

SOP 03
QUALITY SYSTEM REVIEWS

1.0 PURPOSE AND SCOPE

1.1 Purpose and Scope

This SOP specifies the requirements for the annual review and for considering alternatives to improve the effectiveness of the Quality System.

2.0 REQUIREMENTS

- 2.1 The R&D Committee and its subcommittees will schedule a review of the performance of the Quality System at least annually.
- 2.2 The accomplishment of this annual review shall be documented and reported to the R&D Committee.

3.0 PERFORMANCE OF THE ANNUAL REVIEW

- 3.1 The R&D Committee or R&D Committee subcommittee chairpersons shall initiate the annual review each calendar year. The initiation of this annual review shall be reviewed during a scheduled R&D Committee/Subcommittee meeting so all members are allowed input in making suggestions for improving the Quality System.
- 3.2 The R&D Committee/Subcommittee shall request additional reviews of the Quality System if conditions deem this additional review necessary.



R. Amanda C. LaRue, Ph.D.
Associate Chief of Staff for Research