Getting Buy-in for Regulatory Compliance

Compliance-Alliance
www.compliance-alliance.com

Contact
Nancy Singer
nancy@compliance-alliance.com
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.
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.
1. What is your functional area?

- Regulatory
- Quality
- Senior Executive
- CEO
- Sales
- Marketing
- Manufacturing/Operations
- Other (please specify)
2. How often does your company comply with its quality policy?

- Always
- Most of the time
- When it's convenient
- Policy is a joke
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?

- **An educator**
- **Keeps us out of jail**
- **One of the departments**
- **A necessary evil**
- **Deterrent to revenue goals**
- **Policeman who says "No"**
5. Which of the following issues prevent your firm from getting buy-in for compliance issues?

- Occasional internal strife
- Consistent internal strife
- Authority of the RA/QA function
- Senior executives' commitment
- CEO commitment
6. What mechanisms do RA/QA officials use to secure compliance from other departments?

- Internal audits: 80.0%
- Management reviews: 60.0%
- Management support: 60.0%
- Not applicable: 0.0%
7. Which function(s) seem to believe that they can ignore RA/QA's recommendation with impunity?

- Marketing
- Sales
- Senior Executives
- Mfg/Operations
- CEO
- None
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?

- Firing
- Suspension
- Withholding a raise
- Withholding a bonus
- Oral reprimand
10. In your last inspection, if your firm had 483 observations, what percentage did you anticipate?

- 100%:
- 75% - 99%:
- 50% - 74%:
- 25% - 49%:
- Less than 25%:
- Not applicable:
11. In which of the following areas is the need for additional funding the most urgent?

<table>
<thead>
<tr>
<th>Area</th>
<th>Urgency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA/RA Personnel</td>
<td>70.0%</td>
</tr>
<tr>
<td>Skills for buy-in</td>
<td>50.0%</td>
</tr>
<tr>
<td>Training</td>
<td>40.0%</td>
</tr>
<tr>
<td>Software</td>
<td>30.0%</td>
</tr>
<tr>
<td>Admin support</td>
<td>20.0%</td>
</tr>
<tr>
<td>Technology</td>
<td>10.0%</td>
</tr>
<tr>
<td>Travel for Mtgs</td>
<td>0.0%</td>
</tr>
<tr>
<td>Equipment</td>
<td>0.0%</td>
</tr>
<tr>
<td>None</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
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?

- Essential
- Important
- Somewhat helpful
- No help
- Don’t know
- Firm has software