Changing Perceptions: Moving From a Necessary Evil to a Strategic Partner

Moderator

Nancy Singer, Compliance-Alliance, LLC

Panel

Monica Wilkins, Abbott Laboratories

Susan Rolih, Meridian Bioscience, Inc.

Dennis Hahn, Ethicon Endo-Surgery

Lenore Faulhaber, Procter & Gamble

Steven Binion, BD

Part 1
Survey: How to Get Buy-in for Regulatory Compliance

Background

- In 2004, Compliance-Alliance (C-A) conducted a survey on *How to Get Buy-in for Regulatory Compliance.*
- 1094 people completed the survey.
- To see if opinions had changed, in 2014 C-A redistributed the survey.
- 385 people completed the survey.

During the last 10 years, has the climate for getting buy-in for regulatory compliance:

a. Gotten better?
b. Gotten worse?
c. Stayed the same?

State your reason.

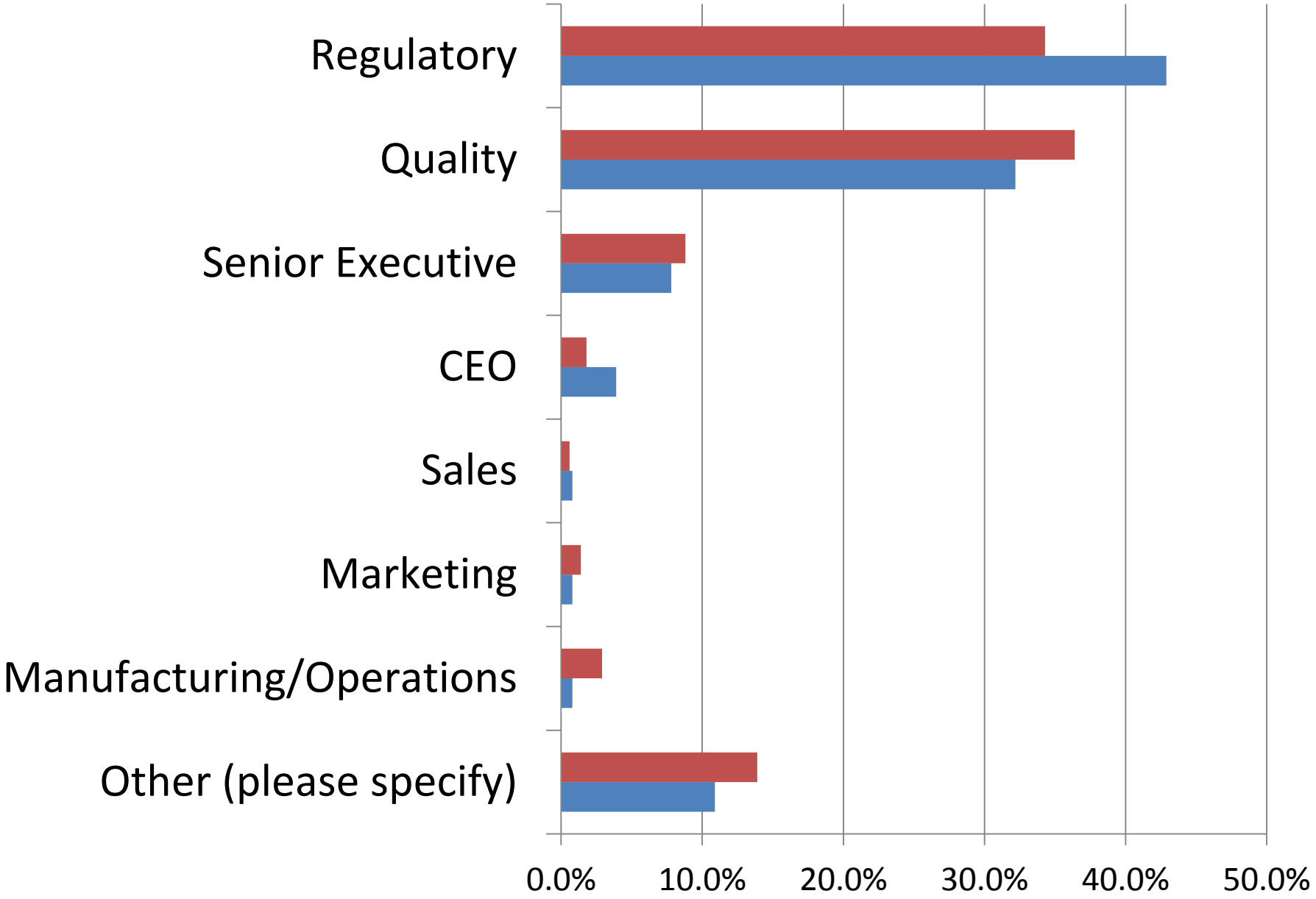
Results

- On the next series of slides, the data are displayed on a bar chart with two rows.
- The top row displays the results from the 2014 survey  .
- The bottom row displays the results from the 2004 survey  .
- Rationale: The data about today is more relevant for our discussion.

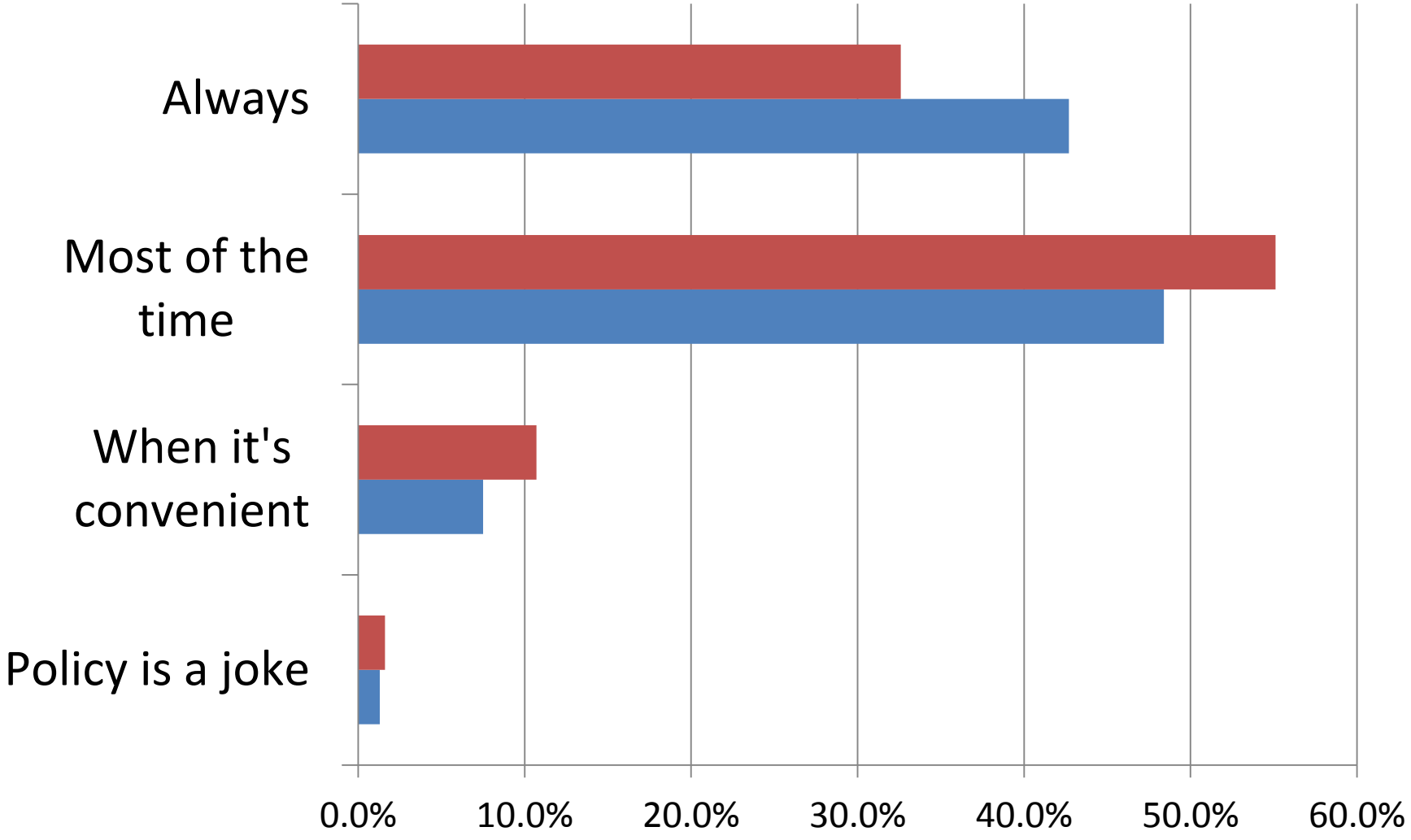
We have an expert panel to help us interpret the data:

- Monica Wilkins, Abbott Laboratories
- Susan Rolih, Meridian Bioscience, Inc.
- Dennis Hahn, Ethicon Endo-Surgery
- Lenore Faulhaber, Procter & Gamble
- Steven Binion, BD

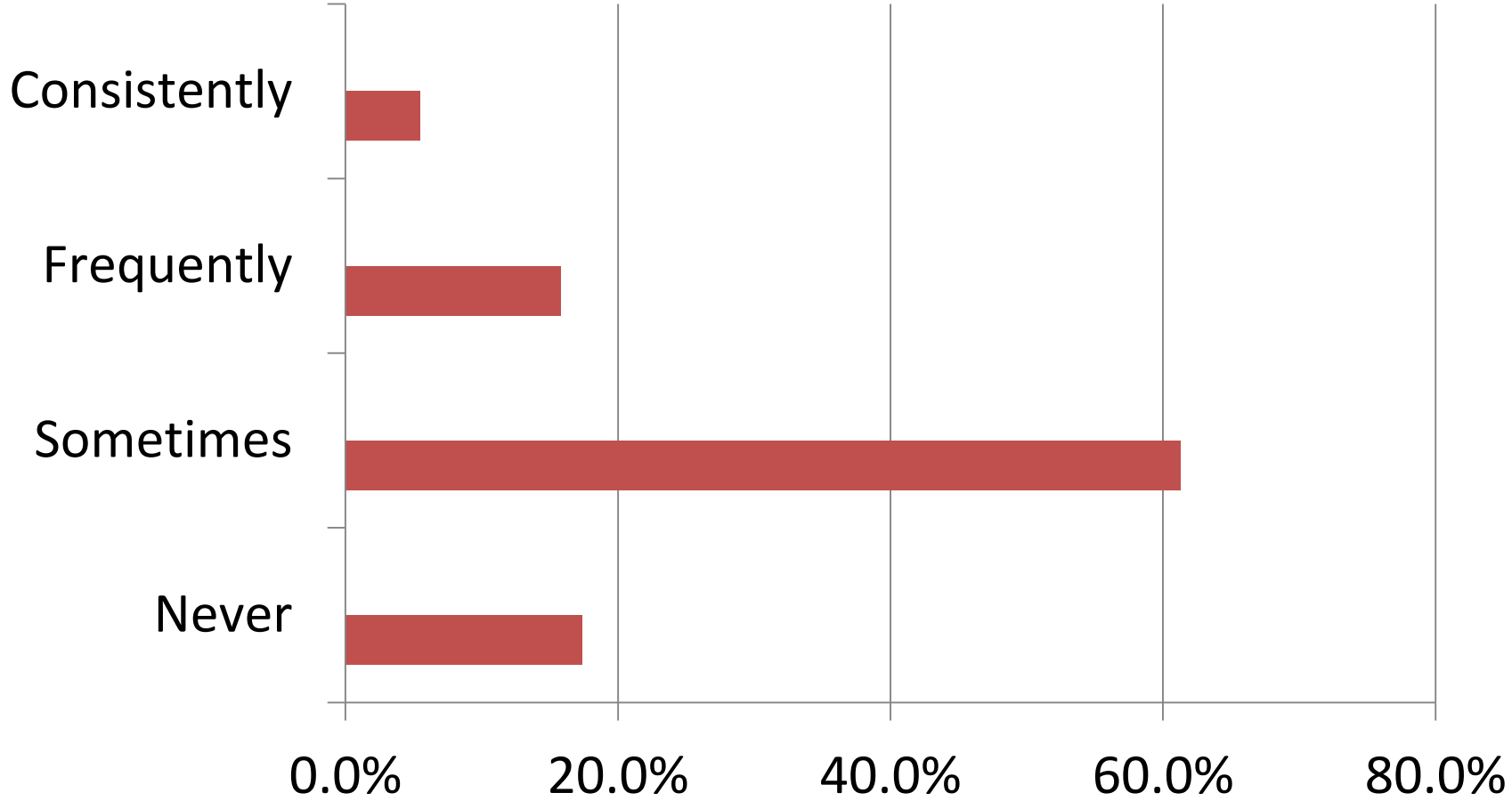
1. What is your functional area?



2. How often does your company comply with its quality policy?

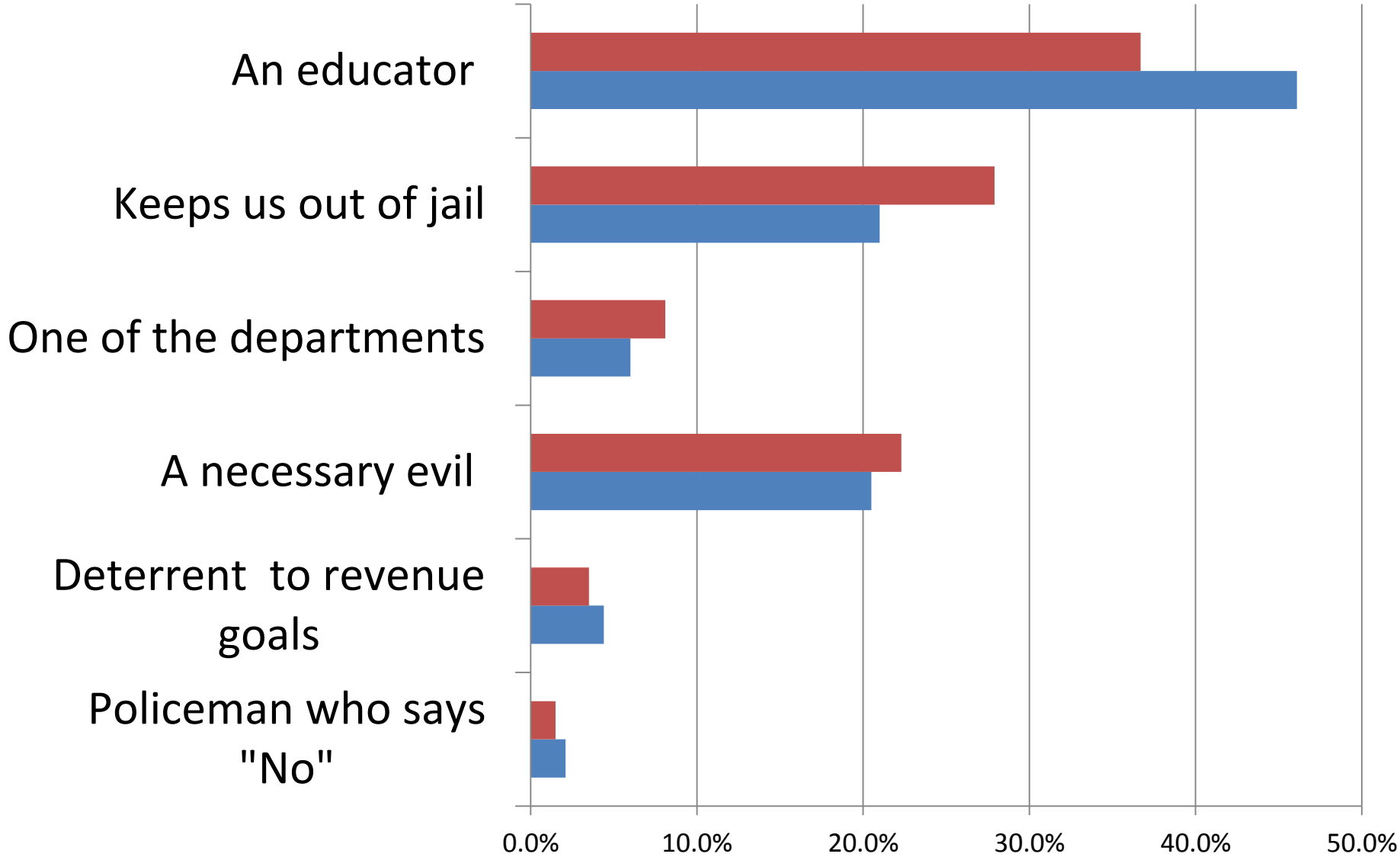


3. How frequently do product launch times negatively impact your company's commitment to its quality policy?*

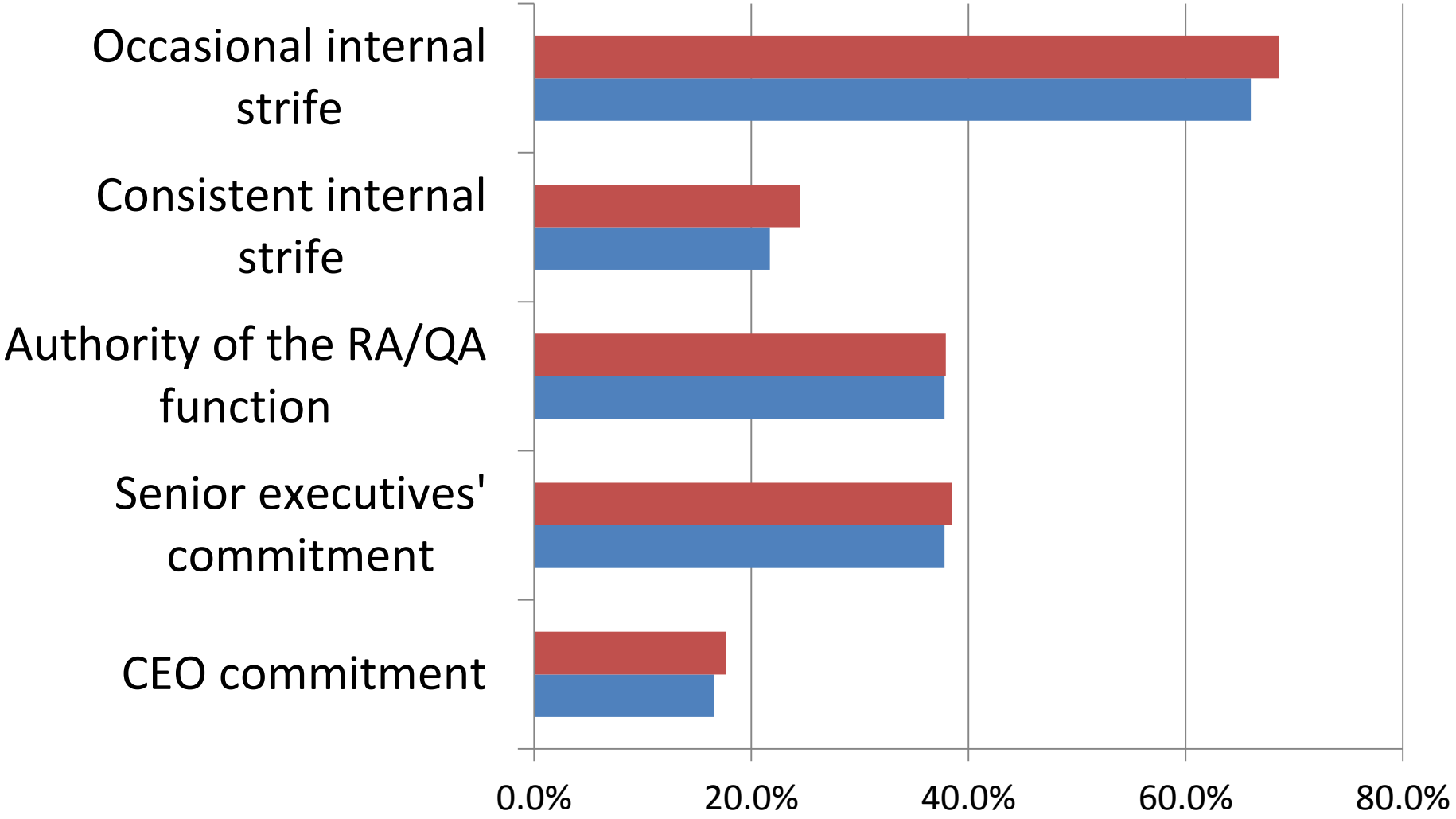


*Only asked this question in 2014

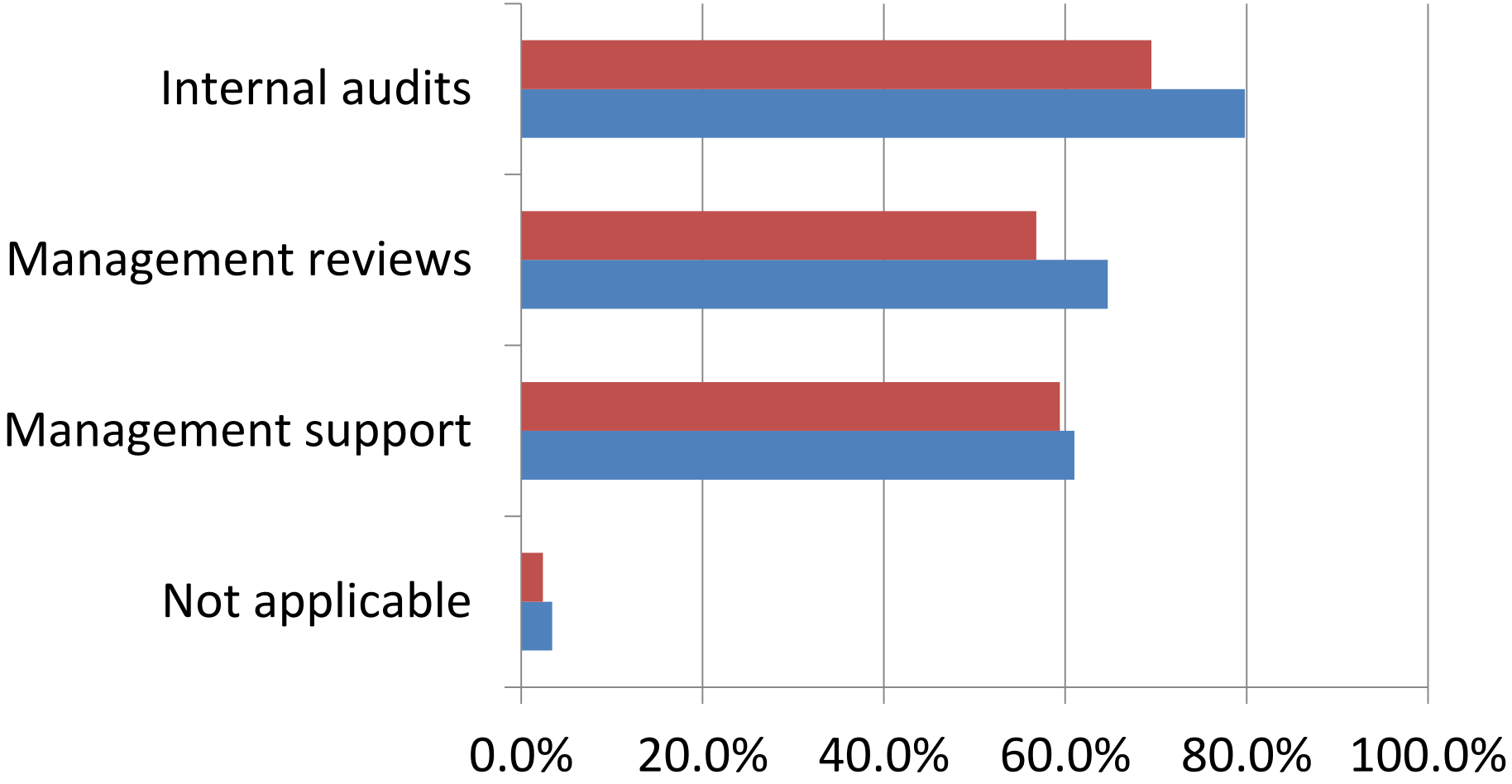
4. How does top management view the RA/QA function?



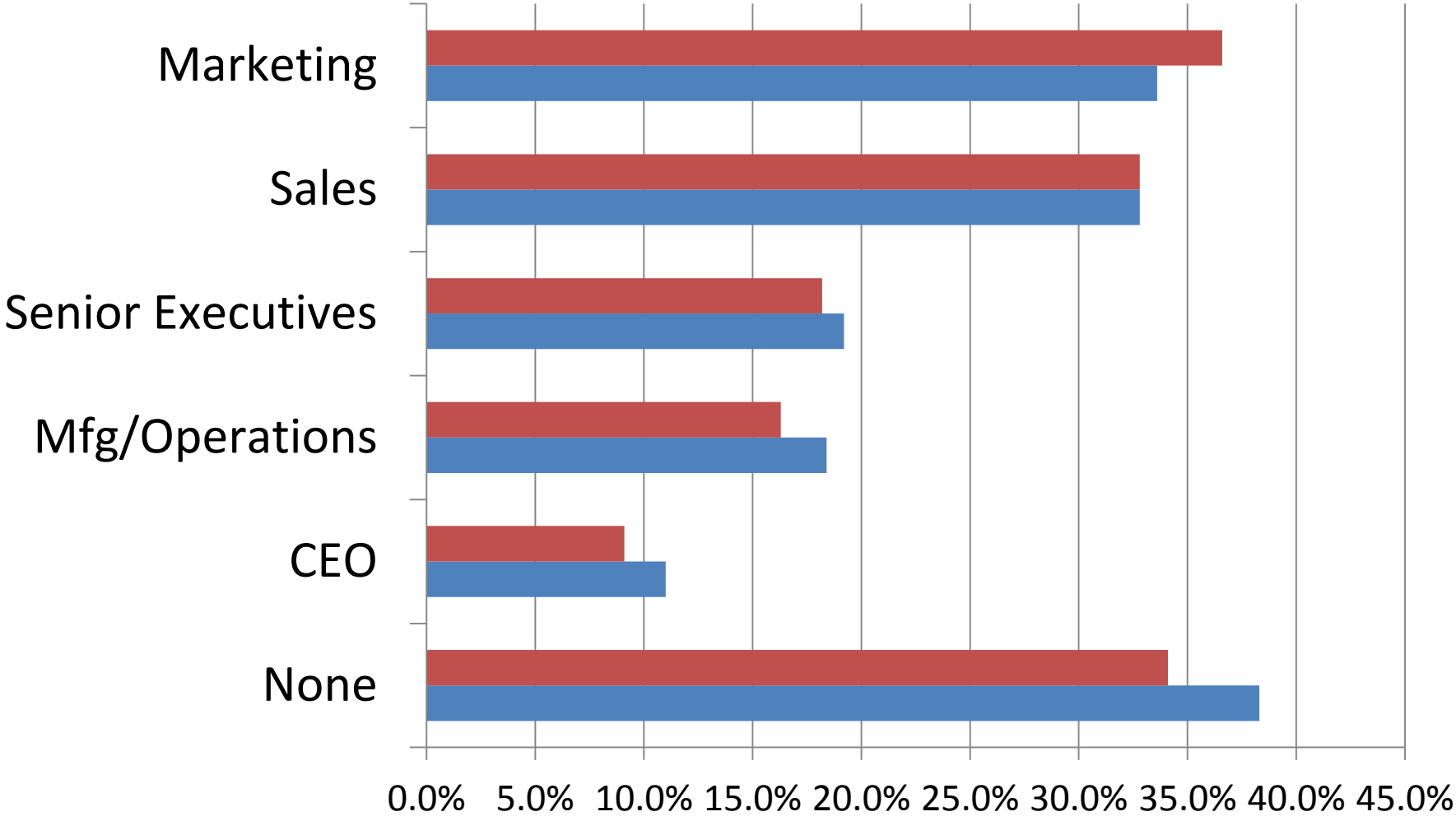
5. Which of the following issues prevent your firm from getting buy-in for compliance issues?



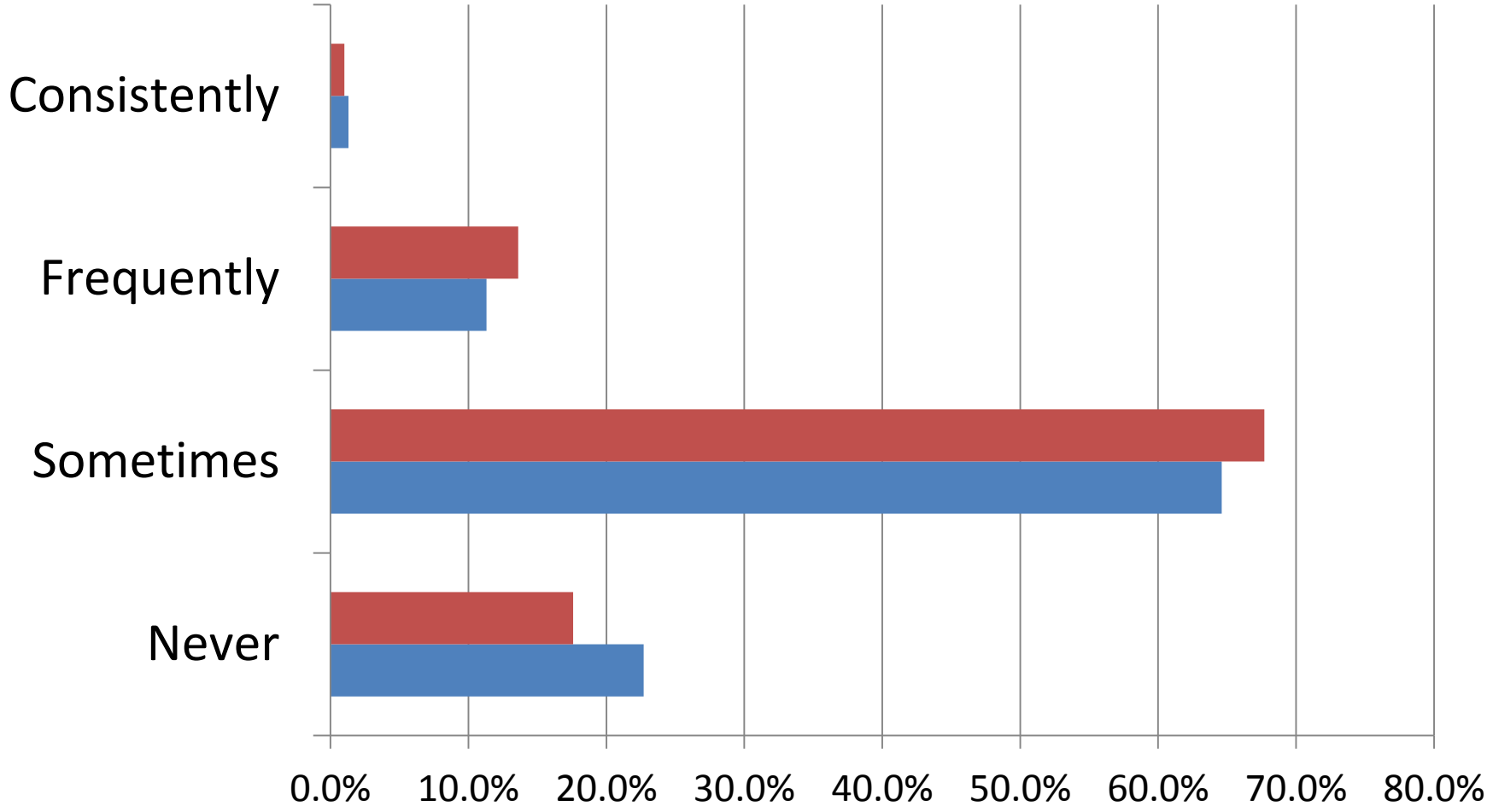
6. What mechanisms do RA/QA officials use to secure compliance from other departments?



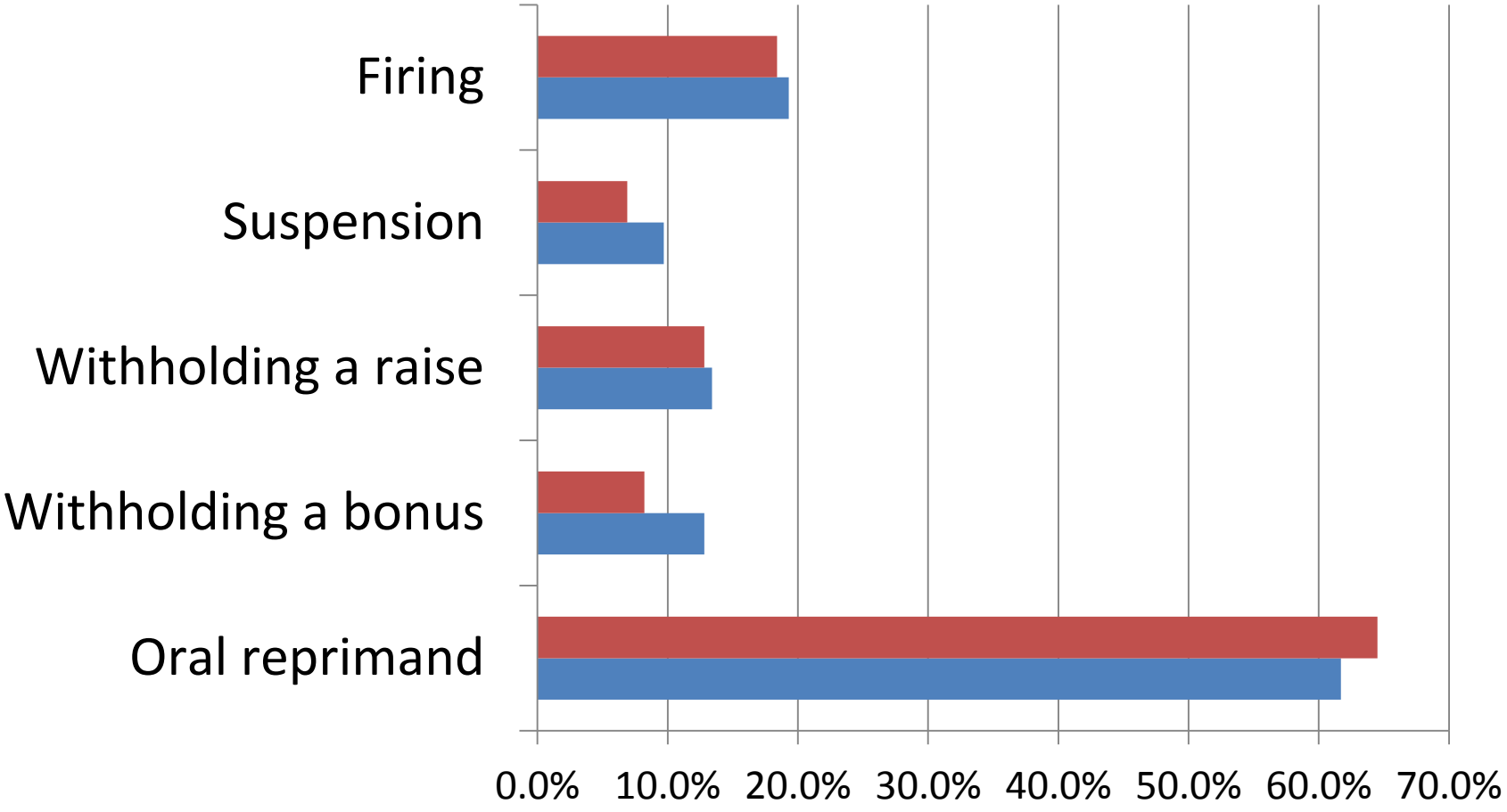
7. Which function(s) seem to believe that they can ignore RA/QA's recommendation with impunity?



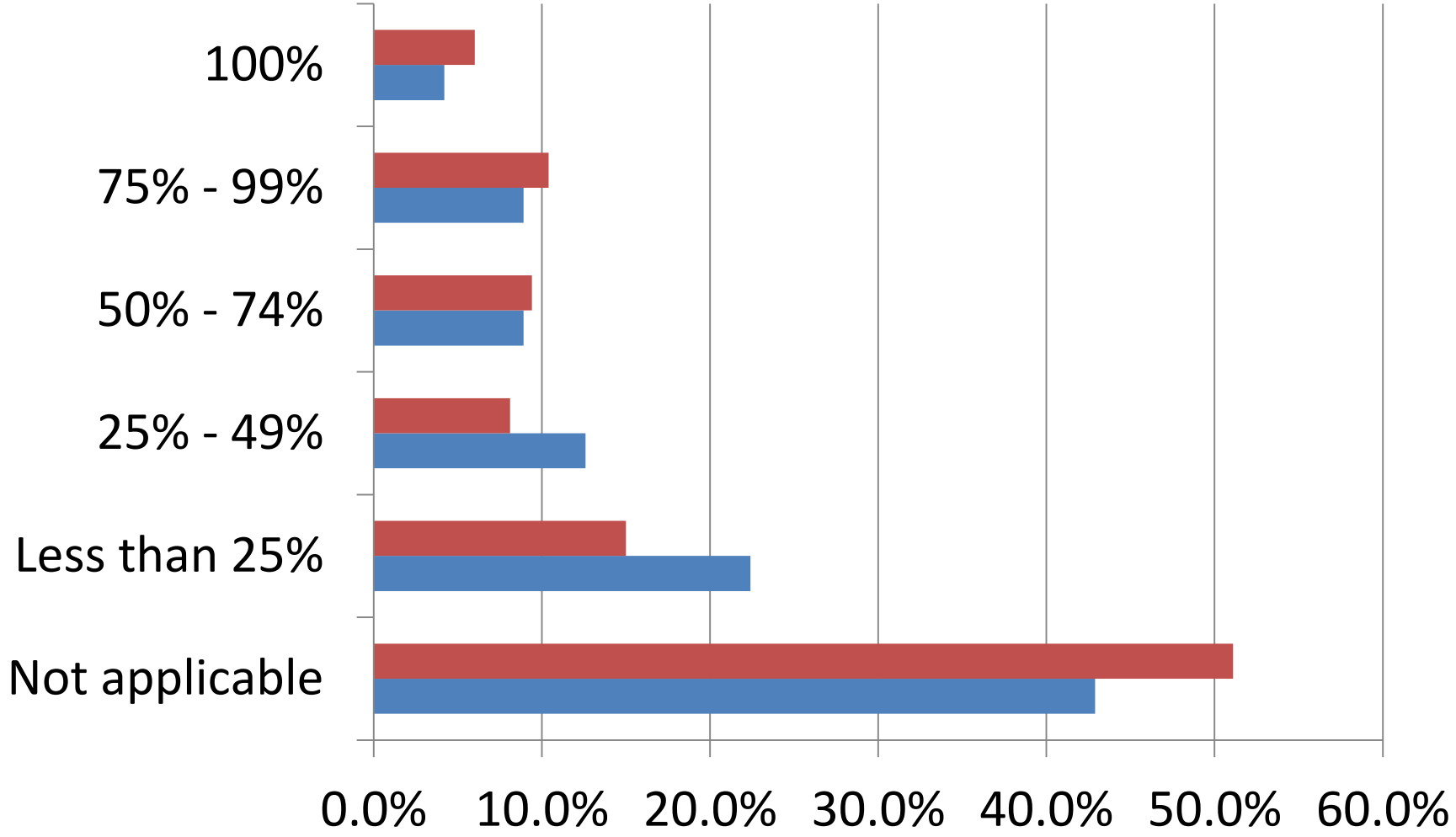
8. Does severe conflict about compliance issues seriously impede productivity within your organization?



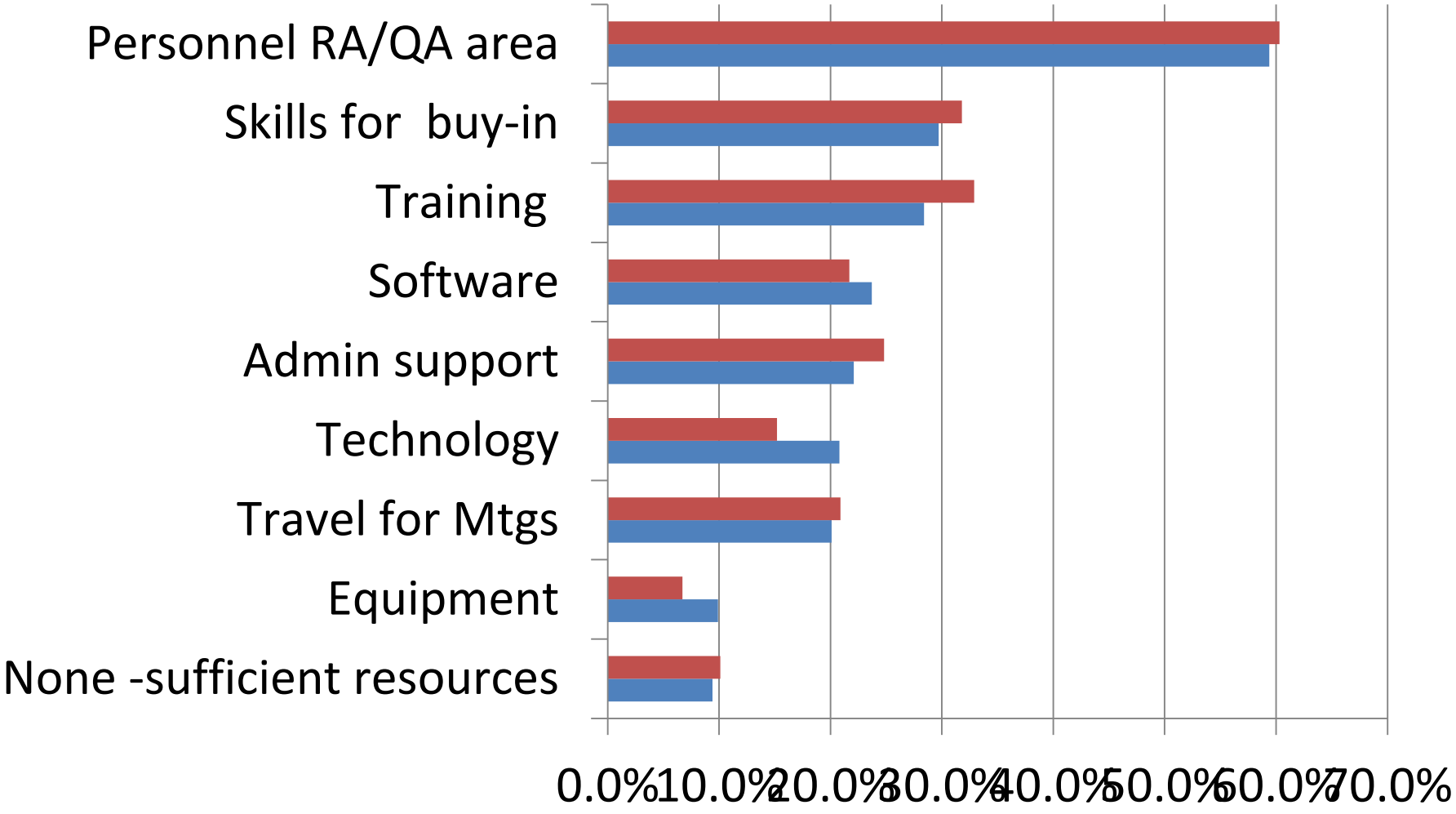
9. During the last two years, what actions have you taken against individuals for failing to follow FDA regulatory requirements?



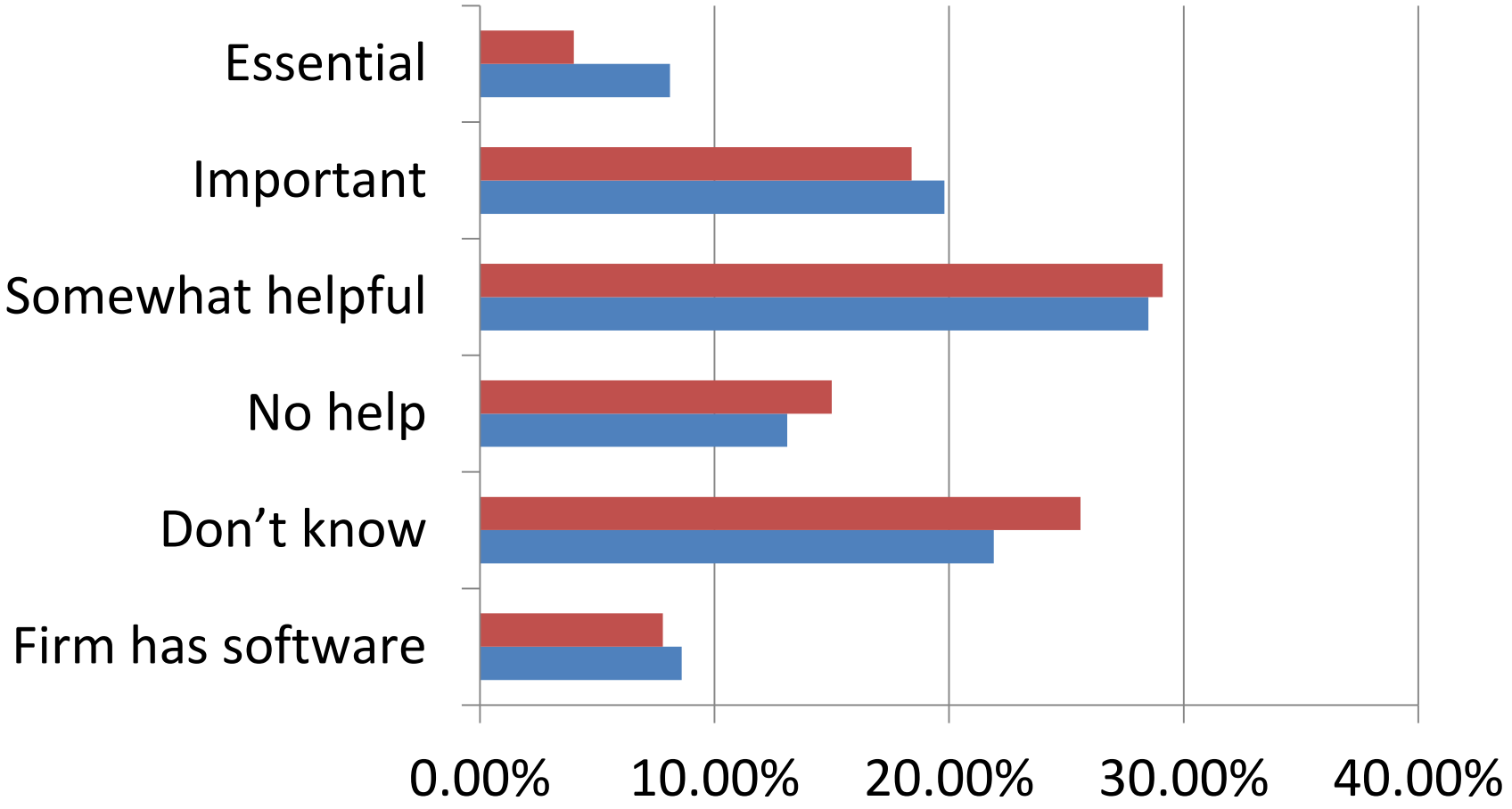
10. In your last inspection, if your firm had 483 observations, what percentage did you anticipate?



11. In which of the following areas is the need for additional funding the most urgent?



12. Would software that had the ability to track each department's obligation under cGMPs or the Quality System Regulation help to get buy-in?



Part 2
Discussion Questions

Question 1

You are the Director of RA/QA for a firm that manufactures medical devices. You find out that the VP of Marketing has arranged to have an advertisement for your product in a pediatric journal, when your product has not been approved for pediatric use.

Which of the following actions do you take?

a. Talk to his boss or the president.
b. Call the journal and have the ad pulled.
c. Do nothing and wait for the FDA to send you an untitled letter, a warning letter, or take some other type of regulatory action.
d. Other (please explain).

Question 2

Personnel in the R&D department refuse to follow the company's procedures for risk management. You keep reminding them, but they continue to ignore you. You know that if the FDA inspects your firm, you'll receive a warning letter for failing to adhere to your procedures. What do you do?

a. Hire an outside auditor.
b. Talk to executive management.
c. Hold a training session on FDA requirements.
d. Wait for the FDA inspection.

Question 3

What is the best way to convince top management that the RA/QA function needs additional resources?

a. Do benchmarking with other companies of your size and find out about the number of employees they have.
b. List all of the required functions and the time it takes to accomplish each one.
c. Call in an outside auditor to point out the work that is not being done.
d. Other (please explain).

Question 4

In convincing top management to comply with the requirements under the Federal Food, Drug, and Cosmetic Act or those under the fraud and abuse statues, the most persuasive argument is:

a. It's the right thing to do.
b. It's the law.
c. It will help us sell better products.
d. If we don't comply, we can be subject to regulatory sanctions.

Question 5(a)

Which of the following authorities **does** the QA function have in the majority of the firms in your group? (Choose all that apply.)

a. Being able to stop the release of product.
b. Being able to shut down a plant that is manufacturing products out of specs.
c. Being able to initiate a recall.
d. Have input into the performance evaluations of other department heads within the company.
e. Being able to recommend that specific people who blatantly violate government requirements be fired.

Question 5(b)

Which of the following authorities do you believe that the QA function **should have** in your organization? (Choose all that apply.)

a. Being able to stop the release of product.
b. Being able to shut down a plant that is manufacturing products out of specs.
c. Being able to initiate a recall.
d. Have input into the performance evaluations of others in the company.
e. Being able to recommend that specific people who blatantly violate government requirements be fired.

Question 6

What is the **best** way to deal with consistently adversarial conduct by one of your internal colleagues?

a. Avoid him/her.
b. When you are going to be in a meeting with them, ensure that you have solidified your position with others before the meeting.
c. Work on a project with him/her and share the credit.
d. Try to discredit him/her so they will lack the creditability to undercut your position.
e. Try to get them fired.
f. Other (please explain).

Question 7

Which of the following is the **most effective** technique to get your colleagues to attend an internal training session on regulatory requirements?

a. Offer food.
b. Bring in an outside speaker.
c. Ask top management to send out invitations to the meeting and after the meeting provide him/her with a list of attendees.
d. Have someone from each department serve on the planning committee for the training session.
e. Other (please explain).

Question 8

You have been asked to sit on a committee to help reorganize your company. What title would you recommend for the person in charge of the quality function?

a. VP of Quality reporting to the President
b. Director of Quality reporting to the VP of R&D.
c. VP of Quality reporting to the Head of Operations.