Good Contracts Lead to Good Relationships

by David A. Vogel, Ph.D.
Intertech Engineering Associates, Inc.
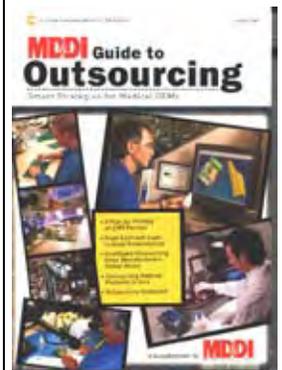
Both parties should benefit when it's time to outsource. Comparing proposals and selecting the right kind of contract are two ways companies can develop good relationships with outsourcing partners.

Medical device manufacturers might consider outsourcing product development or product testing activities for a number of reasons. In general, if an outsource provider has specific experience that you lack, has more resources available, or doesn't carry all the overhead of a large corporation, then you may be better off outsourcing. By outsourcing, manufacturers can often eliminate both direct and indirect development costs. These costs can add up to millions of dollars a year that could be better spent on sales, marketing, and new product development.

The first task is to develop a list of several prospective service providers. These providers should be qualified, experienced, and successful in developing products for the regulated medical device industry. The next step is to compare proposals and begin establishing relationships. To qualify an outsourcing company, it is critical to ask for documented performance data. Ask the company for customer satisfaction surveys, first-pass yield data, or on-time delivery records.

These can be used to track and assess the company's performance. Don't underestimate the importance of this task. Contract developers should also have performance goals and objectives. Be cautious if a company does not have goals, or if its goals do not appear aggressive enough. Additionally, contract service providers should have a corrective action process for continuous improvement.

Proposals should be studied carefully, and it is important that any questions be addressed early and sufficiently.

COMPANY PROFILE

Intertech Engineering Associates, Inc.

Address:	100 Lowder Brook Avenue
	Suite 2500
	Westwood, MA 02090
	www.inea.com - (781) 801-1100
Industry:	(Electro)Medical Devices
Services:	Assessments
	Training
	Consulting
	Hands-on Engineering
Skills:	Product Design
	Risk Management
	Requirements Engineering
	Electronics Development
	Software Development
	Software Verification and Validation
	Production/Quality System Software Validation

A good relationship with an outsource vendor will become more valuable as time passes. The tone of the relationship is set by the proposals and contracts between parties.

This article assumes that a technical evaluation of prospective service providers has already identified companies that are technically capable of the work to be outsourced. The focus here is on how to compare the competing proposals and how to establish good relationships through good contract practices.

Underlying all of the proposal and contract issues discussed here is the importance of clear communication between parties. It is important to avoid the tendency to make optimistic assumptions about how procedures, processes, and other details will be handled. There is no substitute for asking questions and defining the relationship to head off problems before they materialize.

Those experienced with contracts realize that there is no victory in a contract that is unbalanced in favor of one party. Good contracts are good for both parties. A medical device manufacturer wants a high-quality, reliable device developed for a fair price. A contractor wants the reputation for providing such device designs and to turn a profit.

Establish What the Contract Includes

Not all proposals are created equal. To compare proposals from several potential vendors, it is essential that they are as equivalent as possible, especially when attempting to compare the costs. Start by comparing deliverable items that will result from the project. For example, if the project is to develop software, what other documents and deliverables will you receive for the estimated or contract price of the project? Is project management included or will it be billed separately? Are there any project management deliverables such as status reports, cost reports, or project schedules? Make sure you will get the documentation you need to take over responsibility for the product design.

Determine What Assumptions Were Made

It is not unusual for project proposals to be solicited at the very early stages of product concept. Requirements and specifications are incomplete at best, yet vendors are asked to make estimates for project proposals. In the absence of good documentation, a vendor must make some assumptions. To interpret a proposal and monitor its success, it is crucial to understand the assumptions behind the estimates in the proposal. Did the vendor have assumptions about how many requirements would be needed to define the device? Were there any assumptions about the state of the documentation to be provided to the vendor? Is the vendor assuming anything about your response time to questions and issues? How many design iterations are factored into the costs? How many prototypes will be delivered? What is the vendor assuming about the schedule?

Understanding assumptions can be a key tool to help evaluate competing proposals. Additionally, monitoring the correlation between the early assumptions and the reality as it evolves can help keep a project's costs within the original estimates.

Determine What Happens if Actual Costs Exceed Estimates

Costs that exceed estimates are probably the chief concern of all companies when they embark on an outsourced development project. This potential problem is rarely addressed at the proposal phase, even though manufacturers understand that many factors could cause the project costs to exceed the projections. This article examines three reasons that costs exceed projections: changes inflicted on the project, inadvertently underestimating costs, and intentionally underestimating project costs to make the proposal more competitive.

Inflicted project change (feature creep, scope change, delays, etc.) is perhaps the most straightforward. Such changes usually are the responsibility of the client and are typically covered as such in both fixed contracts and time-and-materials contracts. The challenge arises with the difficulty in calculating the exact costs associated with these changes.

Underestimates are caused by numerous disparate reasons ranging from inexperience and optimism to unexpected problems with development tools. The categorization of honest underestimates is a little murky. It's not

competitively advantageous for a development firm to inflate its estimated costs by budgeting thousands of dollars to deal with problems that may or may not arise. Even though experience may tell the development firm that this happens with nearly every project, it would put itself at a competitive disadvantage to add this type of projected cost to the estimate. But is omitting these costs an honest underestimate? And who should be responsible for the cost overruns due to honest underestimation?

Fixed-price contracts charge a premium to cover the unexpected; it seems reasonable that the premium should be used to cover these situations. However, the fixed-price contractor often sees the situation differently. In the contractor's view, most unexpected problems tend to look like out-of-scope problems. For example, problems with development tools are out of scope because the tools are defective, not because there was a project software issue.

Time-and-materials contracts clearly put the cost responsibility for honest underestimates on the client. However, even for time-and-materials contracts, if tasks are consistently running significantly over the estimated amounts, the client should ask for some accounting for the overruns. An accounting at least provides some information to help discern between the honest underestimates and the intentional underestimates.

Intentional, competitive underestimates would seem as easy to deal with as the out-of-scope charges. Unexpected cost overruns due to intentional underestimation should be the responsibility of the contractor. Unfortunately, it is difficult to prove intent, and these kinds of overruns usually end up being misclassified as honest underestimates.

The best time to deal with competitive underestimating is during the proposal phase. Ask for detailed breakdowns of what is included in the costs. If critical tasks or deliverables are missing, challenge the contractor to provide the estimates for those items. Ask about time and budget estimates for specific task groups and compare those estimates to your own experience and to the estimates on competing proposals. The best way to flush out habitual under estimators is to ask questions and get the responses in writing.

Cost Comparison Issues

Obviously, everyone interested in outsourcing a product development project is interested in cost. Unfortunately, comparing costs is not a simple quantitative exercise. Is it better to go with a high-cost fixed-price proposal, or a low-cost but open-ended time-and-materials proposal? Even for the same contract structure, cost comparison at the proposal phase may not reflect the total project cost at the end of the project.

Without some understanding of how cost overruns are handled, there is no value in comparing the cost estimates on project proposals at all. Why would a contract developer estimate a conservatively high project cost and risk losing the project when there is no penalty for winning the contract by intentionally underestimating? Controlling cost overruns is a problem. There are legitimate reasons why costs exceed estimates and some of them may even be the fault of the client. Unfairly punishing a contractor for legitimately high costs only leads to an adversarial relationship with the contractor. Perhaps the best lesson to take from this is that comparing costs on proposals is less of an indicator of project success than other comparisons such as a company's track record, experience, or confidence in management. If a low bidder ends up being late with a product design that is also full of defects, the cost difference in the proposal will not look like much of a bargain.

Bundled Contracts that Assume Profits from Future Manufacturing Revenue

Many outsource medical product development and contract-manufacturing firms offset development costs against future earnings from the manufacturing contracts for the product. If you pay less for product development services in a bundled development and production contract, then you are probably paying more for the manufacturing component. If this is the case, then you should understand what this cost reduction costs your company over the life of the product. Then, compare that amount to production costs from a contract manufacturer that does not provide development services. Make sure you understand any contractual

commitments for manufacturing services (i.e., how long you are committed).

Explore what happens if the development team does not perform as promised. Will the developer or manufacturer be willing to bring in outside resources to finish the engineering job at the same discounted rate?

Contract Basics: Fixed-Price versus Time-and-Materials

A fixed-price contract is what its name implies. It is a contract that makes certain assumptions about the tasks to be performed and proposes a set price for work. If the assumptions are met during the execution of the contract, the price will not change, regardless of how easy or difficult the project ends up being for the contractor.

A time-and-materials contract also makes assumptions about the tasks to be performed and provides an estimate of how long the tasks will take to complete. Work is done at an agreed-upon hourly rate. If the job takes longer than estimated, you pay more than the estimated amount. If the job takes less time than estimated (and it does happen), you pay less than the estimate.

Which Style Contract is Right for You?

Fixed-price contracts usually cost more because they budget for contingencies. However, these are contingencies on the contractor's end of the project, not yours. If your company delays the project, changes responsibilities, or increases the scope of work, expect to negotiate increases to a fixed-price contract. Many fixed-price contracts end up with not-so-fixed prices. It is the contract administrator's job to manage a contingency budget for things that cost more due to the contractor's mistakes. An effective contract administrator will see most problems as out-of-scope issues.

Time-and-materials contracts, when everything else is equivalent, should either be lower in cost or should show contingency-budget line items that would make the total proposal price close to that of a fixed-price contract. If your company adds tasks to the list, you pay more. The contractor is not obligated to work to complete a project that runs beyond the estimated costs unless the client is willing to pay for the completion of the work. Clients often issue not-to-exceed (NTE) purchase orders to cover time-and-materials contracts. This is usually done so that the purchasing and payables departments know that they are not authorized to pay the contractor more than the NTE amount. Specifying an NTE amount in a time-and-materials contract should not be expected to include a guarantee of completion.

It is important to have a written agreement for how NTE purchase orders will affect the completion of a project if the NTE amount is reached or exceeded. Unless it is otherwise specified, a contractor will assume that the amount of the purchase order is not to be invoiced until the client gives authorization to do so. But the contractor assumes that authorization will be received. The client often assumes that the NTE amount acts like a fixed price. That is, if project costs exceed the NTE amount, the contractor absorbs the excess cost, but if the project costs less than the NTE amount, the client saves the difference. Therefore, it is essential to communicate clearly with the contractor and reach a mutual understanding of the fundamentals of your prospective business relationship.

Changes to the Product or Scope of Work

It is almost inevitable that there will be changes once a development project is launched. These changes could come in the form of changes to the product concept, changes in the scope of work expected from the developer, or simply changes that come about as more is understood about the product being developed. As proposals are evaluated and contracts are negotiated, establish an understanding of how these changes will be handled. How will the costs for changes be covered? What are the expectations for the project schedule? Whose responsibility is it to communicate project-effect analyses in the face of change?

Fixed-price contract structures deal with project changes as a series of change orders to the original contract. Time-and-materials contracts have more flexibility for dealing with change but, unless specifically requested, the cost of changes is not likely to be singled out for identification.

Intertech
ENGINEERING ASSOCIATES, INC.

Understand Expected Commitments

Once a project has begun, any number of events can result in the postponement or termination of the project. Delays or cancellations would obviously have a negative financial effect on the outsource contractor. Many vendors protect themselves with contracts that impose penalties for premature cancellation and that include provisions for paying for idle time if a project is delayed. There may be costs associated with restarting a stalled project, and a contractor may not provide a guarantee that a project can be restarted immediately. Few outsource vendors can survive financially with clients that start and stop projects at will. It is essential to understand up front any flexibility you have in turning resources on and off.

Finishing the Job

Not all outsource companies will stay with a job until it is complete. This seems to be one of the two dirty little secrets of the industry: Even when you have worked out all the cost overrun and out-of-scope payment issues (i.e., the contractor is being paid for the work), there is a tendency for development firms, especially independent contractors, to hitch up with the next rising-star project at the expense of a project they are nearly finished with. Contractually, this will probably be a difficult issue, because contracts are generally worded to exist over well-defined periods of time (i.e., the term of the contract) and also are drafted with well-defined terminology (e.g., project completion).

Unfortunately, design and development problems often do not fit these parameters well. It may never be proved that there are no remaining design defects in a product, nor can it be predicted when they will surface if they do exist. Perhaps the best strategy for addressing this issue is to examine the track record of all prospective vendors.

Intellectual Property

Unless you are specific about intellectual property in your contract, you may not end up with exclusive rights to the technology the development firm has created for you. This is the second dirty little secret of the industry. Many outsource companies like to reuse hardware and

software building blocks from project to project. This kind of rationale is more common among development firms that are also manufacturers than it is among those that are involved only in development projects.

The reasoning is that if designs can be reused from project to project, it keeps the costs down and reduces the time to market. The problem with this is that the software you paid to develop could be reused on the next project the developer works on, thus reducing its costs at your expense. Or the software and hardware designs embedded in your device may have been developed at another client's expense. The similarity of the designs could cause legal problems. The former client could sue for having part of its design embedded in your company's device.

This problem can be handled easily by requiring full exclusive ownership of all design and development outputs. Although it is redundant, a contract could also specify that all designs and developments for the project should be original work, not recycled work.

Conclusion

The proposals and contracts between parties can set the tone of an outsourcing relationship. Comparing proposals and selecting the right type of contract is essential to establishing a good long-term relationship.

Design and development is not a perfect science that proceeds without some mistakes, misjudgments, or unexpected turns in a project. Understand this up front. Design contracts allow for the realities of product development. Do not create a contractual atmosphere in which either party feels that mistakes need to be hidden or covered up. In the long run, that is not good for the product or the relationship. If and when things do go wrong, and they will, communicate early and often.

ABOUT THE AUTHOR:

David Vogel is the founder and president of Intertech Engineering Associates, Inc.

Dr. Vogel was a participant in a joint AAMI/FDA workgroup to develop a standard for Critical Device Software Validation which was subsequently included in the IEC 62304 Software Lifecycle Standard. He was also a participant on the joint AAMI/FDA workgroup to develop a Technical Information Report (TIR) for Medical Device Software Risk Management. Currently, Dr. Vogel is a member of the AAMI/FDA workgroup developing a TIR on Quality System Software Validation.

A frequent lecturer for workshops and seminars on topics related to medical device development and validation, Dr. Vogel also is the author of numerous publications and holds several patents.

Dr. Vogel received a bachelor's degree in electrical engineering from Massachusetts Institute of Technology. He earned a master's degree in biomedical engineering, a master's degree in electrical and computer engineering, and a doctorate in biomedical engineering from the University of Michigan.

Intertech Service Offerings:

Risk Analysis and Management
Software Design and Development
Electronic Design and Development
Requirements Development and Management
Documentation and Traceability
Verification and Validation
Evaluations, Reviews, Inspections
Planning
Project Management
Compliance Consulting and Training
Manufacturing and Quality System Software Validation

Leverage INTERTECH's expertise to:

> *Reduce Project Risk*
> *Shorten Time to Market*
> *Cut Development and Test Cost*
> *Assure Quality Products*

ABOUT INTERTECH:

Intertech Engineering Associates has been helping medical device manufacturers bring their products to market since 1982. Through a distinct top-down service model, Intertech offers high-level consulting and hands-on engineering. By balancing technical expertise and practical business experience, we support clients through all phases of product development. While we do make your job easier, Intertech exists not to replace but to partner with clients to help balance the concerns of quality, time and cost.

With considerable experience in FDA regulatory compliance, our time-tested development process can anticipate and solve problems inexpensively on the planning board rather than through costly solutions later in the development, test, or post-deployment phases. By using deliberate processes, Intertech ensures an improvement in quality and can build client expertise.

Call us today for more information or a free consultation at 781.801.1100

INTERTECH Engineering Associates, Inc.
100 Lowder Brook Drive Suite 2500 Westwood, MA 02090 USA

www.inea.com - info@inea.com - Tel: (781) 801-1100 - Fax: (781) 801-1108