6.2 Design Transfer essentials

Finished medical devices must be manufactured using approved specifications and the same materials and components as requested by the design. Manufacturing must be done using the same or similar (documented rationale required) equipment and procedures as it was planned to be used in routine manufacturing (equivalence concept).

6.3 Design Transfer team and reviews

A cross functional design transfer team must be established representing representatives from project management, quality, manufacturing, purchasing, materials management, design and software engineering (where applicable).

Design Transfer is formalized in one Design Review (additional design reviews might be conducted) following completion of all verification and validation activities and a pilot production run which determines adequacy of full scale production. At the design transfer review the document package is reviewed and, if found acceptable, approved for production start. The minutes of the review are made part of the DHF. The minutes may include open issues with required follow up activities with assigned responsibilities. A conditional approval may be given if open issues are minor with high probability of short term resolution.

6.4 Design Transfer process and outputs

Design Transfer shall be a continuous process, starting early in the design process where manufacturing representatives mainly observe and learn and continue to the final design transfer review where the manufacturing personnel are active participants in the process.

The main outputs of a successful design transfer includes validated processes and equipment, medical devices suitable for design validation and the documentation required for manufacture of the medical device.

Final medical devices will be produced using the final production method and equipment.

The same or equivalent quality control equipment and tests will be used to accept first final medical devices.

6.5 Design Transfer Documentation (Device Master Record)

The design transfer documentation package should include various documents; the main deliverables are exemplary listed below.

6.5.1 A manufacturing plan and schedule

6.5.2 Quality Assurance Inspection approvals

- Part and device drawings indicating dimensions confirmed during inspection for critical specifications
- Approved Vendor Lists (where applicable);

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