

Survey Results on Selecting Outside Consultants

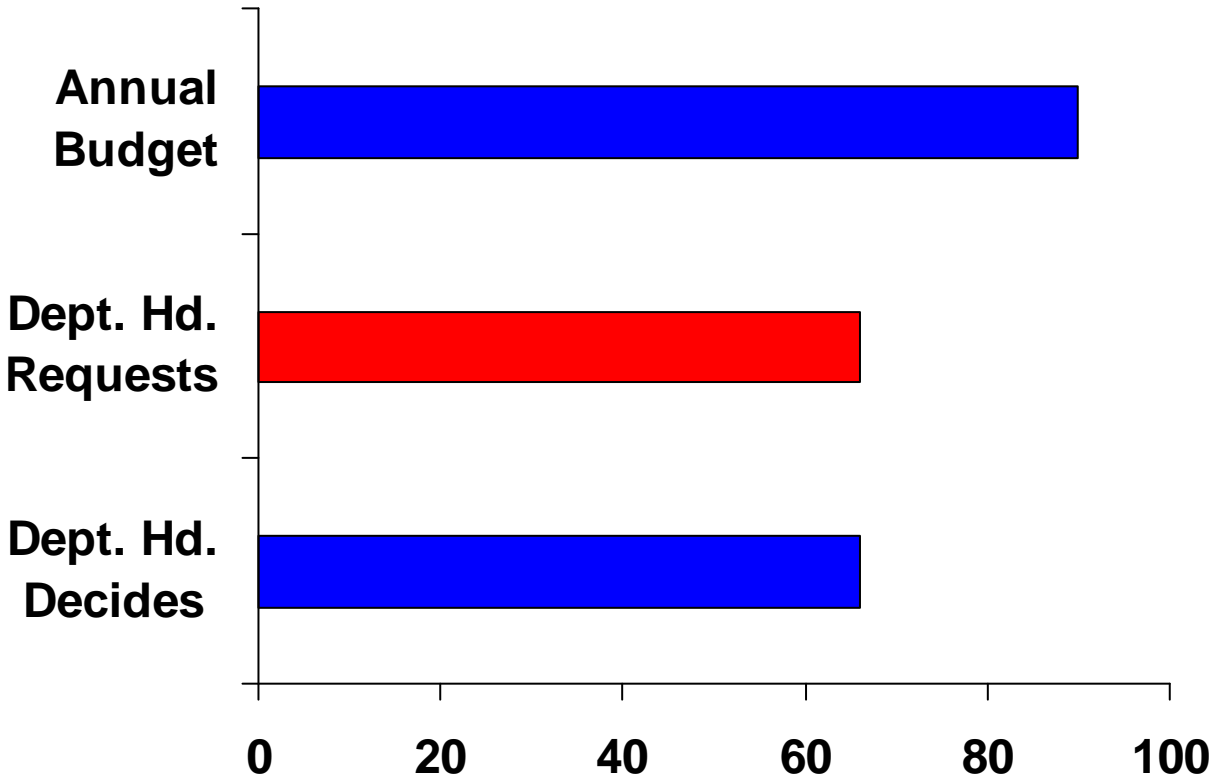
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Survey Results

- 16 question survey
- 228 respondents as of April 19, 2007
- <50 to >10,000 employees

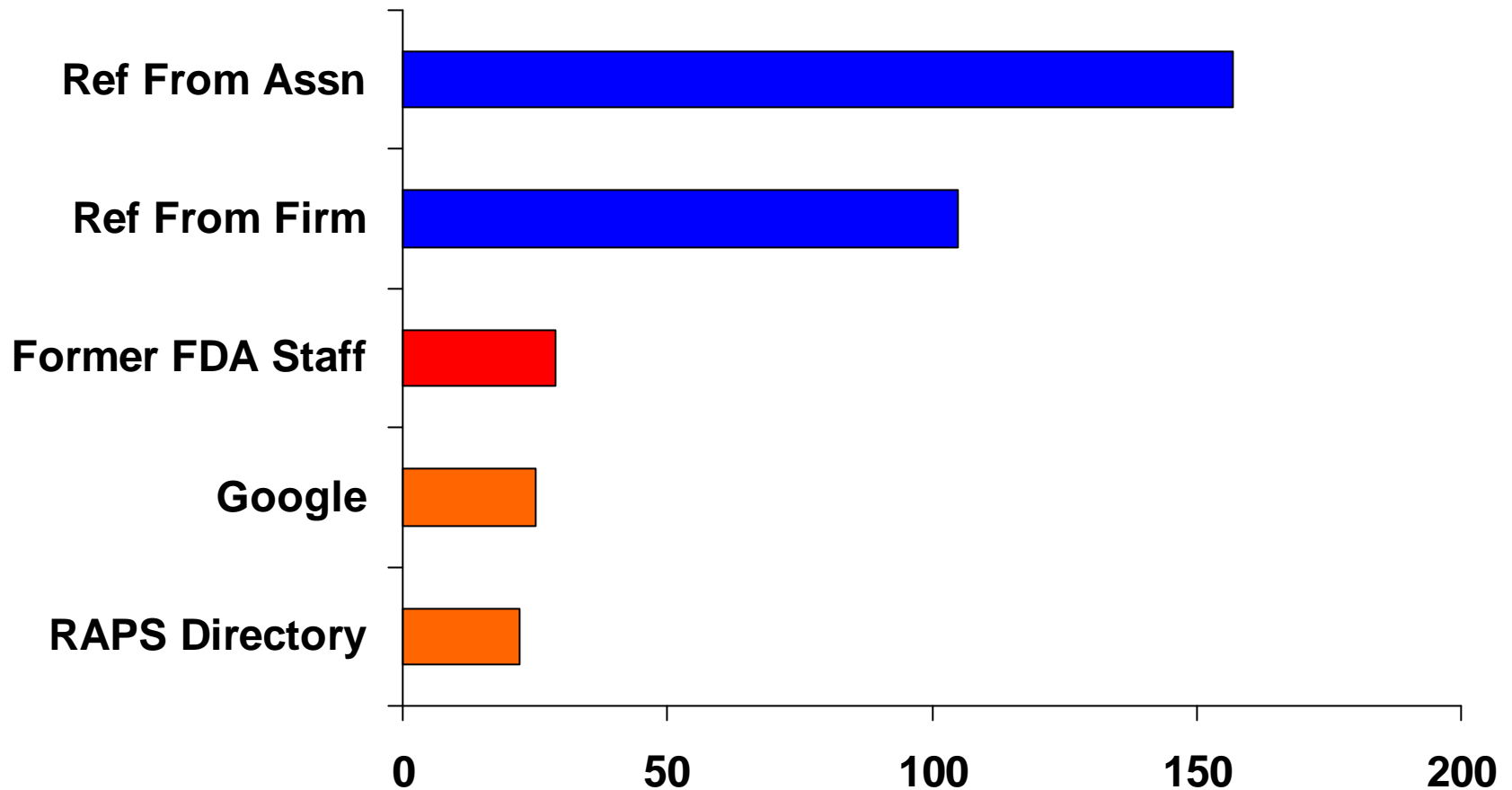
What Is the Internal Process for Requesting the Services of a Consultant?



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.*
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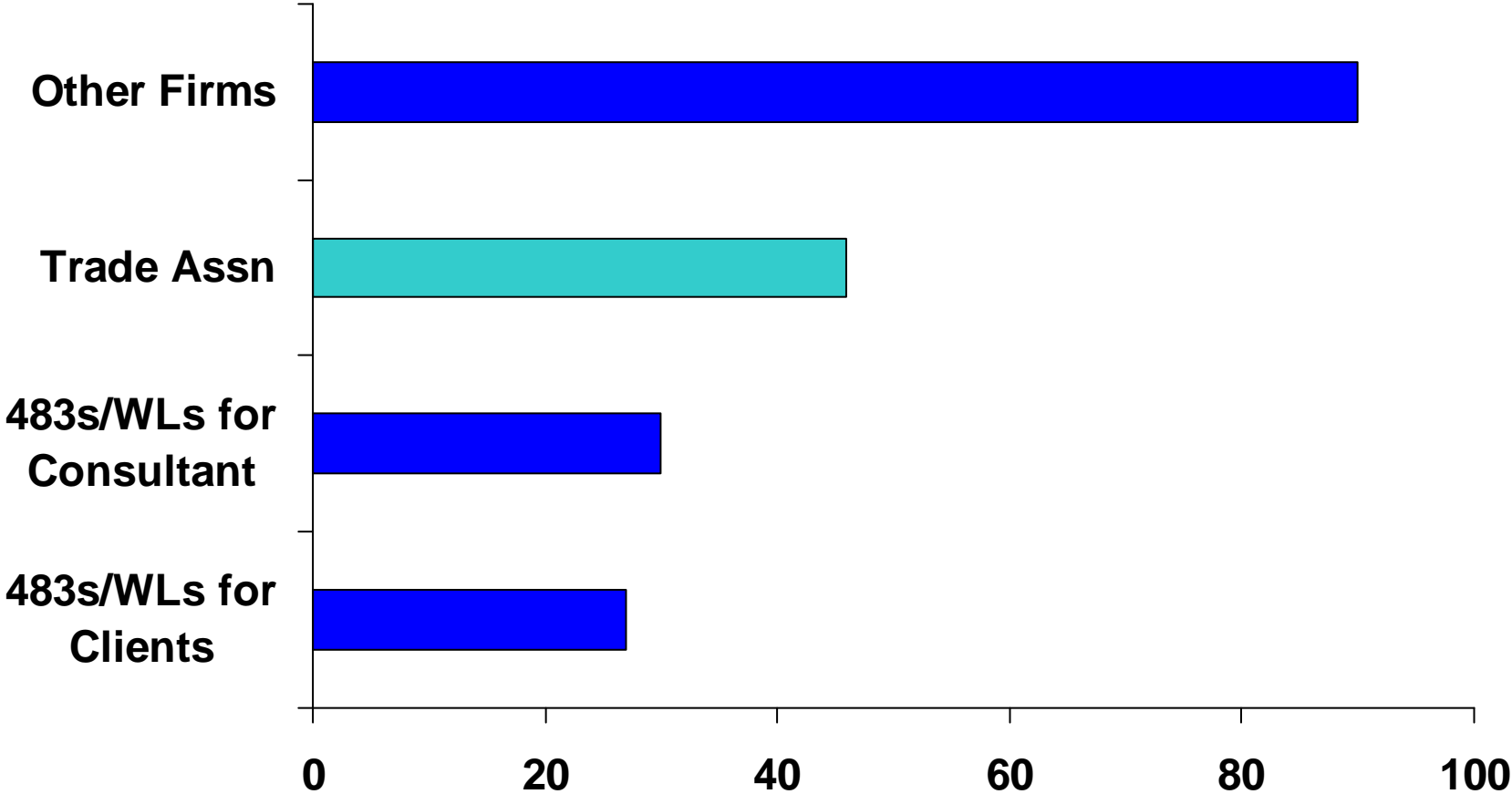
What Is the Process for Locating an Outside Consultant?



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?



Additional Comments

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

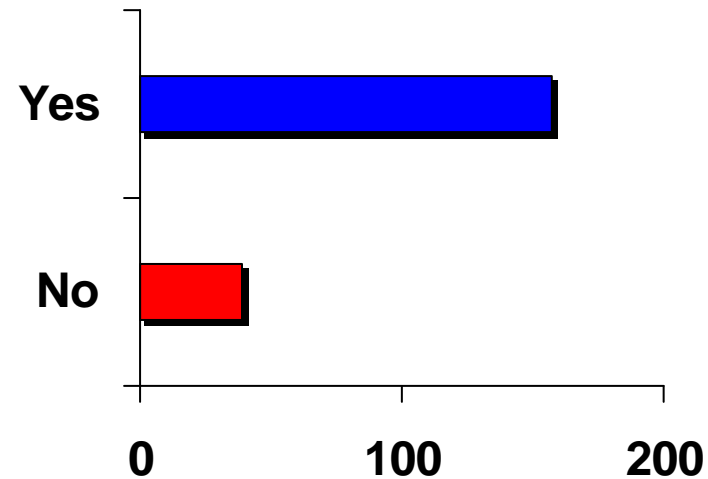
Additional Comments

- 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?



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

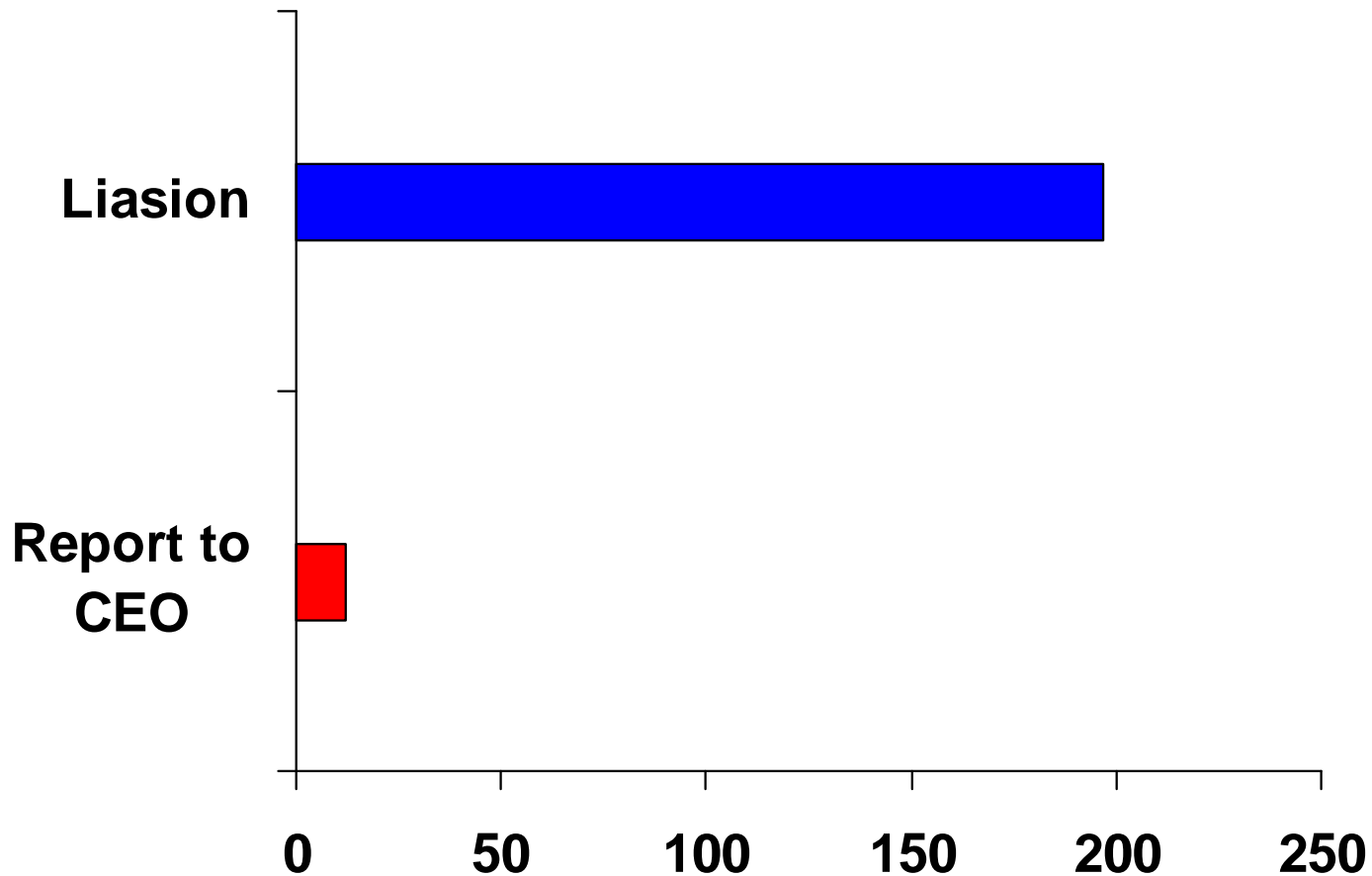
What Is the Process for Getting on the List ?(continued)

- 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?



Additional Comments

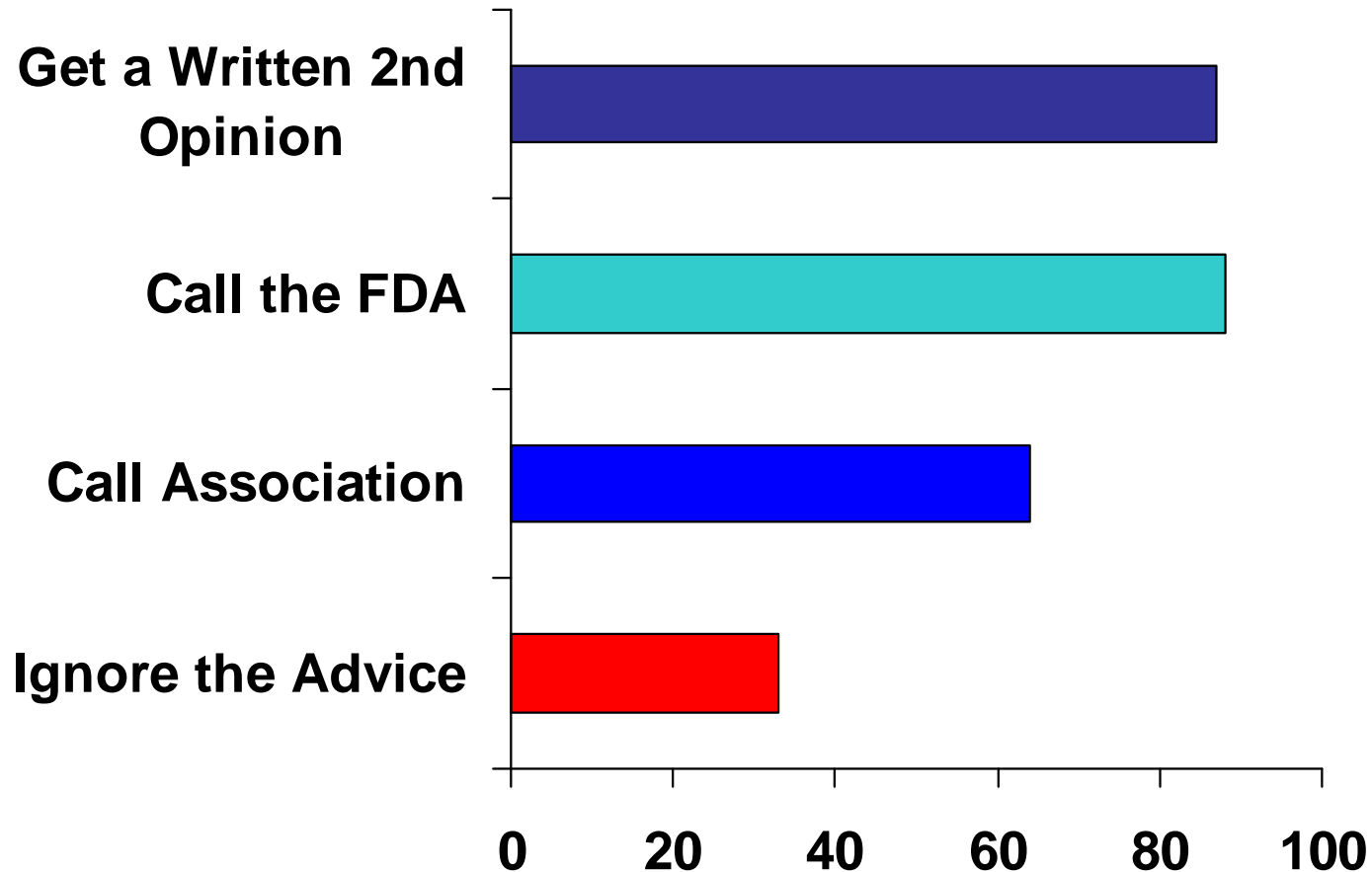
- Ensure staff meets consultant before contract is signed
- Allow limited access to your server
- Explain changes that may impact the project
- Provide access to staff for routine tasks

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?



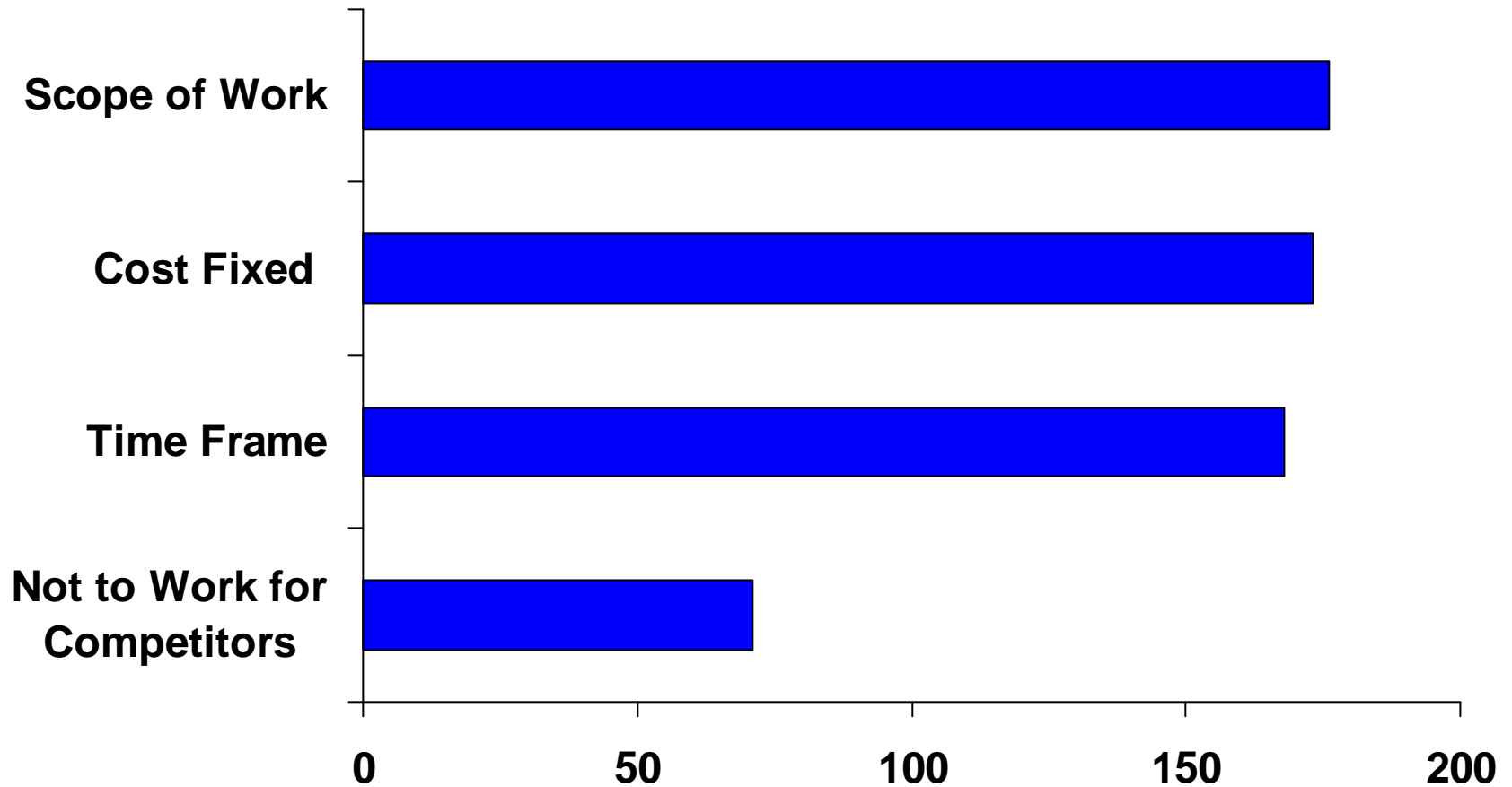
Additional Comments

- 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 2nd 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?



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

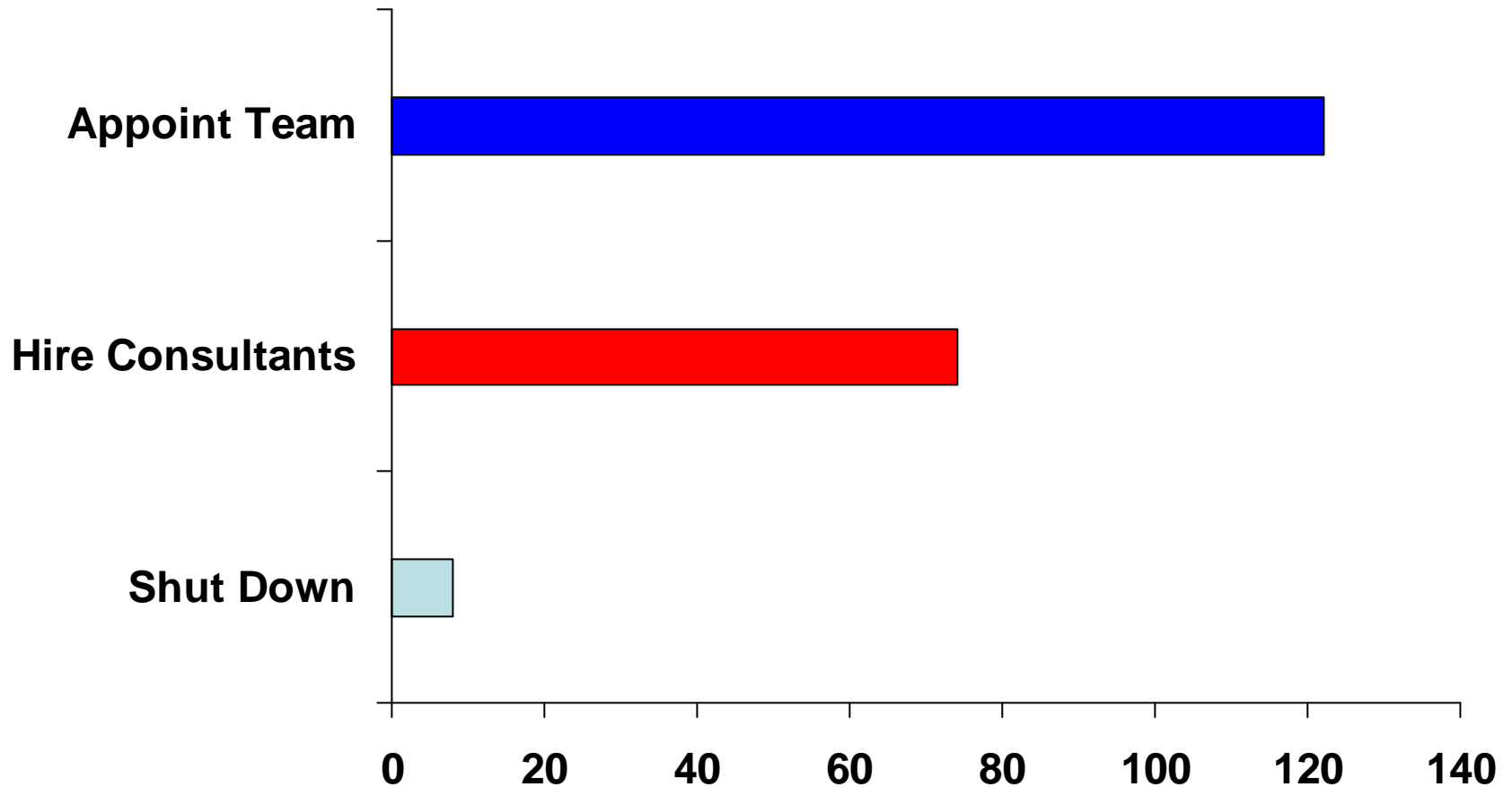
Additional Comments (continued)

- 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

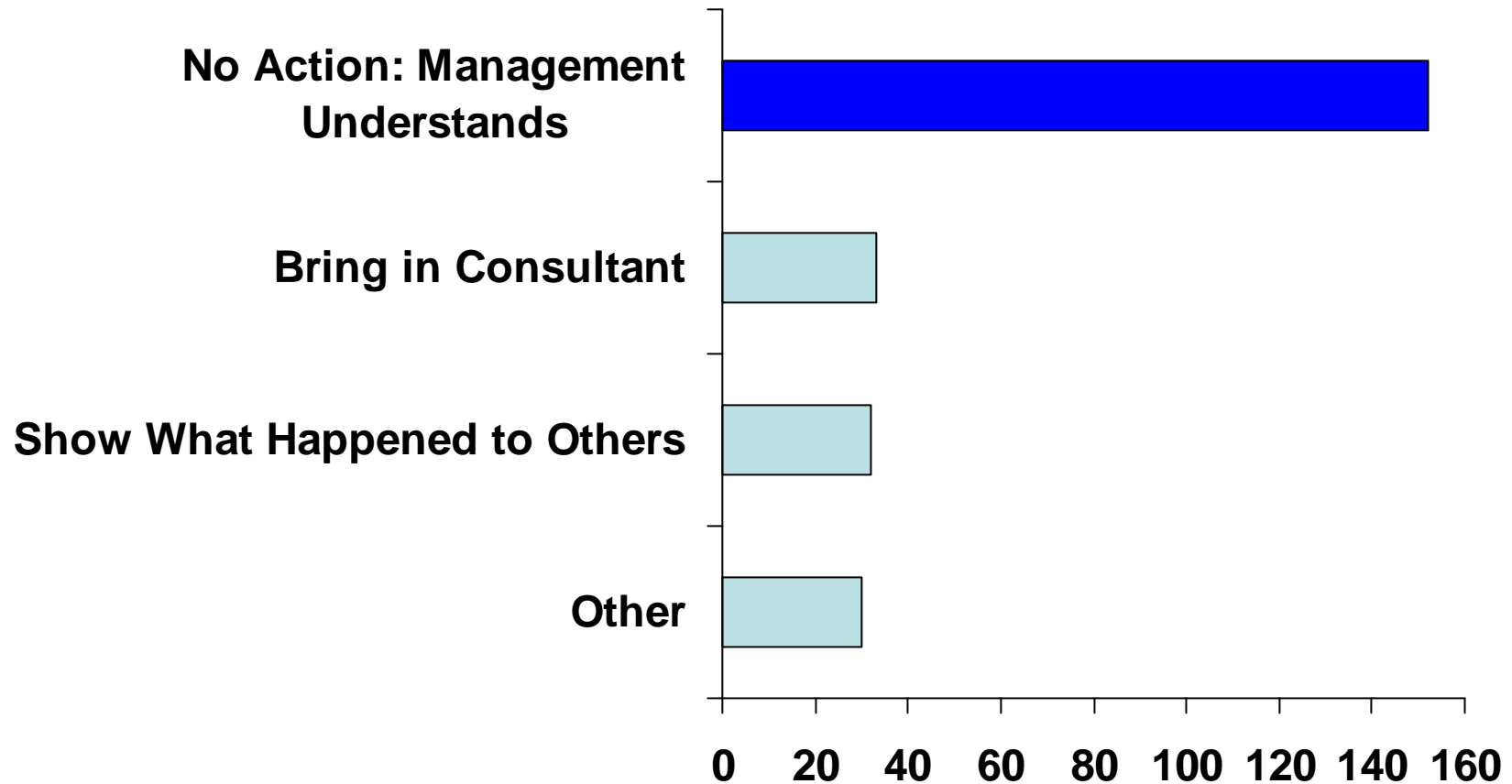
If You Get a Letter from FDA, How Do You Keep the Business Going as You Make Corrections?



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

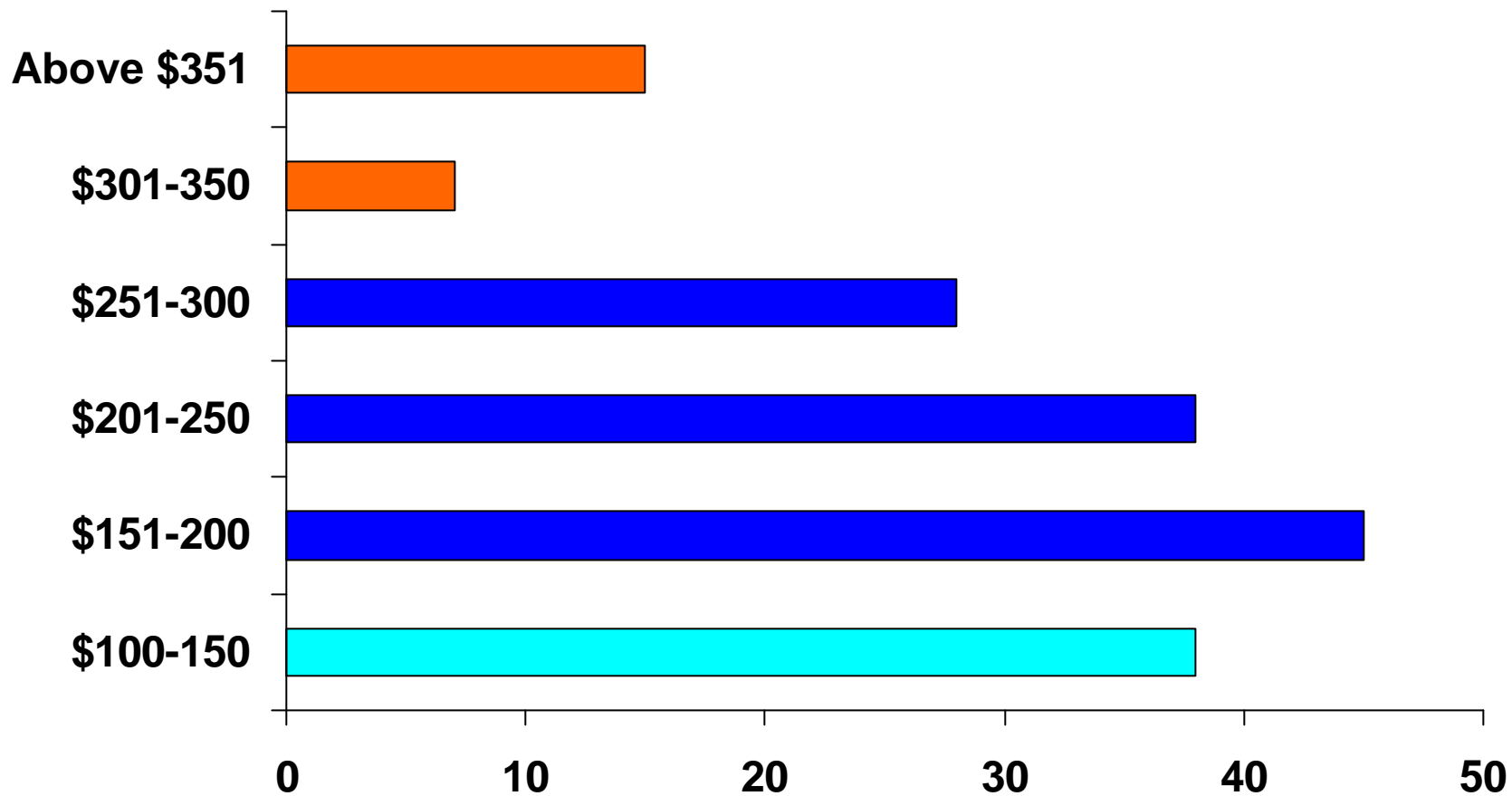
If You Are Subject to Regulatory Action, How Do You Get Resources from Management?



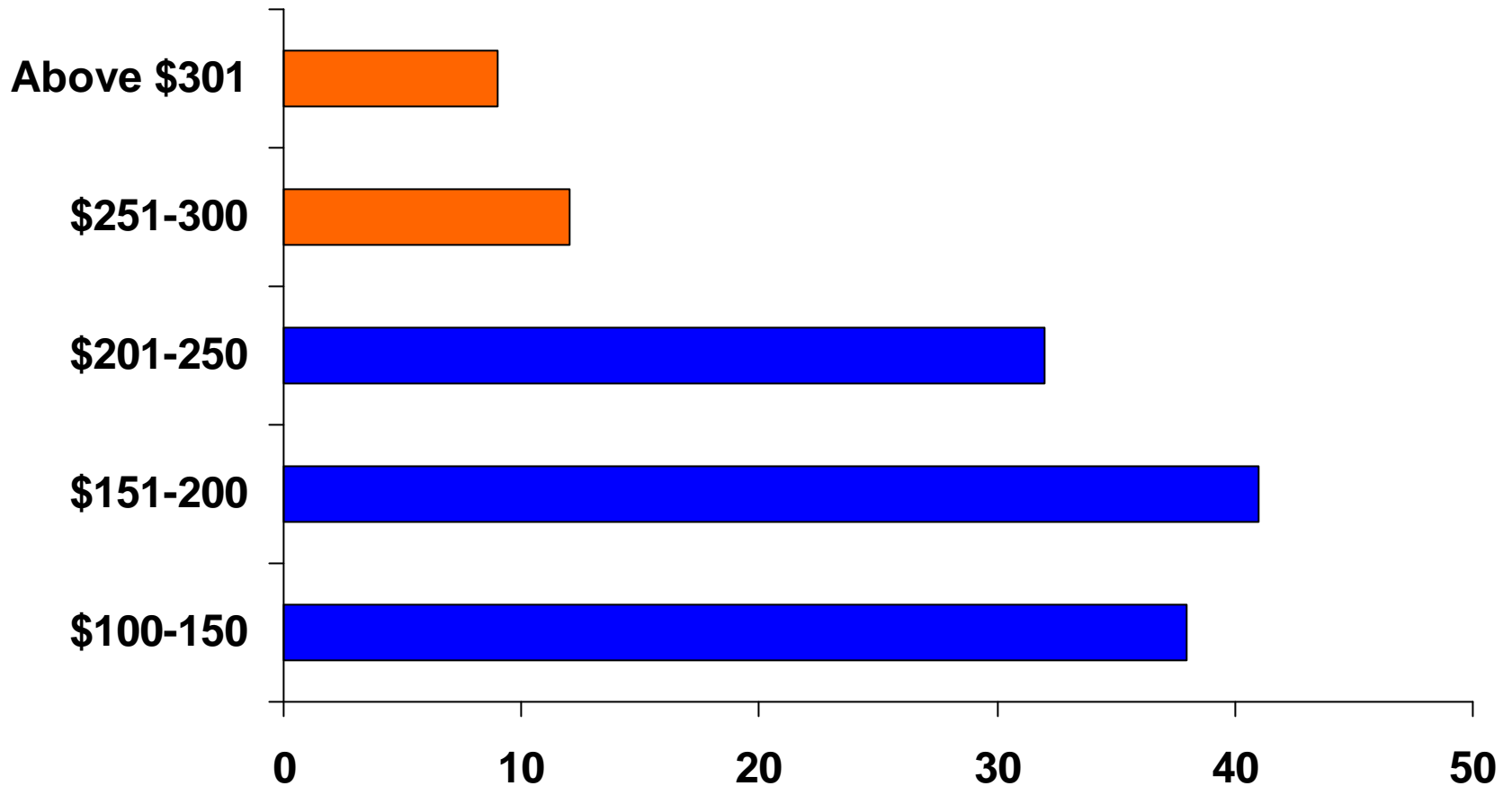
Additional Comments

- Show regulations
- Make a business case
 - Determine "cost of non-compliance"
 - Calculate the cost of COPQ
- Recruit management as active participants

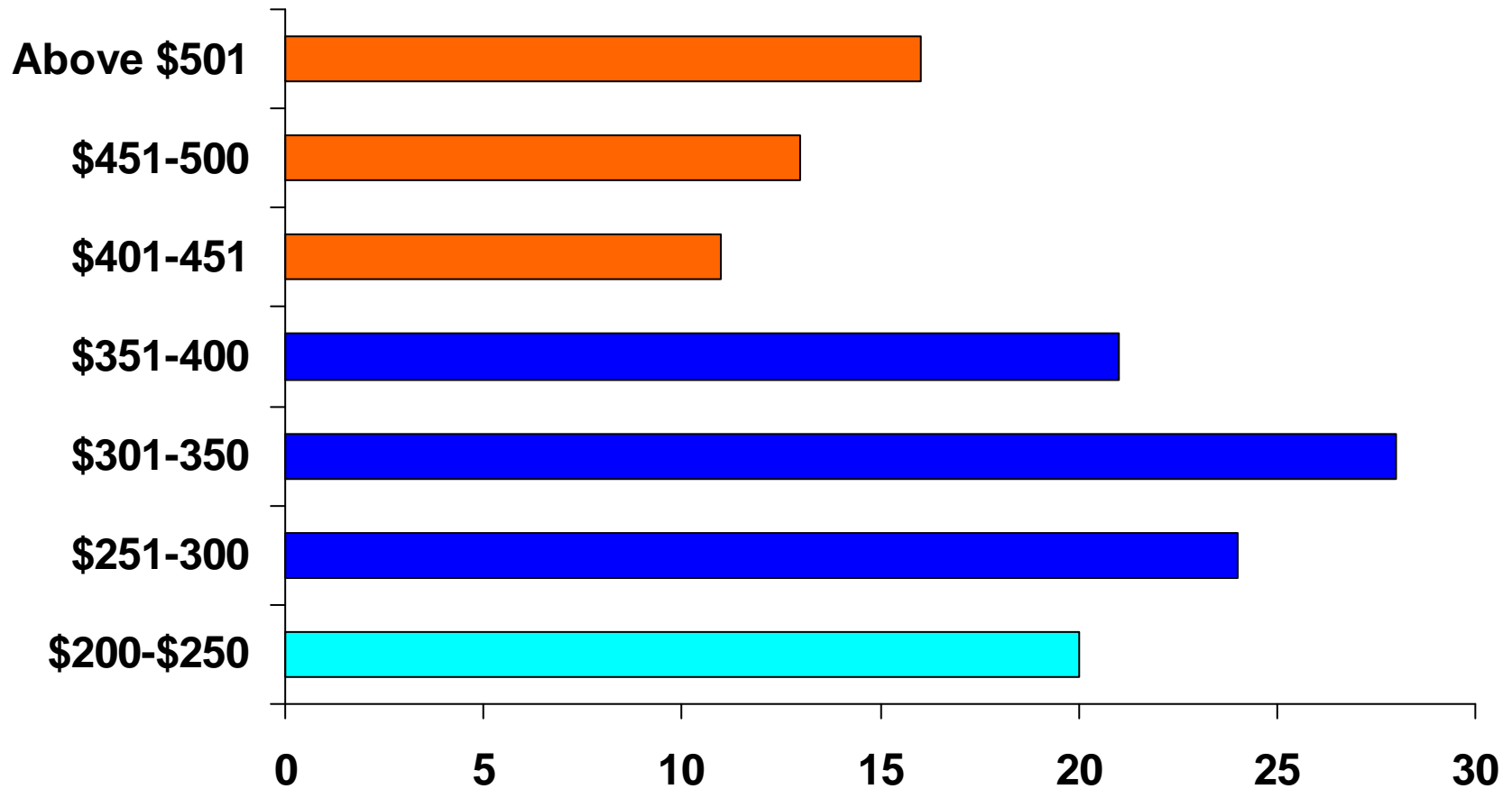
What Is the Price Range for RA/QA Assistance?



What Is the Price Range for Quality Audits?



What Is the Price Range for Legal Advice?



Conclusion

- When you bring in a consultant:
- Understand consultant is there for advice
- You need to
 - Accept responsibility and
 - Own the result