



OPERATING GUIDELINES

COMPUTER VALIDATION COMMITTEE (CVC)

I. OBJECTIVE

To provide current industry perspectives to the **MARSQA** membership on computer validation issues.

II. GENERAL DUTIES

- A. Maintain awareness and stay informed of all the latest computer validation regulatory guidance and industry trends in the life-science industries.
- B. Communicate CVC activities through publication of articles, presentations, Q&A workshops and publishing on the **MARSQA** web site.
- C. Develop/conduct computer systems validation training in conjunction with the Education and Program Planning Committee.
- D. Prepare a committee update for each **MARSQA** Board of Director's meeting.

III. SPECIFIC DUTIES

- A. The Committee will hold meetings to report on computer validation information obtained and to plan/develop training programs and committee activities.
- B. Meetings will be held on an as needed basis. At least one committee meeting will be held per year.
- C. Yearly objectives will be set and communicated to the **MARSQA** Officers and Board of Directors.
- D. Minutes will be taken at each meeting and copies will be provided to the **MARSQA** President and Historical Committee chairperson, as well as active **MARSQA** CVC members.

IV. PROCEDURES

- A. Committee members shall exchange information on computer system validation trends, regulatory interpretations/opinions and computer system inspections conducted by regulatory agencies. Additional information may also be obtained from the SQA's Computer Validation Initiative Committee (CVIC). This information will be communicated to the **MARSQA** membership.
- B. A list of active CVC members may be made available to the **MARSQA** chapter to provide guidance on computer validation issues/activities.
- C. Annual training will be developed and conducted in conjunction with the Education and Program Planning Committee to provide **MARSQA** members with guidance on various topics related to computer systems validation. The committee may also assist the Education and Program Planning Committee, if requested, to provide programs that address the topic of computer validation.

V. RECORDS

The CVC Chair will maintain meeting minutes. The Committee will also maintain validation information/documents, as well as materials that are used for training programs.

VI. TIME REQUIREMENTS

- A. Each committee meeting will be approximately a half day in length and there will be at least one Committee meeting per year. Additional time will be needed for researching information and for planning and implementing training programs.
- B. The Chairperson(s) is invited to attend the **MARSQA** Board of Directors meetings which are held at least three times a year for half or full day sessions.