TOWARDS A VERIFICATION AND VALIDATING TESTING FRAMEWORK TO DEVELOP BESPOKE MEDICAL PRODUCTS IN RESEARCH-FUNDED PROJECTS

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ABSTRACT

Research funded projects are often concerned with the development of proof-of-concept products. Consequently, activities related to verification and validation testing (VVT) are often not considered in depth, even though various design iterations are carried out to refine an idea. Furthermore, the introduction of additive manufacturing (AM) has facilitated, in particular, the development of bespoke medical products. End bespoke products, which will be used by relevant stakeholders (e.g. patients and clinicians) are fabricated with the same manufacturing technologies used during prototyping. As a result, the detailed design stage of products fabricated by AM is much shorter. Therefore, to improve the market-readiness of bespoke medical devices, testing must be integrated within the development from an early stage, allowing better planning of resources. To address these issues, in this paper, a comprehensive VVT framework is proposed for research projects, which lack a VVT infrastructure. The framework builds up on previous studies and methods utilised in industry to enable project key experts to capture risks as early as the concept design stage.

Keywords: Service design, Additive Manufacturing, Project management, Verification and Validation Testing

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1 INTRODUCTION

Additive manufacturing (AM) has opened up many possibilities in the medical field, allowing the development of ready-made, multi-material and bespoke class I, II or III medical devices (MDs) (Morrison *et al.*, 2015). Class I devices are non-intrusive and so present the lowest amount of risks to patients. Nonetheless, to place such products on the market, one must comply with the regulatory requirements and demonstrate that the MD is safe and reliable. Although the EU Medical Device Regulation (MDR) 2017/745 requires manufacturers to have a Quality Management System in line with ISO 13485, the standard does not provide guidance on Verification and Validation Testing (VVT).

With much focus on designing and fast prototyping innovative solutions, research funded projects involving many partners may tend to neglect or delay the evaluation phase (Bjarnason *et al.*, 2014). This is more evident in projects that are user-centric, where most of the efforts are made on collecting the user requirements, generating concepts, prototyping and testing with respect to usability and efficacy, rather than on product quality and reliability (Mao *et al.*, 2005). Although guidelines on how to design parts and form features for different AM technologies are widely available, VVT to assess the quality of the layer by layer forming process aspect of parts remains a seldom researched topic and disregarded in such projects. Carefully planned VVT activities during the design process ensure that products are safe and reliable, have good built-in quality and meet the requirements that they were designed for (Engel, 2010). Given the importance of testing the mechanical properties of AM parts, VVT should be embraced from the beginning of new projects to reduce quality risks, testing time and costs of AM bespoke controllers.

Literature in the field of VVT of tangible products is conspicuously limited and no guidelines or frameworks exist to support additive manufactured products. Within this context, the overall aim of this research is to propose a comprehensive top-down/bottom-up Verification and Validation Testing framework that can be integrated within the design process of bespoke and/or innovative products. Based on this introduction, the rest of this paper is organised as follows. The following subsection provides further information on the motivation of this work. In section 2, a literature review on the development and use of VVT approaches is described, followed by the identified research gap. The developed VVT framework is illustrated and detailed in section 3. The framework is discussed in Section 4 together with a pilot implementation, while future work and conclusions are drawn in section 5.

1.1 The need for a VVT framework for bespoke devices

A high percentage of class I MDs recalls are due to design and software issues (Joshi, Zhu and Xu, 2019). Manufacturers must test products well before going in production. It is easy to have a weak alignment between tasks in new projects, especially ones that are interdisciplinary and involve multiple partners from different countries and whose roles and responsibilities are diverse. Misaligned product development activities eventually result in quality problems, delays and wasted effort (Bjarnason et al., 2014). Moreover, the element of bespoke in the design elicits different requirements from different user groups. Testing and quality control attribute to the highest costs in product development (Engel, 2010) and between 35% to 50% of the development resources (Tahera, Earl and Eckert, 2014). Given that research funded projects, involving academia and industry working on innovative products or technologies, often lack the infrastructure for VVT, a framework is needed to guide the planning and execution of VVT. This would enable a smoother testing strategy that utilises human, material and machine resources in a more concurrent fashion by involving users throughout the design process.

This paper stems from the PRIME-VR2 project in which bespoke virtual reality controllers are developed for rehabilitation of upper limbs in three user groups, namely people with sports injuries, post-stroke impairments and dystonia. In such applications, the movements of the whole arm, hand and fingers need to be monitored accurately and so, bespoke devices are necessary to ensure that the end user is comfortable during rehabilitation activities and accurate data is being collected. In contrast to mass produced controllers, every additive manufactured product is different based on the anthropometrics of each user and other specific functional and non-functional needs. The other difference is that the final bespoke product will be produced in the same way to the samples built during the prototyping phase. A bespoke product is still a technical system whose success depends on

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whether customer's expectations are satisfied or not. Provided that testing is done to improve the design and its manufacturing processes, deficient planning can have a negative impact on the product (Lévárdy, Hoppe and Honour, 2004), especially when the detailed design stage is very short.

As argued in (Engel, 2010), in literature one can find various definitions for Verification and Validation. In this article, the definition proposed by (Hoppe, Engel and Shachar, 2007; Shabi, Reich and Diamant, 2017) is adopted, that is, *verification* is the process of evaluating whether a product was built with the right quality by testing for the technical/engineering requirements of a product and its subsystems and components. On the other hand, *validation* is the process of evaluating whether the right product was built for the customer's needs by testing for the customer requirements. By *testing*, it is understood that a component/system/device is operated under pre-set controlled conditions and the exhibited behaviour is observed and recorded. The aforementioned aim of the study will be achieved by addressing the following research questions: (i) how VVT activities, if any, were employed in emerging technologies to predict the integrity of parts being produced? (ii) what challenges exist in adopting a VVT approach, especially in international consortia? and (iii) how to approach VVT in research projects, given that innovative solutions are being explored?

2 RELATED WORK ON VVT

In many industrial projects, VVT occurs late in the design stage (Engel, 2010). In fact, the guidelines document for the ISO 13485:2016 (Abuhav, 2018) suggest adopting the Waterfall model where VVT activities are only considered after the design process is concluded or a proof of concept is available. This methodology was adapted by (Morrison *et al.*, 2015) in testing 3D printed class III medical devices. In reality, just like manufacturing capabilities become input to the requirements, testing constraints can cause further design iterations. However, testing late in the development process results in fewer opportunities to amend issues, whilst increasing the chances of missing deadlines and quality targets. Therefore, testing should not be treated as a subsidiary product development requirement. In (Ward and Clarkson, 2002), manufacturers are encouraged to adopt a risk-based approach, by analysing the different risks involved to influence the methods of verification and their priority. For instance, designs that pose higher commercial and development risks shall be given higher priority during the design process so that testing can be done early. Although early testing may lead to misleading results and cause manufacturers to incur higher testing costs, such an approach guides the design development and avoids rework. Ward & Clarskon also consider the appraisal of the possible verification methods based on how reliable the tests results would be in the case of prototypes not having the same manufacturing process as the end product.

An improved way of looking at the waterfall model was suggested by (Forsberg and Mooz, 1992) through the V- or Vee-Model, where product development activities post implementation flow upwards. This model suggests that as soon as user requirements are defined, the method of validation must be determined, and as these requirements become more granular and turn into engineering requirements, their verification method is also determined. In this way, impacts due to testing are integrated into engineering requirements. Engel (2010) uses this lifecycle model to define the VVT lifecycle model. A standard procedure for VVT planning, the SysTest VVT Process, has been established by (Lévárdy, Hoppe and Honour, 2004), which consists of nine steps spread over three main stages. As will be explained in the next section, the first stage, VVT tailoring, instils a culture of embracing VVT prior the start of the project.

The need to produce faster and adaptive solutions, especially in software engineering, resulted in embracing Agile development. In the Scrum Agile approach, the development process is divided into a number of short, incremental and iterative sprints of 1-4 weeks by which a minimum viable product is produced at the end of each development period. Garzaniti, Fortin and Golkar (2019) argued that research projects adopting Agile principles in multi-party consortia failed because every partner has its own development process and therefore, "it requires coordination with traditional systems engineering approaches". Garzaniti, Fortin and Golkar proposed a hybrid product development process where at the organisation layer, each partner may adopt an agile or a stage-gate (waterfall) approach, and activities are controlled by the coordination layer, where work packages are defined to achieve the

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deliverables specified in the consortium layer. The authors claim that stages and gates are critical to align activities and arrive at milestones. A partner that adopted the Agile approach had to often make assumptions which proved to be wrong in the later stages, causing unnecessary efforts and deviations. Although there were benefits such as accelerated rapid prototyping, they reported difficulties in coordinating activities due to the asynchronous development and "challenges in implementing rigorous verification and validation due to diverging integration readiness of interdependent system components".

Recognising the large investment that companies dedicate to ascertain the highest quality, research has advanced in finding ways to optimise the VVT strategy by modelling the cost of quality (Hoppe, Engel and Shachar, 2007; Engel, 2010). Other researchers deemed that testing planning and execution takes plenty of a project's resources. Bensalem, Havelund and Orlandini (2014) developed a scheduling and planning system for VVT in software projects. Recent work (Shabi, Reich and Diamant, 2017) focused on developing an intelligent VVT planning system for project managers in industrial projects, which is able to evaluate the project's budget, schedule and risks and suggest an optimal VVT plan. Hence, allowing organisations to optimise the use of resources. However, the model looks at the risks in terms of a cost factor which has a subjective value.

Another way of limiting the cost and time of testing is to determine the essential physical tests required to be performed. Most physical tests are considered to be Destructive Tests (DT) as the component, subsystem or system under test goes through severe conditions. On the other hand, Non-Destructive Tests (NDT) include visual inspections, measurements and simulation tools. The latter could be finite element analysis software or model-based design approaches which could be used throughout the design process (Murphy, Wakefield and Friedman, 2008). Tahera, Earl and Eckert (2014) explain that tests are interlinked. Sometimes a test can confirm multiple criteria but in other cases, a sequence of tests is required to confirm the integrity of products. They also argue that computer-aided engineering modelling and simulation software, or virtual testing, is an alternative way to carrying out testing to provide input to further physical testing or direct feedback to the design. Their approach combined Quality Function Deployment (QFD) and Failure Modes and Effect Analysis (FMEA) to prioritise between testing activities by highlighting which customer requirements are most important and which design features are most critical. They explain that apart from design verification and product validation, industrial testing also occurs during system demonstration. However, their approach does not support the ability of producing ready-made, bespoke solutions thanks to the geometric freedom of AM.

Research funded projects are carried out to explore and generate new knowledge. Even though partners may have experience on already defined technologies, innovative concept development or technologies which are not yet fully explored require appropriate testing. Although testing is an integral part of product development, compared to design, not much literature is available. This literature review showed that for effective planning, testing considerations should be made before project initiation, especially in projects with international consortia. A gap in literature has been identified within projects that are innovating and using manufacturing technologies which are not mature. In the early days, additive manufacturing was only used for rapid prototyping but now it is being used to produce ready-to-market bespoke products. No reference to VVT is made in literature on the development of bespoke products whose design process is user-centred. In such contexts, efforts carried out to develop the first proof-of-concept (POC) should not be discarded but integrated within the entire VVT strategy and planning. Bespoke products commonly vary with respect to dimensions but depending on the application, functional requirements may also change. Although it is difficult to verify and validate every bespoke solution produced through AM, core functional elements in the design must be verified and validated properly. For such reason, design and testing activities must be aligned and run concurrently such that the design is continuously improved whilst reducing testing efforts.

3 A FRAMEWORK TOWARDS A VVT PLAN

The proposed VVT framework for projects involving AM products is shown in Figure 1. It is important to keep in mind that bespoke solutions produced via AM are not prototype parts, even though the fabrication process of prototype-level parts and production-level parts are the same.

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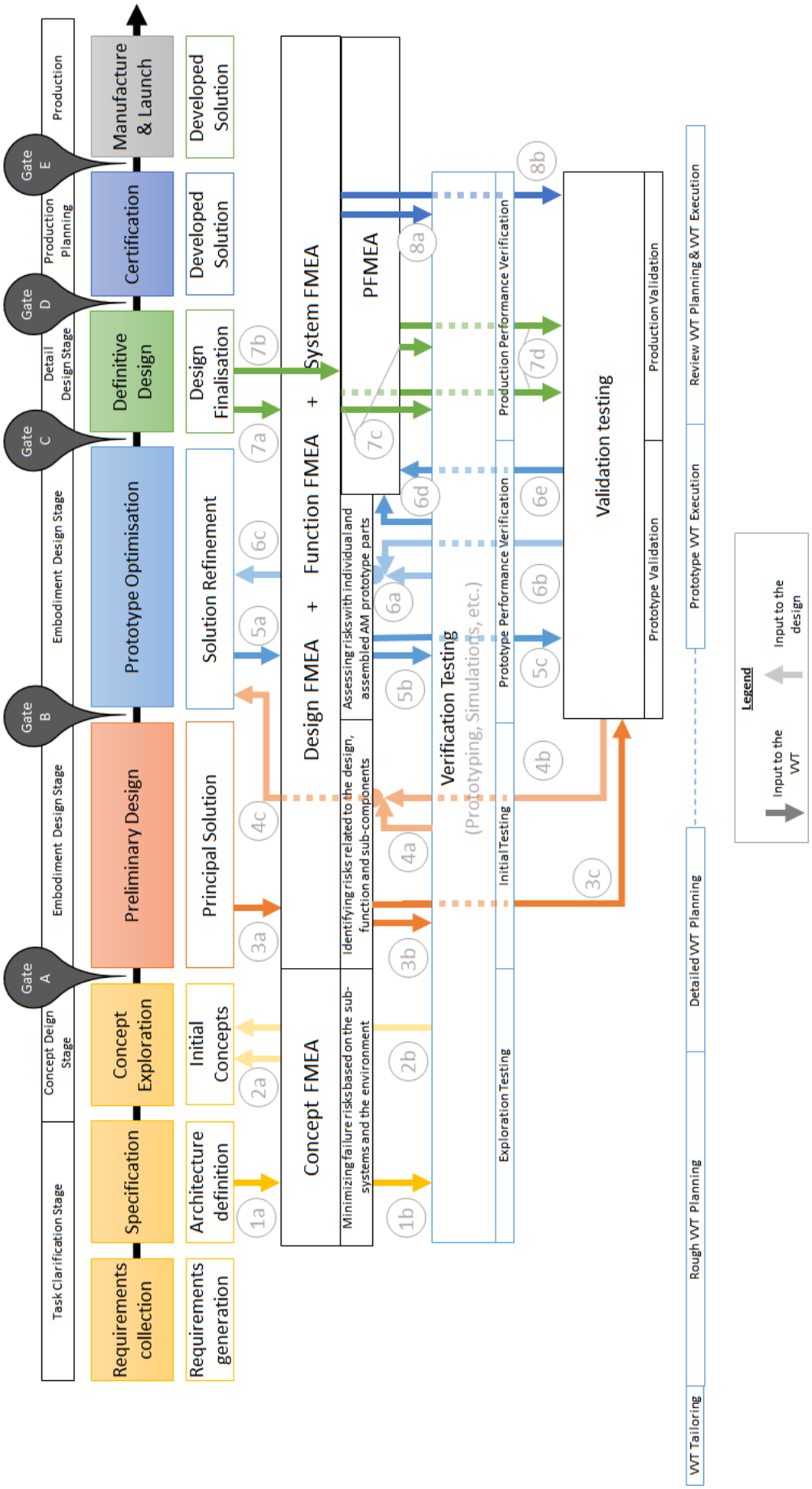

Figure 1: A VVT framework for innovative bespoke solutions

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Similar to (Ward and Clarkson, 2002), this framework emphasises the need to understand the risks involved from an early stage such that foreseeable problems such as defects can be reduced or eliminated, and VVT activities can be planned in advance by making use of risk capturing tools. Since POC projects focus on the design aspect, the systematic engineering approach of (Pahl et al., 2007) was used as the backbone of the framework. The SysTest VVT process found in (Lévárdy, Hoppe and Honour, 2004) has been overlaid on top such that POC solutions can be analysed as early as the product architecture starts to be compiled. Two intermediate stages have been added to the SysTest VVT process by proposing a Prototype VVT Execution and a Review VVT Planning between the Detailed VVT planning and the final VVT Execution stages. Similar to (Garzaniti, Fortin and Golkar, 2019), gates have been used for critical design stages. All five stages are explained next with respect to eight steps, labelled 1 to 8, and five control gates, labelled A to E, which allow the design process to proceed to the next stage.

Furthermore, due to the lack of VVT guidance in standards, a top-down/bottom-up approach is needed in identifying what tests could be done. As shown in Figure 2, the project team's knowledge on similar products, standards from other industries, and user focus groups among other sources, will assist in determining the inputs, that is, the type of tests, and outputs, that is, the criteria of assessment by which innovative bespoke products can be evaluated as fit for the market.

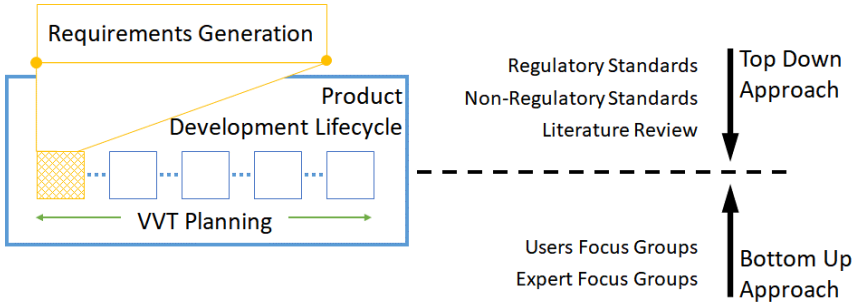

Figure 2: A top-down/bottom-up approach in VVT knowledge input

3.1 VVT Tailoring

As defined in (Engel, 2010), the tailoring stage is carried out before commencing the project and its purpose is to understand the characteristics of the project being tackled and to decide to what extent a VVT methodology will be deployed. Uusitalo et al. (2008) suggest that it is good practice to have personnel dedicated to testing during the whole development process because "testers have different viewpoints than requirements analysists and developers". For instance, they can suggest requirements and also highlight in advance potential testing problems during design reviews. The adopted VVT heuristics depend on their experience, the project parameters (size, complexity and type of the project), limited resources affecting VVT (personnel, schedule, budget, facilities, etc.), and the project's product characteristics parameters (e.g. innovative, complex, upgrade, critical, and so on). The rest of the framework is based on the assumption that research funded projects are fairly large and complex and involve concept exploration research for an innovative product.

3.2 Rough VVT Planning

During this stage, one needs to decide upon the VVT strategy that will be taken for the project. For reference, (Engel, 2010) provides details on how to develop the VVT strategy and master plan. Only when the system architecture and/or system specifications become known it is possible to start laying down of the VVT plan. In this methodology, the quality culture of the automotive industry was adopted such that early risks can be captured in a Concept Failure Mode and Effect Analysis (CFMEA) (Ford Motor Company, 2011). As shown in Figure 1, from the customer requirements, the design team is able to formulate the product architecture and in turn, initial risks (Step 1a) about the product can be foreseen in the CFMEA. These risks could be common risks associated with similar competitive and non-competitive products. The CFMEA starts by considering the product at system level but as the architecture becomes more granular and actual concepts of the product start to be produced, one can start looking at a subsystem and component level.

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3.2.1 Concept FMEA

A CFMEA is a proactive tool that can be applied whenever one is working on a new project. It allows designers to start the verification process by identifying potential risks associated with the product (or technology) before the actual hardware is chosen. Apart from a list of potential concept failures, it provides designers with a list of actions to eliminate failures, to specify specifications and processing parameters, and to highlight potential testing standards and requirements. For instance, there is a tendency that mechanical buttons jam if not designed well. Knowing in advance the causes of failures associated with buttons, designers can prevent failures by adopting button design guidelines or consider to user alternative solutions. For each potential cause of failure, a Risk Priority Number (RPN) is computed by multiplying the severity, occurrence and detectability factors. Based on the RPN, designers and project experts are guided to select the best principal solution, adopt features from various concepts (Step 2a) or foresee ways on how the risk can be mitigated by initial testing (Step 1b).

3.2.2 Exploration Testing

Initial (virtual or physical) verification testing enables designers to test new concepts before incorporating them in the principal solution. Early testing can (i) identify whether a concept is worth of further exploration, (ii) define ways the product should be tested and (iii) get an understanding on the capability of the design. Findings from this test (Step 2b) allow for further conceptualisation or to progress in the design. During this phase, methods for the performed tests are documented as per the guidelines in (Engel, 2010). The design process is ready to proceed past the first gate (Gate A), when the design team is confident with the selected principal solution.

3.3 Detailed VVT Planning & Prototype VVT Execution

During the detailed VVT planning stage, the testing strategy developed in the previous stage is optimised and converted into a master plan that thoroughly covers every component within a product. Note that, the VVT plan keeps being optimised until product certification (Gate D). The experience gained during Exploration Testing will help in defining the details of the verification tests that will be performed during the Embodiment phase. Typical details include the nature of test (virtual/physical), the verification method when to test the components, the number of components or complete products to be tested, equipment required, testing parameters, etc.

The available resources will determine what is achievable. First, it is suggested to consider the applicability of virtual tests. Physical tests on an entire system involve higher costs than testing the sub-assemblies or individual components. The idea is to granulate the necessary testing to the components or smaller subsystem, such that a level of confidence is attained before executing full set of testing including tens or hundreds of samples. Prototype VVT execution refers to all the Destructive and Non-Destructive tests carried out during Embodiment Design stage.

The first run of the detailed VVT planning and prototype VVT execution ends when the principal solution undergoes the first design cycle (Gate B). Since multiple design iterations may occur during Prototype Optimisation, the VVT plan keeps being optimised (Steps 3 and 5) as long as testing provides the necessary feedback (Steps 4 and 6) that the proposed solution does not need further refinement. Note that all testing results must be recorded.

3.3.1 Design FMEA, Functional FMEA, and System FMEA

Based on the principal solution the design team will formulate the Design, Functional and System FMEAs (Step 3a). All three types of FMEAs build upon the CFMEA but consider different aspects of the product. Their main objectives are to identify failure modes and their respective cause, and establish preventive actions to reduce/eliminate the chances of having quality or safety risks.
Design FMEA considers potential failure modes triggered by design deficiencies that cause the product to malfunction before its expected lifetime and/or be a safety hazard to its users. *Functional FMEA* treats the product as a black box and focuses on the intended function that the product was designed for, focusing to identify causes that lead to potential loss of functionality. *System FMEA* concentrates on failure modes caused by interactions deficiencies that may happen at a sub-system level and external to the product being developed such as human-product interactions or interactions with other

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systems in the environment. Since the focus of this paper is the production of bespoke parts, then it means that production parts will differ with respect to the dimensions and form of the system. Tests need to consider and assess the effect on the integrity of the system when the design (design, form, material, etc.) varies. Note that, every time the design gets updated, likewise, the FMEAs get revised.

3.3.2 Initial Testing

The RPN for the identified causes in the FMEAs can be reduced through the preventive/corrective actions such as verification tests (Step 3b), where positive results can assure the designers and project stakeholders that the risk is lower. Engel (2010) suggest two types of testing: White-box and Black-box testing. The former consists of tests that are done at sub-assembly and component level, whereas the latter is testing on the whole product irrespective of the subcomponents. Similar tests (Step 3c) can be done to validate design features with respect to customer requirements. As suggested in (Uusitalo et al., 2008), early tester participation is strongly recommended as this increases the chances of success. The results of such tests, (Step 4a) and (Step 4b), are reviewed in order to update the FMEAs and to prepare for the second iteration of design (Gate B).

3.3.3 Prototype Performance Verification and Prototype Validation

During solution refinement, it is necessary to test the entire prototype system (Step 5a). At this stage the FMEAs have been updated with the necessary preventive/corrective actions. The testing (Steps 5b and 5c) required to be conducted in this stage will eventually validate and verify the prototype (Steps 6a, 6b, and 6c). However, feedback from the verification and validation testing (Steps 6d and 6e) can be used to capture and outline ways of preventing process defects in the Process FMEA. The design process is ready for Gate C signoff when the team, from the last round of testing, knows that only minor tweaks are left to finalise the design.

3.3.4 Process FMEA

The Process FMEA derives from the Design FMEA and is only concerned with the potential failures that result from the AM process producing the parts, material quality, the assembly process, and human errors. It must be underlined that all FMEAs, except for the CFMEA, are living documents, meaning that they can be updated post-production stage in case new mechanisms of failure are detected, or if a foreseen failure was not fulfilled by the VVT performed during development.

3.4 Review VVT Planning and VVT execution

During this stage, the last design iteration confirms that latest changes in the design (Step 7a) and process parameters (Step 7b) produce the desired results. At this point, the design of all components is concluded and no further changes are made. The VVT master plan should be updated according to the results obtained in every design iteration. Furthermore, requirements that need to be tested for certification must be listed and detailed similar to the tests carried out.

3.4.1 Production Performance Verification and Production Validation

The last testing activities (Steps 7c and 7d) are similar to the prototype performance verification and prototype validation (Steps 5b and 5c) with the difference that the final parts tested are production representative parts. Since all parts will be produced through AM technologies, the production representative parts are fine-tuned with respect to the final production parameters established. These final tests will confirm that the system is expected to function as per design intent when handled by the customer and these results may be used to apply for the CE marking. In case a notified body wants to reassess the performance and safety of the product before certification, the manufacturer or an external lab may perform (all or some of) the tests (Steps 8a and 8b) mentioned in the VVT master plan.

4 PILOT IMPLEMENTATION AND DISCUSSION

The proposed VVT framework is being adopted in the development of a bespoke controller for the PRIME-VR2 project. A detailed CFMEA was developed after the system architecture of the controller was defined. The CFMEA was updated every time concept solutions were proposed in order to evaluate their associated risks and suitability. Solutions with a high RPN number were avoided while dubious ones were prototyped and low-fidelity testing was performed. Since a user centred approach is

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being taken, early concept prototypes were also produced in order to get initial feedback from patients, by which it was possible to capture unforeseen handling issues. Furthermore, high-fidelity testing on an innovative structural feature was performed to obtain input for a form generation algorithm. This approach allowed the design team to explore innovative concepts involving 4D printing.

Basing the framework on the existing and proven SysTest VVT process, it has allowed project leaders to plan a Work Package for testing, and so, budget accordingly. By mapping the VVT framework to a widely accepted systematic design process, team members were able to understand the testing strategy. As argued by (Garzaniti, Fortin and Golkar, 2019), a systematic process ensures that all partners converge to the required deliverable by the stipulated deadlines whilst making sure that the required information is made available for the subsequent stages. This is critical in biomedical or similar projects where requirements are complex and can only be elicited through interaction with users.

Due to the nature of bespoke AM-based products whose market strategy varies from mass-produced ones, focus on testing is shifted towards the concept and embodiment design stages rather than on the detailed design stage. Prototypes produced at these phases resemble the final product much more than in traditional manufacturing processes. For this reason, the proposed VVT framework has a potential impact on projects carried out in industry as well, where technologies are not matured or the solution being developed requires different testing solutions. This framework does not prohibit partners from taking an agile approach during early embodiment stage but encourages testing to feed in the design. The combined top-down/bottom-up approach for the definition of verification and validation tests allows experiences from the project partners and stakeholders to define tests based on their key area of expertise when standards are missing. By employing the use of various types of FMEAs, it allows the project team to highlight risks/issues associated with product, manufacturing processes and their constituent technologies, as early as the concept stage. The latter allows the team to eliminate identified unreliable solutions before the design has advanced. However, in situations where relevant expertise is missing, physical or virtual testing may be needed to be performed. In such cases, related industry standards should be used to guide the testing procedure. As a limitation, this framework does not sufficiently take into consideration emerging technology implementation related risks. Furthermore, it still needs to be evaluated across different projects. Mankins (2009) states that the maturity of the technology correlates with the technical risks and thus, the proposed approach can be improved further to factor in uncertainties associated with the use of emerging technologies in the design and fabrication of smart products.

5 CONCLUSION

In this contribution, a VVT framework that aligns testing with the design process of Pahl et al. (2007) has been presented. The framework builds upon previous studies and methods utilised in industry, providing the structure needed to consider testing from an early stage whilst allowing flexibility to adapt to the specific nature of the project. Central to the framework is the utilisation of FMEA tools right from the moment the engineering requirements are available. These permit the project key experts to assess risks and prioritise between tests in order to meet costs and time constraints. The framework also reflects on the evolving nature of the manufacturing industry, which is seeing a shift to bespoke and personalised products through AM. It was also argued that the development of proof of concepts should consider implementing a VVT framework so that they are closer to being market-ready. Finally, this framework also encourages the use of both physical and virtual testing so that projects stay within schedule and budget. Since testing can start early in the design process, the framework can be utilised in user-centred projects which allows the consideration of users when building customised co-designed products.
As the PRIME-VR2 project progresses, this framework will be revised in order to cater for unforeseen development circumstances and include lessons-learned, especially in the validation phase. Through links with sister projects in the medical field, the plan is to test the framework for its validity by encouraging consortia of similar projects to adopt it in order to assess the effect of VVT considerations. The authors will also endeavour to apply and improve this VVT framework in future research funded projects.

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