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| **PDA** Parenteral Drug Association | **PDA Policy / Procedure** | **EX-0021-01** |

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## 1. PURPOSE

1.1. PDA Chapters (Chapters) are a critical part of the PDA organization. The role of a chapter is to provide people in its territory with local opportunities to connect to PDA and with one another. Chapters may organize events (in-person meetings, webinars, etc.) to support this effort. It is essential that these events are appropriately planned, branded, and marketed to ensure they serve their assigned territory and do not conflict with PDA headquarters' (PDA) events. This policy provides guidance to chapters to achieve this aim.

## 2. SCOPE

2.1. All PDA Chapters

## 3. DEFINITIONS

3.1. PDA – includes all PDA offices; in the US, Europe, and Asia

3.2. Press – a bona fide member of the trade or mainstream press with press credentials.

## 4. Planning, Timing, and Topics for Chapter Events

4.1. Chapters should submit a planned calendar of events to PDA by the end of Q3 of the year preceding the plan year.

4.2. Chapters should provide additional updates on any new events added to the plan or changes to existing events as they occur.

4.3. Chapter events will be tracked on a single calendar and reviewed in Chapter Council meetings. The proposed event overview including theme and any additional available detail must be provided as early as possible to facilitate appropriate feedback by PDA.

4.4. Upon receiving the planned calander of events, changes to events, or added events PDA (Programs and Training Departments in US, Europe, and Asia Pacific)

will provide feedback within five business days to ensure any conflicts or issues are identified quickly.  If no feedback is provided in that time, the event may be considered agreed to.

4.5.     All chapter events will be published in the chapter section of the PDA Global Event Calendar at https://www.pda.org/global-event-calendar/pda-chapter-events. All chapter events must align appropriately with the PDA HQ global event calendar. Chapters will refer to the PDA Global Event Calendar for the currently published list of events.

4.6.     Chapters should take care not to advertise any event that could reasonably be expected to compete with PDA such that it draws attendees away from PDA events or trainings.  Competitive events can include those with the same speakers, with presentations on the same technical or regulatory document, or with a broadly similar theme being covered by multiple speakers.  Competitive events should not be advertised within 90 days before the start of a PDA event but can be advertised following a PDA event (or during a PDA event with appropriate coordination).  Consideration will be given to chapter events conducted in launguages other than English, and to events where the theme is applied to specific local conditions.  These considerations should be explicitly noted in the marketing for chapter events, which might othwerwise draw attendees away from PDA events or trainings.

4.7.     PDA will review the chapters calendar of events before adding previously unplanned events to the PDA calendar.  If PDA identifies areas of potential overlap with an existing chapter event, PDA will contact the chapter to work through any competition concerns.  If such a case should occur, a chapter will not be required to move an existing event.

4.8.     Webinars and all types of digital events are easily accessible by attendees outside of the chapter territory. Therefore, it is especially important for the timing and topic of webinar events to be coordinated with PDA. The intent is not to restrict chapters from having webinars but to:

- Make sure the timing and content does not conflict with PDA events and training;
- Provide the chapter with information on relevant global events and training in order to coordinate their promotion.

## 5.     Branding of PDA Chapter Events

5.1.     Chapter events should be branded using the chapter logo to differentiate chapter events from the events organized by PDA. Details regarding the use of the PDA logo and chapter logos are published in the PDA branding guide, which is available upon request.

5.2.     When referring to a PDA chapter in written communications, chapters must use the correct name format to maintain the integrity of the PDA copyright and to avoid confusion.  As displayed on the chapter logo, the correct format for the chapter name is:  "PDA [Chapter Name] Chapter" (ex. PDA Australia Chapter).

5.3. PDA is responsible for providing approved training courses aligned with the official positions of the organization on scientific and regulatory topics. To avoid confusion "PDA Training Course" or "PDA Training" cannot be used in chapter marketing materials unless it is for a PDA training course being offered by, or in conjunction with, the PDA Education department.

## 6. Marketing of PDA Chapter Events

6.1. Chapter events must be marketed solely to the region defined in the chapter charter to the extent possible. This includes using the provided current chapter member/nonmember lists. Chapter events should not be marketed as a global event unless there is a specific agreement between the PDA and the Chapter.

6.2. When an event is co-hosted by two or more chapters, each participating chapter should market the event within their respective regions.

6.3. Chapters may receive requests from members of the Press for access to chapter events. Per PDA policy, members of the press can receive 1 press pass per publication represented (see definition above for who qualifies as a member of the press). When a chapter uses the PDA registration system a Press Pass request form must be filled out by interested members of the press. PDA makes the final decision on whether a press pass request is valid. https://www.pda.org/about-pda/press-pass-request-form For other chapters, please provide information on press interest in chapter events for PDA tracking globally.

## 7. Marketing of PDA Global Events

7.1. PDA will determine the schedule of promotions to a global audience for events planned and run by PDA, including when this is done in partnership with one or more chapters.

7.2. Chapters will use appropriate channels and opportunities through the marketing of their own events and during their events to promote relevant PDA events and trainings. Wherever available, PDA will provide marketing materials that can be used for this purpose including email copy, social media graphics and copy, and powerpoint slides. There is no minimum requirement for chapters to promote PDA events and the provided information is intended only to facilitate support from the chapters where the chapters have determined that it is appropriate for their respective audiences.

## 8. Regulatory Speaker Requests

8.1. Any involvement of speakers from regulatory authorities or related bodies must be reported to PDA. For all regulators, chapters should notify PDA of the intent to invite such speakers prior to submitting a request to the agency. In situations similar to the FDA speaker request procedure outside the US and where PDA regularly engages such speakers, a request for the speaker should be executed

through a PDA office (for example, EMA and other trans-national regulatory agencies in Europe should be coordinated with PDA Europe).

8.2. FDA speaker requests – when requesting a speaker from FDA Headquarters or one of the Centers:

- Identify the desired speaker and topic with as much specificity as you can;
- Fill out PDA's Speaker Request form as completely as possible;
- Submit your request to PDA at least four months prior to your planned event (per FDA recommendation).
- When marketing the event on flyers and in emails let attendees know that an FDA speaker has been invited for the event, even though you may not receive confirmation of a speaker's availability until shortly before the event.

8.3. FDA speaker requests – when requesting a speaker from the local/district FDA branch:

- Identify the District Director or the most senior branch officer.
- Contact the District Director to discuss the speaker/topic desired. He or she will help you determine which speaker would best fit your program need and best represent the FDA.
- Secure agreement with the District Director on the speaker, topic, date and time that works best with your chapter and the speaker.
- Transmit the details of your local agreement to the PDA Chapter Liaison.
- The agreement will be submitted in a formal request letter to the FDA's headquarters office in Maryland to officially secure the commitment and to confirm that all essential parties are notified.