

Virtual Reality as a tool to enhance the training of operators: an application in the pharmaceutical sector

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Abstract: The interest of the literature in the theme and application of Virtual Reality in industrial contexts has increased in the last years. Virtual Reality has proven to be a promising technology in a vast variety of applications. Among these, Virtual Reality can be used as a tool to enhance the training of operators under certain conditions, and it can be considered as a way to perform a gamification of the training process. In this research, an application of Virtual Reality to this extent is presented. In particular, the research shows how to implement this technology to provide several advantages to companies, such as the possibility to train operators without line stops as well as to perform training in environments that are not physically developed yet. Indeed, the research presents the development of an application based on Virtual Reality technology in the pharmaceutical sector, aimed at enhancing the training of the operators that need to avoid the cross-contamination of production lots in the white room of the production facility. The results show how to build and structure an application of Virtual Reality that can be used to certify operators in performing certain delicate operations. In doing so, the procedure to develop the application, as well as the tools used in the developing process are presented. Moreover, the research shows also how Virtual Reality technology can be used to train operators to perform operations in environments not yet developed. Finally, an analysis of the response to the gamification of the training process from the operators is presented, to show feedback and issues that may arise in the usage of the application.

Keywords: Virtual Reality; Industry 4.0; Training; Pharmaceutical; Virtual Model

1. Introduction

In the last years, the interest in the theme of Virtual Reality (VR) in production has strongly risen, due to the evolution of Industry 4.0 (I40) technologies (Havard et al., 2019; Saporiti et al., 2023). VR uses computer-aided design (CAD) models to replicate the physical world as closely as possible while creating a virtual environment that is both immersive and realistic. (Pérez et al., 2020). VR systems aim to imitate not just the surrounding world but also the animations, movements that are typically made within the physical environment, and all of the sensory feedback, that is, sounds, sights, and videos (Burghardt et al., 2020). VR systems are used as an affordable technology to accomplish a variety of goals, including design, training, and programming (Oyekan et al., 2019; Saporiti et al., 2021). VR systems can also be used to develop virtual training fields for operators, in order to facilitate a different way to perform the training (Abbas et al., 2023a, 2023b; Grandi et al., 2021; Kajihara et al., 2008; Yu et al., 2022). It is also proven by the literature that the usage of VR-based systems to perform training of operators could lead to major overall improvements, which consist mainly of a reduction of error and time needed to perform the training, following the *Learning-by-doing* principle (Abidi et al., 2019; Grandi et al., 2021). However, the literature lacks empirical evidence about the usage of such technology to foster this new training methodology in the pharmaceutical industry. Nevertheless, understanding the effectiveness of VR when

used as a substitution or integration of traditional training in this industrial sector can be of great benefit to the dedicated literature. Indeed, with the advent of Artificial Intelligence (AI), immersive technologies such as VR (especially when coupled with simulations (Bertolotti et al., 2020; Saporiti et al., 2020)) could play a pivotal role in the manufacturing industries, and it is necessary to underline the effectiveness of the various use cases. Therefore, this paper aims to fill the gap represented by the absence of empirical evidence of the application of VR in operator training in manufacturing related to the pharmaceutical sector. In doing so, this paper aims to describe an application in a real environment in a pharmaceutical company, detailing the development procedure and the needed tools. Moreover, the research aims to provide a first idea of the perception of this technology on operators, thanks to the exploitation of the feedback provided by the end-users of the presented application via the analysis of the responses of a questionnaire. This paper aims therefore to answer the following research questions:

- RQ1. What is a possible methodology to develop a VR application for operators' training?
- RQ2. How can a deployed VR application be considered suitable for usage in production?
- RQ3. What is the feedback that operators provide in the first period of usage of such systems in a pharmaceutical context?

This paper is structured as follows. First, the case study is described, with an indication of the manufacturing sector in which the application has been developed. Second, the development methodology of the VR training system is reported, with an indication of the tools and techniques that have been exploited. Moreover, at this step, the questionnaire developed to gather users' feedback is presented. Then, questionnaire findings are presented and discussed. Finally, limitations and future research directions are presented.

2. Case Study Description

2.1 Company Description

The research case study is a Swiss company that operates in several industrial sectors and is primarily concerned with the production of elastomers in the pharmaceutical sector. This organization is a well-known engineering partner for cutting-edge systems in global markets such as general industry, mobility, communication, healthcare, and food & beverage. Operational excellence, material expertise, and solution design are among its acknowledged core competencies. With items available in over 100 countries, the company offers a broad client base. With a total workforce of more than 8000 people and an annual gross sale of more than 1100 million euros, the company can be regarded as large. This company presents a very high degree of utilization of 140 technologies. To acquire information about the production, Big Data and Analytics are exploited for data collection and the development of descriptive analytics. To maximize efficiency, Autonomous Robots have been designed and integrated into manufacturing processes. New production environment configurations are developed and tested using Simulation. IoT is being utilized extensively to boost output, cut down on scrap, and increase worker safety. Additionally, Additive Manufacturing has been used to create internal tools for production, such as a hand prototype for a robot. However, the company did not present VR applications antecedent to the development of the one described in this research.

2.1 VR implementation project

The importance of quality controls in the pharmaceutical sector is notably very high. In particular, the company described in this case study suffers from a certain level of cross-contamination of production lots in the cleanroom of its production facilities. To satisfy the various needs of each customer, every order is distinguished using distinct bags and product quantities. Every time an order is finished, the entire line is inspected to make sure the caps aren't lodged in the crevices of the equipment or affixed to the container walls in a way that could contaminate the subsequent batch. Since some goods can be extremely similar to one another, operators produce batches that are as dissimilar from one another as feasible to ensure safety.

The quality check involves the following steps:

1. Every area and piece of equipment in the bagging line must be thoroughly inspected by the operator, including the dosing hopper, the tanks that the caps pass through, and the operator's

workstation. Any remaining caps, even those that have fallen to the ground even though it is certain they are part of the finished order, must be removed. Every line has a barcode TAG, and every item has an object TAG; to move on to the next step, the TAGs need to be read after finishing a step.

2. Once the first operator has performed a first check, a second operator will carry out an identical second check.
3. If the operator discovers leftover caps during the double check, they will alert their colleague, who will repeat the "Line Cleaning" procedure, signing and dating the batch card in the relevant areas, and noting the number of caps found on the batch card.

This process is quite time-consuming and critical to the customers; therefore, the company needs to optimize the operation by ensuring that the operators are completely trained to perform the quality check. However, to perform a training session for operators, the company faces the need to completely stop the production on the machine to allow operators to train in a predefined situation. Once the training process is over, the operators' performance is registered, and the operators are then validated to perform the real quality check. The development of a VR application that allows the avoidance of such a stop has been considered a valuable project by the company. Moreover, the company asked the VR application to be developed on a new cleanroom layout, that was not completed yet at the moment of the development.

3. Development Methodology

An iterative process was used to produce the playable model's architecture. First, preliminary needs have been collected and defined with the company. This encompassed the definition of the process to be simulated in the VR application, as well as the general challenging level and the amount of time at the disposal of the operators' training. Second, two parallel activities have been carried out. The 3D models that were considered necessary for the VR application have been developed. In doing so, CAD software has been exploited, as the new cleanroom machinery 3D models were not supplied by the company. At the same time, the application general structure has been defined, with particular attention to guaranteeing a high level of user-experience friendliness. This involved the definition of the application user interface (UI), the internal structure of the application and the navigation modalities in the application itself. Moreover, this step involved the definition of the hardware and the development software that was needed to ensure a high-quality VR application. Third, other two parallel tasks have been carried out. Once the 3D model development process has been completed, the developed 3D models need to be further elaborated on directly in the VR application development software, to allow them to interact with the simulated environment. In doing so, graphical elements such as animations and colliders, i.e.,

elements that allow to detect a collision between the user and the object, have been developed. Simultaneously, the application structure defined in the previous step has been developed. These steps required an advanced usage of the VR application development software, as well as some coding procedures to write the necessary scripts. Fourth, the 3D models with the embedded interactions and colliders have been inserted into the developed application structure. Therefore, the first version of the application has been deployed. At this point, a series of iterations with the company has been conducted in order to define the final version of the application to be effectively deployed in production. Once the application reached the desiderata of the company, the first tests were carried out with a sample of operators. In the meantime, a questionnaire has been developed aimed at collecting feedback from the operators on several elements of the VR application. Finally, after a series of tests, the questionnaire has been deployed to operators and data have been collected.

The final version was created through continuous refinement in response to each piece of feedback received. Operators tested it within the organization to gather field data that could be valuable for the training program's future development. The development process is depicted in Figure 1.

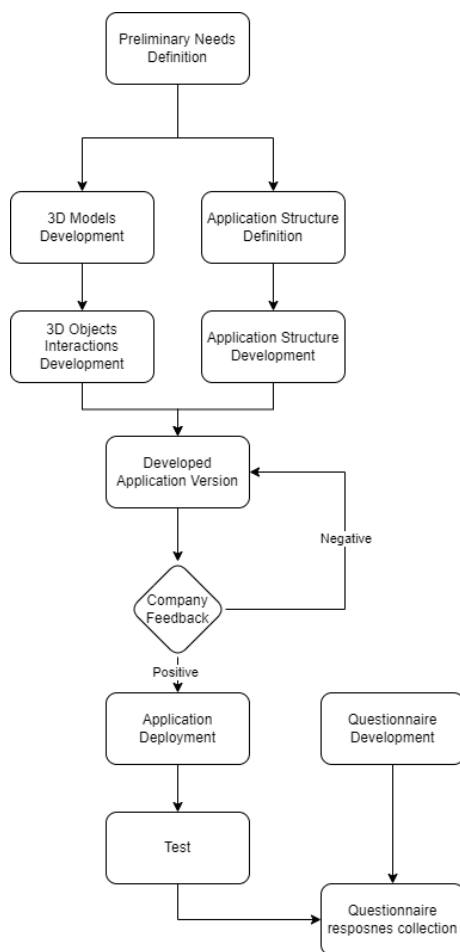


Figure 1: VR application development process

3.1 Software and Tools

To develop 3D models and to convert them into a format that was suitable for usage in a VR application development environment, three main software have been exploited. First, all the models were developed via the exploitation of Autodesk Inventor, a 3D CAD modelling software that allows to produce the drafting, generating shapes, accurately drawing objects, dynamically dimensioning objects using parameters created during the drawing process, analysing the stresses and strains of the object by applying forces and observing its behaviour, assemble parts of the same object, and finally produce the drafting. Second, SketchUp functionalities have been exploited to acquire architectonic profiles that are needed to develop the cleanroom structure. SketchUp is a program used for video game production as well as architectural and urban engineering. Designers frequently use it because, unlike Inventor, it places a greater emphasis on the product's external look while using parameters and graphics that are relatively similar. Finally, Autodesk 3DS Max has been used to perform the type conversion of the developed 3D model to the desired type, i.e. from “.iam” (assembly file) to “.3ds” (object file).

To develop the VR application, the functionalities of Unity have been exploited. Unity is software for developing three-dimensional applications, including video games, or for instantly visualizing engineering or architectural projects. Three components make up Unity. First, a graphics engine that manages all object meshes and enables the training environment simulation to be visualized more simply. Second, a physics engine—a computer program that uses variables like mass, velocity, friction, wind resistance, and others to simulate a Newtonian physics model—allows for the simulation of the attitudes that bodies would adopt in the event of real or imagined gravitational, fluid-dynamic, or magnetic forces. Third, a real-time preview of the game that lets you see the updates as they happen. One of the main reasons that programmers use and like Unity is because it allows them to swiftly design programs and adapt them to work on several platforms, such as PCs, consoles, and mobile devices (Android and iOS). Unity interactions are developed with a programming language called C#.

Concerning the hardware that was necessary to deploy and test the application, the Oculus Rift VR bundle has been used. This bundle is composed of three main elements. First, an advanced Oculus VR headset (model #: HM-A) has been used to be able to provide a fully immersive experience to the user and to ensure that the sensorial effects linked to the visual and audio experience are sufficiently realistic. Second, two touch hand controllers (model #: TO-L/R) have been used to provide an approximation of tactile sensations, as well as to be able to fully visualize the hands of the users. Third, two sensors (model #: 3P-A) have been used to track the movements of the user by exploiting a series of infrared LED signals.

3.2 Questionnaire Development

The questionnaire was developed to understand the feedback of the operators who were the first subjects of the new training modality. The questionnaire was composed of a list of closed questions that needed to be answered on a Likert scale from 1 to 5. Two main performance data have been collected. First, data regarding the time that was needed to perform a complete training session has been recorded, to allow the company to be able to dimension the needed training time for the operators. Second, data regarding the effectiveness of the training have been gathered, in order to understand the real capabilities of the application to act as a training system for the users. More in detail, the questionnaire asked the users questions about the realism, effectiveness, ease of use, the capability of the application to shorten the time needed to acquire a certain skill in quality check procedures and the eventual differentiation in efficiency for new operators for already skilled ones. The test has been deployed on a sample of 21 operators of the cleanroom. To enhance heterogeneity, experienced operators as well as newly hired ones have been included in the test sessions. Moreover, operators with different roles have been included.

4. Results

The VR application has been tested on a sample of 21 operators of the cleanroom to perform a training session on quality checks. However, one of the test users presented motion sickness and has been therefore excluded from the analysis. So, the final number of operators included in the analysis has been reduced to 20. As previously described, two main data elements have been gathered. Regarding the time performance that was needed for the operators to fully complete a training session, the results present a mean value of time needed to complete the training session of 10 minutes and 9 seconds. However, the results present a quite marked variability. Indeed, the standard deviation of the sample has been recorded to be equal to 3 minutes and 34 seconds. This leads to a coefficient of variation (CoV), i.e. an indicator of the stability of a process that is obtained by dividing the standard deviation by the mean value, equal to 0.35. This value expresses a certain grade of variability of the results, indicating that the process is not completely stable, even if not out of control. Therefore, it is possible to indicate a value that is required to complete the training session, even if the value is quite affected by a quite marked variability. Moreover, the effectiveness of the training has been measured. In doing so, the effectiveness has been measured by collecting data regarding the actual performance of the users, thus identifying the number of caps that have been detected by the user for the total number of caps that were randomly generated by the application. The results of the first tests presented a mean value of effectiveness equal to 77.8 %. The standard deviation of the values has been determined to be 17.5 %. This leads to a CoV of 0.22. The results of the effectiveness of the application are reported in Figure 2.

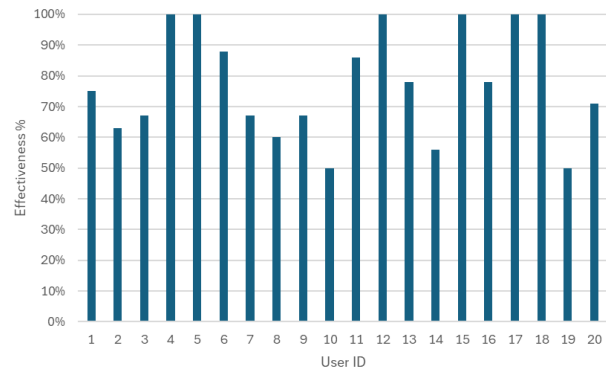


Figure 2: VR-based training session effectiveness

Finally, a questionnaire was deployed to all the participants of the test training sessions. The participants expressed remarkably high values of appreciation for the realism perception of the application. Indeed, 71.4% of participants expressed an evaluation of the realism of the application higher than 4, with a mean of 4.14 and a standard deviation of 0.94. The easiness of usage of the application resulted in less appreciation, even if evaluated generally in a positive way. Indeed, the mean value of the evaluation of the easiness of usage of the application has been determined to be 3.80, with a standard deviation of 1.33. Participants also expressed a quite remarkably high value of appreciation for the effectiveness of the VR training sessions. Indeed, participants expressed an evaluation of this aspect with a mean value of responses equal to 4.00, with a standard deviation of 1.20. Similarly, the participants slightly expressed that the proposed VR training could present a positive effect in the reduction of errors in the quality check, with a mean value of responses equal to 3.62 and a standard deviation of 1.36. Participants were not particularly convinced about the potentiality of the VR training application to reduce the needed time to perform a training session of the operators, expressing a mean value of responses equal to 3.12 and a standard deviation of 1.37.

5. Discussion

RQ1. What is a possible methodology to develop a VR application for operators' training?

This paper presented a practical methodology that can be exploited to develop a VR application for operators' training. In doing so, the steps of the methodology have been described, as well as the tools and the software that are needed to fulfil the objectives. The methodology clearly shows that to develop a VR application for operators' training there is the need of at least two main expertise. First, a CAD industrial designer is mandatory to develop 3D models, in case they are not provided by the company or by the company's suppliers. Second, there is the need for expertise in the usage of VR software, such as Unity, to develop and run the application. The methodology must focus on continuous feedback from the final customers, to develop the application based on an iterative process. The continuous feedback from the final customer is particularly relevant when the VR environment is developed on a still non-existing

environment. Moreover, it is necessary to perform test sessions with the real end users of the VR application.

RQ2. How can a deployed VR application be considered suitable for usage in production?

This paper presented a proposal for the deployment of a VR application for operator training. The paper aims to propose a method to assess the suitability of a developed application for usage in production. In doing so, the testing setup and run have been described. Data have been collected considering in particular the time needed to perform the training and the effectiveness of the training methodology. Both these data are mandatory to understand the practical functionalities and advantages that a VR application for operator training can bring to a company, considering therefore the total time needed to perform the training and the actual effectiveness of the training methodology. The total time needed to perform the training and the actual effectiveness of the training methodology have been then compared with the state-of-the-art data provided by the company subject of the case study. From this comparison, the time needed to perform the VR training resulted slightly longer (+10%) than the traditional training procedure, which is in contrast with the results of the literature (Abidi et al., 2019). This could relate to a slowing effect linked to a low level of familiarity of the operators with the new technology, which seems to be confirmed by the presence of a remarkably high standard deviation in the training times. Moreover, a simple feedback-based methodology has been developed to validate the effectiveness of the deployed VR application. Indeed, the feedback of the users that took part in the test has been recorded, collecting therefore important information the time needed to perform the training, the effectiveness of the training methodology regarding realism, easiness of usage and effectiveness of the developed VR application.

RQ3. What is the feedback that operators provide in the first period of usage of such systems in a pharmaceutical context?

This paper presents a preliminary analysis of the perception of users in the first period of usage of VR applications for training, based on the case study considered. The data, collected through the usage of a questionnaire sustained that the VR training application has been perceived to be extremely realistic and coherent with the reality of the cleanroom. Moreover, the VR training application has been appreciated for a high degree of easiness of usage, even considering the presence of a certain difficulty in the adaptation to the new technology. The users expressed also remarkably positive evaluations of the effectiveness of the VR application, especially for new operators. However, the users expressed some doubts about an eventual complete substitution of the physical training with the virtual one. The VR training process has not been perceived by the users as an accelerator of the training process, probably given the presence of a learning curve of the technology, in contrast with the literature (Grandi et al., 2021). The general appreciation of the questionnaire is consistent with the literature, as VR training is perceived as an enabler of a

training modality that is generally intuitive and more enjoyable (Grandi et al., 2021).

From a managerial perspective, the VR application has been perceived as a great improvement that could lead to remarkable benefits in the reduction of cross-contamination of production lots. Moreover, the company expects a significant reduction in the costs that are linked to the training of operators from the exploitation of the VR training system. However, considering also the results of the questionnaire that collected the feedback of the users, it is quite clear that the managers will have to face a certain grade of change management issues. This issue could be linked to the presence of a learning curve in the familiarity with the new technology, which can have a significant psychological impact on the new users.

6. Conclusion

This paper proposed a practical methodology to develop and test a VR training application in the pharmaceutical context, as well as a reflection on the perception of the users on this new training methodology, by exploiting a case study. The VR application has been developed through the adoption of an iterative process, which encompasses continuous communication with the company, that relies on specific expertise on 3D modelling and scripting. The study partly supports the literature by confirming that the VR-based Learning-by-doing procedure can be considered an efficient training modality. However, this study introduces a new potential issue that is not addressed in the literature. Indeed, the efficiency of VR-based training systems could be conditioned by the presence of a heavy learning curve, that can negatively affect the performances of the users until its stabilization and that may be caused by resistance to technological tools usage as well as to a psychological disorientation when immersed in the VR environment. Moreover, this study affirms that managers play a vital role in the acceptance of this technology and should gradually introduce the VR system. This study presents several limitations. First, the study is based on a single case study, even if particularly exemplary. Second, the questionnaire has been provided to a limited number of operators and only for the first tests. Third, the research lacks a comparison between VR training systems and other traditional training technologies. Finally, a single VR environment and equipment have been exploited, without a comparison with other potential systems. Therefore, extending the application and the results collection to other pharmaceutical companies as well as to other implementation stages and with other VR systems could represent promising future research directions. The study could be also extended to other industrial contexts different from the pharmaceutical one. Indeed, even if the research presents a very specific application of the VR training approach, the methodology presented could be exploited in other industrial contexts as well. The study of the performance of the VR training system in other industrial contexts and the comparison of the results could be a promising future research direction. Finally, an interesting future study could be based on the comparison between VR and traditional training systems, in order to

establish a convenience of a methodology in base of both quality of the results and associated costs.

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