Selecting and Partnering with a Vendor for a Qualified Software Product

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"Computer Validation Forum" discusses topics associated with computer validation in order to provide useful resources for daily work applications. It brings information regarding regulatory requirements for the validation and qualification of computerized systems.

Reader questions, comments, and suggestions are required to fulfill the objective for this column. Please send your comments to column coordinator Sharon Strause at sastrause@aol.com or to journal coordinating editor Susan Haigney at shaigney@advanstar.com.

KEY POINTS
The following key points are discussed in this article:
- Benefits, drawbacks, and concerns of developing software code in-house versus outside contractors are discussed
- Main objectives of vendor management for software development are discussed
- Types of vendor audits and their appropriate use are described
- Audit preparation is a key component to formulating a plan and maintaining control of a vendor project.

IN-HOUSE OR OUTSIDE VENDOR
Let's begin by exploring the benefits, drawbacks, and concerns of developing software code in-house versus contracting for these services from an outside vendor.

Benefits of In-House Development
In-house development provides the following:
- Defined policies
- Standard operating procedures
- Guidelines
- Accountability to senior management for the project
- Resources and budget
- Available personnel with a knowledge of the business
- Team approach for the project.

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Drawbacks of In-House Development
Drawbacks of in-house development include:
• Personnel may not be available, especially if the programming staff is smaller and focused on a particular programming language
• The technical expertise required for project may not be available
• Resources may not be used efficiently
• Long-term maintenance issue (this should be addressed carefully).

Benefits of Software Development by a Vendor
Using an outside vendor can provide the following benefits:
• Internal resource availability
• Technical matter experts availability
• Experience with multiple implementation approaches
• Expertise and knowledge.

Drawbacks of Software Development by a Vendor
The following are some drawbacks to using a vendor for software development:
• Not accountable to company management (just what is in the contract)
• Delays due to communication, lack of knowledge of company policies and procedures, conflicts with their own policies and procedures, or lack of knowledge of company operations
• Budget and resources may be fixed (dependent on contract terms)
• Team approach may not be evident (i.e., we versus them).

Company Concerns with Vendor
Companies do have concerns with vendors that need to be addressed as a part of any contract, but they also play a role in determining whether an outside vendor will be utilized. Concerns include the following:
• Determining that the vendor has the personnel with the expertise required
• How will the project be communicated so that all parties understand their roles?
• Can the vendor work independently or will they require constant communication?
• Can the vendor deliver a functioning system within the time and budget and meet all the internal quality assurance (QA) standards required for the project?
• What about the accountability level?

Vendor Concerns with the Company
A vendor may have its own concerns, as follows:
• Can the project be completed on time and meet the terms of the contract?
• Who will coordinate the plan and keep work in the pipeline assuring that procedures, guidelines, and regulatory requirements are met?
• A vendor has multiple clients and must be able to service all of them, which means the vendor needs to be flexible to meet different standards and requirements as well as regulatory expectations.

OBJECTIVES FOR UTILIZING A VENDOR FOR SOFTWARE DEVELOPMENT
Now that we’ve seen both sides of the argument for software development, let’s determine what actions would be necessary to utilize an outside vendor for software development, rather than doing that work in-house.

The following are four main objectives of vendor management for software:
• Selecting the right vendor
• Working with the chosen vendor
• Keeping control of a software development project (who does what?)
• Developing a vendor partnership.

Selecting the Right Vendor
There are a few ways to approach finding a qualified vendor. First check within your own company to see what other vendors have been utilized and the lessons learned from that company’s contract. Second, check with affiliate organizations, like the American Society for Quality or the Parenteral Drug Association. Third, you can use industry networking resources or industry publications and journals. Fourth, you can ask other vendors for recommendations.

Once you’ve chosen the vendor, it’s time to audit a vendor. The following are three types of audits that you should use with a vendor:
• Pre-selection audit. This audit determines who the vendor will be based on a set of criteria.
• In-process audit. This audit determines how the contact, communication, and coding are proceeding.
• Post-development audit. This audit determines maintenance requirements.

Working with the Chosen Vendor
Once a vendor has been chosen, a contract should be developed between the vendor and the company. The contract should include the following:
The contract should be formal and signed before the work starts. Usually this is a normal function of the vendor management process and purchasing control.

- The contract should have terms and conditions (i.e., type of service, identification of deliverables and associated timelines, requirements for personnel, requirements for documentation, quality and regulatory requirements, etc.).
- The contract should have a section on distribution of work (i.e., company and vendor and associated personnel at each).
- The contract should have quality checkpoints. These could be the in-process audits or documentation deliverables.
- The contract should have a cost and payment schedule.

Key vendor deliverables established as a part of the contract include the following:

- Design and development documentation. If the company is going to do the maintenance of the system, this will be critical. If the vendor were doing the maintenance, this documentation would be part of the in-process and post-development audit review.
- Test plans and results documentation. The vendor would retain this and would be reviewed by the company during the in-process audit reviews and any post-development audit reviews.
- System and user manuals with release note and quality program documentation.
- Training plan and materials. This would be developed with the company.
- Knowledge-transfer process (if maintenance is going to be the responsibility of the company).

Developing a Vendor Partnership

Developing a vendor partnership provides leveraging opportunities for the company. There can be shared work between vendor personnel and company personnel. The company doesn’t have to do extra work when the project is delivered by the vendor. The vendor does what they do best and the company does the same. Both will develop a common language for terminology and deliverables. There will be an inter-dependent work relationship, a reduction in the time needed for a project, and a reduction in the cost required for a project.

Preferred providers give support and development resources on a continuing basis. The vendor will learn the company’s environment in order to better understand the company’s business requirements. All lessons learned can be applied to future projects and especially for on-going support of the projects. A preferred provider means that the company gets “first priority” for vendor resources and a more consistent look and feel to the information management systems being utilized by the company, which is always helpful in the regulatory environment that everyone operates in today. There should be a better compatibility of the systems so that the enterprise works well and efficiently.

AUDIT REQUIREMENTS AND PREPARATION

The following are three types of audits that you should use with a vendor:

- A pre-selection audit determines who the vendor will be, based on a set of criteria
- An in-process audit monitors the contact, communication, and coding of the project
- A post-development audit determines maintenance requirements.

Preparation for All Audits

Preparation for audits is a key component to formulating a plan and maintaining control of an audit. Preparation for the three types of audits will be similar. It begins with a schedule, establishing an agenda, a date and time for the audit, the personnel involved in the audit, the requirements for review, and the audit results following completion of the audit. The requirements for review will change with each type of audit. Audits should show that the vendor is operating in a quality manner and that project deliverables are complete and accurate.

Keeping Control of a Software Development Project

It is important for the company to keep control at all times during the development project. If a good contract has been completed, this should be easy. If not, you will have missing or incomplete documentation; varying quality standards on the code itself as well as the deliverables; more in-house work will be required; and there will be some hostility between the vendor and the company because of missed deadlines, missing functionality, and a system over budget. Good project management is key to keeping control in a software development project.
Pre-Selection Audit
This audit is a critical one because it should reveal the most important areas for the company to understand regarding the usage of this vendor. It should include questions on the following:

• Vendor stability, both financial and the number of years working in the industry
• An organization chart should be requested to see where quality fits into the vendor’s management structure. Is quality a separate department or a function of one of the managers?
• Procedures covering the software development lifecycle, quality manual, quality policy, disaster recovery, document management, etc. (reviewed and assessed against the company’s procedures and regulatory requirements).
• Development methodology. How does development occur? What safeguards are in place to ensure sections of code are secure? What types of testing are completed?
• Measurement systems should be reviewed (i.e., customer issues, “bug” fixes, etc.).
• Resource availability and technical expertise. Does the vendor have enough personnel to do your project as well as others in the timelines that you require? Can you review resumes of the personnel to see what types of education and years of experience the developers of the vendor have?
• Training of the personnel. Is any regulatory training included?
• Industry knowledge or your company’s specific knowledge (you must understand what you might need to train).
• Will they fit with your company? Can you in your discussions determine whether open communication will be possible and factual information pass between the company and the vendor?

In-Process Audits
These audits are performed during the process of development. Depending on the criticality of the development, more than one audit may occur. These audits have a QA person to lead and conduct the audit, a technical specialist from the information technology department to review the technical issues, and a business person for the user needs of the code being developed. The following should be considered during an in-process audit:

• Review the deliverables for the project and any corrections. Are you staying on the established schedule or must negotiation take place? Is the documentation in place? Does the code demonstrate the user requirements?

Post-Development Audits
These audits are usually completed after the software code project has been delivered and is in place in the company. They are usually a result of either enhancement or changes that need to be completed for the code or if the vendor is providing the support of the system.

If the vendor becomes a valued partner, the audit would take place as a part of the company’s audit schedule for vendor management.

CONCLUSION
Developing a partnership with a vendor begins by selecting a qualified vendor that is determined by a pre-selection audit to ensure that the vendor is capable of providing the services you require. A partnership establishes expectations for both parties; examines methodologies for differences; identifies specific deliverables required in the contract; identifies the roles and responsibility for the work and key milestones; reviews checkpoints with key contacts for communication; and allows time for implementation, validation, and review.

Most important, however, is that the company and vendor treat each other as a valued partner working toward a common goal—a quality, regulatory secure, software development project.

REFERENCES
FDA, 21 CFR 820, Quality System Regulation, 61 Federal Register 52654, October 7, 1996. JVT