



BYLAWS

OF

PRODUCT QUALITY RESEARCH INSTITUTE, INC.

Amended as of October 31, 2016

Article I:	Name and Purpose of Institute
Article II:	Board of Directors
Article III:	PQRI Steering Committee
Article IV:	Membership in PQRI
Article V:	PQRI Steering Committee Structure
Article VI:	Technical Committees and Working Groups
Article VII:	Other Subcommittees of PQRI Steering Committee
Article VIII:	Information/Recommendations to Standard Setting Organizations
Article IX:	Amendments

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 at 1500 K Street, N.W., Washington, DC 20005.
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 guidance and 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, growth, 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 elected by the non-governmental PQRI Member Organizations for a term of two years. Two Board members will be elected to a term of three years by the 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 elected by the non-governmental PQRI Member Organizations, has voting rights, and will serve for a term of two years. 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 a majority 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. **Secretariat.** The Secretariat will support the activities of the Board of Directors, Steering Committee, and the Technical Committees. Such support includes, but is not limited to, scientific and legal assistance; financial reporting and administration; development of draft documents and tools as needed for the administration, strategic planning, and external and internal communications of the Institute; and development of minutes and agendas.

7. **Meetings.** A minimum of two meetings of the Board of Directors will be held each year. Other meetings or teleconferences of the Board of Directors may be called by the Chairperson, as needed. 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 and Technical Committee Chairs 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, by email. Actions of the Board will be carried by a majority vote unless provided otherwise by law or by these Bylaws.

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

9. **Vacancies.** Vacancy of the Chairperson of the Board will be filled by election from the non-governmental PQRI Member Organizations. Vacancies in the seats appointed by non-governmental PQRI member organizations will be filled by election from the non-governmental PQRI Member Organization to serve the remainder of the original terms. 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. Travel reimbursement for the Chairperson of the Board and the Chairperson of the Steering Committee may be considered by the Board if reimbursement is not provided by the Chair's employer or affiliated PQRI Member Organization.

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 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 pharmaceutical manufacturing companies or which have membership comprised of individual scientists and technical personnel employed by 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;

d) Have demonstrated the ability to fulfill the obligations of these criteria and to support the objectives and work of the Institute; and

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 contact the PQRI Secretariat with request for membership. The PQRI Steering Committee will review and approve membership and notify the Board of Directors of accepted new members.

3. **Terminating Membership.** Any organization may voluntarily terminate its membership upon 60 days written notification to the Secretariat.

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 Steering Committee. Once the 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. The Chair must be a member of a PQRI Member Organization.

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 majority 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 current Chair, the Vice Chair will assume the position of Chairperson. 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. The Vice Chair must be a member of a PQRI Member Organization.

5. **Steering Committee Immediate Past Chair.** The outgoing Chairperson shall remain on the Steering Committee as Past Chair for a period of two years, as an ex-officio member of the Steering Committee, 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 in person or by teleconference a minimum of three 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 PQRI research programs and projects under the oversight of the PQRI Steering Committee. Technical Committee members must be representatives from PQRI Member Organizations. Member Organizations may place any number of representatives on the Technical Committees. The Technical Committees will: 1) establish strategic direction for their Committees, 2) establish appropriate Working Groups, 3) monitor and provide guidance on Working Groups and research projects, 4) assist Working Groups in obtaining supporting research data, if needed, 5) and 6) perform such other responsibilities as delegated by the Steering Committee. The PQRI Steering Committee will establish the number and type of the Technical Committees. Technical Committees will establish Working

Groups based on proposals approved by the Technical Committee and Steering Committee. Proposals will describe objectives, scope, expertise needed, and potential impact on public health, product quality and the pharmaceutical industry.

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 elected by its representatives, via the Vice Chair election process. 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 elected by the Technical Committee, with PQRI Steering Committee confirmation. The Vice Chair will succeed the Chair, without the need for election, after which a new Vice Chair will be elected.

4. **Working Groups.** Working Groups will be established by the Technical Committees to develop and execute specific research proposals. Working Groups must be chaired or co-chaired by representatives from PQRI Member Organizations. Working Group Chair(s) can solicit Working Group members with the assistance from the Technical Committee, as needed. Working Group representatives should be members of PQRI Member Organizations. Non-member representatives may participate only at the request of the Working Group, when that non-member provides a specific needed expertise. .

5. **Vacancies.** Technical Committees and Working Groups will solicit PQRI membership for new representatives/members as needed

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 Secretariat 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. The Board may appoint other Subcommittees as are deemed necessary for fulfilling the administrative management, growth, or operation of the Institute

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

3. **Disbanding Subcommittees.** When the PQRI Steering Committee and/or Board determines that a Subcommittee no longer serves a necessary role, the Subcommittee will be disbanded.

Article VIII - Information/Recommendations to Government Organizations

Working Groups will present deliverable(s) such as posters and presentations at Conferences, and manuscripts for publication in journals, to its sponsoring Technical Committee for final review and approval and to the Steering Committee and Board of Directors for information. If deemed necessary by the Technical Committee, Steering Committee approval of these materials will be requested. If a vote is required on the research outcomes, government organization representatives on the PQRI Steering Committee will not vote. Final recommendation/information that a Working Group would like to submit to a government organization and/or standard setting body will be reviewed and approved by the sponsoring Technical Committee and Steering Committee. The Technical Committee and Working Group will forward the recommendations to the designated government organizations and/or standard setting bodies. These organizations are not obligated to implement policy based on PQRI information/recommendations and may accept or reject any information/recommendations at their discretion.

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 majority vote.