Streamlining V&V process of medical devices and components

Introduction and motivation

When a medical devices manufacturer (OEM) sources certain critical components from a supplier, the component must comply with specifications and be validated for a certain application. This validation is a documented guarantee that a product can be manufactured reliably and repeatedly to satisfy a predetermined level of quality.

Many companies invest painstaking efforts and valuable time in product or component acceptance activities. The traditional Verification & Validation (V&V) approach in sourcing a new or substitute component is usually done in series of stages on both sides - component manufacturer and OEM.

Validation is often the most time and effort-consuming phase of a component implementation or transition, because some companies are limited in regards to resources necessary to meet the regulatory commitment for implementation, as well as supporting their core competence activities. A mutual V&V Integration Program will alleviate the work load of the medical device provider . This program can significantly accelerate the approval process and time to market of the end product in addition to saving the provider a significant amount of resources.

Current V&V Process Roadblocks & Pitfalls

Conventional validation process of a newly sourced component in medical devices is lengthy in its nature, primarily because of the following reasons:

- Prone to error- differences in test programs of supplier and OEM manufacturer may render faulty results
- Logistical obstacles- shipping of parts, accelerated aging and preconditioning resources, operational issues may delay or hinder the process
- Supplier and manufacturer perform the validation tests in separate series according to their own internal procedures
- Discovery of performance concerns during the late stage of the process causing the whole program to be repeated following fixing the problem
- Repetitive process until the designed product either turns out to be valid or the required changes call for a new validation process
- Integration and merging of Product Specifications on each side
- Increase in heavy expenses on both sides and extended time to market
- Setbacks resulting from the engineering resources allocation priorities, unanticipated bottlenecks, and delayed performance feedback that can impact new product introduction schedule and costs.
- Discrepancies in sampling method selection and setting acceptance criteria.
- Alignment of gaps -inconsistencies in test methods and aging protocols, which may result in differences and failures in acceptance
- Optimize design and perform feasibility studies
- Production site acceptance and performance testing
- Customized validation protocols
- Components integration (tube bonding process, component/set compatibility etc.)

Furthermore, Validation & Verification is more than just performing the tests.
It is well known that the process of developing the appropriate V&V program which addresses every aspect of a product is a key ingredient in qualifying a new or modified medical device. It presents the framework of thorough understanding and complete definition of what the project should include.

Tel: 972-4-698-8120/1
Fax: 972-4-698-0777
www.elcam-medical.com
Baram 1386000, Israel | sales@elcam.co.il

Joint V&V program

It is believed, but also supported by many years of experience and evidence, that a collaborative model of mutual V&V for introducing a new component (e.g. stopcock, luer connector, drip chamber) into a medical device or medical set, will result in better process efficiency, eventually translated into cost and time savings on both sides. It facilitates interdepartmental collaboration which creates synergic value, minimizes variability in the process and meets critical quality requirements with the least amount of time, resources and costs used.

The joint V&V is a service program offered to streamline the V&V process of integrating a new component into a medical device or a set. It is about building a one mutual V&V plan instead of two separate ones to utilize resources most efficiently.

A joint V&V program will include the following elements:

Validation Plan (Master Plan Development)

The joint V&V assists the medical device manufacturer's validation team in the qualification process in a way that saves both time and resources. This service includes developing and executing a validation plan, including identifying and analyzing scope, approach, resources, schedules, the types and extent of activities, tasks and work items, and the approval process.
The plan will incorporate the two parties knowledge about V&V and will assign the different tasks to the right resources, whether by the OEM supplieror the customer and according to each partner 's best capabilities. Naturally, the plan will comply with all industry standards such as the FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001_ 1997 - Design Control Guidance for Medical Devices Manufacturers and the BS EN ISO 13485:2012 - Medical devices - Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)

Risk Analysis

Risk analysis is a key element of validation procedure. The V&V program includes extensive support in building one integrated and comprehensive risk analysis, taking into consideration the intended use and secondary influencing factors (e.g.,interfacing components of the final system/product ormode of assembly) .

Custom Test Procedures

The proposed V&V service approach may provide medical devices manufacturer with custom test procedures that integrate the expertise of both parties about the product testing. It will meet the validation activity requirements of the partner's organization including the documentation of input, expected output,actual output, acceptance criteria, information regarding whether the test passed or failed, and the test conclusions.

Test Execution

Test execution integrates the strengths of the medical manufacturer's and OEM supplier proficiencies so each side is performing what best fits its capabilities. For example, if testing requires sterilization that can only be performed at the manufacturer site, but the testing itself can be done by the supplier, the execution will be performed accordingly. Notwithstanding the above example, test execution will be performed according to agreed test procedures, standard regulation requirements, and provide the necessary documentation to help ensure your compliance with validation regulations.

Experiments are conducted to determine process parameters, variability and necessary controls

Tel: 972-4-698-8120/1
Fax: 972-4-698-0777
www.elcam-medical.com
Baram 1386000, Israel | sales@elcam.co.il

Accelerated Aging

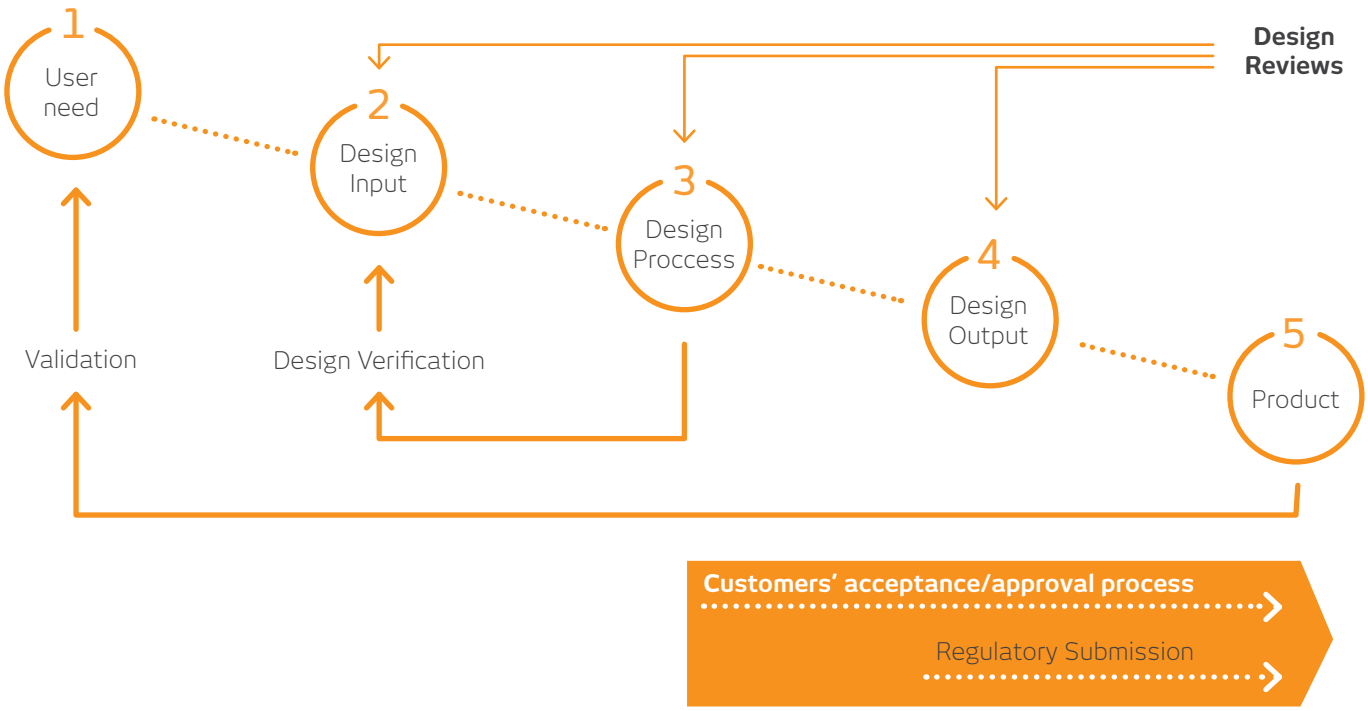
Defining the accelerated aging process and conditions for a manufactured component is required when actual lifespan data is unavailable. critical performances should be performed after aging.

Process Validation Report

The Process Validation Report should include Installation Qualification (I.Q.), Operational Qualification (O.Q.), and Performance Qualification (P.Q.). This report serves as documented proof that a medical component can be manufactured over the long term in accordance with the component drawing, manufacturing testing forms, and meets specifications.

Sampling plans used as part of process validation should be based on statistically valid rationale. Test methods used as part of process validation should be validated, and acceptance criteria, repeatability, and sensitivity should be documented.

The chart below illustrates some of the necessary steps and stage gates for Product Development Process and Validation & Verification.



Regulatory support

A major outcome of the V&V service will be an exhaustive documentation for 510(k) and CE submission, rationale drafting providing justification for any deviation or alternative approach in order to meet the applicable statutory or regulatory criteria.

Contract Review	Development of mutual specifications for a product – agree/ approve	Development of mutual V&V plan including required tests and aging cycles and procedures, development of SOP's, division of costs and work pertaining to the project- agree/approve	Execution of the agreed V&V program, delivery of the service, constant communication	Regulatory support and delivery of necessary documentation for 510k submission

Tel: 972-4-698-8120/1
Fax: 972-4-698-0777
www.elcam-medical.com
Baram 1386000, Israel | sales@elcam.co.il

Conclusions and final remarks

Lack of thorough validation of a required component/device for a certain application may lead not only to loss of time and money but also damage a company's reputation.

Elcam V&V service is a uniquely managed V&V process allowing the medical device manufacturer to save time and money when approving new or substitute medical components to be integrated into their own products. In addition, it may assist in the regulatory approval of the product. Therefore it is recommended to consider using and enhancing the V&V service when sourcing such components and selecting the right source.

The value you receive is confidence which is obtained by high level of transparency to V&V processes and Quality Assurance.

Tel: 972-4-698-8120/1
Fax: 972-4-698-0777
www.elcam-medical.com
Baram 1386000, Israel | sales@elcam.co.il