PRODUCT DESIGN SCOTLAND

A NETWORK OF technology SCOTLAND

PRODUCT DESIGN SCOTLAND TOOLKIT

13 PRODUCT TESTING & DESIGN VERIFICATION

WITH systolic product development

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ABOUT US

With a long tradition of innovation, entrepreneurship and commercialisation, the product design sector is one of Scotland's key industries. Through advances in technology, designers are providing innovative products across a number of global markets, including healthcare, energy, communications and mobility. Integration of these technologies into viable, efficient and commercially attractive products is key, and the partnership between technology and product design is becoming ever more important.

Product Design Scotland, managed by Technology Scotland, the representative body for Scotland's Enabling Technologies Sector, has been established to support the product and industrial design sector in Scotland. The network aims to be the focal point for the community, raising awareness of the critical importance of design to future growth and competitiveness and creating a thriving, collaborative network to drive innovation.

By working with companies and organisations across Scotland, we support the sector through:

- Promoting the value of strategic design to government and industry
- Raising the profile of Scotland's product/ industrial design sector
- Increasing visibility of those operating within relevant supply chains
- Improving competitiveness through collaboration and knowledge exchange
- Creating new networks to shape the future of design in Scotland.

TOPIC INTRODUCTION

Product design and development is always an iterative process (see PDS Toolkit 01).

A structured approach to testing is important to assess the progression of your design through multiple iterations.

A typical product development involves (at least) 3 categories of testing:

1. Feasibility testing – early stage testing to confirm that the core elements of your product can provide the functionality you need, and to explore fundamental requirements such as cost and size, before committing to full development.

2. Development testing – iterative testing during development, to assess the performance of each prototype design.

3. Design verification testing – testing to confirm that late-stage designs meet requirements defined for the product.

WHAT IS DESIGN VERIFICATION?

In this toolkit, Design Verification is defined as a comprehensive progamme of activities which prove that your design does (or doesn't) meet all the requirements which have been defined for your product.

Depending on the project this may include some or all of:

- Reviewing design files and documentation
- Calculations
- Inspection & measurement of physical devices
- Testing of physical devices

WHY IS DESIGN VERIFICATION IMPORTANT?

A formal, carefully planned design verification process ensures that all aspects of the product requirements are reviewed and have been achieved before you launch your product.

(Note: In some sectors, Design Verification is considered to include only "paper based" activities. The definition in this toolkit is broader.)

DESIGN VERIFICATION PLANNING

MAPPING VERIFICATION ACTIVITIES AGAINST DESIGN REQUIREMENTS

1. Ensure that all your design requirements are written down, verifiable and have clear acceptance criteria.

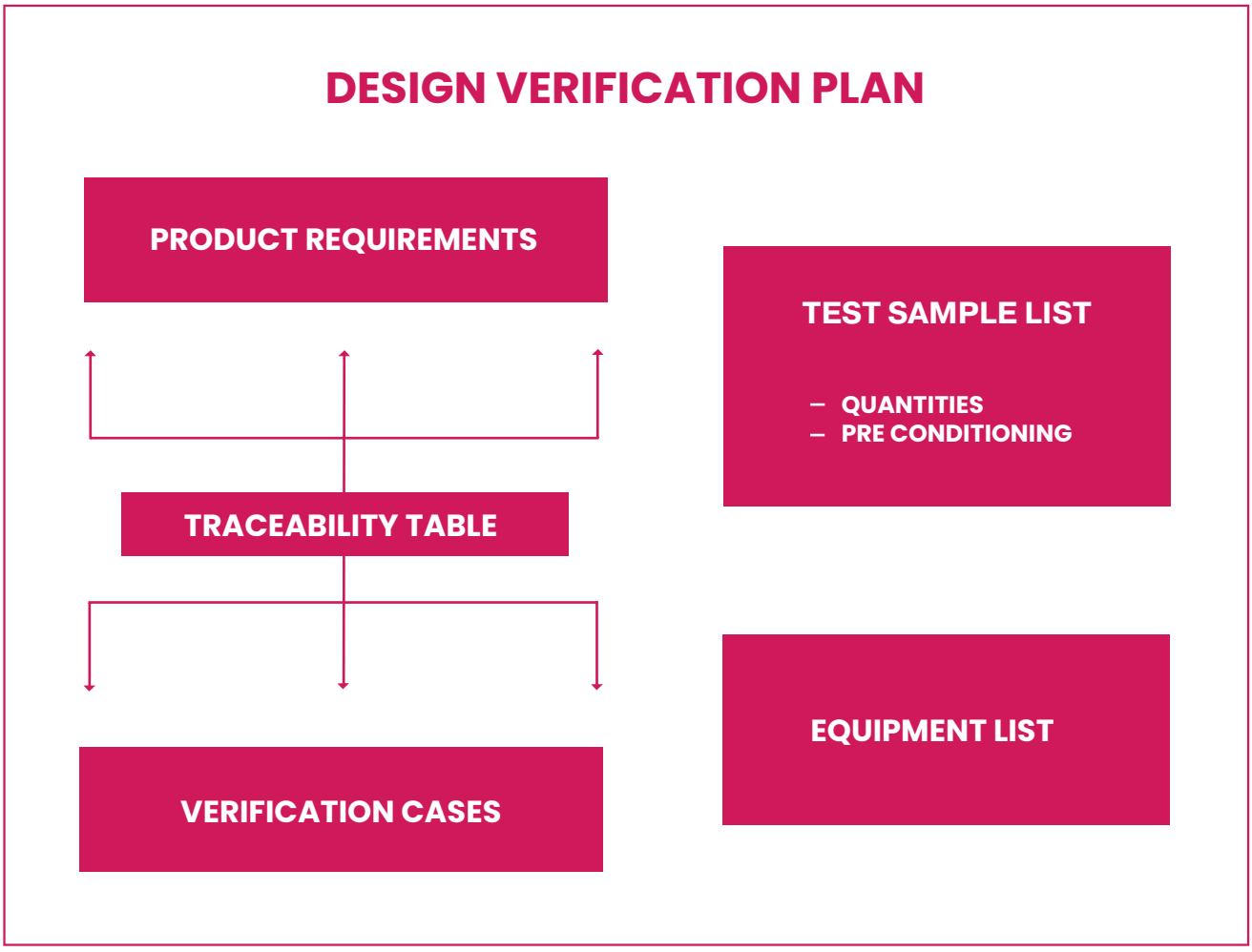
2. For each design requirement, choose the most appropriate method of design verification (e.g. calculation, prototype review, testing, etc.)

3. Prepare a list of design verification cases. Some verification cases may cover multiple design requirements.

4. Create a traceability table (or database) to demonstrate that all design requirements are covered by at least one verification case.

5. Review and sign-off the verification plan.

Bear in mind that testing of physical devices is generally the most expensive and time consuming verification method - where possible physical testing should only be used to verify requirements which are critical to the product function or difficult to prove reliably by any other method.



It pays to start thinking about design verification early in the project. Planning design verification requires significant effort and should be started well in advance of when verification activities will start.

For complex projects, specialist Application Lifecycle Management (ALM) software can help manage traceability between design requirements, verification protocols and verification results.

PREPARING VERIFICATION PROCEDURES

For each verification case, a written procedure should be prepared which defines:

- What part of the product is being verified / tested.
- Documentation required for review.
- Physical samples or prototypes required (including number of samples if repeat tests are required).
- Test equipment required (including any test software).
- A step-by-step procedure with enough detail to be followed by an independent verifier
- Pass/fail acceptance criteria.
- Information to be recorded in the verification records (e.g yes/no checks, measurements, photographs etc.)

Verification procedures should be reviewed and signed off before starting verification

DRY RUNS

If your development process includes multiple iterations of prototypes, there is an opportunity to start “dry-runs” of verification procedures on prototypes.

Dry runs are often useful to help establish the acceptance (pass/fail) limits for verification tests, and to refine the verification procedures.

EQUIPMENT PLANNING

Based on the verification procedures, an overall list of tools and equipment can be reviewed to make sure that everything is available by the time that verification starts. Allow time and budget for calibration of measurement equipment, if required.

This also allows time for training of the individuals who will carry out verification.

CARRYING OUT DESIGN VERIFICATION

PRODUCT VERSION

Formal verification should be run on a prototype which is representative of the final design with respect to the requirement which is being verified.

RECORD KEEPING AND REPORTING

During execution of each verification procedure, records should be kept including:

- Version of product design which is being verified
- Versions of any documentation used in the verification
- Date and location of verification
- People carrying out and/or witnessing the verification
- Results or observations for each step in the procedure
- Overall pass/fail result
- Any deviations from the written verification procedure (e.g. different equipment used, tests completed in a different order)
- Evidence of equipment calibration, test house accreditation and test personnel qualifications, if applicable

WHAT IF SOME VERIFICATION CASES FAIL?

Verification results which do not meet the acceptance criteria defined in the verification procedures should be reviewed and categorised.

Example categorisation:

CATEGORY	DESIGN IMPACT	NEXT STEPS REQUIRED
Acceptance criteria can be relaxed without an unacceptable impact on the product	Product design can be accepted	Update requirement and verification procedure
Verification failure was due to an issue with the verification procedure	Product design may be acceptable	Update verification procedure then run verification case according to the revised procedure
Verification failure is unacceptable for the product	Product design change required	Update design then repeat all verification cases which could be affected by the design changes

REGRESSION ANALYSIS AND TESTING

When design changes are made after design verification, design requirements which could be affected by the design changes need to be re-verified:

1. Carry out an analysis to identify which verification cases could be affected by the design changes.

2. Record the justifications for why verification procedures do / don't need to be repeated.

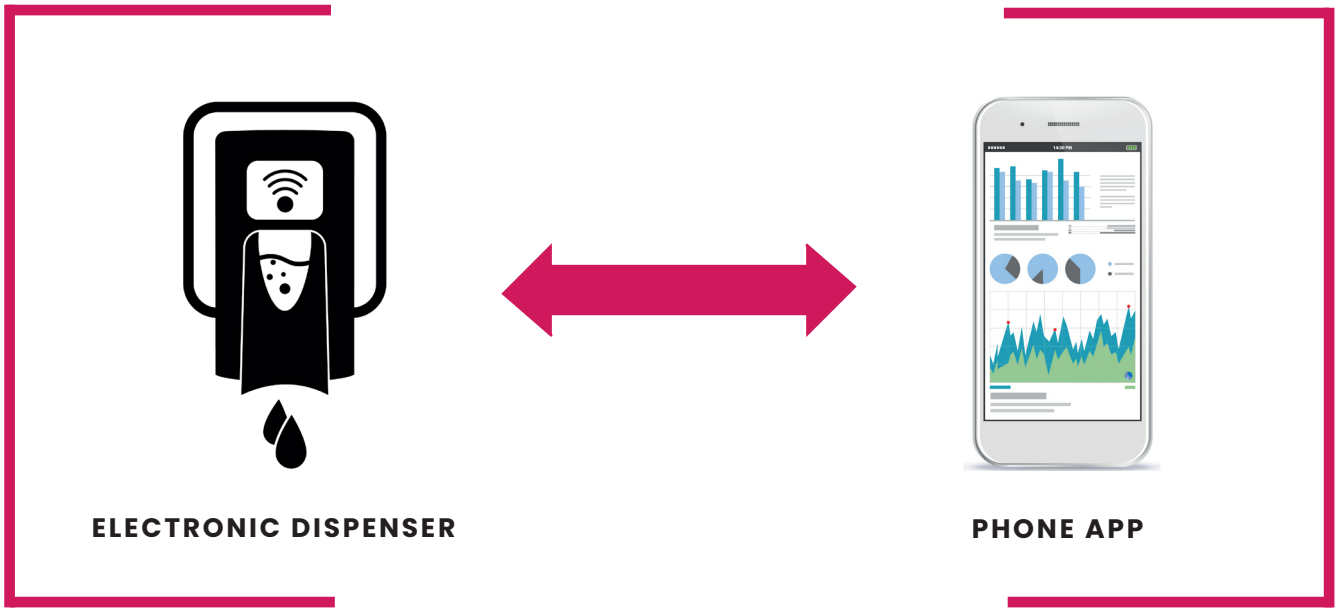
3. Repeat the required subset of verification procedures on the updated design.

CASE STUDY

EXAMPLE PROJECT: OVERVIEW

A pharmaceutical company is developing a new liquid drug which is consumed orally (like a cough syrup). The company decided to develop an electronic dispenser device which helps to control dosing of the drug.

The liquid drug treats a condition which requires regular, twice-daily doses of the drug. Missing a dose will significantly reduce effectiveness. Clinical trials show that the drug is highly effective, but over-dosing can have undesirable side-effects.



An example of design verification planning for this project is shown below.

DESIGN REQUIREMENTS

REQUIREMENT REFERENCE	THE DEVICE SHALL...	ACCEPTANCE CRITERIA	VERIFICATION METHOD	VERIFICATION CASE	VERIFICATION PROCEDURE REFERENCE
R1	Hold 200ml of the liquid drug formulation	200ml ± 5%	Design calculation	Volume Calculation	V1
R2	Allow the user to dispense a single 5ml dose of liquid drug	5ml ± 1%	Physical test	Dispense Tests	V2
R3	Allow the user to dispense drug no more often than every 12 hours	> 12 hours	Physical test		
R4	Connect to a phone app which provides reminders to the user when a dose is due	Reminder displayed on phone within 1 minute	Phone App User Test	Phone User Test	V3
R5	Connect to a phone app which provides a history of doses taken over the past 20 days	User can navigate to dose history in app	Phone App User Test		

(Simplified list – in practice a product of this complexity would have a much longer list of design requirements)

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SYSTOLIC PROFILE

Product design & development is rarely entirely predictable. At Systolic, we believe it's best approached with a sense of adventure alongside your technical expertise and commercial focus.

Like any adventurous expedition, the likelihood of success can be improved by careful planning, clear strategy and understanding the experience of those who have gone before.

Systolic provides efficient, expert product design engineering and product development management services - allowing you to strengthen your team when you need it, as an alternative or bridge to permanent recruitment.

Our approach is to understand your project in detail, identify and focus on the main technical issues, and anticipate common problems before they occur.

Projects range from short-term assistance with strategic decisions to long-term collaboration through the whole product development cycle - from concept to manufacture, including product verification testing and regulatory compliance support.

If you don't yet have a full development and manufacturing team in place, Systolic can also help to shortlist and select right-sized design, technology and manufacturing partners.

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