



The 2024 Guide to Compliant Pharmaceutical Speaker Programs

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WHITE PAPER

ABSTRACT

In today's heavily regulated healthcare landscape, compliant Healthcare Provider (HCP) interactions have never been more important, especially when you consider that HCPs are becoming far more selective as to how they interact with the pharmaceutical industry. On-demand speaker programs stand out as a pivotal tool for disseminating valuable product information, fostering relationships with HCPs, and driving brand awareness.

91% of HCPs Surveyed by Boston Consulting Group preferred Remote Speaker Programs as a pharmaceutical promotional channel.

This guide aims to provide pharmaceutical brand teams with a roadmap for designing and executing compliant speaker programs. Drawing upon industry insights, regulatory considerations, and best practices, this guide addresses key components such as program structure, content development, compliance, logistics management, and measuring success.

THE RESULTS OF EFFECTIVE SPEAKER PROGRAMS

The Role of Speaker Programs in Pharmaceutical Marketing

Speaker programs remain a vital and preferred channel for pharmaceutical companies to engage with healthcare providers and deliver important product information. They offer an opportunity for thought leaders to share clinical insights, discuss treatment options, and address key healthcare challenges in a peer-to-peer setting. In today's digital age, speaker programs have evolved to encompass live and on-demand formats, allowing for greater accessibility, flexibility, and scalability.

While vital, they must be executed with hypervigilance on compliance due to regulatory shifts from 2020.

HCP Preferences and How They Impact Channel Selection

Pharmaceutical companies must change the way they engage with HCPs. That shift will be driven by HCP preferences and opinions.

- Most HCPs still see pharmaceutical sales representatives as trusted advisors.
- 87% of those surveyed prefer all or a mix of remote engagements.
- 80% of HCPs surveyed do not trust pharmaceutical digital content, but state that on-demand content better suits their complex schedules.

- 91% surveyed prefer virtual speaker programs.

To break through the noise, pharmaceutical companies will need a channel that:

- Provides credible content
- Is presented by a peer
- Is available on demand

While maintaining a seamless relationship with brands, on-demand speaker programs have the potential to meet all these requirements in the most compliant way possible.

Key Components of Successful On-Demand Speaker Programs

Successful speaker programs require careful planning, execution, and evaluation. This section explores three key components essential for the effectiveness of speaker programs: knowledgeable speakers, evidence-based content, and vigilant program execution.

Knowledgeable Speakers:

Trusted, knowledgeable speakers are the key to any successful speaker program. They must possess an in-depth understanding of the product, clinical data, and therapeutic areas they are presenting. They should also demonstrate the ability to engage with audiences and address questions effectively. Ongoing training, just-in-time updates, and access to the latest market developments are crucial for maintaining speaker expertise and credibility.

Evidence-Based Content:

Content presented during speaker programs must be grounded in evidence and tailored to meet the informational needs of healthcare professionals. Case studies, clinical trials, and real-world examples provide valuable insights and practical applications for HCPs. Additionally, leveraging digital tools and interactive features can enhance content delivery and engagement, ensuring that key messages resonate with the audience.

Vigilant Program Execution:

Executing a successful speaker program requires careful planning, a deep understanding of the regulatory landscape, attention to detail, and seamless coordination. From registration to post-event follow-up, every aspect of the program should be designed to enhance the attendee experience and maximize engagement. Leveraging technology, such as integrated platforms and interactive tools, can streamline logistics, facilitate compliance, and deliver a memorable learning experience for participants.

BUILDING IN COMPLIANCE

In 2020, a corporate integrity agreement (CIA) published by the US Department of Health and Human Services Office of Inspector General (HHS-OIG) put forth detailed restrictions related to pharmaceutical speaker programs. While a CIA only applies to the manufacturer who entered into the agreement, pharmaceutical companies should consider these restrictions as they strive to design compliant speaker programs.

All Speaker Programs:

Speaker programs cannot take place at restaurants, and alcohol may not be served or be available for purchase at these events.

External Speaker Programs:

As defined by the CIA, these programs involve a healthcare professional speaker who is not a company employee.

Remote-only events:

these programs can be held only virtually, as “the external speakers shall be remote and shall not be in the same location as any audience member.”

No sales involvement:

sales representatives are not to be involved in the selection of external speakers, including the provision of nominations or recommendations.

Must follow new product or indication:

the programs must be completed within 18 months of Food and Drug Administration approval of a new product or indication.

Remuneration cap on programs:

these programs are subject to a total \$100,000 cap on remuneration for each new product or indication, with each non-employee speaker allowed a maximum of \$10,000 payment for each new product or indication.

“Real-time” Q&A Sessions:

the CIA allows such programs to provide “real-time discussion of questions and answers” and allows the program (including question and answers) to be recorded and available during and following the expiration of the 18-month period.

Speaker Program Fraud Alert:

In 2020, the HHS-OIG issued a special fraud alert addressing fraud and abuse concerns with speaker programs conducted by pharmaceutical and medical device companies. The fraud alert reiterates historical OIG and Department of Justice (DOJ) concerns regarding speaker programs. It also challenges older industry practices as suspect under the Federal Anti-Kickback Statute (AKS), raising the bar for pharmaceutical and medical device companies seeking to implement compliant speaker programs. Below is an excerpt of that alert.

This list of suspect characteristics is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement would be suspect under the anti-kickback statute.

- The company sponsors speaker programs where little or no substantive information is presented.
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free).
- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues).
- The company sponsors many programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information.
- There has been a significant period with no new medical or scientific information nor a new FDA-approved or cleared indication for the product.
- HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic).
- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information.
- The company's sales or marketing business units influence the selection of speakers, or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return-on-investment analysis is considered in identifying participants);
- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that considers the volume or value of past business generated or potential future business generated by the HCPs.

MANAGING LOGISTICS AND ENSURING COMPLIANCE

Effective management of logistics and ensuring compliance is essential for the success and integrity of speaker programs. This section outlines key considerations and strategies for training, content development, validating business rules for compliance, and integrating with existing systems to streamline operations and mitigate risks.

Training and Content:

Comprehensive training programs ensure that speakers are well-prepared, informed, and compliant with regulatory requirements. Utilizing presentation builder tools and approved content libraries helps maintain consistency and adherence to compliance guidelines. Additionally, ongoing education and just-in-time updates keep speakers informed of the latest developments and market trends.

Validating Business Rules for Compliance:

Implementing validation rules and business processes helps ensure compliance with regulatory guidelines and organizational policies. Systems should validate speaker qualifications, track training completion, and enforce compliance requirements for content and engagements. Integrating compliance checks into existing systems streamlines processes and minimizes errors, ensuring that all aspects of the program adhere to industry standards.

Integration with Existing Systems:

Integrating speaker program management systems with existing platforms, such as CRM and contracting databases, enhances efficiency and accuracy. Centralizing data and workflows simplify logistics management, expense tracking, and reporting. By leveraging technology and automation, pharmaceutical companies can streamline operations, improve compliance, and optimize resource allocation for speaker programs.

NAVIGATING COMMON IMPLEMENTATION CHALLENGES

Implementing a successful speaker program comes with its own set of challenges. This section explores some common hurdles and offers strategies for overcoming them.

Prohibitively High Costs:

Traditional speaker programs can incur significant expenses related to venue rentals, travel, and logistics. If they are not run compliantly, they may result in even more significant expenses. Transitioning to on demand will reduce costs while maintaining program effectiveness. Additionally, focusing on a smaller group of high-performing speakers, leveraging data analytics to identify top performers, and optimizing resource allocation can help mitigate budgetary constraints.

Earning Audience Attention and Trust:

Capturing and maintaining audience attention in a competitive environment is a challenge for speaker programs. Investing in speaker training, selecting influential speakers with broad recognition, and creating engaging, memorable content can help build trust and credibility with the audience. Leveraging interactive features, such as polls, assessments, and breakout sessions, enhances engagement and fosters meaningful interactions.

Securing Attendee Participation:

Attracting busy healthcare professionals to participate in speaker programs can be challenging when providers have more requests for their time than there are hours in the day. Utilizing remote representatives makes it easier to secure participation while simultaneously learning and documenting the unique preferences of an individual healthcare professional. Leveraging digital tools for registration, communication, and follow-up helps streamline the attendee experience and ensures maximum participation.

THE RESULTS OF EFFECTIVE SPEAKER PROGRAMS

Effective speaker programs deliver tangible benefits to pharmaceutical companies, including increased sales and revenue, enhanced brand awareness and recognition, and improved product education. By engaging with healthcare professionals, fostering relationships, and delivering valuable content, speaker programs play a crucial role in driving business growth and establishing thought leadership in the industry.

In conclusion, speaker programs remain a valuable and essential tool for pharmaceutical companies seeking to educate healthcare professionals, promote brand awareness, and drive business results. By embracing on-demand formats to make it convenient for busy HCPs, leveraging technology and data analytics to highlight trends and actionable insights, and prioritizing compliance and engagement, pharmaceutical teams can maximize the impact of their speaker programs in the evolving healthcare landscape.

As the industry continues to evolve, it is essential for pharmaceutical companies to adapt their speaker programs to meet the changing needs and expectations of healthcare professionals. By adopting innovative approaches, leveraging digital tools, and focusing on delivering value to their audiences, pharmaceutical companies can ensure that their speaker programs remain effective, compliant, and impactful in driving business success.

References

- 2021, Accenture: The “new rules of engagement
- 2022, BCG Analysis: Physician COVID-19 Response BIOPharma Survey
- 2020, Novartis Corporate Integrity Agreement
- 2020, OIG: Special Fraud Alert: Speaker Programs



At Mercialis, we deploy contract sales solutions for life science companies. Many brand teams have requested our skilled sales teams to include speaker program recruitment as part of our call flow. For further information on our contract sales solutions, please contact

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Our comprehensive 360° solution for pharmaceutical speaker bureau management is a proven driver of results for pharmaceutical and medical device companies. From our state-of-the-art online SBM Portals to basic meeting logistics and consultative approaches and program design, our skilled account management and customer service teams provide the knowledge required to manage compliant speaker programs efficiently.

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