Suppliers