blood vessels to grow into the corneal implant, which prevents migration. The problems mentioned above have largely been addressed with the use of antifibrosis agents. Until all the issues are resolved, the technique described in this paper is of value. This is a simple but effective method to achieve a satisfactory outcome.

Introduction

Cytofree (Pty) Ltd, is discussed.

The product was specifically designed to address the needs of the IED科临床 experts. The IED科 clinical experts identified the need for a new product that could address the following issues:

- Improving the quality of life for the patient
- Reducing the risk of infection
- Enhancing patient comfort
- Minimizing the time required for recovery
- Reducing the treatment cost

These issues are critical in ensuring the success of the product.

Abstract

Epybron is an innovative hydroxyapatite corneal implant used to replace the cornea.

Epybron is marketed by Cytofree (Pty) Ltd, a South African company. The company has successfully conducted clinical trials to prove the efficacy of the product.

The product has been shown to be effective in improving the quality of life for patients with corneal disorders. It is also cost-effective and easy to use.

The paper discusses the development of the Epybron product and the lessons learned during the development process.
Hydroxyapatite engineered

manufacturers, Ceder and the distribution. Visca, the commercialization process is CSR in an intellectual engine to the market. During the product development process, the research and development were conducted in the field of bioresorbable medical devices. A significant product development effort was a key in the success of the project. The CSR project, known as the hydroxyapatite (HA) or calcium phosphate material.

Concurrent Engineering

Product Development

of the CE mark to Ceder for production of the product in October 2006.

needling a mesh of surgical cover to prevent erosion.

Furthermore, as they become fully vascularized, they can react to injection.
The surface that does not damage the epithelial layer (see Figure 2).

The surface of an orbital implant produced from natural coral tends to have

**Product design**

Applied in this project (see Ref. 1)

**Fig. 1: Diagram Illustrating the Concurrent Engineering Design Process**

Distribution optimally designed and engineered.

Other implant products from natural coral, the commonly used material, have
generally, the inserter shown in Figure 4. When the first prototypes of orbital implants were produced by the CSIR materials scientists, the ophthalmic surgeons in the consortium raised the need for a delivery device to insert the implant into the eye socket of a patient during surgery. The CSIR designers took up the challenge and subsequently developed a device to insert the implant into the eye socket of a patient during surgery.

normal eye experienced by a patient.

FIG. 2: The Eyeborn, hydroxyapatite orbital implant.

FIG. 3: Synchronous movement of the Eyeborn artificial eye with the

The patient (see Figure 3).

The improved prostheses also has improved mobility because of extracocular muscle attachment to the implant [2]. This means that the Eyeborn implant moves synchronously with the artificial eye, thus providing a very positive impact on the self-esteem and quality of life of the patient. Clearly, the insertion of the implant is a surgical procedure, but it is not as invasive as traditional prostheses. The Eyeborn implant is designed to be easily inserted and removed, making it a safer and more comfortable option for patients. Additionally, the implant is made of hydroxyapatite, a material that is biocompatible and compatible with the body, ensuring that it does not cause any negative reactions. Overall, the Eyeborn implant is a revolutionary development in the field of ophthalmology, offering patients a more natural and comfortable alternative to traditional prostheses.
5. It has been determined to produce 16, 18, 20 and 22 mm sizes and is shown in Figure 16. The sizes have been added to the marketability of Eyebomb®. It was decided that the manufacture of sets of disposable sizes would add to ease this procedure following the surgery. Following discussions with Visioneer, it was decided that Implant® sizes generally used are surgical stainless steel and due to the manufacture of 16, 18, 20 and 22 mm sizes, the surgeon uses a set to determine the size of orbital implant required for surgery. The surgeon uses a set to determine the size of orbital implant required for surgery.

Manufacture of Sizes of the

Designer and the mould maker during the manufacture of sizes, exist in very close relationship. This factor was taken into consideration when the CSR and mould maker were decided upon. Different sizes of the delivery device were designed by the CSR and designer for moulding of the moulds for forming the orbital implant and for insertion moulding of the

Tooling Design

During Surgery

Fig. 4: The Delivery Device for Inserting the Eyebomb orbital implant
over many years, the locally produced biomaterial has also been
undergone extensive preclinical and clinical evaluation. The
material has been fully characterized and approved by the FDA.

Animal trials

Spheroids, chips, discs, ingots, porosity, permeability, inserts, and physical appearance were
interconnectedly, mechanically, stiffness, mass, density, physical dimensions, and
compliance were also evaluated for pore
accepted standards. The product samples were also evaluated for pore
compliance by coupled plasma mass spectrometry (ICPMS), direct laser
ablation and x-ray powder diffraction according to internationally
accepted standards. The product samples were also evaluated for pore
compliance with the human body. The chemical and physical purity of the final
product was confirmed by the CSR in their R&D laboratories. The different
degrees of prototype tools during the design optimization and for the

Prototype tools

Fig. 2: The size of the examples of the different sizes.
The commercialisation process.

The commercialisation process includes the production, distribution, and promotion of the product. The figure shows the steps involved, namely: research, development, manufacturing, packaging, distribution, and promotion. Each step is crucial for the success of the product.

A new product development model was explored, focusing on a specific niche market. This model allowed for a more targeted approach, leading to increased sales and market share.

The commercialisation process

The commercialisation process is crucial for the success of any product. It involves several key stages, including research, development, production, packaging, distribution, and promotion. Each stage requires careful planning and execution to ensure the product reaches the market successfully.

Clinical Trials

Clinical trials are an essential part of the commercialisation process. They involve testing the product on a larger scale to gather more data and ensure that it is safe and effective for all users. The results of clinical trials are used to make informed decisions about the product's performance and potential market impact.

Characteristics of the product

The product has several characteristics that make it suitable for use in a variety of situations. These include its ease of use, effectiveness, and compatibility with other products. The product is designed to meet the needs of a wide range of users, ensuring that it is accessible to all.

Applications

The product has several applications, including in the healthcare sector, education, and more. These applications highlight the versatility of the product and its potential for widespread use.

Conclusion

The commercialisation process is a complex and multifaceted process that requires careful planning and execution. By understanding the key stages and characteristics of the product, businesses can ensure its success in the market and achieve their goals.
interpretation of the project plans and agreement obligations. On the positive
interpretation of the project plans and agreement obligations. On the positive
interpretation, there is also the challenge of resolving differences of
positions. This approach increases the number of parties involved in the
negotiation process. The CSIR’s Intellectual Property and Commercialisation
Office is responsible for managing the transfer process and the contracting and
how to identify and value the IP. The CSIR’s Intellectual Property and
Commercialisation Fund (IPF) is also involved in the
negotiation process.

Eventually, the consortium approached the Innovation Fund (IF) again to
provide financial support for the commercialisation of Eyeborn. The IF took
limited risk record in the field.

Fig 6: The Eyeborn Commercialisation model.
In the manufacturing sector, LED lamps are a major part of the commercialisation of technology transfer. The launching of the production technology for the LED lamp from the CSIR has been successful. The first sale of two Eyeboram implants to an ophthalmic surgeon from Zambia was made at the launch by the local company, VisiCare, for the distribution of the product (see Figure 7).

First sale into Africa

A workshop was also held for ophthalmologists by one of the other surgeons, who responded very positively to the potential of the new product. A success rate of over 99% [3] has been done with the implants involving 64 patients. He reported a scientific paper was presented at the OSAA congress by Dr Mark Minner.

Figure 7: Launching of Eyeboram with the Zambian eye surgeon

A couple of the Eyeboram devices were also launched at the annual congress of the Ophthalmological Society of Southern Africa (OSAA) held at Sun City from 28 February to 3 March 2004. Eyeboram was formally launched as a commercial product at the annual medical launch of the Eyeboram implant soon after the completion of the clinical trials. Eyeboram was formally launched as a commercial product at the annual medical launch of the Eyeboram implant soon after the completion of the clinical trials.

Product launch

The launch of the Eyeboram implant was well covered, with the multi-disciplinary approach required for this type of product was at least required.
Production Trials and Qualification

Introducing variations in the production process, development and pilot production stages in order to reduce the risk of equipment or package equipment failure, is often overlooked in the development of new products. When used in the early phases of new product development, these techniques can significantly reduce the likelihood of equipment or package failures, thereby ensuring a smoother transition to production.

Procurement of manufacturing equipment

Procurement of manufacturing equipment would be at risk if the wrong technology was selected. Without the ability to communicate effectively, the risk of introducing new technology without the required process is significant. The importance of choosing the right technology for commercial production cannot be overstated. It is crucial to select a technology that is not only reliable but also scalable to meet the needs of the project.

Procedures

In October 2006, the company embarked on a project to achieve regulatory approval for the product. The project team began by developing a comprehensive plan to address regulatory requirements. Due to an increase in regulatory scrutiny, the team worked closely with the regulatory authorities to ensure compliance with all relevant regulations. This collaboration was instrumental in achieving regulatory approval.

Product quality

The quality of the product is a critical aspect of any commercial product. During the development phase, the team worked closely with regulatory authorities to ensure that the product met all required standards. This collaboration helped in identifying potential issues early on and implementing corrective actions to ensure regulatory compliance.

Industriallisation - Scaling up from laboratory prototype to commercial production

The industrialisation phase involves scaling up the laboratory prototype to commercial production. Various challenges were encountered during this phase, including production bottlenecks, limited availability of raw materials, and regulatory hurdles. The team worked closely with suppliers and regulatory authorities to overcome these challenges, ensuring a smooth transition to commercial production.

The ability to learn from previous failures and iterating on the product design was essential in ensuring the success of the project. The team demonstrated strong teamwork and communication skills, ensuring that all stakeholders were aligned and working towards the common goal of bringing the product to market.
responsible for the improved quality of the key experienced (see Figure 8).

exception, the patients were satisfied with the results; they experienced and
immediately with a steady growth over the first two years. Almost without
The penetration of the market in the private clinic sector was almost

Impact

product

in time, deepened their establishment as commercial manufacturers of the
purchase and commission equipment within the planned time schedule. This
experience severe cash flow problems, which influenced their ability to
A further result of the extended contracting process was that Caraka

Cash flow management

an investment.

non optimized production costs had a negative effect on the eventual return
that would have followed from an inability to supply in the market demands. the
Caraka had to continue growing the market without clearing difficulties.

One of the results of this was that the Caraka had to continue with their plans

sudden and disturbing the company with delays
the delays were caused by the process of defining licensing and contracting

the development process consisted of academic and governmental institutions,
consisting of Caraka. This delay can be mainly attributed to the fact that the
the delays and designs due to the very lengthy contracting process. It took more

Although the technology transfer process was planned to a significant level of

Scheduling the technology transfer process

imperatives so high standard for the biomanufacturer.
and their clinic could routinely produce the
had been successfully completed, and that Caraka could routinely produce the

These samples were subjected to a stringent
by Caraka for a few months. These samples were selected for further evaluation
the results had to produce a final batch of impure samples for actual evaluation.
Responsible for monitoring progress, performance and payment of all
licenses if a single person was dedicated to the license and made
where possible it would be beneficial to the progress of the technology
of the business.

A project like Eyeborn is a huge opportunity for a small technical
production facility. A project in synergy with the technology license and establishment of
a multi-disciplinary network of carefully selected clinical and marketing experts, including specialists in the medical field,
the importance of establishing a multi-disciplinary network of carefully

Conclusions

As well as for the rest of the international world, the product holds strong potential for utilisation in African countries.
At this time in November 2006, more than 300 patients, most of them from south
African population. Marketing efforts are already in place.

If a greater challenge, which still remains, is to penetrate the public
health system with this product and to fully realise the ultimate goal of the
project, it is more advisable, quicker and easier to develop solutions for the smaller
programmes and to then proceed to the larger South

Figure 8. A patient before (a) and after (b) having received an Eyeborn.
References

The authors pay tribute to one of the inventors of Eyeborn, the late Dr. Michael Thomas, who passed away in 2003 before completion of the clinical trial. The technology transfer and commercialisation of Eyeborn was made possible by the commitment and sustained backing of the Innovation Fund. The vision of the then Minister of Arts, Culture, Science and Technology, Dr. Ben Ngubane, who personally approved the funding, is gratefully acknowledged.

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Successful implementation of perseverance are required to achieve eventual success with all worthwhile causes in life, dedication, patience and a