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06

RISK MANAGEMENT

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PDS PRODUCT DESIGN SCOTLAND

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.

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TOPIC INTRODUCTION

RISK MANAGEMENT FOR NEW PRODUCT DEVELOPMENT

Thinking about what might go wrong can seem a negative way to spend your time, but risk is an unavoidable part of product development and innovation. The more original the product, the tougher it is to anticipate the biggest hazards on the development journey.

This topic introduces approaches for identifying, organising and reducing risks whilst developing new products.

WHAT IS RISK?

Risk is a combination of:

the likelihood of an undesirable event occurring

AND

the severity of the potential harm / damage that would be caused by that event

WHAT IS RISK MANAGEMENT?

In the context of product development, Risk Management is a range of activities undertaken to minimise the risk of undesirable events – which may affect your business, users of your products or wider society.

WHY IS RISK MANAGEMENT IMPORTANT IN PRODUCT DESIGN?

Because new product development is complex and multi-disciplinary, and usually carried out under time pressure, it is impractical to anticipate and investigate everything that could possibly go wrong.

It is important to identify and prioritise hazards so that resources can be focused on the highest risks.

KEY STEPS IN THE RISK MANAGEMENT PROCESS

CATEGORISE RISK TYPES

It is helpful to categorise risks based on their impacts. Risks can impact on your business, your project, the technical implementation of your product, the users of your product and the wider environment in which your product is used.

There are overlaps between the categories but it is very difficult to consider them all in a single risk assessment – it is more manageable to split your risk assessments to consider each category separately.

RISK TYPE	RESOURCES FOR IDENTIFYING HAZARDS
Business/ Commercial	- Quality Management System standards - Business case studies
Project Management	- Project Management methodologies - Project case studies
Technical	- Technical standards - Design guides
End user (e.g. patient or operator)	- Safety & cybersecurity standards & regulations - Usability/ Human Factors standards - Incident report databases
Society & Environment	- Responsible Innovation frameworks

IDENTIFY HAZARDS

A **hazard** is a potential source of **harm** or **damage**.

Every product development project has a different risk profile. Identification of hazards starts with the experience of the extended project team – this should always include people with direct experience of the environment where your product will be used.

There are also many resources available which distil experience from similar development projects and existing products. Examples are shown in the table above and can be used to help identify all likely hazards.

PLAN RISK ASSESSMENT

Risk scoring criteria should be defined before you start to estimate risks – this ensures a consistent approach. The team also needs to agree the threshold above which risks are considered unacceptably high.

		SEVERITY OF POTENTIAL HARM				
		NEGLIGIBLE	MINOR	SERIOUS	CRITICAL	CATASTROPHIC
LIKELIHOOD OF EVENT	FREQUENT					
	PROBABLE				HIGH RISK	
	OCCASIONAL					
	REMOTE			MEDIUM RISK		
	IMPROBABLE		LOW RISK			

The table above is an example risk classification matrix.

ESTIMATE RISKS

Risk is a combination of the probability of a hazard occurring and the severity of the potential harm / damage.

Estimating risks is most effectively done by a multi-disciplinary team. Aim to agree a consensus on the probability and severity of each hazard - there may be different views from different stakeholders.

Once you have estimated the risk level associated with each hazard you can prioritise the highest risks for action.

CONTROL HIGH RISKS

Unacceptably high risks can usually be reduced in some way. Depending on the hazard, examples of risk controls could be:

- hiring or training for specialist skills
- design calculations
- prototype testing
- simplification of the product by removing features
- addition of safety features
- manufacturing tests
- user training
- changing packaging materials to an alternative with lower environmental impact

Risk controls may introduce new hazards which need to be risk assessed.

REVIEW RISKS REGULARLY

Risk levels and priorities can change throughout a product development project. Hazard identification and risk prioritisation should be reviewed periodically, particularly whenever there is a significant change to the product technology or intended use, the target market, or the regulations which will apply to the product.

REFERENCES AND FURTHER READING

ISO 31000:2018 Risk management - Guidelines

ISO 31010:2019 Risk management – Risk assessment techniques

IEC 60812:2018 Failure modes and effects analysis (FMEA and FMECA)

IEC 14971 Application of risk management to medical devices

ISO 12100:2010 Safety of machinery. General principles for design. Risk assessment and risk reduction.

CASE STUDY

RISK ASSESSMENT FOR A DRUG DELIVERY DEVICE

OVERVIEW

A pharmaceutical company is developing a new liquid drug which is consumed orally (like a cough syrup).

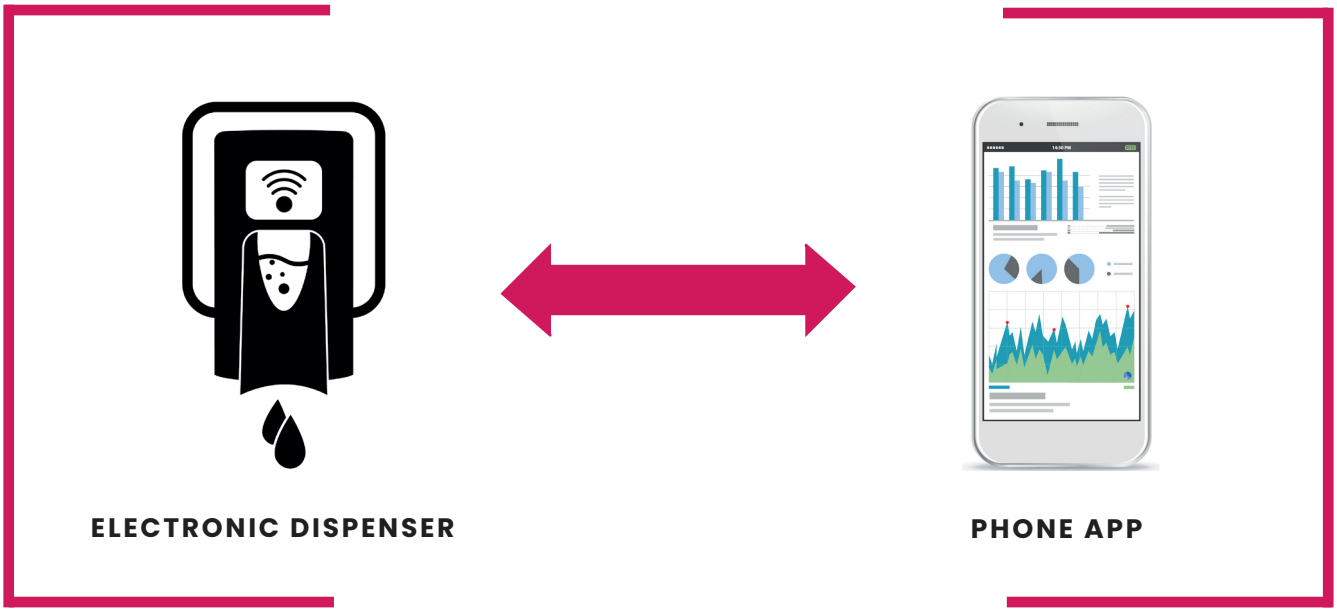
The liquid drug treats a condition which requires regular, twice-daily doses of the drug. Missing a dose will significantly reduce effectiveness.

Clinical trials show that the drug is highly effective, but over-dosing can have undesirable side-effects.

The company decided to develop an electronic dispenser device which helps to control dosing of the drug.

DESIGN BRIEF

- Hold 200ml of the liquid drug formulation
- Minimise air contact with the drug (to prolong the life of the active ingredients)
- Prevent the user from accessing the drug except for the allowed dosing
- Allow the user to dispense a 5ml dose of liquid drug every 12 hours
- Connect to an app on the user's smartphone which provides the following features:
    - Reminders to the user when a dose is due
    - History of doses taken over the past 20 days
    - Advance warning when a new dispenser needs to be ordered
- The use history is also transmitted from the smartphone app to the drug manufacturer for safety monitoring purposes
- After use, the dispenser is returned to the drug manufacturer for refilling



RISK ASSESSMENT

An end user risk assessment was carried out to consider risks to the patient using the electronic dispenser.

For this device, potential harms and hazards include:

1. Overdosing or underdosing - could be due to a defect in the device
2. Deterioration of drug ingredients - could be due to air contact in a defective device
3. Loss of privacy - could be due to hackers intercepting data from the user's phone
4. Cuts or grazes - could be caused by sharp edges exposed if the device is dropped

For each harm, severity and probability were estimated by the project team. Based on the first prototype designs, the risks associated with each harm listed above were classifed as shown:

	NEGLIGIBLE	MINOR	SERIOUS	CRITICAL	CATASTROPHIC
FREQUENT					
PROBABLE					
OCCASIONAL			3	1	
REMOTE		4			
IMPROBABLE			2		

RISK CONTROL

Risk #1 (overdosing or underdosing) was considered unacceptably high for the prototype design. To control this risk it was decided to add a flow sensor in the device to measure the metered dose more accurately.

Risk #3 (loss of privacy) was considered a Medium risk, and a range of options were considered to control this risk. As a result, steps were taken to strengthen the encryption of the data transmitted.

After implementing these design controls the risk assessment was repeated for a second prototype design. The revised risk profile is shown below. Note that the severity of each risk has not been changed, but the probability of risks #1 and #3 have been reduced by implementation of additional design requirements.

	NEGLIGIBLE	MINOR	SERIOUS	CRITICAL	CATASTROPHIC
FREQUENT					
PROBABLE					
OCCASIONAL					
REMOTE		4	3	1	
IMPROBABLE			2		

This case study illustrates user risks, but the same approach can be used to control other types of risk in the project.

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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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