Viamed Operating Procedure VM3/COP 17 Design and development

This document and VOP17 should be read in ther intirety before any design of re- design or product modification is attempted. Both documents are also a route map to where documents are to be located in the Technical Files

7.3.2
Design and development planning
The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.
During design and development planning, the organization shall document:
a) the design and development stages; Q22
b) the review(s) needed at each design and development stage; Q28B
c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; Design & Development folder
d) the responsibilities and authorities for design and development; DocID 7742
e) the methods to ensure traceability of design and development outputs to design and development inputs; Design & Development folder
f) the resources needed, including necessary competence of personnel. VOP02
7.3.3
Design and development inputs
Inputs relating to product requirements shall be determined and records maintained (see 4.2.5).
These inputs shall include:
a) functional, performance, usability and safety requirements, according to the intended use; Q22
b) applicable regulatory requirements and standards; Q22
c) applicable output(s) of risk management; Q22
d) as appropriate, information derived from previous similar designs;
e) other requirements essential for design and development of the product and processes.
These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other.
NOTE Further information can be found in IEC 62366–1. 7.
3.4
Design and development outputs
Design and development outputs shall:
a) meet the input requirements for design and development; Design & Development folder
b) provide appropriate information for purchasing, production and service provision; U1
c) contain or reference product acceptance criteria; M1; Y15
d) specify the characteristics of the product that are essential for its safe and proper use. M3; Design & Development folder
The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Design & Development folder
Records of the design and development outputs shall be maintained (see 4.2.5).
7.3.5 Design and development review
At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to:
a) evaluate the ability of the results of design and development to meet requirements; QC28B
b) identify and propose necessary actions. QC28B
Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel. QC28B

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5). **7.3.6 Design and development verification**

Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5). QC30

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. QC30

Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. QC30

Validation shall be completed prior to release for use of the product to the customer.

Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5). Q30: Y15

7.3.8 Design and development transfer

The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.5). M4;J9;J2;J6;M5;N4;N5;N6;R1;T1;U1;VOP?

7.3.9 Control of design and development changes

The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified.

Before implementation, the changes shall be:

a) reviewed;

b) verified;

c) validated, as appropriate;

d) approved.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk

management and product realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5). QC28B

7.3.10 Design and development files The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes. 16 [1]

1 VM3COP17 Design and Development.doc _ID24002.doc