MEDICAL DEVICE DEVELOPMENT PHASES & MILESTONES

PROOF OF CONCEPT

The perceived product design is determined to provide a baseline for future designs.

PROTOTYPES

A usable prototype of the product is produced to evaluate marketing / sales consideration and finished packaging concepts. This phase can be repeated more than once as product designs evolve.

PRE-CLINICAL EVALUATION

Using prototypes, work with regulatory resources to better understand requirements for final packaging, sterilization, and end-user specifications.

DESIGN QUALIFICATION

The process of qualifying the manufacturing process, simulating a small run of parts. This process is required for the ISO quality systems as the final manufacturing formula is determined.

RISK ASSESSMENT

"Design qualified" product is provided to the customer for risk assessment. All potential risks associated with the product design and usage should be identified.

CLINICAL TESTING

This phase could be the longest and most arduous. "Design qualified" product is provided to be tested in a clinically controlled environment. Often a third party resource is used to conduct the clinical tests.

STABILITY AND SHELF-LIFE TESTING

Such testing should be done utilizing real-time and/or accelerated aging tests. This phase can begin as the materials and packaging are defined as it can take a long time.

REGULATORY SUBMISSIONS

Dependent on where the product will be marketed and sold will determine which submissions are made (FDA, Health Canada, EU, MDR, etc.).

PRODUCT VERIFICATION/FINAL DESIGN REVIEW

After testing and regulatory approvals, the final product drawings are approved. Sterilization specifications are confirmed. No further product changes will be made.

PROCESS QUALIFICATION

IQ/OQ/PQ - Mass production process is finalized and qualified. Typically, three production lots are produced and evaluated for repeatability and reproducibility.

PRE-MASS PRODUCTION

Initial small lot quantities are produced and evaluated. Sales and Marketing can use to fill initial distribution channels. Mass production is fine-tuned and raw materials are procured.

MASS PRODUCTION

Full mass-production of the device/product!

PERIODIC RE-VALIDATION

Quarterly or annual review the current design, process, sales, forecasts, and existing and/or perceived product issues. Consider cost reductions and new improved designs.

Marian is a medical converter and medical device manufacturer. This document is a recommended road map for a successful product launch. Please use for planning purposes only. Many of these phases are the responsibility of the medical device developer while Marian provides support. Marian does NOT sterilize product internally.

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