Survey Results on Selecting Outside Consultants

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Survey Results

• 16 question survey
• 228 respondents as of April 19, 2007
• <50 to >10,000 employees
What Is the Internal Process for Requesting the Services of a Consultant?

- Annual Budget
- Dept. Hd. Requests
- Dept. Hd. Decides
Additional Comments

• SOP
  – Determine need
  – Ensure funds are budgeted
  – Approach management
  – Follow procedure for selecting consultant with appropriate qualifications

• Management initiative: gives access to experts before a significant problem arises.*
What Is the Process for Locating an Outside Consultant?

- Ref From Assn
- Ref From Firm
- Former FDA Staff
- Google
- RAPS Directory
Additional Comments

• Use former employees as consultants
• Hire consultants that we used
• Have a list of approved consultants
• Get referrals from former consultants
• Use MDDI Directory
• Use Compliance-Alliance
What Sources Do You Check before Hiring a Consultant?

- Other Firms
- Trade Assn
- 483s/WLs for Consultant
- 483s/WLs for Clients
Additional Comments

- FDA Debarment List
- Reference from lawyers or other consultants
- Certifications
- Published articles or speeches at conferences
Additional Comments

• Ask questions to determine if the person:
  • Understands the technology
  • Has experience in this situation
  • Will work on your agenda, not their own or a canned approach
  • Is a problem solver or a problem maker
**Additional Comments**

- Also determine if the person will work on the firm’s timeline in terms of:
  - Accessible when you need them
  - Devoting the necessary time to the project
  - Is willing not only to provide guidance but also participate in the tasks
Do You Have an Approved Supplier List?

Yes

No
What Is the Process for Getting on List?

• Have SOP compliant with ISO 13485
• Obtain CV
• Review track record of results with other firms
• Check liquidity (Dunn &Bradstreet)
• Perform background check
• Check certifications/licenses
• Obtain a confidentiality agreement
• Negotiate a contract
• Obtain non-disclosure agreement
What Is the Process for Getting on the List ? (continued)

• Approvals
  – Legal
  – Purchasing
  – Multifunctional team (quality, mfg engineering, purchasing)
    • Indirect sourcing group
    • Quality review board

• Added to the list
What Is the Process for Staying on the Supplier List?

• Continually monitor and evaluate performance
  – Even a good firm changes staff
    • Service they provide can deteriorate over time
    • Take on more clients than they can serve

• Hold regular meetings
  – Review status of projects
  – Track priorities and timelines
  – Develop project plans or action items

• Supplier remains on list for 2 years, then is reevaluated
How Do You Manage the Consultant?

- Liaison
- Report to CEO
Additional Comments

• Ensure staff meets consultant before contract is signed
• Allow limited access to your server
• Explain changes that may impact the project
• Provide access to staff for routine tasks
Advice

“Watch out for consultants who pad their audit observations to create a need for you to hire them to come in and fix the problem.

Make it clear that anything found during the audit will be addressed by internal resources or another 3rd party including any verification that fixes were appropriate.”
What Do You Do if a Consultant Gives You Advice That You Disagree With?

- Get a Written 2nd Opinion
- Call the FDA
- Call Association
- Ignore the Advice
Additional Comments

• Fire the consultant and get a new one
• Request supporting evidence from consultant
• Review risks to patients/customers/firm
• Consult with legal counsel
• Get a 2\textsuperscript{nd} opinion - does not need to be in writing
• Document internally
Advice

“Be wary and willing to challenge the output – some name brand consultants have inserted their personal opinion into compliance advice.”
Which of the Following Terms Are included in Your Standard Contract?

- Scope of Work
- Cost Fixed
- Time Frame
- Not to Work for Competitors
Additional Comments

• Deliverables including *written reports* and final compliance status
  – Just avoid 483
  – Good practice
  – Best practice
  – Set new standard

• Timeline (hours, weeks minimums)

• Not to exceed cost

• Indemnification
Additional Comments (continued)

- Document retention
- Who owns the work product
- How time is charged (1/2 hour, 15 minutes)
- Use of email
- Allowable expenses
  - Travel, meals (per diem)
  - Miscellaneous (phone, copies, secretary overtime, postage)
Additional Comments (continued)

• Compensation
  – Stock
  – Delayed compensation

• Payment & interest

• Terms for ending the contract
  – Notice
  – Return of documents
  – Agreement not disparage company or consultant
If You Get a Letter from FDA, How Do You Keep the Business Going as You Make Corrections?

- Appoint Team
- Hire Consultants
- Shut Down
Additional Comments

- Internal teams assigned at 40 -100% of workload
  - Existing responsibilities reduced
  - Temps brought in
  - Outside consultants provide advice to teams
  - Teams have responsibility for outcome

- Shut down until:
  - Required root causes discovered
  - Corrective actions are completed and evaluated
If You Are Subject to Regulatory Action, How Do You Get Resources from Management?

- No Action: Management Understands
- Bring in Consultant
- Show What Happened to Others
- Other
Additional Comments

• Show regulations
• Make a business case
  – Determine "cost of non-compliance"
  – Calculate the cost of COPQ
• Recruit management as active participants
What Is the Price Range for RA/QA Assistance?

- Above $351
- $301-350
- $251-300
- $201-250
- $151-200
- $100-150
What Is the Price Range for Quality Audits?

- Above $301
- $251-300
- $201-250
- $151-200
- $100-150
What Is the Price Range for Legal Advice?

- Above $501
- $451-500
- $401-451
- $351-400
- $301-350
- $251-300
- $200-$250
Conclusion

• When you bring in a consultant:
  • Understand consultant is there for advice

• You need to
  – Accept responsibility and
  – Own the result