How to Prepare for an Important Regulatory Meeting

Step 1: Gather messages, issues & supporting data (pre-slide or briefing document preparation).
The use of MIRS tables is helpful in the creation of issue cards. What is important at this initial stage is to get the content right. At this point, the various functions involved need to gather—then sort—all of the relevant content to be covered by the meeting. Ideally, the subteams should work to ether compile detailed information and create MIRS tables (especially for groups new to the MIRS process), but the information and the MIRS tables can also be without face-to-face meetings. De Young & Hayden, LLC can gather the information via virtual meetings in order to keep costs down when dealing with international developments.

Once the MIRS tables have been created, sorted, put into a logical rationale, then they should be distributed to the greater team (and others, such as management) for review.

Step 2: Evaluate and focus the content, create a slide/briefing document strategy.
Face-to-face at an offsite is preferred. The greater team needs to gathers to discuss subteam MIRS. That way everyone has a chance to comment, build and buy into the messages and issues on the table for discussion with the regulatory agency. The group can then draft a prototyped slide presentation. Whoever is drafting the briefing document should attend so that the same logic applies to both the slides and the documentation. Decisions need to be made regarding consistent use of data and how the data will be presented. At the end of this meeting, the team wants to have reached consensus regarding content and strategic logic behind the slides and the documentation.

Step 3: Create draft slides (briefing document should be created in parallel, focus here is on slides only).
Individuals should create the slides based on the collaborative discussion, revised MIRS tables and the draft slide outline (referred to as the prototype). Discussion of cosmetics (colors etc) and wordsmithing at this stage should be avoided. The focus should be on ensuring that the slides are message/issue oriented, and that there is a logic to how the data are focused. Slide titles should be significant messages when possible (i.e., “Clean Tox Profile” vs. Toxicology). The backup slides need to have a drill-down logic to them. Hence, the main tox slide will focus on key areas of concern—not all body systems, which can go into backups. These then need to be circulated in advance for review by the greater team. The MIRS should be put into a Q&A format at this point, so that issue cards/table can be finalized. The team needs to be thinking through all possible agency questions and building answers to them. A well-done MIRS greatly facilitates this process.

Stage 4: Review & rehearse face-to-face
Consider having presenters first talk through their presentation without using any slides. Doing so helps to identify how well presenters actually know their materials and the presentation strategy, as well as the level of comfort presenting. The slides can then be walked through presenter by presenter, with the group critique and revision. The presenter can then make whatever chances are deemed necessary by the entire group. (This is a good meeting to bring in management so that they have some say in the final slides. Of course, they can be on the earlier distribution list.) Much group review of Q&A should take place at this point, as well.

Stage 5: Practice and rehearse
At this point the slides should basically be done, so whoever is responsible for the colors, fonts etc. can put them into the final format. Presenters should then practice making their presentation. If they need presentation coaching, then this is a good time to do it. (Done earlier, though, for someone who may have major needs—and done outside of the larger group.) It is important to

drill into and practice Q&A—some based on the MIRS; other questions need to come from expertise drawn from outside of the team (in order to avoid myopia). At this point practice until is it excellent—no surprises. Note: teams tend to spend too little time practicing intense Q&A.

How much time should be invested? For an FDA Advisory Committee for a novel MOA and potential block buster sales—a substantial amount in order to ensure success. For a routine meetings to discuss clinical development issues, get regulatory feedback on specific development questions, the process can be condensed, of course. However, the process is consistent: Work first on content; then on logical presentation; ensure that there are no loose ends; and practice, practice, practice.

DYH