

Managing Speaker Program Risk

Speaker programs offer healthcare professionals access to critical product and disease state information from other HCPs who utilize the products, but they are high-risk from a compliance perspective.

Managing Speaker Program Risk covers the guidelines and policies that must be followed when conducting a speaker program to ensure compliance with applicable regulations and policies. The estimated time to complete this module is 30 minutes.

Introduction

- Welcome
- Module Overview
- Learning Objectives

Program Planning

- Program Requests
- Program Logistics
- Program Attendees
- Audience Requirements
- Company Attendees
- Virtual Speaker Programs
- Scenario: A Request for a Guest
- How Should Mike Respond?

Program Speakers

- Speaker Selection
- Speaker Criteria
- Speaker Compensation
- Speaker Agreement
- Speaker Training
- Scenario: Selecting a Speaker
- Which Reasons are Appropriate?

Program Execution

- Program Owner Responsibilities
- Speaker Preparation
- Attendee Management
- Program Management



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PROGRAM SPEAKERS
Speaker Agreement

An HCP must sign a speaker's agreement before he/she can engage in any work on behalf of our Company.

The speaker's agreement specifies:

- Terms of the engagement
- Services to be provided
- Speaker's obligations
- Speaker's compensation
- Company's obligation regarding expenses
- Confidentiality provisions
- Program cancellation policy



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PROGRAM SPEAKERS
Speaker Training

All speakers receive compliance training and training on the presentations they will deliver.

HCPs must complete training before their first speaking engagements.

HCPs can be compensated for training and reimbursed for expenses.

Training venues should be conducive to medical information training.




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PROGRAM OWNERS
Which Reasons Are Inappropriate?

Which of Allison's reasons below are NOT appropriate criteria for selecting a speaker? Select all that apply. Then select **Submit**.

- The physician is well-respected regionally.
- The physician has extensive knowledge in her product's therapeutic area.
- The physician is a high prescriber.
- The physician has excellent communication skills.
- Selecting the physician will improve Allison's relationship with her.

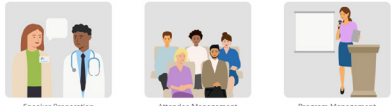


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PROGRAM EXECUTIVE
Program Owner Responsibilities

Select each topic to learn more.

- Speaker Preparation
- Attendee Management
- Program Management



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PROGRAM EXECUTIVE
Answering Off-Label Questions

After the presentation, the speaker may respond privately to an off-label question.

The speaker must:

- Only respond to the attendee who asked the question
- Be clear that the response is based on the speaker's personal experience and professional opinion
- Limit the response to only the question asked
- Be truthful and balanced
- Disclose the source of his or her answer (e.g., a clinical study, personal experience)

The speaker should refer all questions he or she doesn't feel comfortable answering to the program owner for submission to Medical Information.



Program Execution Cont.

- Speaker Responsibilities
- Deviations from Approved Content
- Responding to Audience Questions
- Answering Off-Label Questions
- Scenario: An Off-Label Remark
- What Should the Program Owner Do?
- Scenario: A Request for Off-Label Information
- How Should Dr. Evans Respond?

Post Program Activities

- Reporting Compliance Violations and Adverse Events
- Program Close Out
- Knowledge Check

Conclusion

- Summary
- For More Information
- Assessment