Verification and validation

November 9th 2016

Trev and Spike present the definitive guide to Verification and validation

Objectives

Descriptions and definitions

Examples

ISO 13485:2016 requirements

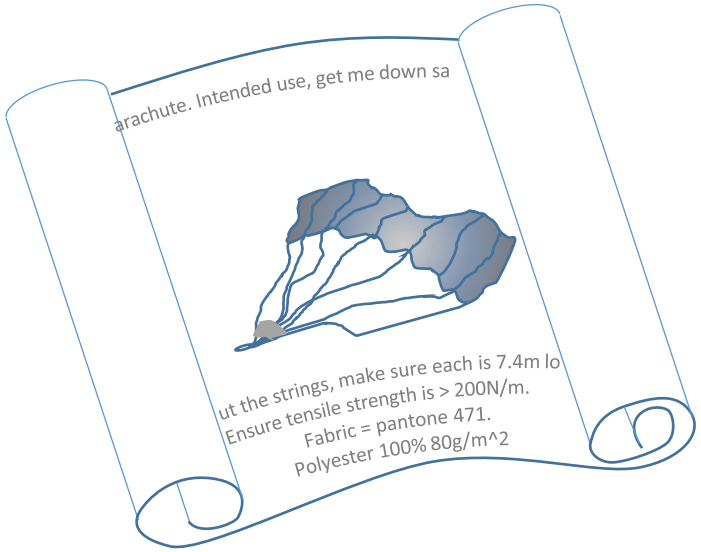
Use of Statistics

Verification (BS EN ISO 9001:2015)

3.8.12

confirmation, through the provision of objective evidence that specified requirements have been fulfilled**.**

Any set of criteria can be subjected to verification.



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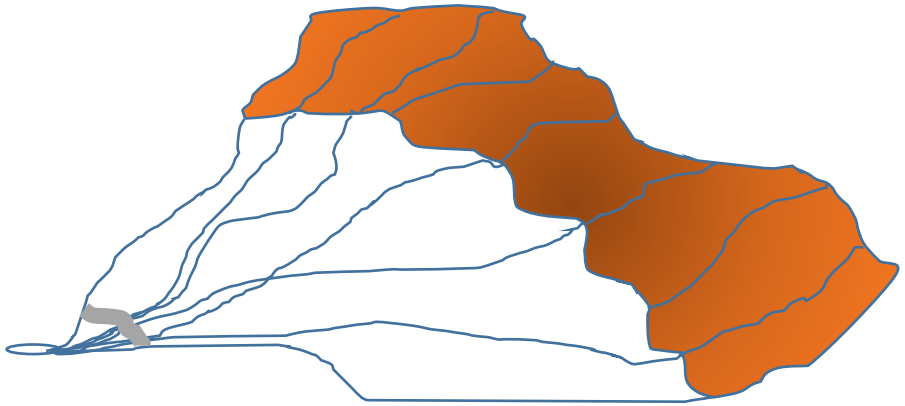


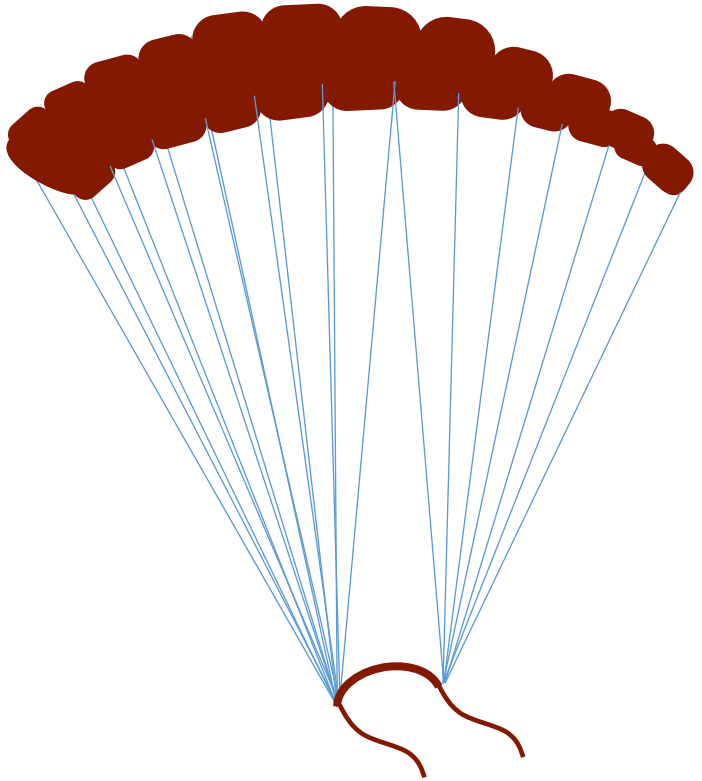
VERIFICATION: Did we make what we said we would make?

Validation (BS EN ISO 9001:2015)

3.8.13

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

The intended purpose is achieved, validation.



Does it do what it says on the tin?

Quality (BS EN ISO 9001:2015)

3.6.2

degree to which a set of inherent characteristics of an object fulfils requirements.

What to conduct V&V on……

Design

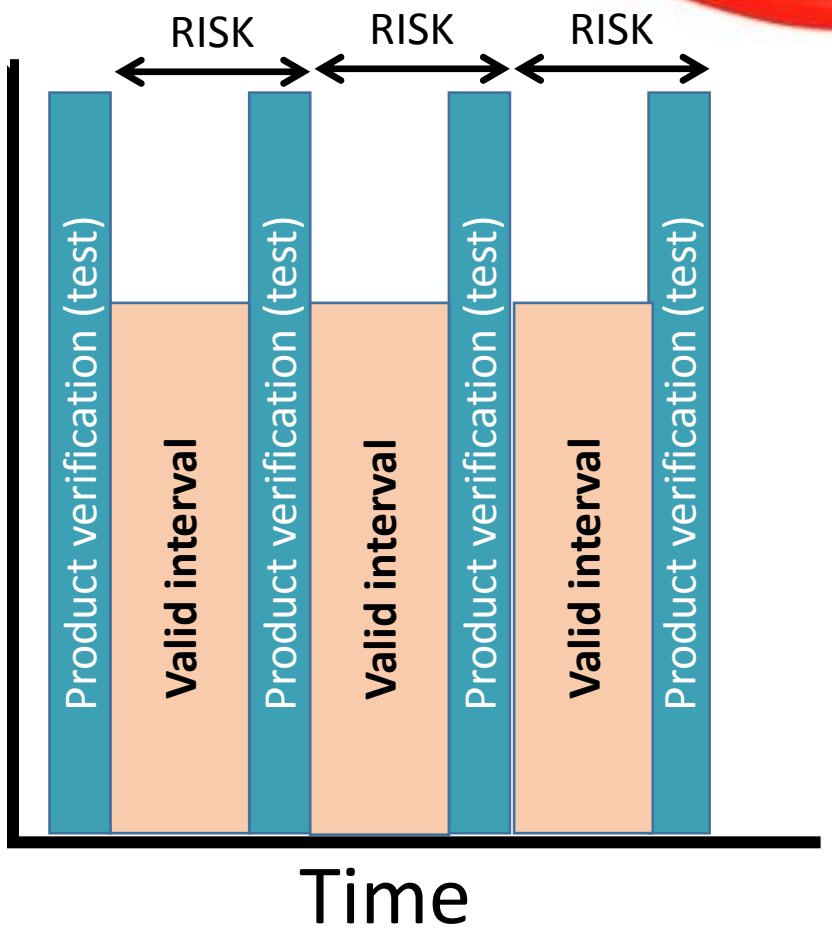
Transfer

Process

Packaging

Product

Relationship, Risk and V&V



V&V Examples

Sterilisation

Software verification EN ISO 62304

5.1.6 The MANUFACTURER shall include or reference in the software development plan the following VERIFICATION information:

a) DELIVERABLES requiring VERIFICATION;

b) the required VERIFICATION TASKS for each life cycle ACTIVITY;

c) milestones at which the DELIVERABLES are VERIFIED; and

d) the acceptance criteria for VERIFICATION of the DELIVERABLES.

Software Validation EN ISO 62304

This standard does not cover validation and final release of the MEDICAL DEVICE, even when the MEDICAL DEVICE consists entirely of software.

Processes which cannot be verified

- Welding
- Soldering
- Aseptic filling
- Packaging
- Gluing/bonding

V&V and ISO 13485

Overview

Design

Software

Special processes

ISO 13485 Audits.

7.3.2 Design and development planning

During design and development planning, the organization shall document: ……

c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;

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.

7.3.6 Design and development verification (Continued)

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).

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.

7.3.7 Design and development validation (Continued)

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.

7.3.7 Design and development validation (…and finally)

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.

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).

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.

7.3.9 Control of design and development changes

Design and development changes shall be identified. Before implementation, the changes shall be:

a) reviewed;

b) verified;

c) validated, as appropriate;

d) approved.

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.

4.1.6 General requirements

The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

7.5.6 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement …….

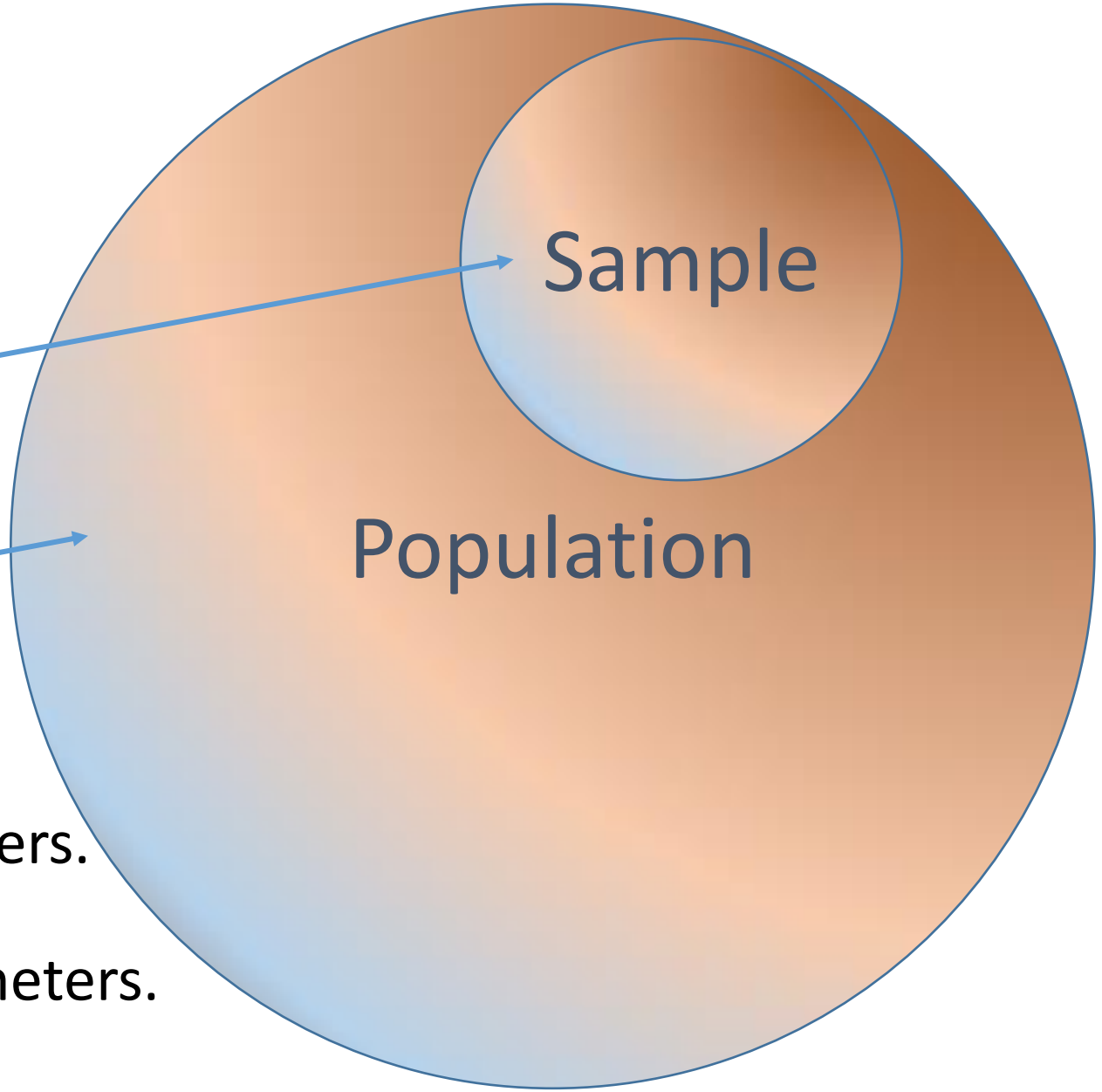
The organization shall document procedures for the **validation of the application of computer software used in production and service provision.** Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be **proportionate to the risk associated with the use of the software**, including the effect on the ability of the product to conform to specifications.

7.6 Control of monitoring and measuring equipment

The organization shall document procedures for the **validation of the application of computer software used for the monitoring and measurement of requirements.** Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be **proportionate to the risk associated with the use of the software**, including the effect on the ability of the product to conform to specifications.

Use of Statistics

What is statistics?



The science of Statistics is:

Analysis of Statistics, not of Parameters.

Statistics are used to estimate Parameters.

What do we look for?

1. Objective (what is the question to be answered?)
2. Sample (what sampling method?)
3. Analyse the data (what method of analysis?)
4. Draw the correct conclusions
5. Can the conclusions be traced back to the statistics?

Example 1- Collecting good data

- Factory move, to statistically prove their manufacturing process is validated after the factory move
- Due to large number of products, they chose to justify their answer by using a representative sample of their whole product range
- Selected their representative sample based on the highest volume product

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Example 2- Analysing the data

- Same manufacturer, same factory move
- Stated they made 200
- Sample size of 57 for testing (90% Confidence Interval, 90% Reliability), fail on any 1 sample failing
- Stated 4 failed, but 196 passed
- Concluded because 196 passed > 57, then study proves the process is validated

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- Stated 4 failed, but 196 passed ?
- Concluded because 196 passed > 57, then study proves the process is validated X

Summary

- Verification – does is meet the criteria?
- Validation – does it meet the intended use?
- Quality – the measure of verification and validation

Questions

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