



BYLAWS
OF
PRODUCT QUALITY RESEARCH INSTITUTE, INC.

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Article I - Name and Purpose of Institute

1. **Name.** The name of the organization is the Product Quality Research Institute, Inc., hereinafter referred to as “PQRI” or the “Institute,” a nonprofit corporation incorporated in Virginia.
2. **Location.** The principal office of the Institute will be located in the offices of the American Association of Pharmaceutical Scientists (AAPS).
3. **Nature.** The Institute is a nonprofit, non-stock, tax-exempt corporation.
4. **Purpose.** The purposes for which the Institute is organized are: charitable, educational, and scientific purposes, within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (or the corresponding section of any future tax law) specifically but not limited to serving as a forum for academia, industry, and FDA and other regulatory and standard setting bodies to work cooperatively to conduct pharmaceutical product quality research and to support development of public standards.

Article II - Board of Directors

All members of the Board of Directors must observe their fiduciary duties and participate in the best interest of PQRI, and must serve without conflicts of interest while serving as Board members.

1. **Responsibilities.** The Board of Directors is vested with the administrative management and operation of the Institute, except for those activities involving scientific decision making which are delegated to the PQRI Steering Committee under these Bylaws.
2. **Authority.** The Board has authority over the collection and disbursement of funds and the administrative procedures required to ensure the effective operation of the Institute, including engaging staff as necessary to support the activities recommended by the PQRI Steering Committee. The PQRI Steering Committee has sole authority over all scientific activities undertaken in conjunction with the Institute as provided by these Bylaws and thus will be responsible for recommending all Institute funds spent in conjunction with these scientific activities, specifically all research conducted under the auspices of the Institute.
3. **Composition.** The Board will consist of five individuals. One Board member, the Chairperson, will be appointed by the Executive Council of the AAPS, in consultation with PQRI Member Organizations, for a term of one year. Two Board members will be elected to a term of three years by individual, non-governmental PQRI Member Organizations, following a rotation schedule and in a staggered fashion. The elected Chair and Vice Chair of the PQRI Steering Committee will be Board members with full voting rights. Elected Board members may serve successive terms if elected by non-governmental Member Organizations. Government representatives on the PQRI Steering Committee are not eligible to serve on the Board.
4. **Chairperson.** The Chairperson of the Board will be appointed by the Executive Council of the AAPS, has voting rights, and will serve for a term of one year. The Chairperson of the Board may serve up to three one year successive terms if approved by the Executive Council of the American Association of Pharmaceutical Scientists. Once the Chair vacates the position, he or she will serve a one year term as Past Chair in an ex-officio, non-voting Board member position to offer continuity to the Board and current Chair.
5. **Treasurer.** The Treasurer will be elected by four-fifths vote of the Board of Directors from one of the voting members of the Board, The Treasurer will serve a term of three years, or the remainder of their term as a Director, whichever is less. The Treasurer may serve successive terms with the approval of the other Board members. The duties of the Treasurer shall be to report on the receipts and disbursements of all funds related to PQRI at each Board meeting or as requested by the Board and on an annual summary basis. The Treasurer will perform such other duties as agreed upon and described by the Board.
6. **Executive Secretary.** The Executive Secretary of the Institute will serve as a liaison between the Board of Directors and the PQRI Steering Committee. The Executive Secretary will keep records of the Institute Board meetings and the meetings of the PQRI

Steering Committee, give notice of and attend all Board meetings and PQRI Steering Committee meetings, prepare and distribute meeting agendas and minutes, assist Technical Committees and Working Groups in discharge of their responsibilities, assist in arranging for meetings and in the preparation and distribution of meeting programs, recommend to the Board of Directors and the PQRI Steering Committee new administrative procedures, as needed, and perform other services as may be requested by the Board of Directors and the PQRI Steering Committee. The Executive Secretary will be appointed by the Board of Directors with the approval of the PQRI Steering Committee.

7. **Meetings.** A minimum of two meetings of the Board of Directors will be held each year in the spring and in the fall. Other meetings of the Board of Directors will be called by the Chairperson at whatever times and places the Chairperson selects. Advance notice of a meeting of the Board, specifying the business to be conducted and the time and place of the meeting, will be provided to the Board members at least two weeks prior to each meeting. Members of the PQRI Steering Committee may attend Board meetings as observers in a nonvoting capacity. Minutes of Board meetings will be provided to the PQRI Steering Committee members and the public.

8. **Voting.** All Directors with voting rights must participate in voting either in person at a meeting or by teleconference/videoconference or, **if unanimous**, by email. Actions of the Board will be carried by a four-fifths vote unless provided otherwise by law or by these Bylaws.

8. **Removal of Member.** A Director may be removed for adequate reason by a four-fifths vote of the Board of Directors.

9. **Vacancies.** Vacancy of the Chairperson of the Board will be filled by the Executive Council of the AAPS in consultation with PQRI Member Organizations. Vacancies in either of the seats appointed by an individual, non-governmental PQRI member organization will be filled by appointment of that same PQRI Member Organization that provided the initial appointment to serve the remainder of the original term. The two seats held by representatives of the PQRI Steering Committee will be filled by the Chair and Vice-Chair of the PQRI Steering Committee.

10. **Dissemination of Information.** Following each meeting of the Board, a report of business will be made available via meeting minutes to the Member Organizations, the Steering Committee and the public.

11. **Compensation.** Board members will receive no compensation (i.e., salary or monetary payment for services) from the Institute for Institute activities. It is generally expected that expenses incurred by a Member Organization's representative(s) will be reimbursed by the Member Organization when attending meetings or activities on behalf of the Institute.

Article III - PQRI Steering Committee

1. **Purpose and Responsibilities.** The PQRI Steering Committee guides and directs the scientific activities of the PQRI. The PQRI Steering Committee will: 1) set priorities for research projects, 2) review research outcomes, 3) assess the overall impact of PQRI scientific activities, and 4) determine the need for continuing scientific activities.
2. **Authority.** The PQRI Steering Committee has sole authority over all scientific activities undertaken in conjunction with the PQRI as provided by these Bylaws. The Steering Committee may, at its discretion, designate any of its scientific activities to the Technical Committees, as it deems necessary for the smooth and expeditious operation of the Institute and its work. The PQRI Steering Committee will be responsible for recommending to the Board of Directors how all Institute funds are to be spent in conjunction with these scientific activities, specifically all research done under the Institute.

Article IV - Membership in PQRI

1. **Membership Eligibility.** The Member Organizations of the PQRI Steering Committee will consist of government organizations, and non-government organizations as the PQRI Steering Committee may admit. Non-government organizations that may be eligible for admission as PQRI Steering Committee member organizations are those which:
 - a) Are non-profit, tax-exempt organizations; Have a membership of significant size comprised predominately of U.S. pharmaceutical manufacturing companies or which have membership comprised of individual scientists and technical personnel employed by U.S. pharmaceutical manufacturing companies;
 - b) Include as a focus of their mission and activities the advancement of pharmaceutical science and technology, and the development and dissemination of technical information regarding human drug quality;
 - c) Have the structure and resources to disseminate information about PQRI to their members, to recruit volunteer scientists to serve on Technical Committees and Working Groups, and to represent their members effectively in PQRI Steering Committee deliberations; and
 - d) Have demonstrated the ability to fulfill the obligations of these criteria and to support the objectives and work of the Institute for at least one year as non-voting members.
 - e) Shall assume a portion of administrative costs of PQRI, the amount of which would be established by the Board.

Government organizations will not be required to meet these criteria in order to be eligible for membership on the PQRI Steering Committee.

2. **Application for Membership.** An interested organization should apply to the PQRI Steering Committee Chairperson for admission as a Member Organization. The PQRI Steering Committee will notify the Board of Directors of accepted new members.

3. **Revoking Membership.** The PQRI Steering Committee may, by two-thirds vote, revoke the membership of an organization if the organization demonstrates an inability to fulfill its obligations to the PQRI Steering Committee. Any organization may also voluntarily relinquish its membership by written notification to the Chairperson.

Article V - PQRI Steering Committee Structure

1. **Representation on the PQRI Steering Committee.** Each Member Organization of the PQRI Steering Committee will appoint a primary representative to represent that Organization at the meetings. Member Organizations may also have observers present at PQRI Steering Committee meetings. The observers may participate in discussion but may not vote on any issues. Only the primary representatives of the Member Organization, or in the absence of the primary representative, such member's designated secondary representative, have the right to vote on the decisions of the PQRI Steering Committee. Each Member Organization may cast only one vote on any specific issue.

2. **Government Member Representation.** Government members will provide one primary representative to the PQRI Steering Committee. The Government representative will not be in a position to make decisions regarding financial matters associated with the administration of the Institute or with the collection of non-government funds.

3. **Chairperson.** The Chairperson of the PQRI Steering Committee will be responsible for presiding at meetings of the PQRI Steering Committee. The Chair of the Steering Committee serves a term of two years, and is contingent upon approval by the Executive Council of the AAPS. Once term is completed, a Chair will assume the position of Immediate Past Chair and fulfill the responsibilities of that position. In the event that the Chair vacates their position prior to the fulfillment of their term, the Vice Chair will immediately assume the duties of Chair.

4. **Vice-Chair.** The Vice Chair of the Steering Committee is responsible for assisting the Chair in all duties assigned by the Chair and Steering Committee. The Vice Chair of the Steering Committee will be elected by a two-thirds vote of the primary representatives of the Member Organizations, or in the absence of the primary representative, such member's designated secondary representative of the Member Organization that serve on the Steering Committee and may or may not be a current member of the Steering Committee. The Vice Chair will serve a term of two years. Upon the completion of the term of the then current Chair, the Vice Chair will assume the position of Chairperson without need for election, but will require approval by the Executive Council of the AAPS. The Vice Chair will serve as a Steering Committee representative on the Board, with voting rights. Upon the Vice Chair assuming the position of Chair, an election will take place to fill the then created vacancy of the Vice Chair position.

5. **Steering Committee Immediate Past Chair.** The outgoing Chairperson shall remain on the Steering Committee as Past Chair for a period of two years in order to provide continuity and assistance to the new Chair, as long as he/she remains affiliated

with a current PQRI Member Organization. As an ex-officio, they can offer input into discussion, but may not vote on any issue before the Steering Committee.

6. **Meetings.** The PQRI Steering Committee will meet as appropriate but at least four times a year to review scientific issues regarding the Institute and its projects. Advance notice of a meeting of the PQRI Steering Committee, specifying the business to be conducted and the time and place of the meeting, will be provided to the PQRI Steering Committee representatives at least two weeks prior to each meeting. Additional meetings may be called by the Chairperson as deemed necessary.

7. **Quorum.** A quorum will be required to vote on membership or other issues brought before the PQRI Steering Committee. A majority of the primary representatives of the Member Organizations, or in the absence of the primary representative, such member's designated secondary representative that serve on the Steering Committee will constitute a quorum for voting.

8. **Dissemination of Information.** Following each meeting of the Steering Committee, a report of business will be made available via meeting minutes to the member organizations, the Steering Committee and the public. Minutes of the meetings should reflect decisions that are made and reflect the discussion leading to those decisions.

Article VI - Technical Committees and Working Groups (Project Subcommittees) of PQRI Steering Committee

1. **Technical Committees.** The Technical Committees will be responsible for developing the PQRI research programs and projects under the oversight of the PQRI Steering Committee. The Technical Committees will: 1) formulate direction for research projects, 2) establish appropriate Working Groups, 3) monitor research projects, 4) provide supporting research data, 5) detail the potential impact of the research projects on the public health and product quality, 6) describe the potential impact of research outcomes on the pharmaceutical industry and 7) will perform such other responsibilities as delegated by the Steering Committee. The PQRI Steering Committee will designate the number and scope of the Technical Committees.

2. **Chairperson.** The Chairperson of the Technical Committee will be responsible for presiding at meetings of the Technical Committee. Chairpersons for each Technical Committee will be selected by its representatives with confirmation from the PQRI Steering Committee. The Chairperson will serve a term of two years. Once the Chair fulfills his or her term of service, he or she will remain as Past Chair, an ex-officio non-voting member which will offer continuity and assistance to the new Chair for a period of one year.

3. **Vice-Chair.** The Vice Chair of the Technical Committee will be responsible for assisting the Chairperson in all duties assigned by the Chairperson. The Vice Chair of the Technical Committee will be selected at the same time as the Chair of the Technical Committee, and will be selected by its representatives with confirmation from the PQRI

Steering Committee. The Vice Chair will serve a term of two years and upon the completion of the term of the then current Chairperson, will assume the position of Chairperson without need for election. Upon the Vice Chair assuming the position of Chairperson, an election will take place to fill the then created vacancy of the Vice Chair position.

4. **Working Groups.** Working Groups under the direction of the Technical Committees will further develop and execute specific research proposals. Each Technical Committee, with the concurrence of the PQRI Steering Committee, will designate the number, scope and membership of the Working Groups. The Technical Committees, with the approval of the PQRI Steering Committee, will appoint a Chairperson for each Working Group.

5. **Vacancies.** The PQRI Steering Committee will approve nominations to fill vacancies occurring on Technical Committees and Working Groups.

6. **Meetings.** Meetings of the Technical Committees and Working Groups will be called by the respective Technical Committee or Working Group Chairperson. A majority of members will constitute a quorum and committee decisions will be made by a majority of the members present.

7. **Reporting Responsibilities.** Minutes of Technical Committee meetings will be made available to Member Organizations and to the public. Minutes of Technical Committee meetings should be submitted to the PQRI Executive Secretary for posting on the PQRI website.

Article VII - Other Subcommittees of PQRI Steering Committee

1. **Subcommittees.** The PQRI Steering Committee may appoint other Subcommittees as are deemed necessary for fulfilling the responsibilities of the scientific activities of the Institute.

2. **Reporting Responsibilities.** Each Subcommittee will report at each PQRI Steering Committee meeting regarding its specific activities or as otherwise required by the PQRI Steering Committee.

3. When the PQRI Steering Committee determines that a Subcommittee no longer serves a necessary role, the Subcommittee will be disbanded.

Article VIII - Information/Recommendations to Government Organizations

Once a project is completed by a Working Group, the outcome will be presented by the Technical Committee to the PQRI Steering Committee for public dissemination. If a vote is required on the research outcomes, government organization representatives on the PQRI Steering Committee will not vote. The Steering Committee will forward policy

development recommendations and related research data to government organizations or standard setting bodies. These organizations are not obligated to implement policy based on Institute information/recommendations and may accept or reject any information/recommendations at its discretion. Government organizations have the sole statutory responsibilities for developing regulatory policy and guidance and may not delegate this responsibility.

Article IX. Amendments

These Bylaws may be amended or repealed and/or new Bylaws adopted at any meeting of the Board of Directors by a four-fifths vote.