to those directly responsible for assuring the quality of such product or the prevention of such problems; and submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review

6.3.6 Non-conformance / Deviation during Development and Production of Combination Products

Any deviations occurring during the development or production of combination products will follow the same procedures as for the drug product.

21 CFR 820.90 (b) Nonconformity review and disposition.(1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

6.3.7 Post Market surveillance

When making a determination whether it is appropriate to collect certain data in the postmarked setting, rather than premarket, among other factors, the device's potential impact on public health needs to be considered. A combination product/ device with a greater degree of uncertainty regarding the benefits and risks of the device if this uncertainty is sufficiently balanced by other factors, including the probable benefits of the device and the extent of postmarked controls might be accepted. Design Input regarding post-marketing activities and post-market Design Changes shall be included in the DHF. A Post-Market Surveillance Plan is created to define market surveillance after product launch.

6.3.8 Post-approval Phase

Post-approval Phase is part of the lifecycle of combination products. During the development phase, design is initially developed and verified. Within the commercialization phase, market feedback (e.g. complaints) and/ or changes occur. With reference to these events change control shall be employed to determine the actions induced from the change. This may require the product to be subjected to re-verification of the design, re-validation of production processes or similar activities.

6.3.9 Training

Training of this SOP is mandatory for all employees who are involved in the development, production and testing of combination products. Furthermore, site management will also have to be trained on this SOP.

6.3.10 Market complaints

When making a determination whether it is appropriate to collect certain data in the postmarked setting, rather than premarket, among other factors, the device's potential impact on public health needs to be considered. A combination product/ device with a greater degree of uncertainty regarding the benefits and risks of the device if this uncertainty is sufficiently balanced by other factors, including the probable benefits of the device and the extent of postmarked controls might be accepted. Design Control documentation regarding post-marketing activities and post-market Design Changes shall be included in the DHF or in a separate product file. The DMR must be