

Backstage at a Panel Meeting—A Perspective from the Trenches

Preparation for an FDA Advisory Committee Meeting is an adventure that most people do not relish. From a marketing perspective these meetings are an obstacle to product approval, which consume time, effort and money. Project management and team decisions based on upfront knowledge of options and practices will produce positive results throughout the project.

The activities involved in panel meeting preparation can be divided into two main categories:

1. Issues and content;
2. Production and logistics.

This article focuses on production and logistics from the perspective of a technical support team that provides behind-the-scenes assistance throughout the project. Five general topics will be addressed:

- team issues;
- graphics;
- technical;
- panel day; and
- logistics.

Team Issues

The dynamics of the industry have resulted in little relationship between company size and project team experience. It is not unusual for only a few project team members to have prior Advisory Committee Meeting experience. Viewing tapes from previous meetings can be instructive, but the dynamics and nuances cannot be appreciated. There is no substitute for attending a panel meeting. Appreciation for the massive effort to prepare the briefing document, core slides and back-up slides must be realistically taken into account when planning time and events. Accurate assessment of internal resources and matching tasks with skills and experience is a must. A clear understanding of processes and supervision will greatly reduce confusion. Weaknesses and voids can be offset with outside help. Scheduling an early team orientation meeting to lay out the plan and process will keep the project on track. Commitment from every team member is vital. Of primary importance is an authoritative project manager with the ability to make decisions or get quick consensus so the project keeps moving forward. Delays at any point can seriously affect the timetable and result in overloading the

back end of the project. The project manager (or some key team member) should have crisis management training. A database with contact information for all team members should be created and distributed. This should include 24-hour phone numbers and home addresses for key people in case documents need to be shipped on weekends and holidays. Team management includes insuring compliance with agreed upon processes and delivery times. Mutual respect among team members goes a long way to assure smooth sailing.

A gatekeeper should be appointed to provide liaison between the various content sub-teams and the graphics production team. Ideally this person is a sponsor employee with a grasp of the entire scope of content needed for the project. Duties include oversight of organizing, prioritizing, and proofing text and slide content. Triage of slide production is an especially important function to ensure the most important slides get produced first. Often the graphics team is operating in a vacuum and needs direction.

Speech and rhetoric coaches are available and can produce significant improvement in the core presentation. If there is only one person who has an obvious need for this kind of help, it can be less noticeable to everyone if the entire speaking team participates in the training. Occasionally there is a recalcitrant speaker on a team. This situation may require management intervention. It is wise to have understudies for each core speaker in the event of an emergency.

Team conduct during the Advisory Committee Meeting plays an important role in audience perception of the sponsor. The sponsor's primary audience is the group of panel members seated at the U-shaped table. In addition, FDA, the media, Wall Street analysts and your competition are in the room. The team and its behavior at the meeting are in full view of all. At all times each team member should behave in a controlled, businesslike manner. It is best to show no emotion regardless of what happens.

The acid test of team preparation is performance during the question-and-answer period. The best performing teams have a well-rehearsed response process that includes:

- verbal response to the question;
- signals between the podium speaker and bullpen;
- response handoff to bullpen responder;
- bullpen captain consultation for potential back-up slide projection;

- queuing of potential back-up slides for possible projection;
- direction by captain to project a back-up slide; and
- organized, controlled demeanor.

It may seem like an unnecessary luxury, but a separate question and answer rehearsal for the entire team can be a major benefit.

Information security procedures should include control of conversation, documents and equipment at all times and in all places. Corporate policy/culture, common sense and awareness by all must be employed. Remember that hotels are public places and not just your team's conference location. Analysts and media are known to roam hotel corridors for bits of overheard information. Extraordinary measures can include security guards, identification badges and using a nonproject related name to book all conference space.

Graphics

Desktop presentation graphics software can be the best and worst part of producing a medical/scientific program. Major strengths are the ability to make global changes and the many hardcopy output options available; however, the lack of table-editing is a major weakness. In the absence of something better, Microsoft PowerPoint has become the de facto standard.

Slide design should be simple. Keep in mind that this is a scientific presentation and not a marketing event. Text and graphic elements should be legible, easily understood, and have suitable color and contrast. Attention should be paid to symbol conventions and axis ranges on graphs.

Data validation should be a major concern, especially for older studies and hardcopy-only information. The quality assurance process should address both transcription and transmission error potential. It is best to maintain the electronic link between data and graph. Graphs that are scanned or imported, as image files only, cannot be easily edited. Remember that graphing software requires data.

The major challenges for slide production are:

- lead time;
- production capacity;
- software application expertise;
- data retrieval and compatibility;
- production management and triage;
- revision control;
- proofing;
- real time edit sessions;
- archiving and distribution; and
- lineage and tracking.

Frequently one or more core speakers or consultants have existing 35 mm slides, electronic files, publications or

other materials, that need to be incorporated into the master slide set. It is wise to ask early on in the project if these materials exist and get them to the graphics team. Having to deal with these issues in a hotel the day before the panel meeting is not the best use of the graphics team's remaining valuable time.

Slide indexing keeps track of slide status and location. An organized list of this information, which is distributed to the team and used during the question and answer session, aids expeditious image retrieval. Teams that understand and use the power of proper indexing and learn the back-up slide content are the ones that perform best during a panel meeting.

A good indexing system has metadata about each image that is useful to the content, graphics and projection/retrieval teams. There are core and back-up images, but life during a panel meeting project is not that simple. A single image could be:

- a core slide;
- a back-up slide;
- toggled from one status to the other;
- both a core slide and a back-up slide;
- put on hold until further notice and possibly recalled;
- of sensitive content and kept in a secure location; and
- revised and placed in another location.

A good indexing system accommodates any of these possibilities. Slide title and subtitle text should be concise, precise and discriminating. Achieving this can take significant effort since images come from different sources and titles are created within the context of a smaller work. A more efficient method involves use of additional fields in the database to categorize and sub-categorize the images by labels determined by the team. Sorting the images by selected categories allows the slide list to be ordered and printed in the way the team thinks about the information. This ordered list is the tool that allows efficient identification and retrieval of back-up slides.

A final thought about back-up slides. The scope of their production is almost always underestimated. In addition, the focus of effort is always on producing the briefing document and the core slides as it should be. However, postponing back-up slide production until these tasks are under control is dangerous. Back-up slide production should be a parallel process, not a sequential one. The three rules of back-up slide production are early, early, early.

Technical Issues

Not so long ago project teams had to decide whether to produce 35 mm slides or use computer projection. Mounted slides and carousel projectors were proven technology while computer projection technology was still evolving. In addition, some consultants advised that using 35 mm slides was an advantage because it demonstrated that the team was in control and not producing a lot of slides at the last minute. Computer projection technology has improved to the degree that its use is

Regulatory Corner

almost universal. Risk of equipment failure is reduced or eliminated by a combination of redundant systems and adequate technical support staff to troubleshoot problems.

Confining the computer work to a single operating system and the same version of software will result in the fewest problems. Use of different fonts may produce errors in character mapping from one font to the other. When consultants and vendors are working at your site or a hotel, it is important to arrange for the proper devices to share files.

Production of the various documents needed for the sponsor team and meeting attendees is by definition a last minute task. It can proceed only when creation and revision of content is completed. Properly managed teams have an enforced cut-off time for revisions so that document production can begin. High volume copying is accomplished on rental machines set up in the sponsor work area or sent to a 24-hour copy service company for expedited production.

Panel Day

The graphics projection team should arrive early to set up. If additional reserved seating is needed it can be arranged either with the executive secretary or by a designated sponsor representative arriving early and placing signs on chairs in the general audience section. A seating chart for the sponsor section is recommended. Attention should be paid to the need for subgroups to communicate during the meeting.

Most panel meetings are conducted in hotel ballrooms with slight variations in floor plan. The committee executive secretary will provide a floor plan on request. Some meetings are on the National Institutes of Health campus at Natcher Auditorium or Jack Masur Auditorium. The location of the computer table in these two rooms could be remote from the sponsor seating area and may require communication by wireless headset. Always communicate with the audio/visual manager of the facility to be aware of special conditions.

It is important for the sponsor team to stay together from the start of the day. If the panel meeting is in a different location from the team hotel, group transportation is usually arranged, and a conference room should be reserved for the team's use at the panel meeting site. It may be useful to equip this room with a copier, fax and printer for use during the day. Starting the day with a group light breakfast is recommended at either the team or panel hotel. If the sponsor has an all-day session, schedule the lunch break as a time for discussion and strategizing with minimal time for dining. A quick light meal is best.

The layout of a typical meeting has the advisory

committee seated around a U-shaped table, a 30-seat sponsor section on one side of the U and a 30-seat FDA section on the other side. The rest of the space is for general audience seating with reserved front row seats for open public speakers. Since the proceedings are audio- and videotaped as well as webcast, microphones are placed in strategic locations. All speakers at the meeting are required to identify themselves and speak from a microphone.

The podium usually is located between the sponsor section and the advisory committee. This arrangement puts the podium in proximity to the committee, the screen and the sponsor team. The podium microphone is fixed, confining the speaker there for the entire presentation. The core presentation is the easier part of the day for the sponsor. Question and answer (Q&A) is the hard part. Most committee chairpersons hold all questions until the sponsor presentation is finished. However, there may be clarification questions allowed after each section. In any case, the team in the bullpen must be prepared to respond to questions at any time. The most successful teams have a well-rehearsed process in place to answer the question, communicate with the podium speaker and get any necessary back-up slides on the screen. A properly designed index and studied response team will make a good impression during Q&A.

Planning and executing a successful FDA Advisory Committee Meeting presentation is a massive undertaking and, too often, the scope is underestimated.

Since it is now customary for FDA to post the proceedings on their Web site, the sponsor is asked to provide a CD with core and back-up slides used during the meeting. The graphics team should log which back-ups are used so the images can be assembled and recorded on CD immediately after the meeting.

Some teams will prepare a set of overhead transparencies of the core presentation to have in the room in case of a catastrophic equipment failure. The committee and FDA usually get one- or two-to-a-page handouts of the core presentation and the audience handouts are usually six-to-a-page. Handouts for the sponsor team may be a combination of sizes based on individual needs.

The sponsor's marketing and public relations staff is very busy dealing with the events of the day and usually will have their own conference room at the panel hotel. If their space is not supplied with office equipment, the presentation team's equipment is shared.

Logistics

The project manager's best friend is a competent meeting planner. It is a mistake not to include this service for the project. Providing the conference, housing, transportation and any other needs for the entire team over a period of several months should not be left to an amateur. There may be a tendency to delegate these tasks to a sponsor administrative assistant but it is not recommended.

It is wise to engage the meeting planner early on in the project. This practice will result in fewer headaches for the project manager and build in the ability to respond quickly to schedule changes and other emergencies.

Most early-on team meetings are at the sponsor site. However, consultant availability plays a major role in event scheduling. Consultants may have very limited availability. It is not unusual for the project team to fly across the country just to have half-day access to a consultant. Another consideration is setting the meeting agenda based on the consultants' schedules. Some will not arrive the night before and most will fly home the day of the meeting. This reduces the amount of time when all of the experts are together. To get the most for the consultant dollar, the high priority issues should be addressed when all are present. Rarely are all of the key players able to attend all meetings. Progress and decision-making suffer when a different subset of the total team is at each meeting. The danger of additional delays and scheduling problems can occur.

A further complication arises when there are cosponsors. Logistics challenges increase, putting additional burdens on the meeting planning process.

The projection/retrieval system for slide images is typically a configuration of laptop computers, preview monitors, graphics cables, switchers and data projectors. It is important to match the output resolution and frequency of the computer with that of the projector. The use of zoom lens-equipped devices also is recommended.

Remember that any system is just a tool. It is only as good as the team using it. Properly designed slides and index and a rehearsed team are the secrets to making the sponsor look good during Q&A.

Booking the team hotel for prepanel preparation should be done with consideration for:

- location of panel meeting;
- whether the team should stay in the same hotel;
- whether other sponsors are presenting to the panel;
- internal proximity of available conference rooms;
- adequate electrical power for equipment;
- available business services; and
- responsive staff after hours and weekends.

Booking as early as possible is always the best approach. Determine if reasons exist for the team to stay in a particular area (i.e., proximity to corporate offices, consultants or contract research organizations). Remember that working in a hotel around-the-clock for several days is a hostile environment. Production capacity can get quickly saturated. Stress is high so it is important to do nothing to add to it.

Delivering documents and equipment quickly requires a reliable service with tracking and retrieval capability. Be aware of all overnight and same-day shipping options in the area. Drop-off times vary by location and may change without notice. Make adequate arrangements for both on-time drop-off and pick-up. Some airlines offer next-flight-out service around the clock. This is expensive but sometimes may be the only option.

Service and equipment vendor arrangements should be made as early as possible. Dedicated time can be arranged with most vendors. Since failures tend to happen at times of peak use, the rental of redundant equipment is recommended and 24-hour emergency services can be arranged.

Conclusion

Planning and executing a successful FDA Advisory Committee Meeting presentation is a massive undertaking. Too often, the scope is underestimated. The information discussed in this article is just one component of the total picture. Many parallel tracks of activity must be planned and executed. Most companies do not possess the resources to proceed in an ideal fashion. Sequential progress tends to supplant parallel activity. Managing the expectations is a key role for the project manager.

One approach to consider is to ask what the team wants to be doing in the final 48 hours before the panel meeting. Starting here and working backwards helps to identify the plan. Of course, there will always be the unexpected that could jeopardize the plan.

To borrow a term from the construction industry, the goal of the project manager should be to minimize the difference between "as planned" and "as built."

As a final comment I pass along a challenge issued to a starting project team by a former vice president of regulatory. The challenge is to prepare and deliver the core presentation in such a manner as to NEVER SHOW A BACK-UP SLIDE!

Steven A. Biedenbach is president of Biedenbach & Stein, Inc., a consulting/graphics company specializing in preparation support for FDA Advisory Committee Meetings. He has been in the pharmaceutical industry since 1972. He can be reached at sabieden@earthlink.net.

© 2001 by the Regulatory Affairs Professionals Society (RAPS). Posted with permission on www.fdametings.com. Reprinted from the August 2001 issue of Regulatory Affairs Focus. This article may not be published, reposted or redistributed without express permission from RAPS and payment of appropriate fees when applicable. To obtain such permission, send a message to acrompton@raps.org.