IMPORTANCE OF DEVICE DESIGN CONTROL APPLIED TO TOBACCO PRODUCTS

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Abstract

There is a misperception that implementing Design Control will restrict innovation, flexibility, and agility of product development. Often perceived as a burdensome regulatory requirement, it is quite the opposite. Implementing a user friendly, simple, and robust "Design Control" process allows a company to not only meet regulations, but to also produce a meaningful device that is reproducible and meets stakeholders needs (including the consumer). To do so, the process requires clear definitions of product attributes, regulatory requirements, communication pathways, and validation. The result is a readable history of the product's design, rationale, and product-life-long traceability to ensure that corrective actions are taken with continuous improvement. The key for project managers is to maintain all objectives on track, whether it is design, regulatory, costs or delays requirements, and to ensure that all stakeholders are aligned.

With this objective in mind, this poster aims at providing key learning from ISO 13485:2016 and QSR (21 CFR 820) that can be applied to device development intended for PMTA, MRTP, and NNHP submissions.

1 WHAT IS CONSIDERED A DEVICE?

As per 21 CFR 820, a medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article, intended by the manufacturer to be used for a medical purpose, alone or in combination to deliver an active ingredient.

The tobacco products considered in this poster do not have a medical purpose, but using the same approach to define what a device is, all mechanical or electronic devices, as well as novel oral pouches delivering nicotine, would fit the definition. Therefore, applying the Device Design Control approach would ensure a comprehensive and traceable development that would provide all necessary documentation during an audit.

2 DESIGN DEVELOPMENT PLAN

A Design Development Plan (DDP) will define "What, Why, When, and How" in a high-level overview. It can be reviewed as often as needed during the product development: comparing the plan versus reality and taking corrective actions that will result in R&D, sales, manufacturing, quality, and regulatory compliance, optimization of time and money spent, as well as overall stakeholder satisfaction. Regulatory compliance should not only ensure key competent authorities (such as the FDA) are satisfied, but also that any other applicable regulation (such as Child Protection), or applicable standards (such as ISO) are followed.

The DDP should be implemented as early as the decision to make the product and will serve as an umbrella for all other plans, such as Design Verification, Transfer and Validation, Clinical Investigations, and on into Production, as illustrated in **Figure 1**.

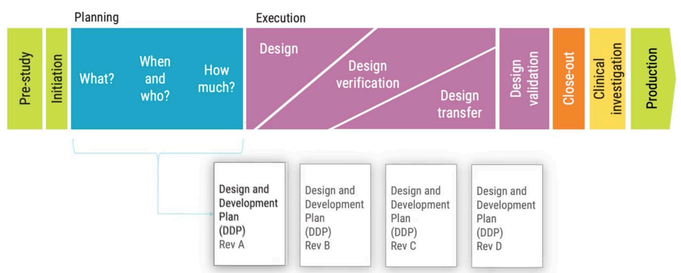
The steering group is responsible for:

- Setting the goal for the project and that the goal will benefit the fulfilment of the company's strategy.
- Ensuring the project receives the agreed-upon resources.
- Support the project manager and monitor the progress.

The project manager is responsible for:

Delivering the result of the project in accordance with the DDP and the requirement traceability matrix.

Figure 1. Device Design Control Overview

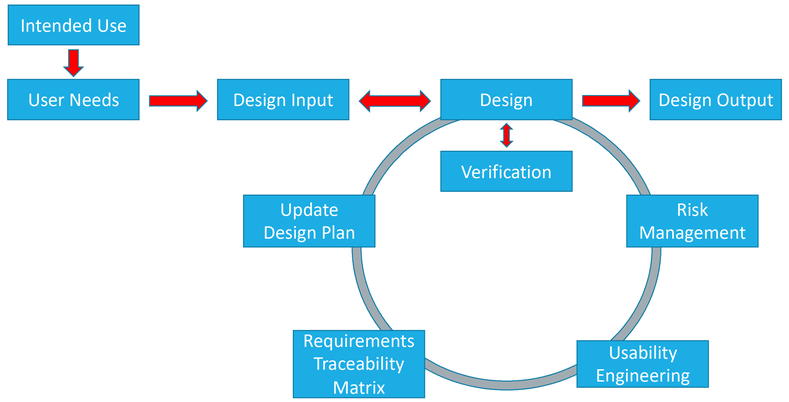


TIP 1: Keep it simple: define "must have = shall" and "nice to have = should" requirements and schedule Design Reviews to capture progress and corrective actions. Invite a neutral person not involved in the project at these reviews to ensure a fresh eye to look at key milestones of the project, helping to avoid "Group Think."

3 OVERALL DESIGN CONTROL CYCLE

The Overall Design Control cycle is defined in the DDP and allows to implement control from high-level system requirements to in-depth and detailed system and sub-systems requirements. Multiple review cycles will occur during development with revisions and corrective actions until the device is finalized and ready to be validated.

Figure 2. Design Control Cycle

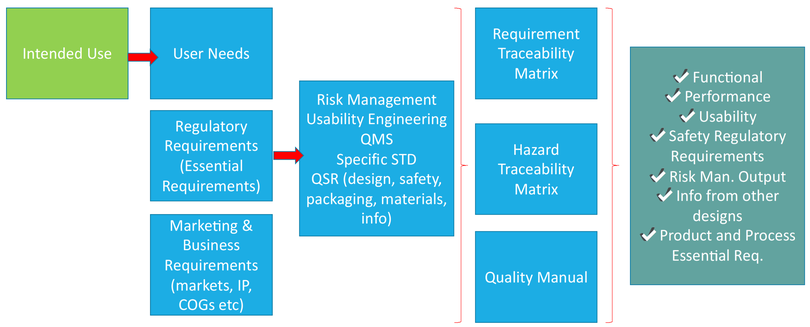


TIP 2: Agree on objective priorities associated with the Plan to avoid unexpected shifts in deliverables expectations. E.g., 1. Compliance, Safety & Performance 2. Budget 3. Time to Market 4. User Satisfaction 5. Intellectual Assets (Patent Opportunity).

4 IT ALL RELIES ON DESIGN INPUTS

The first and most important step is to clearly define the Intended Use, both in terms of marketing and any claims. This will derive who will use the product, what it will do, where and when it will be used. On the next step, User Needs will define the problem to be solved by the design. In addition, Design Input (both regulatory and marketing) will compile the abstract solution to the problem. Design Inputs list all the requirements that may come from safety, performance, and usability, as well as requirements from regulatory standards, information learned from the other designs, essential requirements for processes, and output from risk management exercise, as illustrated in Fig. 3.

Figure 3. Comprehensive Design Inputs



5 EVERYTHING IS TRACED VIA THE TRACEABILITY MATRIX

TIP 3: If it is not documented, it was not done.

Figure 4. Traceability Matrix

User Need	Design Input	Design Output	Design Verification	Design Validation	Records
Use interface related from user's perspective	Necessity, implementation independent, unambiguous, singular, verifiable, conforming	Specs, Drawings, codes, prototypes etc.	Plan, Protocol, Report. Complies with specifications	Plan, Protocol, Report. Meets requirements on user needs and intended use (production Units or equiv.)	List all relevant records.
Example: Fast charging time	<20 mins	Specs 15-20 mins	Charging time	Charge test	Documents (trainings, SOPs, test reports etc.)

Traceability is key to ensuring all the needs have been met. The Design Inputs are a list of requirements to meet the user needs with acceptance criteria. These requirements enable the engineers to build the product. Each requirement is verified using technical tests, demonstration, and analysis before being validated by using a production device in real or simulated environment as shown in Fig 4.

6 KEY DOCUMENTATION

To successfully pass regulatory authorities audits, documentation, and maintenance of the Documents Management System is very important. Fig 5 lists the key documentation that should be available and maintained.

Figure 5. Documents To Be Maintained and Provided During Audits

TIP 4: The Risk File is a critical part of the product documentation, for more details on how to implement Risk Management refer to TSRC 2021 Poster Nicotine Tobacco Product Hazard Assessment.

7 CONCLUSIONS

As an overview a Design Development Plan should cover deliverables listed in Table 1.

Table 1. Design Development Plan Deliverables

1.Initiation phase
Project charter
2.Planning phase
Intended use and use specification
General product description (nicotine form, strength, formulation etc)
User interface evaluation plan
Requirement traceability matrix
Design and development plan
Risk management plan
Prel. hazard analysis
Regulatory strategy
Design review 1

3.Design, design transfer, design verification phase
Mechanical manufacturing specifications
Formulation specifications
Ingredients specifications
Labelling specifications
Packaging specifications
Assembly instructions
Instructions for use
Formative evaluation
Quality plan
Supplier evaluation records
Master validation plan
Equipment requirement specifications
Process validation plans and records
Verification protocols/records
Pre-production products
DMR
Design transfer checklist
Design review 2

4.Design validation
Clinical evaluation report
Summative evaluation
Design validation protocols/records
Risk management report
General safety and performance requirement checklist (GSPR checklist)
PMS plan
Risk management file
Technical documentation
5.Design release
Final design review 3
DHF
Purchasing Control
CAPA

Implementing good control on Device Design development will not only ensure that the product meets user and regulatory requirements, but it will also ensure that marketing and business requirements such as Cost of Goods, appearance and time to market are also met, in addition to saving money on testing and clinicals that potentially would not be accepted by regulatory bodies due to poor DDP.

References

ISO 13485:2016
QSR (21 CFR 820)
https://medicaldevicehq.com
TSRC 2021 Poster Nicotine Tobacco Product Hazard Assessment.