

# NEW JERSEY PHARMACEUTICAL QUALITY CONTROL ASSOCIATION CONSTITUTION AND BYLAWS

## **Preamble:**

To formalize the operation of this Association by working under a Constitution and Bylaws that will clearly prescribe and maintain the purposes, organization and procedures of the Association.

## **Article I.**

The name of this organization shall be the "New Jersey Pharmaceutical Quality Control Association".

## **Article II.**

The purposes of the Association shall be:

1. To promote the general good and welfare by contributing to the general education and enlightenment of New Jersey metropolitan area college students, particularly those interested in the field of Pharmaceutical Quality.
2. To foster among its Members the fullest understanding of the current quality objectives, procedures and requirements of the Pharmaceutical Industry.
3. To assist Members to broaden their quality perspectives of the whole pharmaceutical and related industries<sup>1</sup>.
4. To be informative and stimulating for those concerned with quality in the Pharmaceutical Industry.
5. To encourage communication among Members toward discussion and better understanding of their mutual problems and their solutions.
6. To provide opportunities for Members to hear and to discuss ideas of qualified individuals concerned with special areas of quality in the Pharmaceutical Industry, such as FD&C Act and regulations, official compendia, cGMP and other regulatory requirements.
7. To assist Members to improve the effectiveness of their efforts in the application of quality principles.

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<sup>1</sup>. Wherever "the industry" or "the pharmaceutical industry" is mentioned in this document, it shall be understood that "and related industries" is included.

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8. To provide opportunities for Members to become more fully informed of the relationship of quality to other responsibilities and activities of the pharmaceutical and related industries.
9. To provide a forum where a Member may present a problem and discuss it with his peers without incurring the risk of divulgence of his operations, or those of his company outside of the Association.
10. To provide opportunities for Members to develop qualities of leadership through experience in holding office, conducting meetings, and engaging in discussions.
11. To disseminate information and to stimulate creative thinking toward improving the efficiency and effectiveness of quality principles.

## **Article III. Membership**

There may be three types of membership: Members, Associate Members and Honorary Members.

### **1. Member**

Any person who has a position of direct responsibility for quality control, quality assurance, regulatory affairs, regulatory compliance, manufacturing, packaging or R&D in the pharmaceutical or related industries may become a Member of the Association upon being approved and paying the current dues.

The Membership Committee determines that the person has sufficient credentials to be approved for the Membership of the Association or if not, should be considered for Associate Membership as described in item 4 of Article III.. The degree of responsibility and authority, which the person has within their function (as defined above), are two of the criteria by which their judgment may be made. Guidelines, used by the Membership Committee in helping them determine the acceptability of a prospective member in meeting the above criteria, are given below:

#### **A. Requirements to become a "Member"**

- A.I. The person should be a manager or have equivalent responsibilities. It is not sufficient for the individual to be a first level supervisor unless that individual has sufficient other duties or credentials.
- A.II. If the person has a staff function; he/she should report to a director level or equivalent and should have significant duties and credentials.

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A.III. In unclear cases, (e.g., individuals in positions not described above), the individuals' overall credentials, including education and experience, may be used in making a judgment of acceptability. The individuals' credentials should be considered sufficient to allow them to compete successfully for the manager's position or equivalent in any organization, regardless of the size.

A.IV. An individual may not be considered for new membership if he/she is a member of an employment-recruiting firm.

A.V. An individual working as a consultant in the Pharmaceutical Industry may be brought up for new membership (based upon prior industry experience) only if recommended by the Membership Committee and approved by a majority vote of the Executive Board.

a. A consultant in the Pharmaceutical Industry may be considered for new membership if he/she meets the following criteria:

i. His/her industry position, prior to becoming a consultant, meets the current criteria for new membership.

and/or

ii. His/her overall education and experience is such that he/she is judged to have the potential to be a significant asset to the Association.

This experience should include consulting in such areas as stated in Article III, section 1. For example, an individual with no significant industry experience (i.e., could not meet the criteria set forth above) and five years of experience consulting in a narrow area in manufacturing and in a minor supporting role would not normally be considered for membership.

B. New members who have applied for membership but whose membership has not yet been approved, may attend monthly meetings at the non-member rate.

If a non-member inadvertently pays membership dues, the dues money will be returned until the person applies and is approved for membership.

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## C. Reinstatement of Former Members

Any individual who left the organization in good standing may be reinstated into the organization even if his/her current job would not meet the guidelines for new members, provided that:

- C.I. His/her current employment meets the general criteria written into the bylaws.
- C.II. He/she is not employed by an employment-recruiting agency.
- C.III. A former member working as a consultant may be considered for reinstatement by the Membership Committee on a case-by-case basis. If reinstated, he/she may not use the membership to solicit business during organizational meetings or functions. (Note statement in section 4 of this Article.)

## D. Member Privileges

D.I. Members shall be entitled to receive adequate notice of all meetings of the Association, and shall have the right to attend all meetings of the Association, and to engage in the discussions. They shall have the right to vote on all propositions presented to the Membership for a vote: to hold office in the Association and otherwise, to take part in the activities of the Association.

## 2. Associate Member

### A. Requirements to become an "Associate Member"

- A.I. Any individual who has a position in quality control, quality assurance, regulatory affairs, regulatory compliance, manufacturing, packaging or R&D in the pharmaceutical or related industries and who does not meet full membership requirements, may become an "Associate Member" upon payment of the current dues and approval of the membership committee.
- A.II. An individual having a position that is closely associated to the pharmaceutical industry (e.g. a graduate student or teacher/professor in related studies or a consultant for the industry) may be considered for Associate Membership with the approval of the Membership Committee (In unclear cases, based upon the judgment of the Membership Committee, approval of the Board might be requested).

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- a. Any individual who works for an employment-recruiting firm may not be considered for associate membership.

A.III Associate Member's Dues

- a. Dues shall be the same as required for full members.

A.III. Rights and Responsibilities of an Associate Member:

- a. An associate member may attend any luncheon without further payment.
- b. An associate member may attend the year end Recognition Dinner Dance paying the same as a full member.
- c. An associate member may not become a member of the Board.
- d. An associate member does not have voting rights (i.e., they cannot participate in a vote involving by-law changes), however, they may express their opinion on any point of view and/or participate as part of a consensus reaching decision, either as part of a committee or as part of the association.
- e. An associate member may become a member of any acting or ad hoc committee, but may not become its chairperson.

B. The ability of an Associate Member to become a Full Member

- B.I. Any Associate Member whose job responsibilities increase so that they meet the requirements for full membership, as defined by the by-laws, may become a full-member upon applying for full membership, being accepted by the Membership Committee and paying the appropriate dues.

- B.II. Any Associate Member who has remained an associate member in good standing for five consecutive years, regardless of their job responsibilities, may become a full-member, after approval by the Membership Committee and upon paying the appropriate dues.

**3. Honorary Member**

- A. Any person who has served as "Chairperson" of the Association automatically will become an "Honorary Member" upon retirement. In addition, the Members of the Association may elect to "Honorary Member" status, any person, on retirement, which has served as a Member of the Association in such a way as to substantially advance the purposes, or the work of the Association over an extended period of time.

- B. Honorary Member Privileges Honorary Members shall be entitled to receive notice of all meetings of the Association and a copy of the

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minutes of all such meetings. They shall have the right to attend all meetings of the Association and to take part in discussions, and have the privilege of voting but not of holding elected office. They shall not be liable for dues.

### **4. Unacceptable Member Organizations**

The Membership Committee may choose to reinstate a former member who works as a consultant, as stated above. Any current member who, upon changing jobs and becomes a consultant may remain a member, provided he/she does not use the Association as a means of soliciting business during meetings or functions.

(If upon warning by the current Executive Board, the individual continues to solicit business, membership will not be renewed the following year and they will be so informed.)

If a current member becomes a member of an employment-recruiting agency, his/her membership will not be renewed the following year and he/she will be so informed.

Current and new Members may be informed of and view the Constitution and Bylaws via the Association's website, [www.njqca.org](http://www.njqca.org) or may request a copy in writing.

### **Article IV. Executive Officers**

1. The executive officers of the Association shall be:

Chairperson  
Chairperson-Elect  
Treasurer  
Secretary

2. The Chairperson, Chairperson-Elect, the Treasurer and the Secretary shall be appointed each year by the Board of Directors and presented to the Members at the Annual Installation Dinner. The new officers shall be announced at the September meeting.

3. Appointed Officers shall assume their office effective July 1<sup>st</sup>.

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**Article V. Board of Directors**

1. The Board of Directors shall consist of:
  - The Immediate Past-Chairperson
  - The Current Executive officers
  - The Membership and Bylaws Committee Chairperson
  - The Education Committee Chairperson
  - The Chairperson of the USP Committee
  - The Chairperson(s) of any standing committees
  - The Program Chairperson
2. The immediate Past-Chairperson shall serve as Chairperson of the Board of Directors. The current Chairperson of the Association will serve as Vice-Chair of the Board of Directors and will assume the responsibilities of the Chairperson of the Board of Directors, if the immediate Past-Chairperson is unable to accept the position.
3. The Board of Directors will meet between fiscal years to plan the upcoming program year.

**Article VI. Duties of the Executive Officers**

1. Chairperson
  - The Chairperson shall arrange and conduct the business of the Association. He/she shall preside at the regular meetings, and shall conduct the meetings in an orderly manner.
  - The Chairperson shall be allowed to disperse funds.
  - The Chairperson shall train the incumbent Chairperson (“Chairperson-Elect”) and the Program Chairperson.

2. Chairperson-Elect

The Chairperson-Elect shall serve as Chairperson of the Association during the year following that in which he/she was appointed “Chairperson-Elect”. He/she shall, on request, assist the current Chairperson in carrying out the work of the Association, so that the Chairperson-Elect will be fully aware of all activities, etc. when he/she takes office as Chairperson. He/she shall conduct the meetings in the absence of the Chairperson. He/she shall succeed to the chairmanship at the expiration of the current Chairperson’s term, or by act of the Board of Directors as prescribed in Article VII. The Chairperson-Elect shall be allowed to disperse funds. The Chairperson-Elect shall train the incumbent.

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## 3. Treasurer

- The Treasurer shall maintain a duplicate list of the membership, collect and disperse funds as authorized and perform those duties as prescribed in Article XIV. The Treasurer will deposit all funds collected into the Association account and disperse as directed by the Chairperson for Association business.
- The Treasurer shall report to the Association at each regular meeting, or on due request from the Chairperson, the current status of the Association's finances.
- The Treasurer will receive membership renewal forms and renewal checks. The Treasurer will submit, by January, the names of all members delinquent in dues to the Board of Directors.
- The Treasurer shall train the incumbent.

## 4. Secretary

- The Secretary shall maintain the membership roster. The current membership roster will be made available to each member via the Association's website. The Secretary will prepare the minutes for each of the Association's monthly meetings and have them posted to the Association's website.
- The Secretary shall prepare all Board of Director meeting minutes and distribute them accordingly. The Secretary shall send out monthly meeting notices three weeks prior to the meeting date. Reminder notices will be sent out approximately one week prior to the meeting. In August, the Secretary shall send out membership renewal notices/forms to all members. The Secretary shall train the incumbent.

## **Article VII. Duties of the Board of Directors**

The Board of Directors shall function in a counseling capacity. It shall assist the Chairperson of the Association in planning and arranging the affairs and monies of the Association. It shall meet on the call of the Chairperson or Vice-Chairperson of the Board of Directors. In the event that an appointed officer of the Association cannot fulfill the duties of their office, the Board of Directors will appoint a replacement to assume the duties for the remainder of the term.

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**Article VIII. Committees**

1. Standing Committees

The Chairperson will appoint from the membership, subject to the approval of the Board of Directors, the following standing committees to function until dissolved by the Board of Directors. Each subsequent Chairperson of the Association may replace and/or remove committee members when necessary with the approval of the Board of Directors.

- A. Education Committee – composed of at least two members and a chairperson.
- B. Membership and Bylaws Committee – composed of at least two members and a chairperson.
- C. Program Committee – composed of the appointed officers and a Program Chairperson, replaced yearly by the Chairperson of the Association.
- D. USP Committee – composed of at least two members and a chairperson.
- E. FDA/NJPQCA Joint Conference Committee – composed of at least two members and a chairperson.

2. Ad Hoc Committees

The Chairperson may appoint from the membership, temporary Ad Hoc Committees to deal with specific problems, or situations.

**Article IX. Duties of Committees**

1. Standing Committees

A. Education Committee

The Education Committee shall arrange for all the educational programs of the Association and administer the certification program. The Committee will collect monies for its programs and transfer all monies to the Treasurer. All monies generated by the Committee will be absorbed by the general fund. The Committee will make an annual financial report to the Association.

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## B. Membership and Bylaws Committee

The Membership and Bylaws Committee will consider and pass on all applications for membership in the Association. They will collect all data appropriate to determine the qualifications of prospective members.

The Committee Chairperson will report at the regular meetings of the Association on all applicants approved for membership by the Committee.

The Committee will also report to the Board of Directors any violation of the rules of the Association and may then recommend any necessary action.

The Committee will also maintain the official copy of the Constitution and Bylaws of the Association, propose changes as needed.

## C. Program Committee

The Program Committee will meet on the call of the Chairperson of the Association and arrange a suitable program for each meeting. The Committee shall be responsible for obtaining speakers, providing for plant trips and choosing appropriate topics. The Program Committee Chairperson will invite each speaker, introduce the speaker at the meeting and write a suitable thank-you after the meeting. The Program Committee Chairperson will also provide for travel directions and arrangements and any audio-visual equipment requested.

## D. USP Compendial Discussion Group Committee

The USP Compendial Discussion Group Committee will meet on a monthly basis or as needed, preferably after the planned monthly NJPQCA meeting, to discuss the issues in the current compendial revision publications allowing time for review of the publication within each company before the meeting.

The Discussion Group will meet with the objective to share issues related to Compendial (USP and PhEur) proposals of a general nature (i.e. General Chapters/Tests, General Notices, Excipients, Policies and Announcements/General Information, Stimuli Articles/Scientific Notes, Interim Revision Announcements/ Official Announcements-Rapid Implementation). Each member company will select its individual approach with the Pharmacopoeias. If the Discussion Group Members decide that a formal recommendation is needed from the NJPQCA

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Compendial Discussion Group Committee, it will be included in the minutes for comment/review. It will also be announced at the main NJPQCA meeting and a copy of the draft letter to the compendia will be available at that meeting and provided to all of the NJPQCA Executive Board members prior to sending the response to the compendia.

The NJPQCA Compendial Discussion Group Committee will be composed of consistent contact representatives from participating companies. Discussion Group Members can invite or involve others from within their company who would have the appropriate expertise or specialized knowledge to provide specific input on relevant issues applicable to the pharmaceutical industry as a whole. Minutes will be issued by the Chair or designee and a short report will be given at the following NJPQCA meeting.

The NJPQCA Compendial Discussion Group Committee can also be utilized as a training/learning resource to share how Pharmacopoeias work, how different Compendial Committees operate and to share feedback from the Compendial Conferences. This may include visits to the Pharmacopoeias to discuss issues with their staff. NJPQCA Compendial Discussion Group Committee should ensure that at least one Member attends the USP Open Conferences and reports back to the Committee.

## 2. Ad Hoc Committees

The Ad Hoc Committees may consist of any number of members that the Chairman of the Association feels is required for the work of the Committee. The Chairman of the Association will designate the Committee Members and appoint the Committee Chairman and assign the job function. Ad Hoc Committees will report directly to the Chairman of the Association.

## 3. The Chairperson of the Association

The Chairperson of the Association is an ex-officio member of each and all committees appointed during his/her term of office.

## **Article X. Meetings**

At least seven (7) meetings of the Association shall be held between September and the following June. All Members shall be sent a notice of each meeting sufficiently in advance of the respective meetings to provide time to reply and make a reservation for the meeting.

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Members may bring guests to meetings, unless the Chairperson of the Association, or the speaker(s), if any, limits the meetings to Members only. However, it is the responsibility of the host Member to be sure that the guest(s) know and abide by the Confidentiality requirement of the Association (Article XI of this document).

Prior to the end of each fiscal year, there will be an Installation Meeting. Any Member and their spouse or guest may attend. The Chairperson-Elect will handle arrangements for this meeting with the assistance of any other members appointed by the Chairperson of the Association.

The Board of Directors of the Association will establish what charges shall be made for attendance at this meeting and the location.

Exceptions to the above may be made only with the approval of the Board of Directors.

## **Article XI. Presentations and Discussions – Confidentiality**

It is a basic principle of the Association that presentations and discussions at its meetings shall be kept confidential. Minutes of the meetings shall be in the most general statements, and no recording may be made of any presentation, or discussion, nor may any notes in detail of the same be published, or distributed in any form, without the consent of the person(s) giving the presentation or entering into the discussion. These requirements and their rigid observance are essential to full and free discussion. Violation of this Confidentiality requirement may result in the loss of the privilege of membership in the Association.

## **Article XII. Voting**

Any member<sup>2</sup> in good standing may present a proposal for a vote of the Members. The manner and time of voting shall be as described in this Article.

Minor proposals and questions may be brought before a meeting, by any member in good standing and in attendance at the meeting, for a vote. Voting may be by ballot, by voice vote, or by show of hands according to the Chairperson's choice. A majority of the qualified members present shall carry the proposal. Proposals of major significance, or any involving the Constitution and Bylaws shall be submitted for a vote of the Members, only after a notice has been given to the entire membership in writing. For minor amendments to the Constitution and Bylaws, each member will

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<sup>2</sup> An associate member does not have voting rights (i.e., they cannot participate in a vote involving by-law changes), however, they may express their opinion on any point of view and/or participate as part of a consensus reaching decision, either as part of a committee or as part of the association.

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receive a ballot, in which their approval or disapproval may be registered. This will assure that every member, whether present or not at the next meeting, will have the opportunity to vote. Approval is achieved if two-thirds of the responses vote yes and if the total number of responses represents at least twenty-five percent (25%) of the Members in good standing. The Secretary will tabulate such ballots and the official copy of the document will be amended by the Membership and Bylaws Committee. For other proposals of major significance and major amendments to the Constitution, notice will be given at least one meeting prior to the meeting at which the proposal will be voted and a written notice will be issued to each member at least two weeks prior to the meeting at which the proposal will be voted. Approval requires acceptance of two-thirds of the Members in good standing, if a quorum is present. If a quorum is not present, the mail ballot, as described above, will be utilized.

### **Article XIII. A Quorum**

For the purposes of this Association, twenty-five percent (25%) of the Members in good standing at the time of the voting shall constitute a quorum.

### **Article XIV. Yearly Dues**

Nominal dues shall be assessed each year on each Member. The Board of Directors shall set the amount of the yearly dues. Each Member shall be notified of the amount of dues for the year along with a membership renewal form. The Secretary prior to the opening meeting of the Association's fiscal year will issue this notice. Dues are payable upon receipt of such notice. Members who have paid their dues are considered "Members in good standing". Any Member who has not paid his/her dues by the end of the calendar year will be considered delinquent and cited by the Treasurer to the Board of Directors for appropriate action, as detailed in Article VI.

New Members approved for membership on or before April 1<sup>st</sup> of that membership year will be assessed the standard yearly dues. After April 1<sup>st</sup>, membership approval will be held until the September meeting.

### **Article XV. Use of Funds**

Funds obtained by the collection of dues and from other sources will be utilized for the regular expenses of the operation and work of the Association. With the approval of the majority of the Members in good standing present at the regular meeting, the Association may designate a suitable amount of funds for any special grants and/or awards not specified below.

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Examples of approved uses of funds include:

1. Annual grant to an institution of learning for the training of individuals in the area of Pharmaceutical Quality or related fields within the Pharmaceutical Industry.
2. Outgoing Chairperson's award granted annually to the college/university of choice of outgoing chairman each year.

The Board of Directors shall have the financial records of the Association audited once each year by a Certified Public Account, appointed by the Chairperson of the Association. The fiscal year runs from July 1<sup>st</sup> through June 30<sup>th</sup>.

## **Article XVI. Effective Date of this Constitution and Bylaws**

This Constitution and Bylaws shall become effective on its approval by vote of two thirds of the Members in good standing present at a meeting providing a quorum is present, (or by mail ballot, as described in Article XII) after a written notice is given to the Membership at least two weeks prior to the meeting at which the amendment will be voted and after it was announced at least one meeting prior to the meeting at which the amendment will be voted.

## **Article XVII. Dissolution or Termination**

In case of dissolution, or termination of this Association, any residual funds then on hand shall be distributed as scholarship(s) and be presented to deserving student(s) or organizations selected by the Board of Directors of the Association at the time of dissolution or termination, with the assistance of appropriate academic recommendations.

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**History of changes to the NJPCQA Constitution and ByLaws**

<b>DATE</b>	<b>REVISION</b>
March 2,1954 to January 30,1968	The Association met and operated in an informal manner.
January 30,1968	The Constitution and Bylaws were approved and adopted by the Membership.
February 18,1969	Amended to allow contributions to students interested in the field of Pharmaceutical Quality Control.
April 23, 1973	Amended to create the two positions of the Treasurer and Secretary from the single position of Secretary-Treasurer.
November 22,1983	An Amendment to modify the requirements for membership and to redefine a quorum was presented.
October, 1985	An Amendment to broaden the membership of the Board to include the Chairperson of certain key committees, to establish new committees, to allow a mail vote to be used, to restate the proposed amendment of November 22, 1983, to restrict invitation to the Business and Installation Meeting to Active and honorary Members and their spouses and guests, and to redefine the requirements for Honorary Membership.
July, 1996	An Amendment to clarify membership of the standing committees specified certain uses of funds and added a provision for the use of a certified public accountant (CPA) for annual audit and tax preparation.
September, 1997	The final paragraph in Article XIV (Yearly Dues) was added to define a sliding scale of membership dues from January of the membership year onward.
October, 2003	Remove the word "Control" from Article II. Delete Associate (Inactive) Members. Consultants in the Pharmaceutical Industry may be considered for membership. Executive officers are presented at the Installation Dinner and announced at the September meeting. The Chairperson and Chairperson-Elect shall be authorized to disperse funds. The membership roster and monthly meeting minutes will be posted on the Association's website. Executive officers assume office on July 1 <sup>st</sup> . Delete references to the Nominating Committee. The USP Committee and the FDA/NJPQCA Joint Conference Committee are added as standing committees. New members approved for membership on or before April 1 <sup>st</sup> will be assessed the standard yearly dues. Delete the grant to Quality New Jersey. Delete "Amendments and Revisions" section (redundant with Voting, Article XII)
July, 2008	Under Article. III Members, <b>Added</b> "Associate Membership" to accommodate those persons that are interested in membership but do not meet the criteria for full membership. Other formatting changes were made.