AAPS Meetings Guide

AAPS updates this guide annually. To ensure you are using the most up-to-date reference, visit [www.aaps.org/workshops](http://www.aaps.org/workshops)

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Purpose of This Guide

AAPS welcomes proposals for face-to-face events from multiple sources, including individual members, groups of members, AAPS volunteer leaders, and partner organizations. This guide will help organizers understand how proposals are evaluated and managed so that they can develop an effective proposal with minimal frustration, and so that AAPS can approve and organize an event as quickly as possible. This guide does NOT apply to the development of PharmSci 360 (AAPS’ flagship annual conference).

There are a number of questions AAPS asks about each proposal, many of which an organizer either cannot answer, or cannot answer without help from AAPS staff. This is why AAPS assigns staff member to help each organizing team develop and submit a final proposal as soon as the association receives the first draft of a proposal at meetings@aaps.org.

If you have questions while developing your idea, contact AAPS at meetings@aaps.org at any time.

The Most Important Question: What is Your Goal?

The most important question that AAPS considers is one that organizers must answer: What is the goal of the event? AAPS holds events to advance its mission: advancing the capacity of pharmaceutical scientists to develop products and therapies to improve global health.

Every AAPS event is expected to deliver programming that provides value and changes the skills, knowledge, and/or attitudes of participants. Events that don’t affect participants in this way fail to advance the organization’s mission.
Roles & Responsibilities

Organizers

Organizers’ most important contribution is to provide scientific expertise. They identify a topic that is important to a group of scientists, and developing a program that will explore that topic. Their responsibilities include:

- **Identifying the goal/purpose of the event.**
- **Identifying a focused target audience.** AAPS will not approve an event that is designed for “everyone” or “every skill level.” Cross-disciplinary programming is encouraged, but not without a clearly stated target audience.
- **Assisting staff in conducting a market scan to identify any competition for the event.**
  
  Organizers will be asked to name competing events and meetings, and to differentiate their event from others that have been held recently.

- **Developing a program outline, session titles, session descriptions, and learning outcomes/objectives that describe in specific terms how participants will be changed by participating in this event.** Change may focus on expanding knowledge, developing a new skill, challenging participants’ perception or attitude about an issue.

- **Selecting the appropriate learning format for the program.** This is done in consultation with AAPS staff. “Learning format” refers to how information is conveyed. Examples of popular
formats include: lectures, debates; panel discussions; hands-on experiences with software and
equipment; tours; etc.
- Selecting speakers and facilitators.
- Inviting speakers and facilitators after a program is approved.

Organizers do not have any authority to create contracts or obligations on behalf of AAPS. This includes:

- **Organizers may not book hotels or other meeting spaces.** In the event of an employee booking
  space at a company facility, AAPS must give approval prior to the reservation being made.
- **Organizers may not make offers to potential exhibitors or sponsors.** AAPS appreciates
  introductions to these parties, but organizers may not make guarantees by oral or written
  contract to a potential partner.
- **Organizers may not incur promotional expenses.** This includes printing flyers, renting lists, or
  hiring consultants.

**AAPS Staff**

Staff are responsible for the business plan that supports an event. Staff collaborate with organizers to
test ideas and plans, to safeguard the use of the AAPS brand and resources, and ensure the needs of
AAPS members are kept at the forefront of planning. Staff responsibilities include:

- **Collaborating with organizers through the proposal development process.** Organizers cannot
  answer all the questions that staff must ask about a proposal on their own. Staff work with
  organizers to move the development process along quickly and with as little frustration as possible.
- **Ensuring the identification of effective and relevant content by testing ideas that are proposed to
  AAPS.** Staff will conduct surveys, lead market scans, produce reports on past events, and/or collect
  other data as necessary to test an idea.
- **Work with the Scientific Meeting Screening Committee to have the proposed screened by an
  appropriate target audience represented in the membership.** Staff collect, evaluate, and report on
  the feedback received from screeners.
- **Coordinating and developing the final program and agenda.**
- **Contracting and fulfilling logistics.** Including but not limited to selecting locations, meals, and audio-
  visual support.
- **Managing speakers.** Including but not limited to issuing invitation letters, or in some cases,
  supporting the issuing of invitations.
- **Assigning and issuing reimbursements.**
- **Contracting with exhibitors and sponsors.**
- **Marketing and promoting the event.** Staff will create and carry out the promotional strategy for the
  event. This includes mailings, emails, social media, list rentals, and the website.

**AAPS Scientific Meeting Screening Committee**

The AAPS Scientific Meeting Screening Committee is appointed annually by the AAPS Board of Directors. The
Committee serves as a resource to assist staff in ensuring appropriate scientific review occurs for
every proposal. The Committee is composed of members from across the drug development cycle who
are able to identify industry experts who can review meeting proposals.
What Makes a Good Proposal?
AAPS produces events that pursue the organization’s mission: to advance the capacity of pharmaceutical scientists to develop products and therapies that improve global health.

Successful proposals have:
- A specific goal
- A clearly define target audience
- An outline that includes proposed titles for education sessions and learning objectives that relate to the goal

The purpose of completing the submission form (Appendix 1) and drafting an outline (Appendix 2) is to collect this information. Organizers may contact AAPS at meetings@aaps.org while completing the form for help – staff want to begin collaborating with you on your proposal as soon as you are ready.

How AAPS Evaluates a Proposal
AAPS events are a collaboration between scientist organizers, who bring the expertise to identify a critical topic in the pharmaceutical community and to develop a program to address it, and AAPS staff, who bring an expertise in event execution, as well data about AAPS’ membership and trends in the performance of AAPS events.

AAPS uses two lines of inquiry to test a proposal that has been developed by organizers with the support of staff:

1) The goal of the program and its drafted outline are screened by other scientists in AAPS’ membership to determine if the target audience will respond to this event if it is scheduled
2) The business case for the program is reviewed by a team of staff members who evaluate the proposal’s logistics and budget; make recommendations about additional features, such as posters or exhibitors; and reach out to potential partners who may co-present the event

Learning Format Matters, Too
AAPS events utilize the best principles and practices in adult learning. Interactive learning opportunities are particularly valued. AAPS is especially interested in proposals that include:

- Free discussions and open exchanges of ideas
- Demonstrations
- Debates
- Lecture-style presentation
- Skill-building through hands-on exposure
- Case studies
Evaluation Process

Step 1—Submit to AAPS
After submission, an AAPS staff person will be assigned to shepherd organizers through the review process. This staff person will help you clarify details in your proposal so that the case for it is as strong as possible.

A teleconference will be scheduled by AAPS Staff to meet with your organizing team to review your program proposal.

Step 2—Blind Peer Review
Your program outline will be blind-screened by a group of your subject matter expert peers assembled by the Scientific Meeting Screening Committee and staff. It will be scored using a scoring rubric that explores the value of the program to the intended audience. The qualitative feedback and average score will be shared with the organizers, but the identity of the reviewers and their individual feedback and scores will be kept confidential.

Step 3—Business Case Process/Approval Recommendation
AAPS staff will meet to consider business case for the proposal and make the final approval or rejection recommendation.

Questions that staff will consider include:

- Is the target audience too narrow, too broad, or too heavily dependent on a particular type of member?
- Who are the competitors for this program? Is there another conference or event that already “owns” this space?
- Are there partnering opportunities, either in the content with another organization or in exhibits and sponsorships by industry?
- What does historical data for related AAPS events say about this program? Or is this an emerging topic or format?

What if the Proposal is Rejected?
AAPS wants to host events that help scientists. A rejected submission can be revised and resubmitted anytime. Staff will work with organizers to refine the proposal and resolve the issues that led to rejection.

How AAPS Decides on Posters, Exhibits, Receptions, Etc.
AAPS and organizers will discuss which event features – posters, exhibits, receptions, etc. – may enrich an event. AAPS has final approval on such additions, although organizers are welcome to recommend them when describing their goal for the event.

Abstracts and Posters
AAPS reserves the right to manage a poster exhibition in the way it believes best suits the event. Generally, organizers should expect:
1. **AAPS will require a minimum number of accepted abstracts/posters, and will cancel the poster presentations if the minimum is not met.** AAPS sets this minimum based on the goals of the event and the business plan for the event.

2. **AAPS discourages poster exhibits that compete with PharmSci 360.** PharmSci 360’s call for abstracts runs throughout the spring, and the poster presentations are made in the fall. AAPS will not run calls for abstracts or present posters at times that conflict with the PharmSci 360 schedule.

3. **AAPS manages the call for, selection, and presentation of abstracts to ensure an unbiased, transparent process.** Organizers may be called upon to screen abstracts and assist with scheduling, but AAPS’ decisions are final.

**Exhibition and Sponsorship**

AAPS appreciates organizers’ suggestions for potential exhibitors and sponsors, as well as introductions to those parties, when possible.

Only AAPS can enter into a contract with an exhibitor or sponsor. Organizers may not promise opportunities to potential exhibitors and sponsors.

**Travel Support and Reimbursement**

AAPS offers travel support with the goal of bringing the best possible scientific knowledge to an event. This philosophy applies to all AAPS programs including PharmSci 360, webinars, workshops, etc.

AAPS uses a variety of strategies to support speakers’ participation in events. To understand how AAPS approaches the use of its resources, read the following information closely. **All travel support and reimbursement opportunities will be determined during the business-planning process by staff and are subject to limitations and individual confirmation prior to any event.**

**Travelships**

Whether travelships are appropriate for an event, and the qualifications for them and method of distribution, is determined by staff during the business-planning process. They must fill a critical need to bring science to a meeting, and must be reasonable and financially sustainable based on the event size and audience demographic. Travelships are not an option for every event.

**Speaker Reimbursement**

AAPS recognizes that volunteer time and contributions are vital to our organization’s success and we highly value the leaders who help us advance our mission.

As a non-profit organization, AAPS is unable to provide full travel reimbursement and full conference complimentary registrations to all volunteers. Only AAPS Staff can approve, manage, and allocate funding for reimbursement and this will be communicated prior to the event.
Appendix 1 – Submission Form
Complete this form located at meetings@aaps.org to submit your draft proposal.

**AAPS Submission Form**

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<table>
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<tbody>
<tr>
<td><strong>1. Date of Submission</strong></td>
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<td><strong>2. Target Audience</strong></td>
<td></td>
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<tr>
<td><strong>Identification</strong></td>
<td>Who is this program being designed for and what challenges do they face? Be specific: AAPS does not accept programs that are for “everyone” or “all skill sets.”</td>
</tr>
<tr>
<td><strong>3. Justification</strong></td>
<td>Why is this program needed?</td>
</tr>
<tr>
<td><strong>4. Goal</strong></td>
<td>How will participants be changed by this event? How will this improve their performance at work?</td>
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<tr>
<td><strong>5. Learning Outcomes/Objectives</strong></td>
<td>Support the stated goal by outlining a few specific outcomes you expect participants to experience</td>
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<tr>
<td><strong>6. Gap Analysis</strong></td>
<td>What gap in a pharmaceutical scientists’ knowledge does this program fill? Why do you believe this is a gap?</td>
</tr>
<tr>
<td><strong>7. Program Topic/Proposed Title</strong></td>
<td>(10 word maximum)</td>
</tr>
<tr>
<td><strong>8. Program Summary/Description</strong></td>
<td>(250 words maximum)</td>
</tr>
<tr>
<td><strong>9. Learning Format</strong></td>
<td>Roundtables, symposia, debate, tour, breakout sessions, panels, etc.?</td>
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<tr>
<td><strong>10. Optional -- Identify any potential co-sponsoring organizations</strong></td>
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<tr>
<td><strong>11. Competition</strong></td>
<td>What events, programs, meetings, etc. compete with this program? (include URLs, if</td>
</tr>
<tr>
<td>12. <strong>Optional -- Recommended Length, Date, Location</strong></td>
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<td>-------------------------------------------------------</td>
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<tr>
<td>AAPS has final authority on the logistics of any program. However, you may recommend the length of the event, the date, and a specific location. Explain your recommendation.</td>
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13. Which of these areas align with the knowledge presented in this program? (select 10 maximum)

| Analysis and Pharmaceutical Quality | Microdialysis |
| Animal Pharmaceutics and Technology | Modified Release |
| Bioanalytical | Nanotechnology |
| Bioequivalence | Non-Clinical Dose Formulation and Analysis |
| Biomarkers in Translational Medicine | Nutraceuticals and Natural Products |
| Biosimilars | Ocular Drug Delivery and Disposition |
| Biotechnology | Oral Absorption |
| Cellular and Molecular Toxicology | Patient-Centric Drug Development, Product Design, and Manufacturing |
| Chemical and Biological API Manufacturing Technology | Pharmaceutical Impurities |
| Chemistry, Manufacturing, and Controls (CMC) | Pharmaceuticals in Global Health |
| Clinical Pharmacology and Translational Research | Pharmacogenomics (PGx) |
| CMC Statistics | Pharmaco-imaging |
| Contract Research Organization (CRO) | Pharmacokinetics, Pharmacodynamics, and Drug Metabolism |
| Dermatopharmaceutics | Pharmacometrics |
| Discovery Modeling and Simulation | Physical Pharmacy and Biopharmaceutics |
| Drug Candidate Selection | Preformulation |
| Drug Discovery and Development Interface | Process Analytical Technology |
| Drug Metabolism | Process Development |
| Drug Transport | Process Modeling and Simulation |
| Excipients | Protein Aggregation and Biological Consequences |
| Formulation Design and Development | Protein Purification, Storage, and Transportation |
| Generic Pharmaceuticals | QbD and Product Performance |
| In Vitro Release and Dissolution Testing | Regulatory Sciences |
| Inhalation and Nasal Technology | Stability |
| Ligand Binding Assay Bioanalytical | Sterile Products |
| Lipid-Based Drug Delivery Systems | Systems Pharmacology |
| Manufacturing Science and Engineering | Targeted Drug Delivery and Prodrug |
| QbD and Product Performance | Therapeutic Product Immunogenicity |
| Other (fill in box) | |

14. List any external groups/organizations that should be notified about this event, or who may wish to partner in presenting this event. Include URLs, if possible.

15. **Identify Chair/Co-Chairs**
These individuals will work with AAPS Staff and lead their selected organizing team in developing the program content and identifying and soliciting speakers.

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<th>CHAIR (1 only, required):</th>
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16. **Overview and Program Outline** *(see example on next page)*
   a. With your submission form, you must submit a program that includes the following:
      i. Number of sessions and length of program
      ii. Session title and the topic to be covered
      iii. 3-5 learning objectives for every session
         1. Learning objectives should be measurable, specific, and describe what the participant will leave that session knowing.
      iv. Proposed speaker information
         1. Speakers do not have to be confirmed at the proposal stage but tentative names and/or needed affiliations (i.e. this speaker must be FDA) should be included.
Appendix 2 – Example Program Outline

EXAMPLE PROGRAM OUTLINE

Suggested Title: Essentials of Regulatory Compliance for Pharmaceutical Scientists

Proposed Structure:

- 1-day Workshop
- 8 Session Presentations
- 1 Panel Discussion
- 1 Breakout Discussion
- Maximum 10 Speakers

Program Outline and Objectives

1. Overview and Orientation of Regulatory Compliance—Connectivity and Impact
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Introduction to statute, regulation and guidance relationships.
      ii. Presentation of an overview of each quality pillar: GLP, cGMP and GCP.
      iii. Positioning the quality pillars in eCTD submissions.
      iv. Review of regulatory information resources.

2. GLP: Summary of Nonclinical Regulatory Requirements
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Introduction of GLP safety and toxicology studies and explanation of how they fit into the regulatory lifecycle.
      ii. Comparison and contrast of critical GLP roles and responsibilities from the perspectives of the Sponsor, Study Director, Principle Investigator and Quality Assurance.
      iii. Delineation of the critical constituents of GLP study protocols, data, and reporting requirements.

3. GLP: Formulation, Formulation Analysis and Bioanalytical Perspectives
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Understanding relevant GLP formulation nuances.
      ii. Formulation assay method development and validation considerations.
      iii. Points to consider regarding formulation sample analysis stability, potency, and content uniformity.
iv. Critical aspects of bioanalytical method development, and regulated method validation, sample analysis, and data reporting.

4. cGMP: Pharmaceutical Quality System (PQS)
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. An in-depth review of ICH Q10.
      ii. Explanation of Quality Risk Management principles.
      iii. Provision and insight into the value of linking development knowledge to manufacturing, and knowledge management to continuous improvement.

5. cGMP: Quality Investigations
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Provision of corrective action and preventative action (CAPA) basics.
      ii. Review key learnings and principles from other industries.
      iii. Description of the use of metrics and trend analysis.
      iv. Differentiation of how to perform appropriate quality investigations during development and commercial batch manufacturing, and when managing investigations of external vendors such as suppliers and CROs.

6. GMP Site Inspections
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Comparison and contrast of general inspections and pre-approval inspections (PAI).
      ii. Provision of information regarding PAI preparations, responding to PAI findings and understanding implications of PAI inspections.
      iii. Differentiation between global agency paper inspections and site inspections.

7. GCP: Overview and Background
   a. Possible Speaker(s): xxx
   b. Learning Objectives
      i. Understanding the origin and requirements of human subject regulations under US and ICH GCP practices for clinical research.
      ii. Review of pertinent models for conducting clinical research, focusing on new drug development and approval.
      iii. Review of essential ICH Guidance (E6(R1)) and Federal regulations for the conduct of clinical trials.

8. GCP in Action
   a. Possible Speaker(s): xxx
   b. Learning Objectives
i. Understanding how to put GCP into action from obtaining Informed Consent, to composing a Protocol, to selecting Clinical Sites and ending with describing the Data Review Committee.

ii. Understanding to who has the accountability and responsibility of GCP in the clinical settings.

iii. Understanding GCP similarities and differences among the different Phases of drug development.