

Building Promotional and Event Review Processes in an International Environment

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Agenda

1. Introduction
2. Types of meetings
3. Risk areas
4. Decreasing risk
5. Advisory boards meetings

Types of Meetings

- Congress / conventions
- Company directed Symposia
- Advisory board / consultant meetings
- CME
- Hospitality events
- Visiting speakers / speaker training
- *Will not discuss Internal Company Meetings*

Key Risk Areas - Meetings

Review and approval

Documentation

- Lack of necessary approvals (Needs Assessments, Fair Market Value determinations)

Agenda and meeting set-up

- Insufficient time dedicated to meeting content
- Meeting covers off-label content

Venue and hospitality

- Unsuitable venue, lavish hospitality and entertainment
- Time of year
- Concurrent cultural events

Participants

- Invitation of spouses/partners
- Non-qualified HCPs invited to scientific meetings
- Excessive number of invitees
- Ratio of company attendees to invitees

Materials:

- Educational vs promotional
- Gifts

Criteria for having off-label discussions

Local Rules

- Limits and approvals from all countries involved

Sponsorships

- Remuneration
- Government employees
- Contracts

Execution

Agenda

- Significant ad-hoc changes

Material

- Changes to material and presentations after approval

Venue

- Hospitality above approved level

Speakers

- Presentation deviates from agreed topic or content

Participants

- Large number of cancellations leads to excessive hospitality
- Spouses/partners present

Follow-up/Documentation

Budget and expenses

- Actual costs deviate from approved budget
- Fair market value documented

Contracts

- Not all contracts retained

Material

- Relevant material not retained

Participation

- List of participants not retained

Methodology for addressing FMV not observed or not consistent

Decreasing risks

- Policies and procedures
 - Appropriate review and approval processes
 - Centralized system for review and approval
 - Documentation and retention
- Training
- Monitoring and auditing
- Corrective plans in the event of changes/issues
- Communication
- Timing

Risk Areas – Advisory Boards

Agenda

- No clear business need defined and documented
- Lack of time for discussion and feedback
- Significant deviations from planned agenda

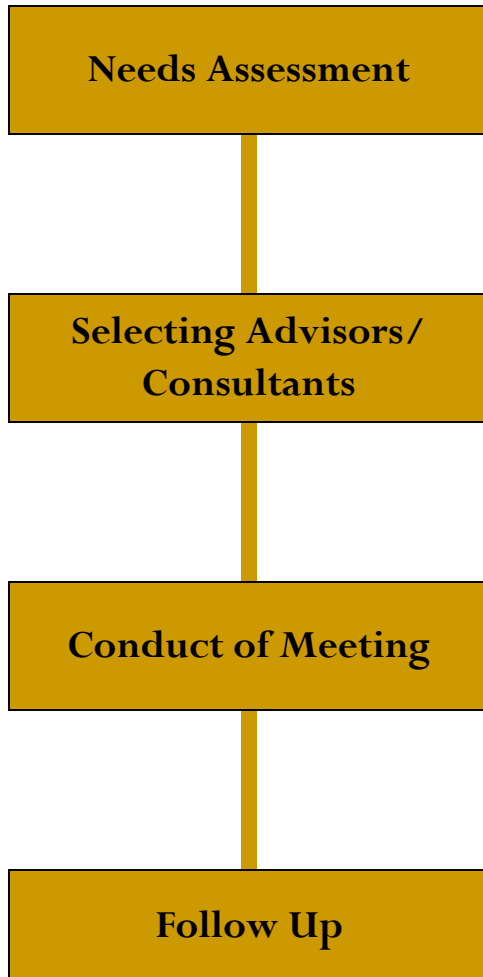
Set-up and Participants

- Lack of necessary approvals
- Actual attendance insufficient or excessive to satisfy business needs
- Individual contributions insufficient to satisfy business need
- Presentations made, rather than advice/input received
- Presentation aimed at driving promotion
- Excessive number of
 - Participants
 - Meetings
 - Geographic meetings
- Inappropriate criteria for participation selection
- Involvement of sales staff

Materials/Documentation

- Material has promotional character
- Deviation from approved content
- Incomplete documentation/retention
 - Presented material
 - Contracts
 - Results/input obtained
 - Intended use of information
- No contracts in place
- Payment above fair market value for country of practice

Advisory Boards



- Bona fide need
 - Non-duplicative or cumulative
 - Appropriate number of members
- Members selected for expertise, qualifications
 - Not prescribing potential
 - Note: “advocate/influencers/KOL” development
- Written agreement
 - Clear deliverables
 - Fair market value for services, reasonable expenses in country of practice
- No strings attached
- Content of meeting matches purposes/needs
 - Not disguised messaging/promotion
- Appropriate venue
 - Modest (or no) social/entertainment
 - No expenses for spouses/guests
- Feedback is captured and used
- Documentation

Example 1

Marketing wants to have an advisory meeting at a golf resort inviting HCPs from around the world.

Is this allowed?

Example 2

What criteria should be followed to assure that a meeting is educational, not promotional?

Example 3

What rules should be followed for company directed meetings vs non-company directed meetings?