Advisory Board Handbook

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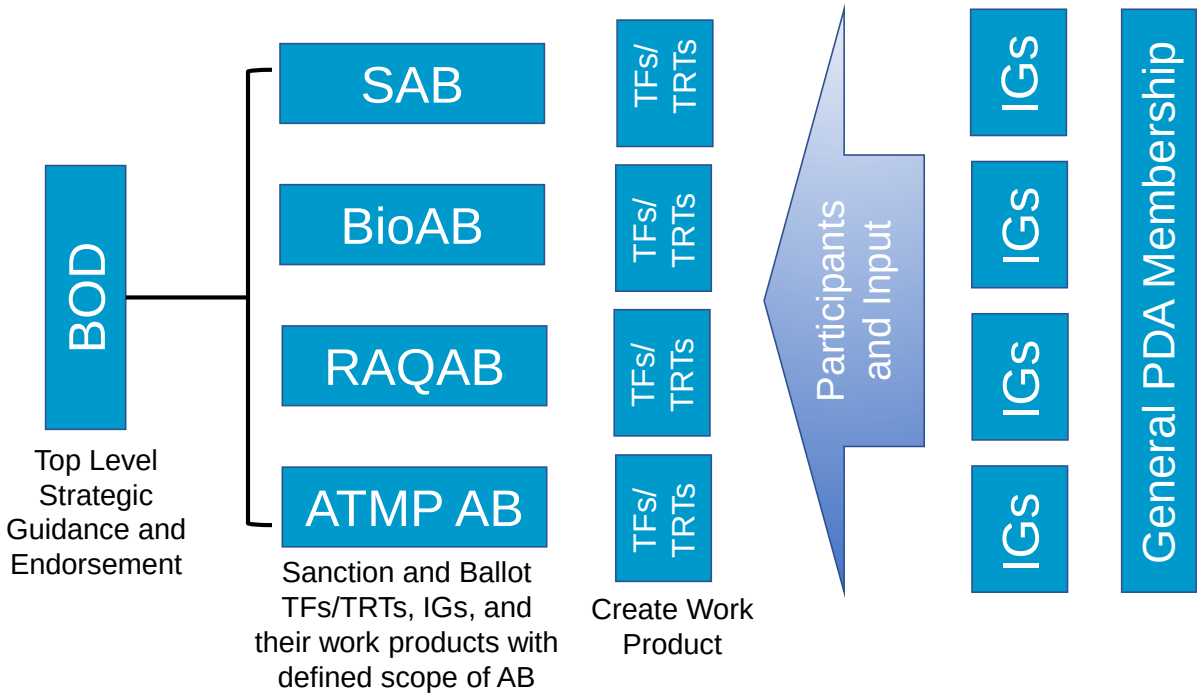
Welcome to PDA's Advisory Board

The Parenteral Drug Association (PDA) is pleased to provide an overview of the organization, governance, roles, responsibilities and business processes of PDA's Advisory Boards. This handbook provides a high-level outline of the PDA publications processes for technical documents and other PDA publications as well as a quick guide to applicable PDA support services for the Advanced Therapy Medicinal Products Advisory Board (ATMP AB), Biopharmaceutical Advisory Board (BioAB), Regulatory Affairs and Quality Advisory Board (RAQAB), and Science Advisory Board (SAB). The handbook aims to aid in understanding the terminology and timelines used in these processes as well as highlight best practices when developing regulatory comments. Lastly, this handbook clarifies the interactions between the Task Forces (TF), Technical Report Teams (TRT), Advisory Boards (AB), and PDA Scientific and Regulatory Affairs (S&RA) staff.

There are three groups that drive the development of technical documents, which you will see referred to throughout this handbook:

- Task Forces are groups of PDA volunteers who have conceived an idea for a technical document or other deliverable and have met defined threshold criteria for forming the team and have created a clear scope and purpose for the end product. A Technical Report Team is one type of Task Force.
- Advisory Boards manage a portfolio of Task Forces, providing oversight, monitor their progress, and ultimately vote to approve or disapprove the content developed for those teams for publication review.
- The PDA Scientific and Regulatory Affairs staff facilitates the entire development process by guiding teams through each step of the publication process and participates in AB activities (excluding votes).

Organization and Governance of PDA



The PDA Advisory Boards (ABs) provide scientific and technical expertise to the PDA Board of Directors as well as day to day content management of scientific and technical initiatives intended for PDA publication. The ABs guide and support the development of Technical Reports, Standards, Points to Consider documents, PDA Research, and *PDA Journal of Pharmaceutical Science and Technology (JPST)* and *PDA Letter* articles. The ABs collaborate on matters of overlapping expertise and relevance. As appropriate, each AB develops and makes recommendations to the PDA Board of Directors on proposed PDA positions, which may include comments to regulatory bodies regarding existing or draft guidances. The ABs support the creation and ongoing activities of Interest Groups in which PDA members review, discuss, and advance industry understanding of technical and quality-related topics. Each also contributes to PDA's educational mission by assisting the PDA Training Department in curriculum development.

Science Advisory Board

The Science Advisory Board (SAB) is composed of a diverse group of experts drawn from industry, regulatory agencies, and academia who provide guidance and set strategic direction for PDA on technical topics associated with pharmaceutical manufacturing and quality. These may include:

- Aseptic processing, sterility assurance, and microbial testing

- Manufacturing and packaging, and science
- Product quality analysis and testing, including visual inspection
- Analytical method development
- Application of data science

Biopharmaceutical Advisory Board

The Biopharmaceutical Advisory Board (BioAB) is composed of a diverse group of experts drawn from industry, regulatory agencies, and academia who provide guidance and set strategic direction on technical topics associated with biopharmaceutical and biotechnology-related manufacturing and quality. These may include:

- Upstream and downstream processing science for biopharmaceutical manufacturing
- Raw and ancillary materials
- Product class-specific manufacturing and quality testing aspects for vaccines, protein therapeutics, and other biologics
- Emerging technology, including analytical methodology and data application

Regulatory Affairs and Quality Advisory Board

The Regulatory Affairs and Quality Advisory Board (RAQAB) is composed of a diverse group of experts who provide guidance and set strategic direction on regulatory and quality topics spanning the lifecycle of healthcare products. This includes:

- Advancing harmonization, convergence and alignment in the regulatory space through regulatory engagement and advocacy,
- Driving and advancing guidance for industry,
- Scanning and analyzing the regulatory horizon, and
- Addressing such quality topics as quality risk management, data integrity, and quality metrics and quality culture.

Advanced Therapy Medicinal Products Advisory Board

The Advanced Therapy Medicinal Products Advisory Board (ATMP AB) is composed of a diverse group of experts drawn from industry, regulatory agencies, and academia who provide guidance and set strategic manufacturing and quality direction on technical topics associated with cell, gene, tissue, and other novel therapeutic modalities. These may include:

- Raw and ancillary materials
- Drug product and drug product manufacturing science
- Quality systems
- Product and process comparability

- Analytical methods
- Supply chain

Member Responsibilities & Expectations

A PDA Advisory Board can be comprised of up to 25 voting Members. Liaisons between ABs attend their assigned AB's monthly meetings and serve as the interface with the sister ABs and share information across all four Advisory Boards. Each AB is supported by non-voting PDA staff members, a non-voting AB Operations Manager from the PDA membership (ideally an Early Career Professional), and by the leaders of the associated PDA Interest Groups (IG). Each AB has one or more IG liaisons who update the AB about activities within the IGs. They also may have non-voting Early Career Professionals working on special AB related developmental projects.

The AB chair and vice-chair are approved by the Board of Directors and assume each post for a period of two (2) years. The AB Operations Manager serves for not more than 2 years and is selected by the AB chair, vice-chair, and PDA staff. Members each assume their positions for a period of three (3) years and are selected by the AB leadership team (chair, vice-chair, past chair and PDA staff). Members may serve two (2) consecutive three-year terms, following the PDA BoD procedure.

Participation in the AB requires a commitment on the part of every member of the Advisory Board. In particular, the regulatory commenting responsibilities of the AB are time sensitive and require adherence to strict schedules to ensure that comments are prepared, reviewed and approved in a timely manner to meet specified deadlines. It is the responsibility of AB members to review, comment and ballot within the allocated timeframes.

- **AB Member Expectations**
  - Timely response to Ballots.

    A response is required for all balloted technical documents (**2 weeks** is allotted for voting, unless noted otherwise).

    - **For a ballot to be approved:**
      - It must be voted on by at least 75% of all voting members of the AB (Quorum).
      - 50% + 1 of all voting members of the AB must vote to approve.

        (e.g., if the advisory board is comprised of 20 voting members, at least 15 voting members must have voted and 11 must vote to approve)

        Note: Lack of technical Knowledge in a specific area is not an appropriate reason to abstain. In such situation the AB member should review the document for editorial and/or structural issues.
      - Members can abstain from voting if:

- ❖ The member is unable to review and respond to the ballot due to prior commitments or time constraints. This type of abstention should be very infrequent.
- ❖ Voting on the ballot would constitute a conflict of interest for the member.

A reason for abstention must be provided; Abstentions will be tracked and monitored.

- ♦ AB members are expected to vote on at least 80% of official ballots

- Attendance/participation in AB meetings:
  - o Face to Face Strategy Meetings (Target 2 times per year)
  - o Monthly Teleconferences (*required unless time zone restrictions*)
  - o Ad-hoc Teleconferences, if applicable
  - o AB members are expected to attend 75% of regularly scheduled AB meetings.
- Active participation in AB (e.g, Leadership Team, Task Forces, Liaison or Regional roles, Goal committees, etc.).
  - o Serve in at least one of the following (e.g.):
    - ♦ Leadership Team (chair, vice-chair, past chair)
    - ♦ Lead or participate on commenting teams to collect comments, and prepare PDA's formal comments
    - ♦ Liaison (e.g., Task Force, Cross-Technical AB, Book Committee, Education AB, Interest Group) or regional representative.
      - ❖ The interest group liaison facilitates interactions between the interest group and the AB under which they serve. They also act as a resource for IG Leader questions or concerns, support IG leaders in succession planning, and attend IG leadership meetings when possible.
      - ❖ The task force liaison assures that a timeline is established and being met, assures that the deliverables are clearly established based on the approved PDA Project Proposal and provides periodic updates to the AB.
      - ❖ The AB liaison is a member of one AB and an observer in an additional AB. They represent their AB and may only vote with their AB.
    - ♦ Support PDA publications, with articles (e.g. PDA Letter)
    - ♦ Support PDA conferences; serve as a member or vice-chair of a PDA conference committee
- Share information applicable to the AB:
  - o Verbal updates at AB meetings
  - o Urgent issues can be distributed via email or the PDA Workspace
- Provide data for the knowledge, skills and aptitude (KSA) matrix and update as appropriate.

- Provide detailed review and input for technical reports during the scientific/technical review period. This can include consultation with subject matter advisor or other professionals in your professional network.
- Advisory Boards may elect to appoint subject matter advisors to specific Technical Report Teams. AB members will frequently serve in this capacity themselves. Advisors serve to help TRTs in overall planning and strategy and provide guidance on potential scientific and technical concerns.

- **Advisory Board Chairs and Vice-Chairs**
  - Lead AB meetings (monthly and face to face strategy sessions).
  - Ensure projects approved for inclusion into the development process are in alignment with PDA mission and strategic goals.
  - Promote Technical Report Team/Task Force leader interaction with the AB.
  - Represent their AB at the PDA Portfolio Steering committee and Board of Directors meetings.
  - Develop AB strategies in line with PDA mission and strategic goals.
  - Lead teleconferences to discuss key issues.
  - Prepare Meeting Agendas, review minutes and ensure follow up on AB goals. Ensure issues are captured in meeting minutes and action items are assigned and completed.
  - Represent AB on other PDA activities and projects as needed.
  - The Chair approves individuals for AB membership (new AB members, additional terms for current members).
    - Candidates for AB membership should be sought in advance and groomed for succession when possible
    - The past chair should mentor the candidates as they come to assume a role on the Advisory Board
    - When possible, as a best practice, the Chair and Vice-chair should, with the help of PDA staff and current AB members, identify potential new member and develop a slate of candidates for balloting by the existing AB members
  - Identify with PDA staff a Vice-chair candidate.
    - The candidate for this position should be sought in advance and groomed for succession (6 months prior to taking on role)
    - The Vice-chair should seek and mentor the next successor for the Vice-chair role as they take on role of chair
  - Serve as final decision makers on:
    - Issues escalated from the scientific/technical review of the technical document, as well as those arising from the balloting process
    - Selection of Subject Matter Advisors (SMAs)

  - Extension of timelines for deliverables
  - Coordinating initiatives that may be of interest to multiple PDA Advisory Boards.
- Ensure that liaison roles, term limits and succession plans are initiated and maintained.

- **AB Operations Manager (Developmental Early Career Professional Role)**
  - With the Chair and Vice-Chair drafts the meeting agenda and distributes it to the AB
  - Prepares the AB meeting notes/minutes
  - Hosts virtual meetings
  - Manages the AB roster
  - Maintains a listing of AB members knowledge, skills, and aptitudes
  - Tracks member term timing
  - Manages balloting process (except for the posting of ballots which is performed by PDA staff), balloting metrics and comment collation
  - Follows up on action items; with escalation to leadership (as needed)
  - Organizes face to face meetings in coordination with PDA staff
  - With the Chair, Vice-Chair and staff (as needed) prepares the face-to-face Meeting presentation materials
  - With the Chair and Vice-Chair prepares BoD presentations

    Note: This role of the AB Operations Manager is designed for a PDA Early Career Professional to allow them to build their professional network and technical expertise through their involvement in the Advisory Board and the technical discussion and reviews performed.
- **RAQAB Regional Representatives (in addition to member expectations)**
  - Provide regular updates to RAQAB on key Quality (GMP/GDP)/Regulatory CMC issues in their region:
    - Verbal updates at RAQAB meetings or email updates prior to RAQAB meetings (as appropriate)
    - Submit draft guidances / regulations / legislation to RAQAB for review, comment and decision to proceed to commenting team (as appropriate)
    - Alert RAQAB to any issues arising from draft and final guidances
    - Identify non-PDA and regulatory regional meetings that could be of interest
  - Ensure that quality and regulatory issues arising from their respective area(s) of interest are addressed at the monthly RAQAB meeting.
  - Represent PDA RAQAB at meetings with regulators in their assigned region.

AB Member Selection Process

- **Assess the need for new AB members:**
  - Expiration of respective terms, member resignation, or the need to expand the advisory board.
  - For existing members assess the active participation in the AB and PDA activities
- **Assessment process of potential new members:**
  - Commitment to PDA. e.g., length of membership, PDA activities experience, other outside experience.
  - Broad & diverse group of experts:
    - Based on Expertise / Knowledge, Region; Employment (small and large firms; consultancies, etc.)
- **Screening:**
  - AB Leadership team (chair, vice-chair, immediate past chair & PDA Staff) reviews the pool of interested candidates:
  - Sort candidates to identify ones with high potential, necessary expertise, geography, and fills diversity goals.
  - Solicit updated information and confirm the candidates are still interested
- **Selection:**
  - The AB Leaders approve with consultation of the AB members.

AB Responsibility for Technical Report Development

Technical reports are an important component of PDA's goal develop scientific and technically sound, resources to advance science, technology and regulation for the pharmaceutical and biopharmaceutical industry. The technical reports are developed through the expertise of our global membership" and represent the current best practices provided through expert authorship groups and a rigorous peer review process. PDA Technical Reports are recognized globally for their ability to apply sound scientific practice and current regulatory policy to daily operations in the production and quality control of medicines. PDA Technical Reports are an important contribution to the scientific literature and provide an enduring resource for best practices in pharmaceutical technology.

A close partnership between ABs and TRTs/TFs is a key success factor for timely delivery of technical documents. Advisory Boards are also responsible for oversight of all PDA member proposals to create Technical Report Teams. To facilitate this process, the AB is supported by non-voting S&RA staff. The Advisory Boards will (on occasion) assign a Subject Matter Advisor (SMA) to a Technical Report Team when subject matter guidance or development support is needed.

Role of the PDA Scientific and Regulatory Affairs Staff

PDA staff form a close partnership with the ABs to ensure the quality and timely development of all technical documents. PDA staff members facilitate development from the proposal and formation of a Technical Report Team, Task Force, or commenting team, through to completion of the approved tasks.

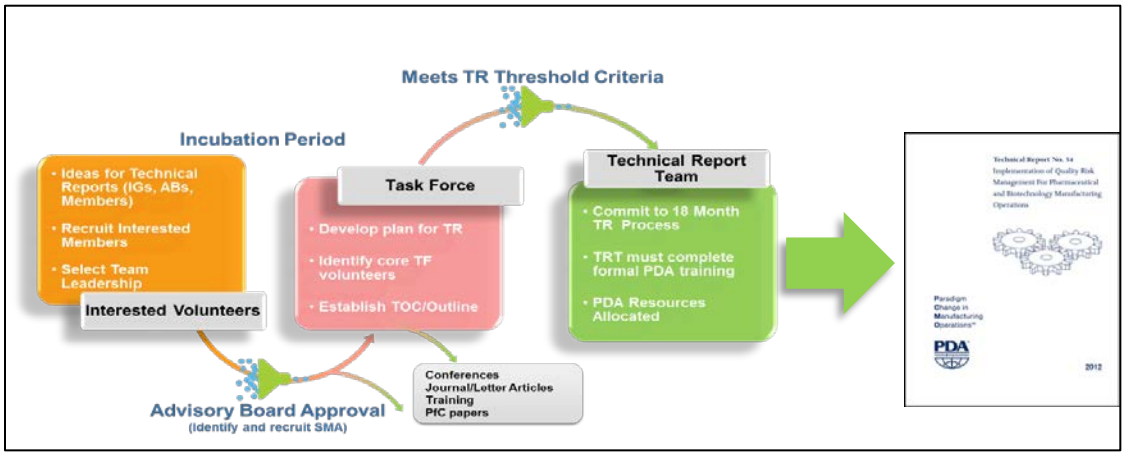
- **PDA Staff Activities**
  - Partner with AB chairs to formulate agendas and structured reviews of project dashboard.
  - Define policy and procedures regarding the technical document development processes.
  - Provide updates and 'intelligence' on various issues and topics, including regulatory updates.
  - Submit comments to regulatory agencies and publish in PDA communications channel.
  - Support Technical Report Team/Task Force chair / vice-chair and PM in their responsibilities.
  - Provide administrative and logistical support to AB:
    - Posting of Ballots
    - Work closely with and ensure the AB Operational Manager is fulfilling their role (if there is no AB Operational Manager in place work with the AB leaders to ensure those task are completed).

Technical Report Process

The Technical Report development process defines roles and responsibilities, applies time frames to the steps involved, and provides guidance on best practices for producing quality technical reports.

- **Overview**
  - Advisory Boards may approve Task Forces to progress towards TRT formation
  - Technical Report Teams must meet acceptance threshold criteria to commence the Technical Report process
  - AB-appointed Subject Matter Advisors (SMAs) may assist with concept development during the drafting of the Technical Report. SMAs can also be recommended by the TRT.
  - PDA staff provide support as needed

Overview of the TR Process



Technical Report Process Map

The process map highlights milestones for all parties and defines time periods for each step that will allow for completion of TR development and publication in 18 months.

TF: Task Force
TRT: Technical Report Team
S&RA: Scientific & Regulatory Affairs Staff

AB: Advisory Board
BoD: Board of Directors

Milestones

1. TR Proposal approved by S&RA (Threshold criteria met)
2. Preliminary draft delivered to S&RA for Design Review
3. Working draft delivered to reviewers
4. Final draft delivered to PDA for Advisory Board and BoD balloting
5. Technical Report approved for publication by BoD
6. Technical report is published

- **Technical Report Team Formation Threshold Criteria**
  - Four main threshold criteria:
    - Project plan and clear definition of technical report
    - TR Team has obtained critical mass with international representation

  - TR Team agreement to PDA timeline and training completion
  - Volunteer agreement forms have been completed and signed
- Examples of what meeting the threshold criteria may look like in practice:
  - Task Force has identified 10-15 qualified volunteers based on skills, experience and global representation
  - The volunteers:
    - Have selected a committed and accessible chair and vice-chair
    - Understand and commit to a plan for completion of a TR working draft in 12 months
    - Commit to completing TR process training at kickoff
    - Agree to TR volunteer confidentiality terms and use of PDA publication tools
    - Assign a responsible party for each stage
    - Apply a time frame for each stage
    - Define process milestones

Scientific/Technical/Regulatory Peer Review

Advisory Board members are given the opportunity to participate in the peer review process in advance of the formal AB Ballot but are not required to do so. If an AB member has a strong interest in a particular technical document, they should make every effort to participate in the peer review rather than reserving detailed scientific/technical feedback until the approval balloting process. Peer review requires adherence to strict timelines to ensure that comments are prepared, reviewed and approved in a timely manner to meet specified deadlines.

- **General principles for peer review:**
  - Comments should be representative of the Advisory Board member's skills, knowledge and expertise, and should not be influenced by corporate or personal perspectives/interests
  - All comments should completely describe the concerns of the reviewer, and be clear enough to avoid multiple misinterpretations
  - When language is unclear or needs improvement, replacement text should be proposed
  - Comments should facilitate a common understanding of the topic
  - All comments must be submitted electronically via the comment matrix

Tools and Resources

PDA has implemented valuable tools to enhance the review process and accessibility to all members involved in AB document management, balloting, Technical Report development and Task Force communication. The resources in place include PDA's online workspace, the Cross-Functional Dashboard, training modules and this PDA Advisory Board Handbook. These resources will be discussed below.

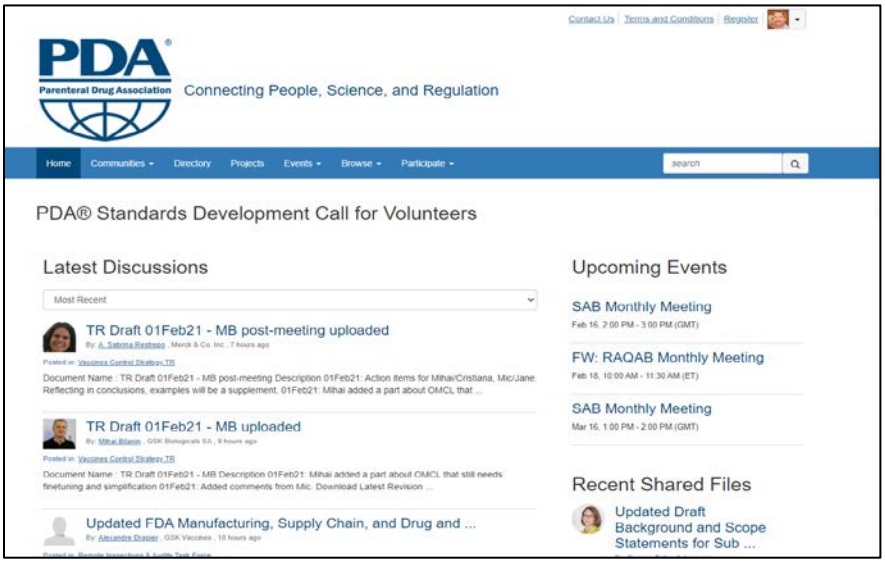
- **PDA Workspace (workspace.pda.org)**

  All Advisory Board members must complete PDA Workspace training and complete the registration process.

  The workspace provides:

  - Single source for all AB information:
    - Communication/ collaboration, including document, comment and revision tracking
    - View AB and TF/TRT rosters
    - Submit/review reference documents
  - Facilitates balloting process:
    - Votes are recorded in the Workspace
    - View results as soon as ballot closes
    - Generates automated voting reminders during ballot open period
    - Access to all previous ballots and voting records.

The PDA Workspace Member Homepage



- **Cross Functional Dashboard**
  - Updated dashboard content updated monthly by S&RA staff
  - Updates on all projects pertinent to each AB
  - Keeps all staff informed of ongoing technical projects

The Technical Report Dashboard (Example)

Project Name	Description	Project Type	Governing Body	Volunteer Project Lead(s)	Project Status	Document Stage	Kick Off Date (Original or Restart)	Planned SRA Project Activities Completion Date (Handoff to Publications Group for Document
Revision of TR 27 – Pharmaceutical Package Integrity Testing		TR	SAB	Don Singer/ Marla Stevens-Reily	Meeting Target	BoD Ballot	30-May-12	15-Feb-21
Microbial Data Deviations Investigations in the Pharmaceutical Industry	Comprehensive guide for conducting microbial deviation investigations	TR	SAB	Julie Brown/ Chris Murdock/ Marc	Meeting Target	AB Ballot	15-Sep-18	15-Mar-21
2020 PDA Particulate Matter in Flexible Containers Survey		Survey	SAB	Neal Zupec	Meeting Target	Survey Write-up	9-Jul-20	15-Mar-21
Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers		TR	SAB	Janie Miller	Meeting Target	Copy Edit	9-Aug-20	15-Mar-21
Parenteral Packaging: Current Best Practices for Glass Vial Handling and Processing	Guide for setting up and maintaining glass handling equipment to avoid	TR	SAB	Roger Asselta/ Tony Perry	Meeting Target	AB Comment Res.	27-Oct-03	15-Apr-21
Revision of TR 13 – Environmental Monitoring		TR	SAB	Kurt Jacques / Marc Glogovsky	Meeting Target	Post-Peer Review	23-Dec-19	15-Apr-21

- **Training Modules**
  - Conducted at initiation into AB
    - Also done for Technical Report Teams and Task Forces
  - Comprehensive presentation of the 18 month Technical Report development process and available tools
- **PDA Advisory Board Handbook**
  - Reference manual for all AB members
  - Available on the PDA AB workspace (under the 'Handbook' folder in your Advisory Board's workspace Document section)

Progress Reviews - Best Practices & Tips

- **Suggested Meeting Structure and Practices**
  - Individual technical document progress reviews should have a regular schedule with a calendar horizon of at least six months.
  - Each quarter a scheduled AB meeting should include a review of the Cross-Functional Dashboard for project being run under the AB.
    - Technical documents/projects with delays should be discussed regarding reasons for the delay and action plans for remediation.
    - Teams with repeated delays should receive an invitation from the team leader to attend the next AB meeting to discuss problems and potential solutions.
    - Subsequent agendas which include specific project discussions should specify purpose, presenter, time allocation, decisions required and decision maker.

- Decisions and action items should be clearly defined by the AB chair and documented in the minutes by AB Operations Manager.

Regulatory Commenting

The RAQAB should be a major and significant source for identifying global regulatory issues of interest to PDA members.

Once a regulatory issue is identified as potentially meriting commenting, a PDA commenting team is formed to study and prepare written responses to regulations or guidance documents. The recommendations they prepare, called PDA Regulatory Comments, are approved by the ATMP AB, RAQAB, BioAB or SAB, as appropriate given the subject matter. After AB approval, regulatory comments are approved by the PDA's Board of Directors and then submitted to the originating agency/organization for consideration for inclusion into the final regulatory document.

PDA has defined a set of commenting competencies based on the scientific interests and expertise of the PDA membership. Health Authority publications which fall into these areas of competency fall within the scope of PDA commenting activity. The scientific areas include:

> Aseptic Processing, Manufacturing and Testing, Process Engineering, Biotechnology, Microbiology, and Process Validation, Compliance and GMP, Supply Chain, Quality Systems, and Submission Content and Format.

Some topics that have been determined to be generally out of scope include GCP, GLP, Labeling, and Medical Errors.

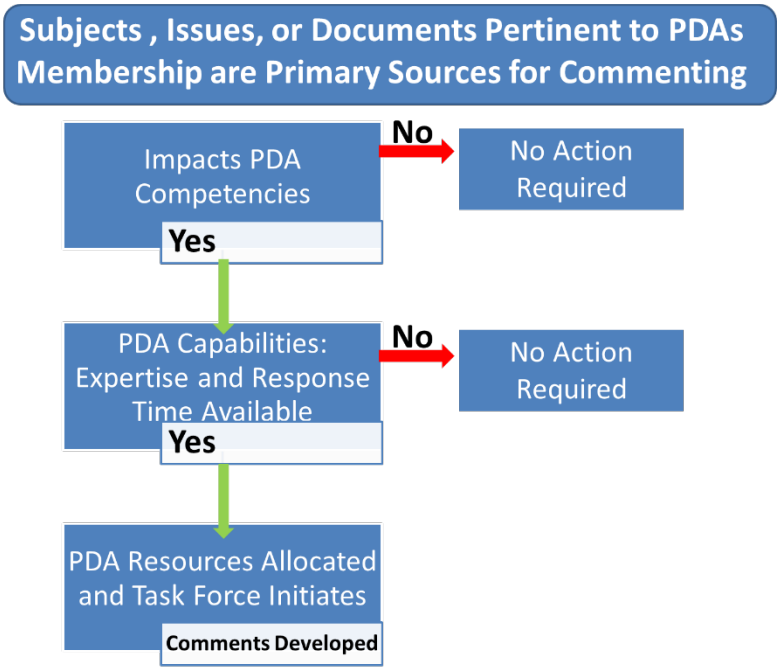
The primary product types in scope are API and drug products for parenterals and other pharmaceuticals. PDA will also consider commenting on documents relating to combination products, vaccines, and veterinary products if the topic is within the PDA commenting competencies.

The primary sources of documents for PDA comment are EMA, FDA, ICH, MHLW/PMDA, MHRA, PIC/S, WHO and BRICK Countries. PDA also considers documents issued by China, Canada, Swissmedic, Australia and emerging nations if publications are within the PDA commenting competencies as well as publications by Pharmacopoeias (e.g., Ph. Eur., USP, JP) for comments.

In addition to considering whether a document is within PDA's scope, commenting decisions are also determined by the commenting period available and the availability of members with appropriate expertise to participate in a task force. Generally, a minimum of 60 – 90 days is needed to develop and approve PDA Regulatory Comments. PDA feasibility and resources are taken into account when concurrent draft regulatory requirements or guidance are open for commenting.

PDA regulatory comments are posted to the PDA Web site for public viewing and may be highlighted as they are completed in the PDA Letter and other PDA outreach media.

General Process of Selecting Documents for Commenting



- **General Principles for Commenting**

  PDA has defined policies for Commenting teams to follow when preparing Regulatory Comments. PDA comments should not 'add to' the current or proposed regulatory requirements/ expectation. PDA avoids making comments which add to the regulatory burden, unless patient safety is otherwise adversely impacted. When language is unclear or needs improvement, PDA offers proposed replacement text accompanied by a rationale for the recommended change. Comments should be scientifically sound and have value for patient protection through product and process quality. Comments should facilitate a common understanding of what is expected by the guidance, thus avoiding divergent interpretations. Comments should represent a consensus of the team members' expertise and not simply copy company comments. Cost alone is not grounds for PDA objection to a draft rule or guidance; exceptions must be justified, and scientific or technical rationale provided. When commenting on a revision of an existing guidance, PDA generally will limit its comments to new or changed elements. In general, the volume of comments (number of pages) should not exceed the volume of the original document.

- **Commenting Team Policies**

  A volunteer leader is needed as a first step in the commenting process. Team members may be chosen from within the ABs, from relevant Interest Groups or from members at large who have expressed interest in participating on a commenting team. Occasionally a task force may seek out specific individuals because their expertise is needed for a particular topic. Comments should represent a verbal 'consensus approval' by the team, not a silent 'no one objects.' Team members need to participate in the process to advocate and, if necessary, explain their comments.

- **AB Responsibilities**

  During the balloting process and in their supervisory role over task forces, AB members should ensure that comments are representative of the commenting team's consensus as a whole and not reflect only those of a single member or company. AB members can help the commenting team identify IG or other specialists within the PDA membership (when needed) to deliver technically accurate comments. AB members should complete ballots in a timely manner so the response can be submitted to the regulatory agency within the given timeframe.

- **Changes to Team Comments**

  PDA staff may modify/ change comments to resolve issues, align with other PDA positions and ensure PDA's reputation with regulators remains strong. Comments also may be modified by PDA governing bodies (e.g. ABs & BoD) as appropriate prior to submission.

Frequently Asked Questions

- **What are the balloting options?**
  The Balloting Form offers the following voting options: Approve without Comment, Approve with Comment, Approve with Mandatory Revision, Disapprove with Comment, and Abstain. An explanation of the meaning of each voting option is provided on the form.

- **How do I get involved with submitting regulatory comments?**
  Generally the AB initiates the need to comment on draft guidance documents; however recommendations from the PDA membership are welcome. We advise members to reach out to AB leadership with any suggestions.

- **What is a "Task Force"?**
  A "Task Force" is the name PDA uses for any member-based team approved by an Advisory Board. The task force has a leader and roster of approximately 4 to 15 members. Task Forces report progress on a periodic basis to the Advisory Board and were needed request advice from the AB with a mutual goal of developing a PDA technical document. A formal

proposal must be submitted for each Task Force and fora Technical Reports the proposal must meet PDA's "threshold criteria" for entering the Technical Report process and becoming a Technical Report Team.

- **When and how does a Task Force's concept finally become a Technical Report?**
  The Task Force and the concept must meet PDA's "Threshold Criteria" for entering the technical report process and then adhere to an 18-month schedule for writing, reviewing, and publication of the Technical Report.

- **Where can I see the entire Technical Report Process?**
  A slide set used for internal training of PDA Advisory Boards and Teams is located at **workspace.pda.org** under the Library section of your Advisory Board's workspace. The slide set reviews the reasons for developing the technical report process, many of the concepts introduced in the process and the specific process steps with the respective responsible groups.

Interacting with PDA Members Interested in Developing Technical Reports

The following are questions you might receive from PDA members interested in developing a technical report:

- **I'm interested in developing a PDA Technical Report. What do I do?**
  Discuss your idea with other knowledgeable PDA members and begin to develop a clear concept for the project deliverables.

  PDA encourages an informal, organic process based on shared member interests. Interest Groups and Chapter meetings are ideal forums for testing concepts and finding interested colleagues. Once you feel that the concept and purpose are mature, seek out PDA Advisory Board members or PDA staff to help you understand how to draft a proposal to form a "Task Force". This is the next step in developing a Technical Report.

  You may recruit other PDA members to help in this process.

- **How do I find advice on bring my concept forward?**
  In general, it's best to approach one of the Advisory Board chairs because they are very experienced in the process, however any Advisory Board member will be more than willing to help you understand how to bring your concept forward. PDA Science and Regulatory Affairs (S&RA) staff can also help address queries and they are listed at http://www.pda.org/staff.aspx. This is an informal process and asking questions is both expected and encouraged. We are here to help one another.

- **Which Advisory Board should I approach for help with my project proposal/ concept?**

There are four PDA Advisory Boards. The Scientific Advisory Board (SAB) is responsible for technical reports and other types of PDA efforts relating to pharmaceutical parenteral technology. Examples of topics under the SAB are sterile filling, sterilization technology, and small molecule drugs. The Biotechnology Advisory Board (BioAB) is responsible for technical reports and other topics specific to the areas of biotechnology and biologics. Examples of topics under the BioAB include vaccines, protein therapeutics, and other biologics products, the reprocessing of biopharmaceuticals, bioburden and biofilms. The Regulatory Affairs and Quality Advisory Board (RAQAB) is responsible for topics related to regulation of pharmaceuticals. Examples of topics under the RAQAB include quality systems requirements and data integrity. The Advanced Therapy Medicinal Products Advisory Board (ATMP AB) is responsible for technical reports and other topics specific to cell, gene, tissue, and other novel therapeutic modalities.

Use your best judgment as to which Advisory Board best fits with your concept and then contact one of the chairs. The Advisory Board chairs will help you decide which Advisory Board would best fit your concept. Remember, this is an informal process and we are all here to help one another.

PDA Science and Regulatory Affairs staff is always available to help. They are listed at http://www.pda.org/staff.aspx.