

Design for Manufacture

ACEA7004

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1 ABSTRACT

This report details the early development phase of a vaccine container. A list of requirements was given, where a concept design was produced from using tools such as quality function deployment, and failure mode and effect analysis as well as research into competitors and regulations. The design was then revised using design for excellence methodology, where there was heavy importance of design for assembly, manufacture and disassembly. These design for excellence considerations made optimisations in the design which would not previously be explored without these methodologies. By revising and optimising the design at this early phase it would have reduced time and cost in an industrial environment. The Design for manufacture was considered, however until a specific machine has been specified it would be difficult to optimise the design to suit. The next design phase would be finite element analysis to understand if the features of the vaccine container are fit for purpose or do they need to be revised.

2 TABLE OF CONTENTS

1	Abstract.....	1
3	List of Tables	4
4	Table of Figures.....	4
5	List of Abbreviations	6
6	Introduction	7
7	Design Methodology & Tools.....	8
7.1	Design for Excellence	8
7.1.1	Design For Assembly	8
7.1.2	Design For Manufacture	9
7.1.3	Design For Disassembly.....	10
7.1.4	Voice of the Customer	10
7.1.5	Quality Function Deployment.....	10
7.1.6	Failure Mode & Effect Analysis	11
8	Product Development.....	12
8.1	Concept	12
8.2	Research.....	12
8.2.1	Regulation	12
8.2.2	Market Research	14
8.2.3	Manufacturing Research.....	16
8.3	Product Definition.....	17

8.3.1	Core Purpose of Vaccine Container	17
8.3.2	User Base.....	17
8.3.3	Customer Needs.....	17
8.3.4	Quality Function Deployment	20
8.4	Version One Container Development.....	26
8.4.1	Maintain Cold Chain Features.....	27
8.4.2	Transportation	28
8.4.3	Assembly Features	29
8.4.4	Reusability.....	30
8.4.5	DFA.....	31
8.5	Version Two Container Development.....	32
8.5.1	Revised Features	33
8.5.2	Design for Manufacture	34
8.5.3	Design for Disassembly	34
8.5.4	Mould Development	35
9	Standard Operation Procedure & Assembly Diagram	36
10	Conclusion.....	40
11	Calculations of Heat Transfer.....	42
11.1	Thermal Diffusion & Apparent Heat Capacity.....	42
12	References	44
13	Appendix.....	48

3 LIST OF TABLES

Table 1 List of Requirements	18
Table 2 DFA Results.....	31

4 TABLE OF FIGURES

Figure 1 DFM Process Flow Diagram	9
Figure 2 Market Research of Competitors Solutions.....	15
Figure 3 Market Research of Competitors Solutions to Assembly	15
Figure 4 QFD V1 Quality demands vs Quality characteristics	20
Figure 5 QFD V2 Quality demands vs Quality characteristics	21
Figure 6 QFD V3 Quality demands vs Quality Characteristics	21
Figure 7 Feature Design Flow Diagram	22
Figure 8 FMEA Vaccine Container V1.....	23
Figure 9 FMEA Vaccine Container V2	24
Figure 10 V1 Vaccine Container Exploded View	26
Figure 11 V1 Vaccine Container Inner Box.....	26
Figure 12 V1 Vaccine Container Assembled	26
Figure 13 Outer Container Birds Eye View.....	27
Figure 14 Poke-Yoke Features.....	27
Figure 15 Cross-Sectional View of Labrinth Seal.....	28
Figure 16 Transportation Features	28
Figure 17 Outer Box Assembly Features.....	29
Figure 18 Inner Container Assembly Features.....	29

Figure 19 Assembly Process	29
Figure 20 Handles of Outer & Inner Containers	30
Figure 21 V2 Assembled Container	33
Figure 22 Integrated Support.....	33
Figure 23 Mould Development Example	35
Figure 24 Assembly Diagram.....	39

5 LIST OF ABBREVIATIONS

DFX – Design for Excellence

DFM – Design for Manufacture

DFA – Design for Assembly

DFD – Design for Disassembly

DMFA – Design for Manufacture and Assembly

FMEA – Failure Mode and Effect Analysis

RPN - Risk Priority Number

LoR – List of Requirements

QFD – Quality Function Deployment

VoC – Voice of the Customer

EPS – Expanded Polystyrene

MDR – (European Union) Medical Device Regulation

HSE - Health & Safety Executive

COSHH - Control of substances hazardous to health

SOP – Standard operating procedure

FEA – Finite element analysis

6 INTRODUCTION

This report will give detail of the development of a vaccine container to transport nine vaccines while maintaining the cold chain. During the early phase of the development, research will be carried out to see what regulations concern the design and manufacture of vaccine to ensure the developed vaccine conforms to the regulation. Market research will be noted to give an understanding of what technologies competitors use. A list of customer requirements has been given which will form the early designs. Development tools will be used such as a list of requirements, quality function deployment and failure mode and effect analysis. The early designs will then be considered with design for excellence in mind, in the hope that optimisation of design will occur thus reducing cost. Once the optimisation has occurred design revisions will be carried out then manufacturing recommendations can be made, which will further alter the design. Once the design has been theoretically finalised then a standard operating procedure will be given to give best working practices that will extend the products life.

7 DESIGN METHODOLOGY & TOOLS

This section will give detail of methodologies and tools to understand customer needs, capabilities of manufacturing, design considerations, failure modes and new product development.

7.1 DESIGN FOR EXCELLENCE

Design for excellence is a method of achieving targeted objectives. It considers elements of which may not be thought of in the initial development of products (Barbosa & Carvalho, 2013). DFX is a family of different aspects of design which can be found in appendix 1. In this report, there will be an emphasis on design for manufacture, design for assembly and design for disassembly. With the incorporation of DFM, DFA and DFD of design that needs to be incorporated to simplify products; reduction of assembly/disassembly, manufacturing costs and time to market; and improve quality (Kuo, et al., 2001)

7.1.1 Design For Assembly

This is the idea that the lowest assembly cost can be achieved by designing a product in a way that is the most economical to assemble (Boothroyd & Alting, 1992). The DFA methodology questions parts of the assembly to see if they are vital or can be designed out. DFA asks three questions of every component to warrant their existence in the assembly. The questions are detailed below from Boothroyd, et al book of Product Design for Manufacture and Assembly.

1. *“During operation of the product, does the part move relative to all other parts already assembled. The only gross motion should be considered—small motions that can be accommodated by integral elastic elements, for example, are not sufficient for a positive answer.*
2. *Must the part be of a different material than or be isolated from all other parts already assembled? Only fundamental reasons concerned with material properties are acceptable.*

3. *Must the part be separate from all other parts already assembled because otherwise, necessary assembly or disassembly of other separate parts would be impossible?"*

(Boothroyd, et al., 2002)

The criteria that the questions result in are vital to reduce the complexity of a product. It gives an insight into what economic cost comes from complex geometry.

7.1.2 Design For Manufacture

This is the way of selecting processes for the manufacturing of components based upon the capabilities of various processes. The processes to be considered are material selection, process selection, modular design, standard component usage, multi-use parts and minimise assembly (Kuo, et al., 2001), (Kirkland, 1988), (Kobe, 1990). DFM is incorporated in most industrial CAD/CAM software packages and can give designers an understanding of the capabilities/constraints of the manufacturing process, an estimation of cost and time taken to manufacture (Autodesk, 2021). By having the ability to simulate such elements of the manufacturing process it reduces iterations of design, development cost and time.

Figure 1 summarises the steps taken when using DFMA in design. DFA is used to simplify and reduce the components needed to construct the product, then DFM can estimate the cost and further optimise the design to make manufacturing more economical.

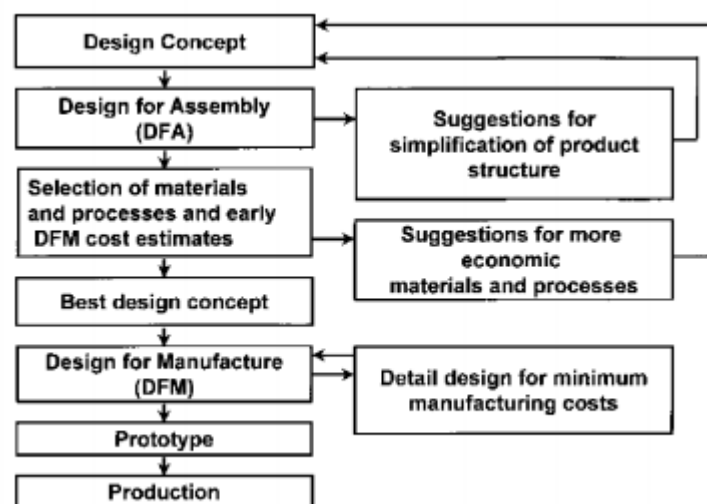


Figure 1 DFM Process Flow Diagram

(Boothroyd, et al., 2002)

7.1.3 Design For Disassembly

This is the method of incorporating the design for disassembly into the early phase of development. With the ever-increasing pressure for products to be recycled, it is important to incorporate it into the design. There are two main ways that a product can be disassembled, reverse assembly and brute force (Leonard, 1991). Reverse assembly is as suggested, it is the assembly process in reverse and the later removing parts by force. While either one is an efficient method of disassembling, the reverse assembly takes time and knowledge of assembly of the component, while brute force takes a lot of energy (Jovane, et al., 1993). Both are very difficult to make efficient or automate thus making the importance of DFD in the development of design in mind of the end of product life (Ashley, 1993) (Harivardhini, et al., 2017).

7.1.4 Voice of the Customer

The voice of the customer is a method of capturing what the customer expects and demands. VoC gives a detailed understanding of what the customer wants, why they want it and how much they are willing to pay for such products/services (Green, et al., 2020). The customer can come in many forms, the customer could be internal to a business or external such as an end-user. Both are as important as each other which is why it is important to understand their requirements (Melander, 2020). VoC can be captured in many different ways, with the use of mobile devices it is far easier to reach out to the end-user and gather feedback.

7.1.5 Quality Function Deployment

Elements of the VoC can then be used in a quality function deployment which is a tool for what quality characteristics can be used to satisfy the demanded quality from the customer (Ficalora & Cohen, 2010). Correct use of a QFD in the planning process will give a deep understanding of the product and what is required. It develops relationships between quality characteristics and demands thus giving a visual representation of what effects each have on the other. A QFD also priorities each of the customer's demands as well as evaluating and comparing the product to competitors (ReVelle, 2002).

A QFD should be used in a waterfall, so the demanded quality becomes the quality characteristics in following QFD. Examples of QFD in practice can be seen in appendix 2,3 and 4

7.1.6 Failure Mode & Effect Analysis

FMEA is a method of identifying possible failures in a design, manufacturing/assembly process or of a product. An FMEA will give details of process function, potential failure mode, potential effects of failure, causes of failure, current process controls, and recommended actions (Pahl, et al., 2007). The failures modes are scored based upon severity, occurrence and likelihood of detection, a value of risk priority number is calculated. The RPN value can indicate the priority the lower the number the better. FMEA is commonly used after QFD to understand the features and what possible effects they have or if there has been any change to a product/process (Rah, et al., 2016). An example of FMEA in practice can be found in appendix 5 and 6.

8 PRODUCT DEVELOPMENT

8.1 CONCEPT

A list of requirements has been given for the vaccine transportation container which follows:

- *“The container should be reusable (as far as is possible)*
- *The integrity of the storage containers should be maintained over multiple uses*
- *The containers should be stackable (3 high has been suggested)*
- *The process of preparing, filling, and using the storage containers should be as efficient and free from potential error as possible*
- *Must transport 9 vials*
- *Material: Expanded polystyrene*
- *Internal and External box*
- *Dimensions: 180x160x180 (mm), 340x320x340 (mm) 20mm wall thickness*
- *Provision or allowances for carrying and handling the storage containers should be incorporated”*

(University of Wales Trinity Saint David, 2021)

8.2 RESEARCH

This section will give details of research that affects the design, use and manufacturing of vaccine transportation containers.

8.2.1 Regulation

The department of health instructs the principles, practices and procedures of immunisation against infectious disease (Department of Health & Social Care, 2020).

With regards to vaccine storage and transportation, it states: *“Validated cool boxes and cool packs from a recognised medical supply company should be used in conjunction with validated maximum-minimum thermometers. Cool packs should be stored in accordance with the manufacturer's instructions, usually at +2°C to +8°C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature. In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit”*

(Department of Health & Social Care, 2020)

Medical Device Regulation (MDR) states the legal requirements to comply with the European Union law:

- *“The device has been correctly classified against the new risk classification criteria (Annex VIII of the MDR and IVDR)*
- *General safety and performance requirements are met, including for labelling, and technical documentation and quality management systems (Annex I of the MDR and IVDR)*
- *Increased requirements for clinical evidence are met (Annex XIV of the MDR and IVDR)”*

The MDR also covers the manufacturing of medical devices within the European Union.

(Medicines & Healthcare Products Regulatory Agency, 2021).

Health & Safety Executive, Regulation for control of substances hazardous to health (dry ice).

“COSHH is the law that requires employers to control substances that are hazardous to health. You can prevent or reduce workers exposure to hazardous substances by:

- *finding out what the health hazards are;*
- *deciding how to prevent harm to health (risk assessment);*
- *providing control measures to reduce harm to health;*
- *making sure they are used ;*

- *keeping all control measures in good working order;*
- *providing information, instruction and training for employees and others;*
- *providing monitoring and health surveillance in appropriate cases;*
- *planning for emergencies.”*

(Health & Safety Executive, 2021)

8.2.2 Market Research

Market research has been carried out to understand other competitors solutions to storing and transporting vaccines. As seen in figure 2 there are several solutions to meet the regulation and LoR, these features will be incorporated into the design of the vaccine container.

Several of these containers are recommended by Unicef as vaccine safe, which is an indication that they conform to the regulations and can sustain the cold chain.

Features that will be considered for the development of vaccine container:

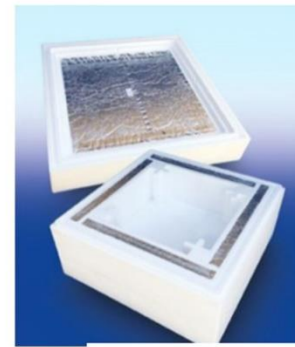
- | | |
|------------------------------|----------------------|
| • Foil lining for insulation | • Instruction labels |
| • Ice retainer/support | • Stepped seal |
| • Security strap | • Embossed handles |
| • Ergonomics | • Assembly |



Thermocon



AIVC-44



OHLRO



DYHQQ



Nilkamal



B Medical

Figure 2 Market Research of Competitors Solutions

(B Medical, 2021), (APEX, 2021), (Nilkamal, 2021), (DYHQQ, 2021), (OHLRO, 2021), (Thermocon, 2021)

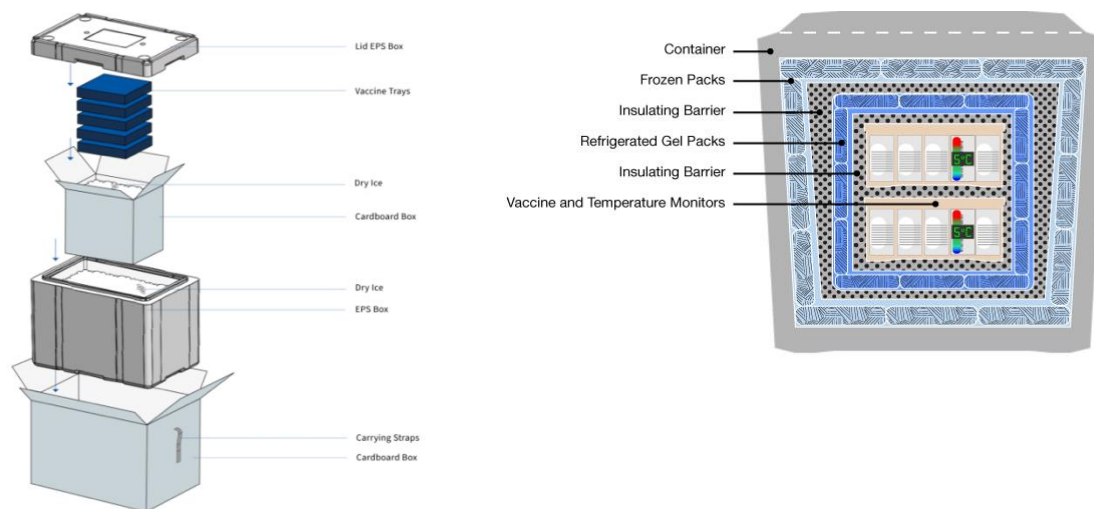


Figure 3 Market Research of Competitors Solutions to Assembly

(Public Health Canada, 2020), (Storopack, 2021)

8.2.3 Manufacturing Research

The manufacturing process of EPS done by expandable foam moulding. Solid Polystyrene is expanded with a blowing agent, which is fed into a mould and expanded and formed with heat. Alternatively, the prefoaming can be incorporated into the forming process (Groover, 2010).

Tolerances of moulding Polystyrene:

	50mm Dimension	10mm Hole
Polystyrene (Groover, 2010)	$\pm 0.15\text{mm}$	$\pm 0.1\text{mm}$

Manufacturing considerations of expandable moulding:

- Holes are easily achievable in moulding, however, they cause interruptions in flow and complicate the removal of parts.
- Draft angle is an important factor of moulding, parts should have a draft angle on the sides to help facilitate removal of the part.
- Tolerances give allowable manufacturing variations to the specification. As with all polymer moulding, it is subject to shrinkages. Even with predictable process control variation is inevitable.

With the understanding of the manufacturing process, the considerations can be incorporated into the design of the vaccine container.

8.3 PRODUCT DEFINITION

The production definition will be given by the use of product development tools such as QFD and FMEA.

8.3.1 Core Purpose of Vaccine Container

To Sustain cold chain environment through the transportation and storage of 9 vaccine vials through the supply chain to end-user.

8.3.2 User Base

The customer of the vaccine container will be medical services. Within the medical services, specific people will be in contact with the container thus must be defined.

- Trained medical staff (end-user)
- Logistics staff (supply chain)
- Medical Manufacturer staff (Producer)

8.3.3 Customer Needs

From this list of requirements set out in the concept phase, an in-depth LoR is detailed in Table 1

List of Requirments			
Customer Demands	Importance	Feature/Design	Capability
Cold Chain Management	10	Material selection/Design/Visual Indicators	Low heat transfer coefficient/Dimensions
Transportation	9	Stackability/Transportation/Payload stability	Design features/Dimensions
Vial Yield	9	Vial Holder	Must contain 9 vials
Reusability	8	Reusable box	Hard-wearing material/Design features

Robust	7	Density/Impact Resistance	EPS/Design features
Stackability	7	Lid/Container lock feature	Male & Female/Embossed feature
Ergonomics	7	Easy to handle, transport & assemble	Handles/Box dimensions
Ice Void	7	Uniform ice coverage	Box dimensions/Design features
Error Proofing	6	Poke-Yoke/ Orientation	Orientation inserts/Vial holder
User Experience	5	Easy to use/ Intuitive	Operation indicators/ Design features

Table 1 List of Requirements

(May-White, 2021)

The LoR in table 1 details the requirements, importance, feature/design and capability. From research into vaccine transportation, some key features are of high importance.

Cold Chain Management (10) – The thermal properties of the container are of the highest importance due to the conditional environment that a vaccine needs to be stored. *“The cold chain refers to the maintaining potency and integrity of the vaccine by ensuring optimal conditions during storage.”* (Saskatchewan College of Pharmacy Professionals, 2020). To keep the vaccine at the optimal temperature the container must have good thermal properties to reduce loss of temperature. If the temperature exceeds the specification then the cold chain is broken resulting in a reduction of vaccine potency and effectiveness (Centers for Disease Control and Prevention, 2021). Temperature indications must be present to ensure optimal conditions at the point of use.

Transportation (9) – The transportation of the vaccine container is integral to the cold chain. Due to vaccines being transported by freight, the container must be stackable and secure. Many vaccines use

dry ice as a medium to maintain the cold chain. Dry ice is hazardous to health and is classed as a dangerous good, which is regulated by the (EU) No 965/2012 and ICAO Doc 9284 'Technical Instructions for the Safe Transport of Dangerous Goods by Air' (European Union Aviation Safety Agency, 2021). To adhere to the regulations the container must include features to secure when stacked and not open unexpectedly.

Vial Yield (9) – The requirements of transporting 9 vials of vaccine with dimensions of $\varnothing 46 \times 100$ (mm).

Reusability (8) – The container must be reusable, to ensure there is no shortage of containers that will aid in supporting the supply chain. EPS naturally is a tough reusable material if handled correctly. EPS can be recycled at the end of the life cycle.

Robust (7) – The structural integrity of the container is vital if all the above demand met. This can be achieved by EPS natural rigidity and toughness as a material with design features such as wall thickness and sealing system (Zhu, et al., 2014).

Stackability (7) – Stackability is vital in the transportation and storage of containers. Stability, when stacked, is required for a height of 3 containers.

Ergonomics (7) – The containers will be handled by trained operators, to reduce the risk of injury and possible damage features must be used to reduce the occurrences. Dimensions are set as 180x160x180 (mm), 340x320x340 (mm). The assembly and disassembly must be efficient with minimum damage to components.

Ice Void (7) – The ice around the vaccine container must be a minimum of 60mm thick. It must also be easy to insert and remove.

Error Proofing (6) – The assembly process will need to be designed to ensure that is done correctly. Poke-yoke is a method of giving visual indications when the process is out of specification (Toyota, 2021).

User Experience (5) – The process of transportation and use must be easy to understand and intuitive. Users of this container may not speak a common language thus instruction must be able to be understood regardless of language. All aspects of transportation and use will have a detailed process map to give best practices and identify defects.

8.3.4 Quality Function Deployment

To better understand the customer needs and the quality characteristics needed to satisfy such needs several waterfall QFD's have been used which can be found in appendix 2,3 and 4.

The list of requirements will be used as the customer needs. The quality characteristics given are engineering features that can be measured thus will be an indication of the performance of each feature. As a waterfall suggests the quality characteristics in figure 4 will become the quality demands in the following QFD as seen in figure 5 and 6.

Quality Characteristics (a.k.a. "Functional Requirements" or "Hows") Demanded Quality (a.k.a. "Customer Requirements" or "Whats")	Insulation	Robust	Stackability	Dimensions	Cooling medium volume	Error proofing	Ergonomic	User experience/intuitive
Maintain cold chain	⊕	⊕		⊕	⊕	⊖		▲
Contain 9 vials				⊕		⊖		▲
Be able to transport		⊖	⊖	⊖	⊖		⊖	▲
Easy to use			⊖	⊖	▲	⊖	⊖	⊖
Reusable	⊕	⊕	⊖		⊖	⊖	⊖	⊖

Figure 4 QFD V1 Quality demands vs Quality characteristics

(May-White, 2021)

Quality Characteristics (a.k.a. "Hows") Demanded Quality (a.k.a. "Whats")	Expanded polystyrene	Minimum wall thickness	Male/female features	Handles	Poke-Yoke assembly process	Uniform cooling medium	Sealable lid	Visible instructions
Insulation	○	○				○	○	
Robust	○	○		▲	○	▲	○	
Stackability	▲		○	○	○		○	○
Dimensions	▲	○	▲	▲	○	○	○	
Cooling medium volume		○			○	○	○	
Error proofing			○	○	○	○	○	○
Ergonomic	○	▲	▲	○	○		○	
User experience/intuitive				○	○		○	○

Figure 5 QFD V2 Quality demands vs Quality characteristics

(May-White, 2021)

Quality Characteristics (a.k.a. "Hows") Demanded Quality (a.k.a. "Whats")	Manufacturing process	Oriental features	Stackable lid and container	Embossed handles	Labyrinth seal	Total quality management	Container support inserts
Expanded polystyrene	○	▲	○	▲	○		
Minimum wall thickness	○			▲		○	
Male/female features	○	○	○		○	○	
Handles	○		○	○		▲	
Poke-Yoke assembly process		○	○		○	○	○
Uniform cooling medium	○					○	○
Sealable lid	○	▲	○	○	○	○	○
Visible instructions		▲	▲	○			▲

Figure 6 QFD V3 Quality demands vs Quality Characteristics

(May-White, 2021)

From the respective QFD's some key quality aspects have been addressed and solutions have been found to satisfy the originally demanded qualities.

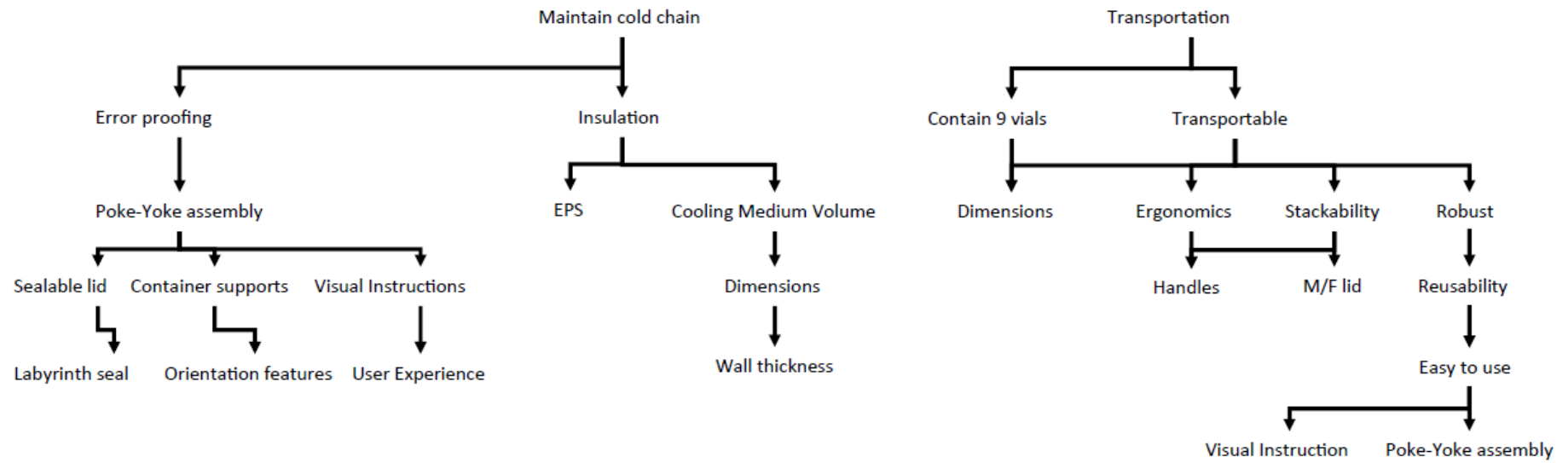


Figure 7 Feature Design Flow Diagram

(May-White, 2021)

DESIGN FAILURE MODE AND EFFECTS ANALYSIS

Item: Vaccine Transportation Container Responsibility: WMW
 Model: VT 1 Prepared by: WMW
 Core Team: William May-White

FMEA number: 123

Page :

FMEA Date (Orig): 22/04/2021

Rev:

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v e r e n e s s	C l a s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r r e n c e	C u r r e n t P r o c e s s C o n t r o l s	D e t e c t i o n	R P N	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
												Actions Taken	S e v e r e n e s s	O c c u r r e n c e	D e t e c t i o n	R P N
Container Assembly	Container structure integrity	Break of Cold Chain	8		Operator error/Impact	4	N/A	2	64	Process Control	WMW	Regular Function Checks				0
Container Assembly	Lid not seated correctly	Break of Cold Chain	8		Damaged lid/Operator error	7	N/A	5	280	Lid/seal locators	WMW	Design Feature				0
Container Assembly	Incorrect inner container seating	Damaged container	7		Operator error/Over filling	6	N/A	5	210	Add Fill lines	WMW	Process Verification				0
Container Assembly	Damaged Lids	Loss of function	6		Operator error/Material Fatigue	7	N/A	4	168	Handle Redesign	WMW	Design Feature				0
Holding/Stacking	Damaged stacking locators	Instability when stacked	5		Operator error/Material Fatigue	5	N/A	2	50	Process Control	WMW	Process Control/Training				
Manual Handling	Dropping of container	Break of Cold Chain	8		Ergonomics/Loss of grip	5	Risk Assessment/Process Control	2	80	Training	WMW	Training Operators				
Manual Handling	Dropping of container	Injury	5		Ergonomics/Body movements	3	N/A	5	75	Risk Assessment/Process Control	WMW	Process Control				
Ice Handling	Damage cooling medium	Hazzadous to health	9		Damage to ice park	4	N/A	3	108	Risk Assessment/Process Control/Training	WMW	Process Control				
Filling Ice into container	Contamination	Break of Cold Chain	8		Inner conatiner lid not seated correctly	6	Process Control	2	96	Upper ice insert to secure lid	WMW	Design/Process Verification				
Filling Ice into container	Overfilling	Damaged container	5		Operator error	8	Process Control	6	240	Add Fill lines	WMW	Design/Process Control				
Filling Ice into container	Lid not seated correctly	Damaged container	6		Operator error	5	Process Control	7	210	Add Fill lines	WMW	Design/Process Control				
Removing Ice from container	Container structure integrity	Damaged container	5		Operator error/Material Fatigue	3	Process Control	4	60	Design Ice Removal Part	WMW	New Component				
Removing Ice from container	Spillages	Injury	7		Melted Ice	7	N/A	3	147	Design Ice Removal Part	WMW	New Component				
Transportation	Damage during transportation	Delivery not met/Break of Cold Chain	7		Lack of stability when stacked/ Excessive movement in transprotation	5	N/A	6	210	Design Locators	WMW	Design Features				

Figure 8 FMEA Vaccine Container V1

(May-White, 2021)

DESIGN FAILURE MODE AND EFFECTS ANALYSIS

Item: Vaccine Transportation Container Responsibility: WMW FMEA number: 123

Model: VT 2 Prepared by: WMW Page:

Core Team: William May-White FMEA Date (Orig): 22/04/2021 Rev:

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v e r e n e s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r r e n c e	Current Process Controls	D e t e c t i o n	R P N	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
											Actions Taken	S e v e r e n e s s	O c c u r r e n c e	D e t e c t i o n	R P N
Container Assembly	Container structure integrity	Break of Cold Chain	8	Operator error/Impact	4	N/A	2	64	Process Control	WMW	Regular Function Checks				0
Container Assembly	Lid not seated correctly	Break of Cold Chain	8	Damaged lid/Operator error	7	Lid/seal locators	2	112	Process Control	WMW	Regular Function/ Checks				0
Container Assembly	Incorrect inner container seating	Damaged container	7	Operator error/Over filling	4	Ice fill indicators	3	84	Process Control/Awareness	WMW	Process Verification				0
Container Assembly	Damaged Handles	Loss of function	3	Operator error/Material Fatigue	5	Recessed Handles	3	45	Regular Checks	WMW	Regular Function Checks				0
Holding/Stacking	Damaged stacking locators	Instability when stacked	4	Operator error/Material Fatigue	3	Process Control/Training	2	24	N/A	WMW					
Manual Handling	Dropping of container	Break of Cold Chain	8	Ergonomics/Loss of grip	3	Risk Assessment/Process Control/Training	2	48	N/A	WMW					
Manual Handling	Dropping of container	Injury	5	Ergonomics/Body movements	3	Risk Assessment/Process Control/Training	5	75	Workstation layout	WMW	Process Verification				
Ice Handling	Damage cooling medium	Hazzadous to health	8	Damage to ice pack	4	Risk Assessment/Process Control/Training	2	64	Workstation Ventilation/Process Control/Awareness	WMW					
Filling Ice into container	Contamination	Break of Cold Chain	8	Inner container lid not seated correctly	3	Upper ice insert to secure lid	2	48	N/A	WMW					
Filling Ice into container	Overfilling	Damaged container	5	Operator error	3	Ice fill indicators	2	30	N/A	WMW					
Filling Ice into container	Lid not seated correctly	Damaged container	5	Operator error	4	Ice fill indicators	3	60	Process Control	WMW	Process Verification				
Removing Ice from container	Container structure integrity	Damaged container	5	Operator error/Material Fatigue	3	Upper Ice Container/Process Control	4	60	Process Control	WMW	Process Verification				
Removing Ice from container	Spillages	Injury	6	Melted Ice	5	Process Control/Drainage at workstation	3	90	Workstation Design/Process Awareness	WMW	Process Verification				
Transportation	Damage during transportation	Delivery not met/Break of Cold Chain	4	Male/Female locators damages/ Excessive movement in transportation	3	Stacking locators	6	72	Transportation Control	WMW	Process Control & Verification				

Figure 9 FMEAVaccine Container V2

(May-White, 2021)

The QFD's in figure 4, 5 & 6 have indicated what design features must be included in the vaccine container to satisfy the customer demands. The key aspects are shown in figure 7 the feature design flow diagram is a visual representation of what quality demands to affect each other. As can be seen, there are several demands which are related and thus shows the importance of satisfying them.

The FMEA in figure 8 & 9 gives detail of the failure modes of the design and the processes involved. Figure 8 is the first FMEA before any inclusion of considerations of DFMA. Figure 9 is with the inclusion of DFMA.

8.4 VERSION ONE CONTAINER DEVELOPMENT

After the considerations of LoR, QFD and FMEA a first phase development was carried out. Many features and components have been included. The DFMA method will be used to optimise the design further to simplify the assembly and reduce manufacturing costs. The exploded view in figure 10,11 and 12 is the completed assembly, exploded view and inner box respectively.



Figure 12 V1 Vaccine Container Assembled



Figure 11 V1 Vaccine Container Inner Box

(May-White, 2021)

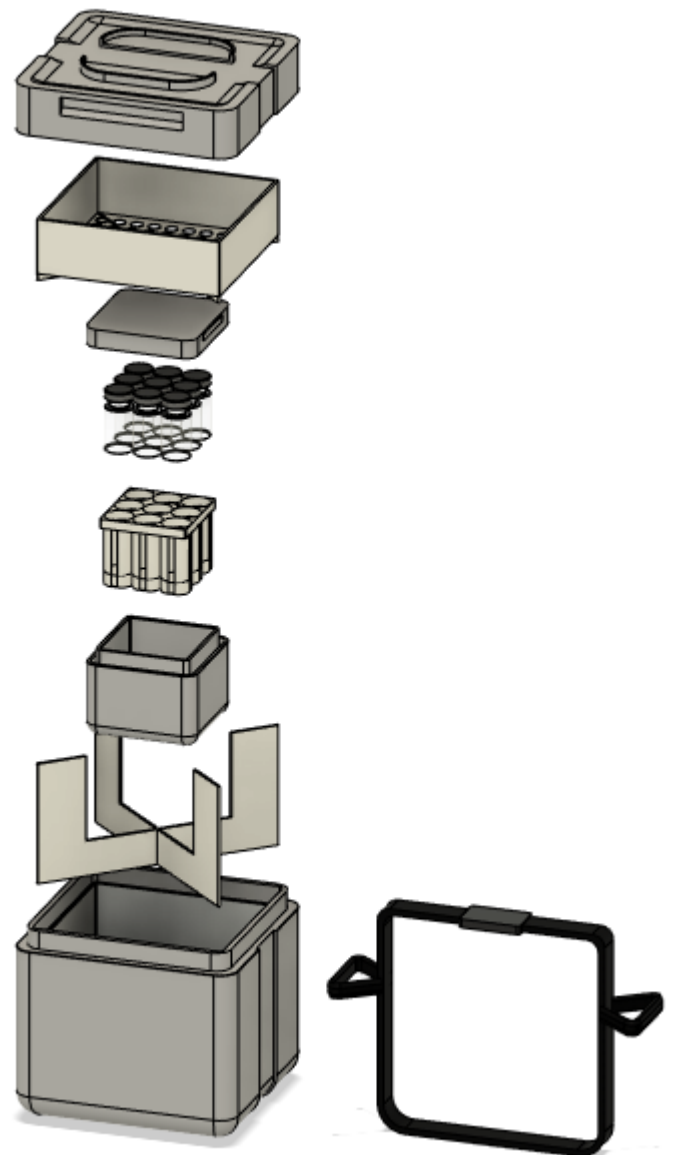


Figure 10 V1 Vaccine Container Exploded View

Note: The figures given will use the colour cycling function to better distinguish between each component. All Figures are referenced from the CAD model vaccine container V1 by the author (May-White, 2021)

8.4.1 Maintain Cold Chain Features

To ensure that the cold chain is maintained the features that are incorporated into the design are detailed below.

Cooling medium volume - The inner container is suspended in the middle of the outer container by the use of supports. This allows for almost full coverage of the cooling medium. The wall thickness is uniform around the container and the inner dimensions meet the specification of the LoR.

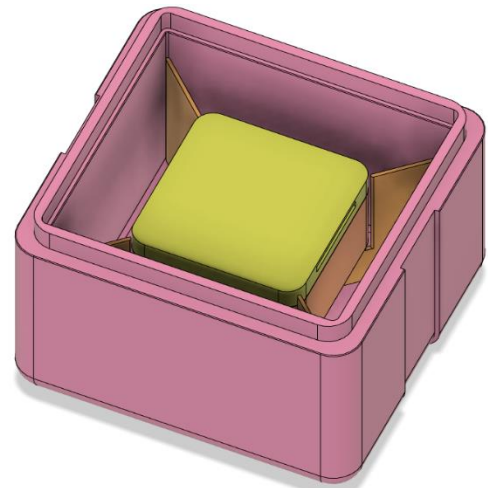
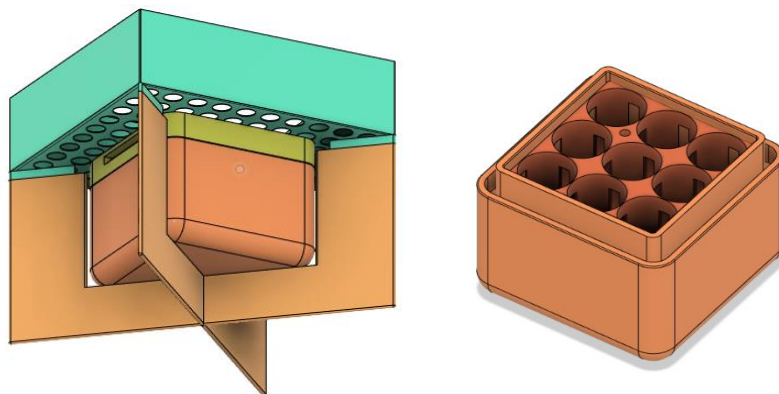


Figure 13 Outer Container Birds Eye View

The Poke-Yoke Assembly features are shown in figure 14

the inner container is suspended in supports to ensure that it is seated correctly with shaped cooling mediums around the inner container. The upper support will allow for the cooling medium to be placed on top which will not only secure the inner container it will also give a visual fill line to stop overfilling. The inner

container has vial holders to ensure that the vials do not move in the transportation, are equally spaced and have a



flow of air between each *Figure 14 Poke-Yoke Features*

vial as recommended in sections 8.2.1. The assembly process is intuitive while the working method will be provided, the container can be assembled by trial and error.

The labyrinth seal shown in figure 15 will allow for correct assembly thus maintain the cold chain. The inner container has no orientation, however, the outer container is orientated due to the closing and handling strap.

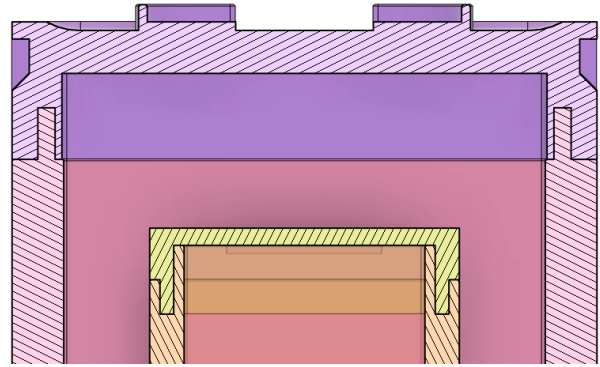


Figure 15 Cross-Sectional View of Labyrinth Seal

8.4.2 Transportation

The transportation features are seen in figure 16. The box has a strap that will be used in the handling of the container as well as securing the lid to further maintain the cold chain. The handles are ergonomic and allow for the user to carry the box at a comfortable height. It will further aid in the reduction of injury if picked up from ground level. The lid and container have male and female embossed features to secure the boxes when stacked. The vial holder in figure 14 will aid in the transportation by securing the vials inside the inner container.

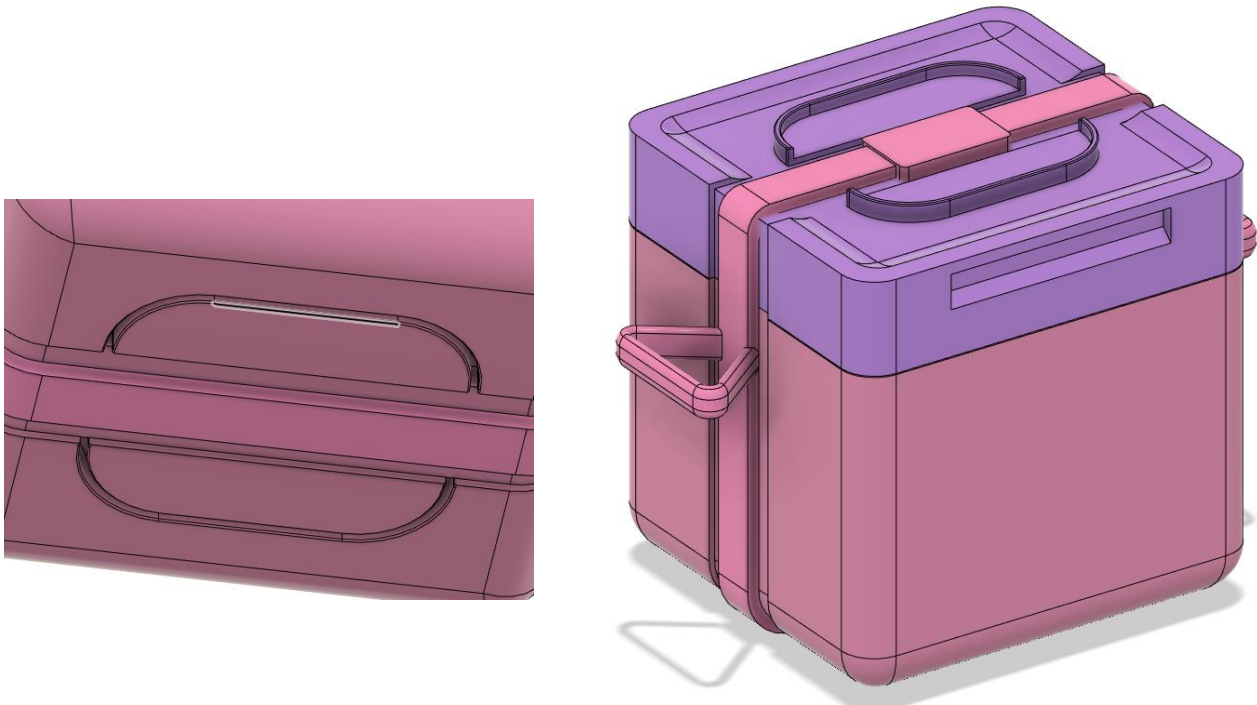


Figure 16 Transportation Features

8.4.3 Assembly Features

The assembly features are detailed in figures 17,18 and 19. Figure 18 give an example of how the containers are assembled and disassembled. The strap is removed, followed by the lid, upper support and the removal of the inner container. Once the lids are removed the upper support sits above the container ensuring the operator can get a firm grip which will ease the removal of the cooling medium and be able to dispose of it. The inner container has the vial support that sits below the container which allows the operators fingers to remove with vials. A spacing of 20mm is given which should be satisfactory in removing the vials. However further investigation will need to be conducted to ensure the spacing is adequate.

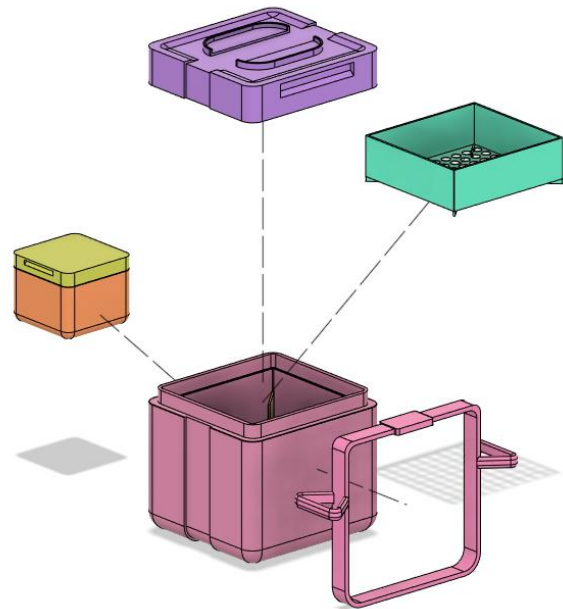


Figure 19 Assembly Process



Figure 18 Inner Container Assembly Features

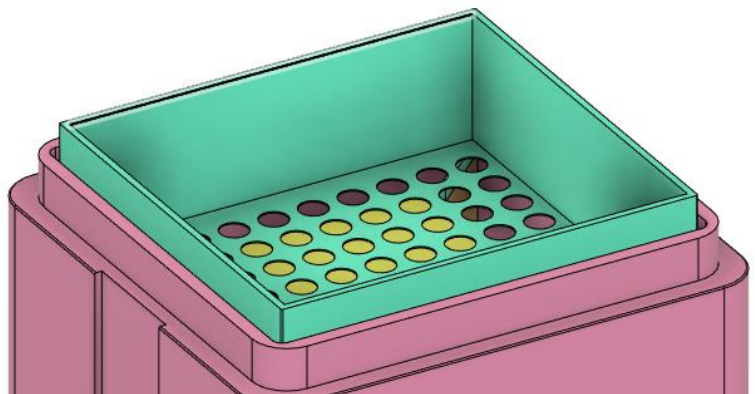


Figure 17 Outer Box Assembly Features

8.4.3.1 Ergonomic Features

The handles which will aid in the removal of the lids can be seen in figure 20. Each of the lids has an embossed handle allowing the user to gain a firm grip when removing the lids. Due to EPS materials properties, an embossed feature was best suited giving better structural integrity thus reducing failures.

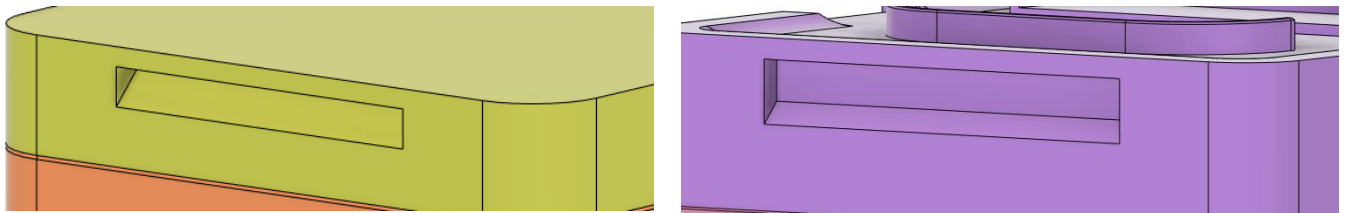


Figure 20 Handles of Outer & Inner Containers

8.4.4 Reusability

The containers have been designed with modularity in mind, if a part of the assembly became damaged then the other parts can be salvaged as spares. Also if a different inner container is needed then new support can be designed which will allow the outer box to be reused. Furthermore, if there was a leak/contamination then the containers can be disassembled and cleaned.

8.4.5 DFA

Outer Container

	Container	Lid	Lower support	Upper Support	Strap
During operation of the product, does the part move relative to all other parts already assembled?	No - Static once used	No - Static once used	No - Static once used	No - Static once used	No - Static once used
Must the part be of a different material than or be isolated from all other parts already assembled?	No - Must be EPS due to properties	No - Must be EPS due to properties	Yes - Better material properties	Yes - Better material properties	Yes - Better material properties
Must the part be separate from all other parts already assembled because otherwise, necessary assembly or disassembly of other separate parts would be impossible?	Yes - Used for assemblies	Yes - Used for assembly	No - Required for reuseability	No - Required for reuseability	No - Required for fastening

Inner Container

	Container	Lid	Vial Holder
During operation of the product, does the part move relative to all other parts already assembled?	No - Static once used	No - Static once used	No - Static once used
Must the part be of a different material than or be isolated from all other parts already assembled?	No - Must be EPS due to properties	No - Must be EPS due to properties	Yes - Better material properties
Must the part be separate from all other parts already assembled because otherwise, necessary assembly or disassembly of other separate parts would be impossible?	Yes - Used for assemblies	Yes - Used for assemblies	Yes - Used for assemblies

Table 2 DFA Results

8.5 VERSION TWO CONTAINER DEVELOPMENT

While version one of the vaccine container satisfies the LoR, further optimisation is required to incorporate DFMA and DFD. The questions of DFMA will be asked of every component with a justification of its existence. The DFA results can be seen in Table 2, where the answer and justification can be given. The results have shown that there are efficiencies that can be made in the assembly. The final assembly drawing can be found in appendix 7, due to many geometry changes required to satisfy the manufacturing of the containers, only basic dimensions will be given in appendix 8 and 9 with features being subject to change in the next development stage.

The container support can be integrated into the design however the functionality of reusability and ability to be cleaned will be lost. The geometry of the support causes the issue, the support legs are thin thus damage would likely occur which may render the box unusable. If integrated there would be a large reduction in manufacturing cost and materials. The upper support can be also be made from the same material but cannot be integrated. The strap can be removed and a new fastening feature can be integrated into the lid due to the excessive material. Furthermore, with the removal of the strap, handle or grips must be integrated into the design to ensure good ergonomics and stackability.

The inner box the vial support could be integrated into the design however due to complexity in the geometry the tooling required would make it complex thus increasing manufacturing costs. The material of the inner support can be made from EPS, but the intricacy of the design and thin walls may be an area of concern. Alternative materials should be considered, such as a hard polymer, with good thermal properties.

8.5.1 Revised Features

After the considerations of DFA, revisions have been made to the container. The strap has been removed and replaced with a push fitment lid, while it may not offer the level of security a strap would be seen in figure 22. It is still fit for the purpose of the container, furthermore, it will reduce the manufacturing costs. Embossed areas have been put in place to aid in the handling of the container. The embossing will give grip to the user when transporting the box. The ergonomics will need to be verified further, under full weight to ensure the embossed handles are fit for purpose.

The lower support has been integrated into the container, the width of the support has been increased due to the material properties of EPS being an issue at such thin wall thickness. This will allow for one mould in the manufacturing process to make the container.

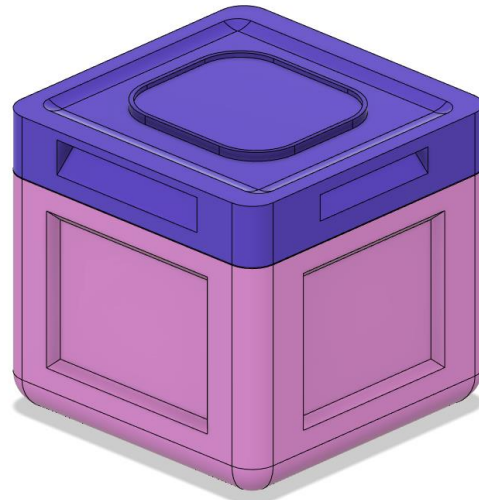


Figure 21 V2 Assembled Container

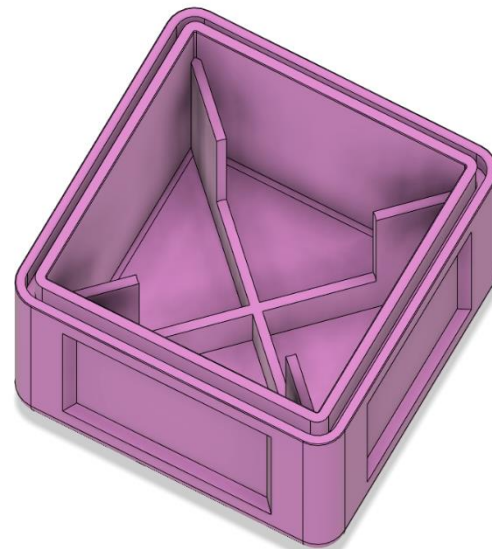


Figure 22 Integrated Support

8.5.2 Design for Manufacture

The design has been optimised to reduce the number of components needed to satisfy customer requirements. However, further optimisation with regards to the manufacturing of the design. Further revisions need to be made to consider the manufacturing process, as previously mentioned in section 7 to reduce costs in the manufacturing process features and geometry must be simplified. Due to the nature of moulding features such as draft angle must be considered to allow for easy removal of the part. The body of the container would need the largest draft angles due to the size as recommended by (Groover, 2010). The draft angle will be governed by the machine capabilities thus an exact figure will need to be given from the machine vendor.

Expanded foam moulding as a process commonly prefers reduction in straight edges (Karmakar & Subbiah, 2018). Fillet on straight edges has been added to the design to allow for better removal of the part. By increasing the effectiveness of the ejection process there will be a reduction in the likelihood of damage.

8.5.3 Design for Disassembly

After the revisions from DFMA, there have also been improvements in the disassembly. By reducing the number of parts, thus reducing the different type of material. Before the revisions, it was likely that there would be four types of material to be recycled. The strap and retaining clip would have to be forcefully broken apart to recycle the different materials. With the integration of the lower support and the container, it now can be recycled as one. The upper support and vial support are the only components that are made from a different material other than EPS due to the geometry, however, the material selection of this will be governed by the recyclability. Further investigation will need to be carried out to find a suitable material.

8.5.4 Mould Development

Figure 23 is an example of a mould that could be used to manufacture the transportation container. Four dies to form the lower part of the container, while a fifth die will give the wall thickness and the inner support. Polystyrene will be injected into the mould and then heated to give the final form and mechanical properties. The four lower dies will open and the part will be ejected. The upper support will have the largest draft angle aiding in the removal of the part.

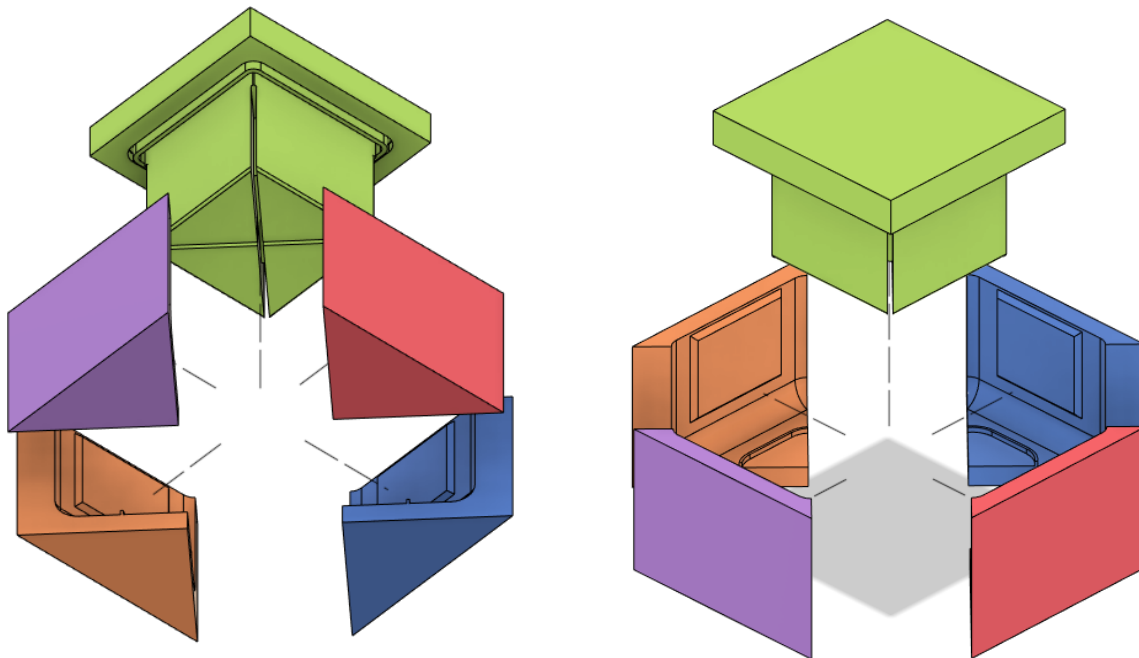


Figure 23 Mould Development Example

9 STANDARD OPERATION PROCEDURE & ASSEMBLY DIAGRAM

Please see figure 23 for the assembly diagram.

PROCESS SHOULD ONLY BE CARRIED OUT BY A TRAINED OPERATOR.

PPE REQUIRE:

- NITRILE GLOVES
- CRYOGENIC HANDLING GLOVES
- EYE PROTECTION
- CLEAN WORK ATTIRE

WORK STATION SET UP:

- EXTRACTION OPERATIONAL
- DRAINAGE SYSTEM OPERATIONAL
- CLEAN AND SANITISED

QUALITY CHECKS: (PLEASE REPORT ANY INSTANCE THAT DOES NOT CONFORM TO QC'S)

- ALL EQUIPMENT IS DAMAGE-FREE
- THE COLD CHAIN IS WITHIN SPECIFICATION
- VIALS TO BE CHECKED TO SPECIFICATION
- COOLING MEDIUM IS CORRECTLY INSERTED & BELOW FILL LINE

HAZARDS

- COLD MEDIUM HANDLING
- ASPHYXIATION
- MANUAL HANDLING

Assembling process of vaccine container

1. Insert vial holder into vaccine container (ensure it is inserted square to reduce damage to the container)
2. Insert vaccine vials into container (place one at a time, outside vials first then inner one last)
3. Insert the thermometer into the hole
4. Secure lid ensuring tight fit (check that lid is secured correctly and there is no space between lid and container body)

Assembling process of transportation box

1. Insert lower cooling medium into the box (check cooling medium is NOT above fill line)
2. Insert vaccine container into the box (ensure it is inserted square to reduce damage)
3. Insert side cooling medium into the box (check cooling medium is NOT above fill line)
4. Insert upper support into container (ensure it is inserted square to reduce damage)
5. Insert cooling medium into upper support (ensure it is not above upper support)
6. Secure lid ensuring tight fit (check that lid is secured correctly and there is no space between lid and container body)

Manual handling

- Only handle container at embossed faces on lower container
- Ensure the container is correctly slotted into grooves when stacking (container should be level)
- The maximum stack height is 3

Disassembly Process

1. Open transportation container only using embossed handles on the lid
2. Remove cooling medium by removing upper support
3. Dispose of waste cooling medium inline with facility SOP
4. Remove side cooling medium inline with facility SOP

5. Remove vaccine container place on a flat secure surface
6. Remove remaining cooling medium inline with facility SOP
7. Open vaccine container using embossed handles on the lid
8. Remove vaccines centre on first

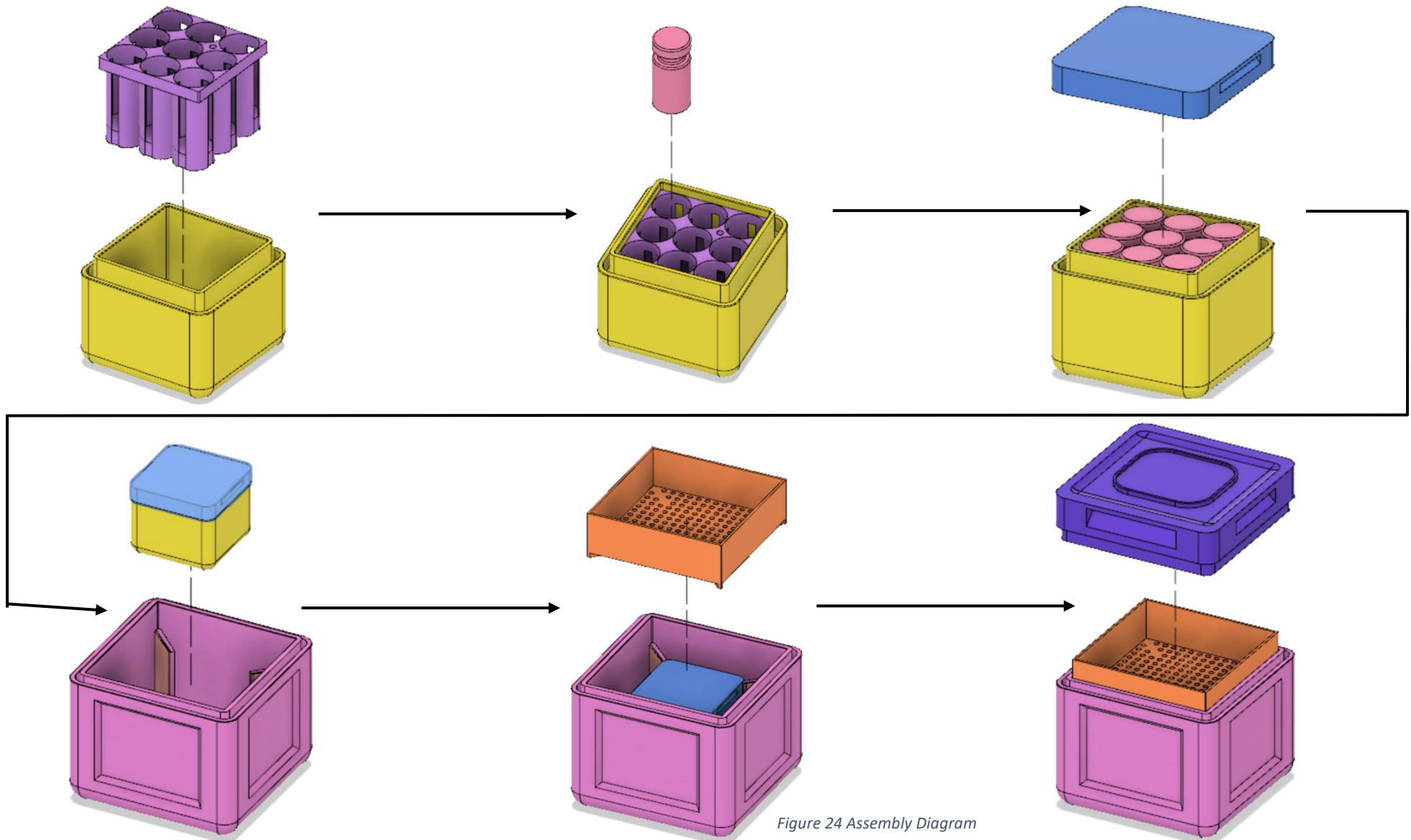


Figure 24 Assembly Diagram

10 CONCLUSION

To conclude, the early stages of the development process of the vaccine container shows the importance of factoring in elements of design for excellence. Before DFA and DFM were considered the vaccine container satisfied the demands of the customer however, the design was far from optimised and had many unnecessary parts. If DFMA would have not been considered then the manufacturing cost could have been substantial in many ways. The further a design is through the development process the higher the cost of any changes. If elements such as draft angle and manufacturing process tolerances are not considered then this could be costly. The cost of actually manufacturing more components would have been substantial if produced in high volume. After the revisions of the design from the DFMA, there are substantial improvements.

The next phase in the development would be to test the design features with EPS material. The embossed handles while they satisfy the customer needs in this early phase until they are simulated with load in FEA it is difficult to determine if it is fit for purpose. Once the simulation has been satisfied then prototypes can be explored and have real-world testing in aspects such as load capabilities, ergonomics and cold chain management.

The SOP for the assembly process will also need revisions. Once more specifications such as cold chain and traceability information are gathered, they will need to be included in the SOP. This is required under regulations from the department of health and without such information, the vaccine will not be used. Further design features related to this would be a place for documentation to be stored on the container and a readable external thermometer.

11 CALCULATIONS OF HEAT TRANSFER

11.1 THERMAL DIFFUSION & APPARENT HEAT CAPACITY

Transient heat transfer through conduction is formulated below in the thermal diffusion equation

$$k \cdot \nabla^2 T = \rho \cdot c \cdot \frac{\partial T}{\partial t}$$

Where, $\nabla^2 = \frac{\partial^2}{\partial x^2} + \frac{\partial^2}{\partial y^2} + \frac{\partial^2}{\partial z^2}$

This equation is a method of modelling the phase change solid to liquid, it is used in rectangular enclosures using finite difference formula (Shen, et al., 2010)

The apparent heat capacity is a method of simulating the melting of ice in a rectangular enclosure also using explicit finite-difference. In the apparent heat capacity, there is a mushy zone which includes the phase transition from solid to liquid. The transition phase is said to be between -0.5 and 0.01°C (Scanlon, 200).

- Conductivity $k_m = \frac{2 \cdot k_s \cdot k_l}{k_s + k_l}$

- Density $\rho_m = \frac{\rho_m @ -0.5^\circ\text{C} + \rho_l @ 0.01^\circ\text{C}}{2}$

- Specific Heat $c_m = \frac{c_s + c_l}{2} + \frac{L}{\Delta T}$

where $\Delta T = (0.01 + 273) - (-0.5 + 273) = 0.51 \text{ K}$

- k_s is the thermal conductivity of ice,
- k_l is the thermal conductivity of water,
- ρ_s is the density of ice,

- ρ_l is the density of water,
- c_s is the specific heat of ice,
- c_l is the specific heat of water,
- L is the latent heat of fusion (ice to water).

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13 APPENDIX

DFA	Design for assembly
DFD	Design for disassembly
DFEMC	Design for electromagnetic compatibility
DFESD	Design for electrostatic discharge
DFI	Design for installability
DFM	Design for maintainability
DFM	Design for manufacturing
DFML	Design for material logistics
DFP	Design for portability (software)
DFQ	Design for quality
DFR	Design for redesign
DFR	Design for reliability
DFR	Design for reuse
DFS	Design for safety
DFS	Design for simplicity
DFS	Design for sustainability
DFT	Design for test

(Jack, 2013)

Appendix 1 List of Design for Excellence

Title: Vaccine Container

Author: William May-White

Date: 25/05/2021

Notes:

Legend		
⊖	Strong Relationship	9
○	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
-	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
X	Objective Is To Hit Target	

Title: Vaccine Container

Author: William May-White

Date: 25/05/2021

Notes:

<

Title: Vaccine Container

Author: William May-White

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Notes:

Legend		
⊙	Strong Relationship	9
○	Moderate Relationship	3
△	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
-	Negative Correlation	
▼	Strong Negative Correlation	
▽	Objective Is To Minimize	
▲	Objective Is To Maximize	
X	Objective Is To Hit Target	

				Column #																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (X)																
Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Quality Characteristics (a.k.a. "Whats")																
				Demanded Quality (a.k.a. "Whats")																
1	9	11.9	395.1	Insulation	⊙	⊙														
2	9	17.8	592.7	Robust	⊙	⊙		▲	⊙											
3	9	8.8	292.7	Stackability	▲		⊙	⊙	⊙		⊙									
4	9	19.6	651.2	Dimensions	▲	⊙	▲	▲	⊙	⊙	⊙									
5	9	10.7	356.1	Cooling medium volume		⊙			⊙											
6	9	13.2	439.0	Error proofing			⊙	⊙	⊙	⊙	⊙									
7	9	11.0	365.9	Ergonomic	⊙	▲	▲	⊙	⊙		⊙									
8	9	7.1	236.6	User experience/intuitive				⊙	⊙		⊙	⊙								
9																				
10																				
11																				
12																				
13																				
14																				
15																				
				Target or Limit Value																
				Optimal material properties	20mm	Required	Required	Reduce errors in assembly process	60mm	Stop contamination	Required									
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	1	4	4	3	6	6	3	3								
				Max Relationship Value in Column	9	9	9	9	9	9	9	9								
				Weight / Importance	328.4	550.3	228.4	398.0	386.2	436.5	783.1	209.0								
				Relative Weight	9.9	16.6	6.9	12.0	11.6	13.1	23.6	6.3								

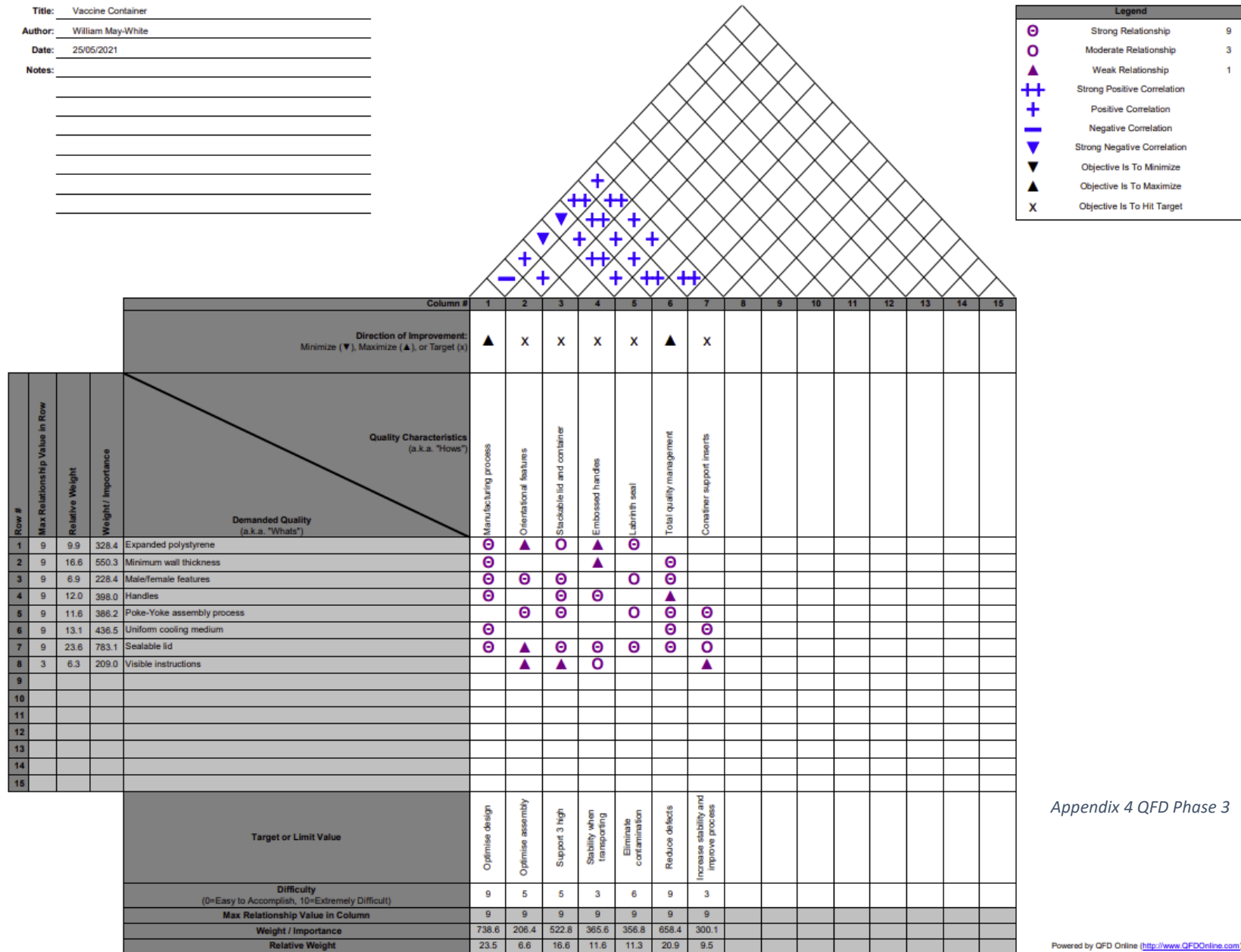
Appendix 3 QFD Phase 2

Title: Vaccine Container

Author: William May-White

Date: 25/05/2021

Notes:



Appendix 4 QFD Phase 3

DESIGN FAILURE MODE AND EFFECTS ANALYSIS

Item: Vaccine Transportation Container Responsibility: WMW FMEA number: 123

Model: VT 1 Prepared by: WMW Page :

Core Team: William May-White FMEA Date (Orig): 22/04/2021 Rev:

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v e r e n e s s	C l a s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r r e n c e	D e t e c t i o n	R e p a r t s	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
											Actions Taken	S e v e r e n e s s	O c c u r r e n c e	D e t e c t i o n	R e p a r t s
Container Assembly	Container structure integrity	Break of Cold Chain	8		Operator error/Impact	4	N/A	2	64	Process Control	WMW	Regular Function Checks			0
Container Assembly	Lid not seated correctly	Break of Cold Chain	8		Damaged lid/Operator error	7	N/A	5	280	Lid/seal locators	WMW	Design Feature			0
Container Assembly	Incorrect inner container seating	Damaged container	7		Operator error/Over filling	6	N/A	5	210	Add Fill lines	WMW	Process Verification			0
Container Assembly	Damaged Lids	Loss of function	6		Operator error/Material Fatigue	7	N/A	4	168	Handle Redesign	WMW	Design Feature			0
Holding/Stacking	Damaged stacking locators	Instability when stacked	5		Operator error/Material Fatigue	5	N/A	2	50	Process Control	WMW	Process Control/Training			
Manual Handling	Dropping of container	Break of Cold Chain	8		Ergonomics/Loss of grip	5	Risk Assessment/Process Control	2	80	Training	WMW	Training Operators			
Manual Handling	Dropping of container	Injury	5		Ergonomics/Body movements	3	N/A	5	75	Risk Assessment/Process Control	WMW	Process Control			
Ice Handling	Damage cooling medium	Hazzadous to health	9		Damage to ice park	4	N/A	3	108	Risk Assessment/Process Control/Training	WMW	Process Control			
Filling Ice into container	Contamination	Break of Cold Chain	8		Inner conatiner lid not seated correctly	6	Process Control	2	96	Upper ice insert to secure lid	WMW	Design/Process Verification			
Filling Ice into container	Overfilling	Damaged container	5		Operator error	8	Process Control	6	240	Add Fill lines	WMW	Design/Process Control			
Filling Ice into container	Lid not seated correctly	Damaged container	6		Operator error	5	Process Control	7	210	Add Fill lines	WMW	Design/Process Control			
Removing Ice from container	Container structure integrity	Damaged container	5		Operator error/Material Fatigue	3	Process Control	4	60	Design Ice Removal Part	WMW	New Component			
Removing Ice from container	Spillages	Injury	7		Melted Ice	7	N/A	3	147	Design Ice Removal Part	WMW	New Component			
Transportation	Damage during transportation	Delivery not met/Break of Cold Chain	7		Lack of stability when stacked/ Excessive movement in transprotation	5	N/A	6	210	Design Locators	WMW	Design Features			

Appendix 5 FMEA V1

DESIGN FAILURE MODE AND EFFECTS ANALYSIS

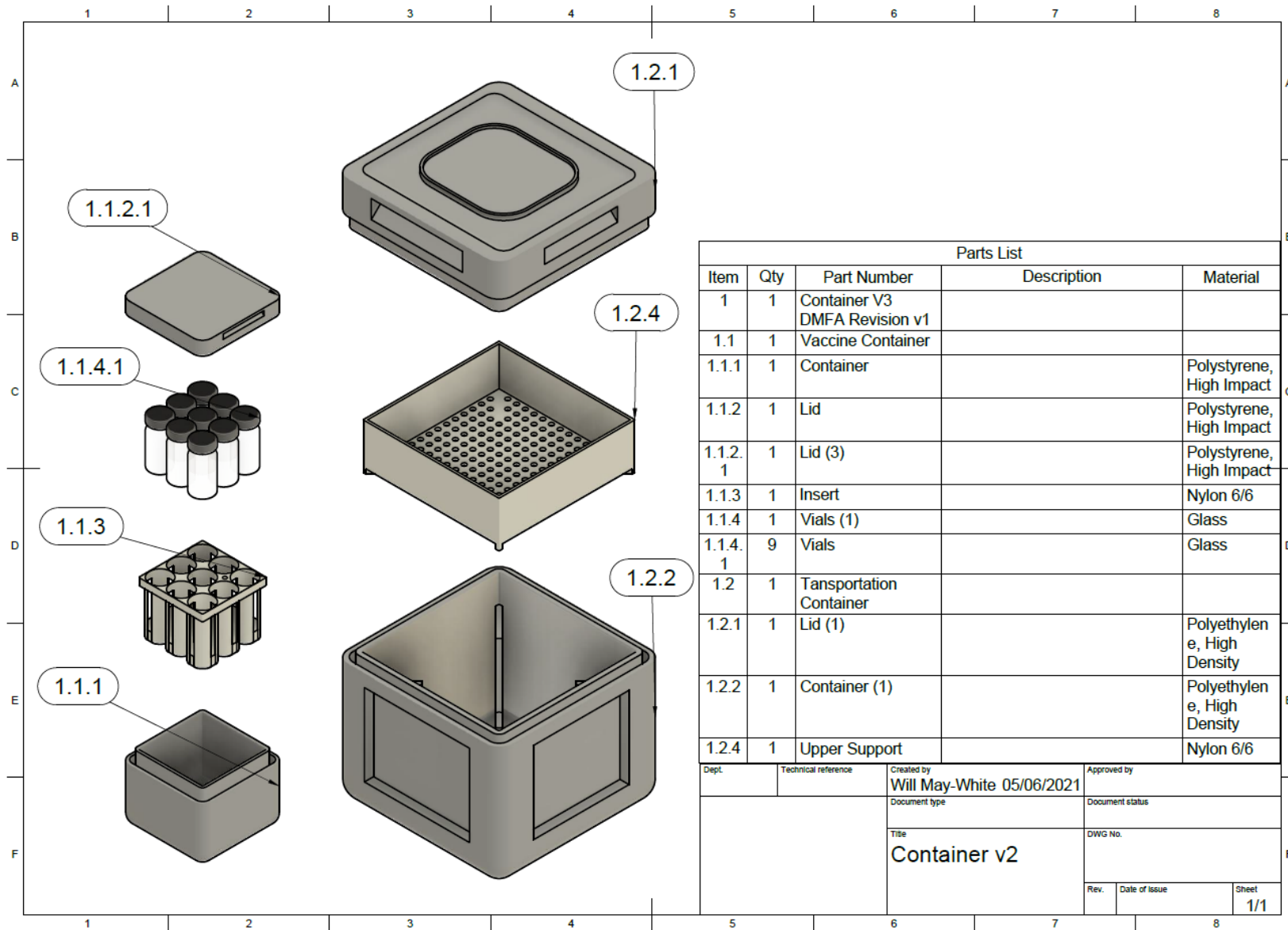
Item: Vaccine Transportation Container Responsibility: WMW FMEA number: 123

Model: VT 2 Prepared by: WMW Page:

Core Team: William May-White FMEA Date (Orig): 22/04/2021 Rev:

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v e r e n e s s	C l a s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r r e n c e	C u r r e n t P r o c e s s C o n t r o l s	D e t e c t i o n	R P N	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
												Actions Taken	S e v e r e n e s s	O c c u r r e n c e	D e t e c t i o n	R P N
Container Assembly	Container structure integrity	Break of Cold Chain	8		Operator error/impact	4	N/A	2	64	Process Control	WMW	Regular Function Checks				0
Container Assembly	Lid not seated correctly	Break of Cold Chain	8		Damaged lid/Operator error	7	Lid/seal locators	2	112	Process Control	WMW	Regular Function/ Checks				0
Container Assembly	Incorrect inner container seating	Damaged container	7		Operator error/Over filling	4	Ice fill indicators	3	84	Process Control/Awareness	WMW	Process Verification				0
Container Assembly	Damaged Handles	Loss of function	3		Operator error/Material Fatigue	5	Recessed Handles	3	45	Regular Checks	WMW	Regular Function Checks				0
Holding/Stacking	Damaged stacking locators	Instability when stacked	4		Operator error/Material Fatigue	3	Process Control/Training	2	24	N/A	WMW					
Manual Handling	Dropping of container	Break of Cold Chain	8		Ergonomics/Loss of grip	3	Risk Assessment/Process Control/Training	2	48	N/A	WMW					
Manual Handling	Dropping of container	Injury	5		Ergonomics/Body movements	3	Risk Assessment/Process Control/Training	5	75	Workstation layout	WMW	Process Verification				
Ice Handling	Damage cooling medium	Hazzadous to health	8		Damage to ice pack	4	Risk Assessment/Process Control/Training	2	64	Workstation Ventilation/Process Control/Awareness	WMW					
Filling Ice into container	Contamination	Break of Cold Chain	8		Inner conatiner lid not seated correctly	3	Upper ice insert to secure lid	2	48	N/A	WMW					
Filling Ice into container	Overfilling	Damaged container	5		Operator error	3	Ice fill indicators	2	30	N/A	WMW					
Filling Ice into container	Lid not seated correctly	Damaged container	5		Operator error	4	Ice fill indicators	3	60	Process Control	WMW	Process Verification				
Removing Ice from container	Container structure integrity	Damaged container	5		Operator error/Material Fatigue	3	Upper Ice Container/Process Control	4	60	Process Control	WMW	Process Verification				
Removing Ice from container	Spillages	Injury	6		Melted Ice	5	Process Control/Drainage at workstation	3	90	Workstation Design/Process Awareness	WMW	Process Verification				
Transportation	Damage during transportation	Delivery not met/Break of Cold Chain	4		Male/Female locators damages/ Excessive movement in transprotation	3	Stacking locators	6	72	Transportation Control	WMW	Process Control & Verification				

Appendix 6 FMEA V2



Appendix 7 Assembly Drawing

