CHALLENGES AND OPPORTUNITIES IN PRODUCT DEVELOPMENT – ACT-O2-HEM A STORY OF UPS AND DOWNS!

Blood Transfusion Medicine

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Introduction

The design and development of an initial research idea to a safe and valuable product is long-lasting and only a few make the vital step to success. Also, the realization on a national and even on a global scale is a major challenge. Here, we present the emerging challenges and opportunities with an incorrect and correct handling of THREE key points during product development on the example of ActO_2Hem®. **ActO_2Hem®** is an active bovine hemoglobin solution suitable for applications with insufficient oxygen supply, like healing of chronic wounds, cell culture productivity, organ preservation as well as a red blood cell replacement.

Scope of the Project

1. Develop an active hemoglobin solution derived from bovine red blood cells as a starting material for general Biotech and pharmaceutical use.

2. Research and find suitable applications in the need of an oxygen delivery system.

Three key points to consider during product development

1 Market Analysis

A proper and thorough market analysis to evaluate potential opportunities besides the initial idea.

2 Regulations & Requirements

Understanding the vast amount of various country-specific regulations and requirements.

3 Active Communication

Active and constant dialogue with the authorities and the investors.

Act-O_2-Hem – A story of ups and downs

1 How it started:

The initial scope of the project was to develop an animal-derived blood substitute for human use. However, wrong assumptions and failures made it difficult to continue the project. Only an active use of the three key points for product development successfully revived the project.

2 Challenges in ActO_2Hem® product development and past failures:

a) The market was never properly researched. The need for an oxygen carrier in other areas was never explored.

➡ **The registration of an animal derived human blood substitute is a huge challenge and very time consuming.**

b) The import/export barriers for bovine blood-derived products originating from Europe were never properly addressed.

➡ **Global upscale of the product is impossible without knowing the international regulations.**

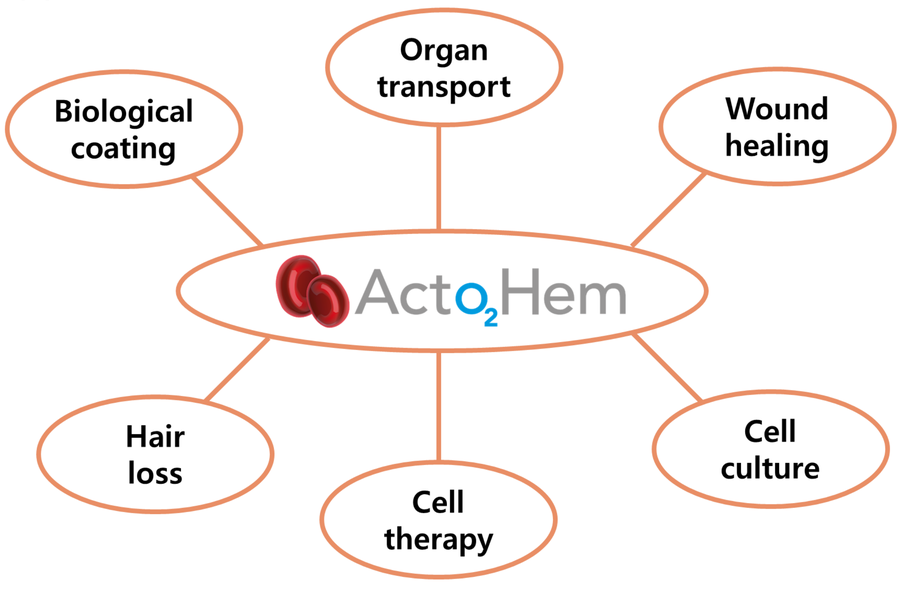
c) The scope of the project was too narrow. Potential other applications were neglected or ignored and not communicated to the investors

➡ **The investors abandoned the project because of insufficient communication.**

3 New opportunities emerged by applying all 3 key points:

a) **ActO_2Hem®** is still in the development as a starting material for Hb particles. New investors came on board.

b) New applications besides a blood substitute were identified during time:



➡ **Increased cell culture growth and viability by adding ActO_2Hem®.**

➡ **ActO_2Hem® can be implemented in an alginate-gel while maintaining fully active.**

➡ **ActO_2Hem® can be used as substitute for RBC packs added to organ transplant media.**

4 Development of a transferable technology:

➡ **Meets all legal requirements in safety, purity and quality as a biological starting material for pharmaceutical use.**

a) High oxygen transport capacity

b) High purity (>99%)

c) Low methemoglobin levels (< 5%)

d) Endotoxin levels below 0.25 EU/ml

➡ **The technology is easily transferable to any country in the world.**

5 Data are available upon request:

For more information and data please visit:

- www.actohem.com

Or contact us directly.

Conclusion

The successful product development is a long and exhaustive road with many ups and downs. However, a regular and close interaction with potential customers, legal authorities, and investors allow to not only develop an innovative new product but even to embrace new market opportunities over time. In conclusion, **ActO_2Hem®** is the first of its kind **transferable** technology that meets all legal requirements in safety, purity, and quality as a biological starting material for pharmaceutical and general Biotech use. As of today, **ActO_2Hem®** has become the basis of the development of custom-tailored products in various areas like wound healing, cosmetics, medical devices, diagnostics, cell culture applications, and new possibilities will emerge.

Funding and Partners

This project has received funding from the Eurostars-2 joint programme with co-funding from the European Union Horizon 2020 research and innovation programme

SPONSORED BY THE Federal Ministry of Education and Research

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