Evolution of an Internal Auditing Program

Johanna Stamates
Executive Director
Research Compliance and Quality Assurance
Demonstrate the importance of flexibility in compliance/auditing programs
Study the past if you would define the future

Confucius
Research Compliance and Quality Assurance

Internal Auditing program founded in 1999 and initially charged with audits of human subject research and animal studies.
Office name: indicates mission and demonstrates importance of compliance

Philosophy: in tune with the compliance culture of the organization and the “general current philosophy” of compliance/auditing

Complexity: the detail of the audit process organically developed to address the needs of the researchers/organization

Scope: initially clearly defined, but expanded upon as needed
THE JOURNEY OF A THOUSAND MILES BEGINS WITH ONE STEP

Lao Tzu
<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the compliance status of your organization?</td>
</tr>
<tr>
<td>Does your audit program contribute to the general research mission?</td>
</tr>
<tr>
<td>Has your auditing program evolved with your organization?</td>
</tr>
<tr>
<td>How do your researchers perceive your auditing program?</td>
</tr>
<tr>
<td>How do you measure your program's productivity?</td>
</tr>
</tbody>
</table>
Where do you stand?

What needs to be done?

What are your next steps?

What is the overall/final goal?
WHAT DO OTHERS DO?

You are not in a bubble – **Network!**

- What are the audit processes and their complexity?
- How do you interact/communicate with auditees?
- What kind of meetings with the auditees take place?
- What is the length of the audit process/audit report (drafts vs. final)?
- Is assistance available for researchers to respond to the audit report?

If possible, have an external/independent evaluation of your program
<table>
<thead>
<tr>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of your auditing/compliance program</td>
</tr>
<tr>
<td>Compliance culture and compliance status of your organization</td>
</tr>
<tr>
<td>Your team’s maturity</td>
</tr>
<tr>
<td>Restructuring needs – office/processes</td>
</tr>
<tr>
<td>Time commitment</td>
</tr>
<tr>
<td>Marketing the changes</td>
</tr>
<tr>
<td>Measuring the changes</td>
</tr>
</tbody>
</table>
IMPLEMENT

- Involve leadership
- Strategize – don’t overthink
- Map it out and make decisions
- Plan to disseminate information
- Document changes - plan to measure the outcome
- Revise your SOPs

Team Discussion
During the implementation of major changes, you will make additional “incidental” discoveries.

At times it is better to just do “everything” at once rather than leaving “some” for later.
**PAST**

Information to the auditees was provided as needed

Complex and lengthy audit process

Lengthy audit report

Issuance of Final Audit Report

Terminology focused on severity

Auditors provided feedback for audit response

**NOW**

Increased transparency — better interactions with auditees

Faster audit process — increased productivity

Shorter audit reports — easier reading, less intimidating

Issuance of Draft Audit Report — increased collaboration and buy-in

Changes in terminology — less intimidating and/or “punitive”

Support/assistance from CAPA Manager for audit response

**Friendly and collegial approach**
**MEASURES**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 1 – 6:</td>
<td>Introduction to and discussion about changes in auditing program; 6 departments; anonymous survey to all attendees</td>
</tr>
<tr>
<td>Month 6:</td>
<td>Review and analysis of survey I</td>
</tr>
<tr>
<td>Month 6 – 12:</td>
<td>Implementation of additional changes as needed; several audits will be conducted at the 6 selected departments/divisions</td>
</tr>
<tr>
<td>Month 12 – 18:</td>
<td>Revisiting of the same departments/divisions to provide and receive feedback; anonymous survey will be sent again to all attendees</td>
</tr>
<tr>
<td>Month 18:</td>
<td>Review and analysis of survey II and comparison of surveys I and II</td>
</tr>
</tbody>
</table>
Learn from the past, think about the future, live in the present and keep an open mind
Questions

At the U, we transform lives through teaching, research, and service.

Thank you
Contact Information

Johanna Stamates  
Research Compliance and Quality Assurance

http://uresearch.miami.edu/RCQA

Telephone: (305) 243 4215

E-mail: jstamates@med.miami.edu