AAPS Workshop Proposal Guide

Contents

Workshop Proposal Process

1. **Complete and submit a workshop proposal form to meetings@aaps.org**.
2. AAPS staff approve workshop proposals in consultation with the Scientific Advisory Committee.
3. Anticipate that AAPS may need several weeks to assess a proposal because the association may have to consult multiple parties to determine the proposal's viability. The proposal form is posted at www.aaps.org/elearning.
4. AAPS will schedule a call with organizers to discuss dates and deadlines if a proposal is accepted.
5. Rejected workshop proposals may be re-submitted with modifications or submitted to a different program in a different format, such as symposium for one of AAPS' signature conferences.

Why AAPS Conducts Workshops

AAPS conducts workshops so that it may offer more opportunities for scientific engagement. Each workshop is built with the goal of creating an exchange of research, application, and ideas among a relatively small group of scientists and partners, the latter of whom enrich the event with partner presentations and financial support.

Workshops also give AAPS the ability to be nimble in the face of a rapidly evolving scientific and business environment because of their short timelines, manageable sizes, and singular focus.

Basis of Assessment for Workshop Proposals

In determining whether to present a workshop, AAPS uses a structured and data-driven decision-making process based on the following success factors:

1. **Relation to Mission**: The event must further AAPS' mission of bringing scientists together in a focused area to advance their science. This may specifically yield tangible outcomes in the form of scientific opinions or white papers.
2. **Benefit to Members**: The event benefits members by creating an environment for scientific exchange that advances professional knowledge and expertise that is projected to attract 50 or more participants, in addition to the organizers and speakers.
3. **AAPS Scientific Positioning**: The event fits into AAPS' scientific agenda for the year, as described in the Four Seasons of Science and in consultation with the AAPS Scientific Advisory Committee as necessary.
4. **Credibility of the proposed program**: AAPS values its credibility as a scientific society and a convener of scientists above all other concerns, and will assess the proposed sessions, speakers, organizers and other factors of the meeting with this in mind.
5. **Timing and Resource Management**: The event fits into AAPS' planning cycle.
6. **Financial Viability**: The event's proposed budget is financially sustainable through a combination of projected income from registration and sponsorship, and well-managed expenses in format and venue choices.

Scientific Program Content Sourcing and Development

Workshop proposals must generally fit the following elements.

1. **Workshops are stand-alone events**: Workshop agendas must be accessible to scientists who are new to AAPS and a topic. A workshop may be the continuation of a conversation or may carry over topics from another event, an AAPS Community discussion, or other AAPS engagement. They may also set up an envisioned discussion or help develop an opinion or white paper that will be published later. But each workshop must be accessible to scientists who have not participated in prior conversations or have no interest in future ones.
2. **Workshops must present a scientific agenda that advances the science that will be addressed**. Organizers should assess resources already available on a topic – including the agendas of competing events – to determine if a topic should be explored before developing a proposal. AAPS staff will consult with the Scientific Advisory Committee and when necessary, the experts in specific AAPS Communities, on the viability of any proposal.
3. **Any person, organization, or partner can propose an AAPS Workshop**. AAPS assesses proposals as described above, and independent of whether the proposal was developed by a group of

AAPS members, an AAPS partner, a sister organization, or another party. Any proposal that meets AAPS' expectations for presenting credible research, challenging discussion, and a variety of informed viewpoints on an issue is welcome, regardless of its origin.

4. **AAPS Workshops are not training or education events**. Proposals for courses or similar education programs that seek to teach the fundamentals of a science should be submitted separately to AAPS. Contact AAPS at meetings@aaps.org to discuss developing a course.

5. **Workshops are evaluated annually to determine if they remain viable**. AAPS's calendar is a limited resource. Only programs in which members demonstrate continuing interest through attendance numbers, are repeated. Workshops that are held annually or otherwise are repeated are continually evaluated to determine if they are still viable.
New workshops are launched on-line in order to minimize financial risk to AAPS on an untried topic area.

Workshop Organizing Committee Members, Speakers, and Moderators

A workshop's organizing committee members, as well as the proposed speakers and moderators, must be diverse, seeking to represent different views on a topic, and to engage scientists from a variety of backgrounds.

The diversity AAPS expects to see in an organizing committee's members and the program's speakers and moderators includes:

a. **Differing scientific viewpoints**, which are critical to the discussion of new and emerging issues in which scientific differences of opinion or approach exist.

b. **Differing organizational backgrounds**, especially when an AAPS partner proposes a workshop, assure participants that the scientific agenda and speakers represent the full view of the science under discussion.

c. **Differing individual backgrounds,** demonstrating to members that AAPS is a welcoming and inclusive environment for scientists from varied backgrounds.

d. **Differing individuals --** in workshops that are repeated, the organizers on the committee and proposed speakers must change regularly to engage new scientific voices. Committee members should serve no more than three consecutive terms on an organizing committee.

e. **Differing chairs** – in workshops that are repeated, chairs may only serve 1-2 terms on an organizing committee to assist the committee in being open to many viewpoints.

Workshop organizers will be assessed based on their likelihood of collaborating successfully to deliver a workshop. AAPS cannot deliver successful programs if organizers will not accept the value of science from others, including industry scientists, partners who wish to participate in the program, etc., and the expertise of staff on matters of logistics including scheduling, pricing, etc.

Travel Reimbursement

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. AAPS staff will issue a travel reimbursement policy for in-person workshops that is aligned with reimbursement policies for AAPS' signature events.

Workshop Scheduling

1. **AAPS announces its schedule of workshops, conferences, and meetings no later than the first quarter of the calendar year each year**. This assists AAPS members and partners in planning their attendance.
2. **Workshops generally require at least six months from proposal to execution to deliver**. In-person workshops may require an even longer planning cycle in order for adequate marketing and logistical planning.
3. **Proposals that require collaboration with another organization require more planning time**. AAPS must negotiate and enter into an agreement with the legal representatives of the other organization, which is generally its Executive Director or a staff member with decision-making authority. Based on strategic considerations by AAPS leadership, an agreement may be either for a single event or a series of events.
4. **Workshops are stand-alone events.** AAPS is not accepting proposals for workshops in conjunction with PharmSci 360, the National Biotechnology Conference, the Land O' Lake Conferences, or other events.

Collaborations and Co-Sponsorships

AAPS will only enter into collaboration agreements with other scientific organizations where AAPS can exercise control over the quality of the science and the finances of the event.

1. Each proposal to collaborate with another organization, from a simple exchange of marketing to a complex co-presented event, will be weighed against AAPS' goals for international growth, engagement in particular scientific areas, and AAPS' business and marketing plans.
2. Each proposal to collaborate with another organization must be based on written contract signed by the AAPS Executive Director and a legal designate of the partnering organization.

Post-Workshop Publications and Recordings

1. Workshop organizers who commit to delivering a publication following the event must meet staff-determined deadlines. AAPS will in turn provide organizers with support for developing a publication.
2. AAPS Journals hold the right of first refusal on any publication emerging from an AAPS workshop. AAPS editors will determine their interest in a publication within 3 weeks of receiving a draft.
3. Workshops will be recorded in their entirety at AAPS' discretion. Recordings will be made available to registrants and members for up to a year after the event.

Organizing Committee (Chair, Co-Chair, etc.) Agreement

As a member of the organizing committee of a workshop, **you agree to**:

1. Commit to a timeline and deliverable dates with staff during a kick-off meeting.
2. Acknowledge that AAPS may cancel the workshop if your committee misses agreed-upon deadlines.
3. Provide a minimum of 3-5 opportunities for partner presentations in each in-person program that are deemed acceptable by the AAPS Business Development Team.

4. Limit your engagement to developing the scientific program unless requested by staff to assist in logistics.
5. Acknowledge that registrations by attendees are purchased on a first come/first-serve basis.
6. Recruit all speakers and moderators.
7. Assist with speaker management and communication as staff requires.
8. Promote the workshop to your personal networks by email and through social media.
9. Promote the workshop to your AAPS Community.
10. Assist the Business Development Team in identifying prospective sponsors and appropriate contacts. The Business Development Team manages AAPS' relationships with its partners, including soliciting, negotiating, and billing.
11. Acknowledge that AAPS Journals hold the right of first refusal on any opinion, white paper, or other publication emerging from an AAPS workshop.
12. Acknowledge that organizing committee members, speakers, and moderators are recognized at AAPS' discretion, and AAPS will limit the discounts and benefits offered to these individuals.

Appendix 1: Workshop Proposal Form

1.	**Date of Submission**	
2.	**Target Audience Identification** 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."	
3.	**Justification** Why is this program needed?	
4.	**Goal** How will participants by changed by this event? How will this improve their performance at work?	
5.	**Learning Outcomes/Objectives** Support the stated goal by outlining 3-5specific outcomes you expect participants to experience	
6.	**Gap Analysis** What gap in a pharmaceutical scientists' knowledge does this program fill? Why do you believe this is a gap?	
7.	**Program Topic/Proposed Title** (10 word maximum)	
8.	**Program Summary/Description** (250 words maximum)	
9.	**Learning Format** Roundtables, symposia, debate, tour, breakout sessions, panels, etc.?	
10.	**Optional -- Identify any potential co-sponsoring organizations**	
11.	**Competition** What events, programs, meetings, etc. compete with this program? (include URLs, if available) How will you differentiate your program?	
12.	**Optional -- Recommended Length, Date, Location**	

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.	

13. Which of these areas align with the knowledge presented in this program? (select 10 maximum)

o Bioanalytical	o Ocular Drug Delivery and Biopharmaceutics
o Bioequivalence and Bioavailability Science	o Oral Biopharmaceutics and Absorption Modeling
o Biomarkers and Precision Medicine	o Personalized Medicine
o Biopharmaceutical Product Attributes and Biological Consequences	o Pharmaceutical Discovery and Preclinical Development
o Chemical and Biological Active Pharmaceutical Ingredient	o Pharmaceutical Impurities
o Chemistry, Manufacturing, and Controls (CMC)	o Pharmacokinetics, Pharmacodynamics, & Drug Metabolism
o CMC Statistics	o Pharmacometrics
o Drug Transport	o Preformulation & Formulation Design/Development
o Excipients	o Process Analytical Technology
o Gene and Cell Therapy Products	o Protein Purification, Storage, and Transportation
o Global Health	o Regulatory Sciences
o In Vitro Release and Dissolution Testing	o Stability
o Inhalation and Nasal	o Therapeutic Product Immunogenicity
o Lipid-Based Drug Delivery Systems	o Topical and Transdermal
o Manufacturing Science and Engineering	o Veterinary Pharmaceutics, Biologics, and Technology
o Modified Release	o Women in Pharmaceutical Science
o Nanotechnology	o 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 with work with AAPS Staff and lead their selected organizing team in developing the program content and identifying and soliciting speakers.

	CHAIR (1 only, required):
Name:	
Company:	
Address:	

Country:	
Phone	
Email:	

	CO-CHAIR (optional):
Name:	
Company:	
Address:	
Country:	
Phone	
Email:	

	CO-CHAIR (optional):
Name:	
Company:	
Address:	
Country:	
Phone	
Email:	

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 of a 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.
      iv. Investigation of implications of contract manufacturing.

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.