

White paper

Outsourcing of product development projects

Sponsored by BAAT Medical

Gert Nijenbanning January 2018

New product development

New product development (NPD) is a knowledge intensive activity that highly depends on the competence of a team of individuals. At start of a project everyone has a vision about how the product should look like. Often, a clear understanding about the optimal set of technical specifications that will fulfil the user needs in the most economical way is not available. These unidentified issues must be elucidated during the project. This makes outsourcing of NPD different from outsourcing manufacturing.

In today's environment, hospital administrators have taken a primary role in the purchase of products, and they see the importance of a product's cost in line with patient outcomes. Due to this new relationship, engineers, who previously concentrated primarily on surgical results, now have to consider manufacturing costs and regulatory pathways if they expect their products to be successful in the marketplace. This is why it's essential to identify financial goals at the beginning of the project. This will include the price of the product, the manufacturing costs and the margins needed for the whole process including regulatory. Because of the knowledge intensity and the costs driven business, outsourcing of NPD activities did come up strongly in the last decade. According to the Millennium Research Group, the global market for outsourcing is estimated as \$7.1 billion dollars in 2009. Of that volume, the engineering segment was valued at 8.6% growing to 14.4% in 2009.

Critical success factors

Once an orthopaedic OEM makes the decision to source out an NPD project, it cannot simply give an order to a contractor and just wait for the results. The success of outsourcing NPD projects depends on the following critical success factors:

- mutual understanding of project objectives, including economic targets.
- avoid drift in design requirements, leading to 'scope creep'.
- be realistic about lead times of various processes like manufacturing and testing.
- plan own resources for communication and transfer of the results.
- understand each other concerns regarding project risks.

The control parameters for an NPD project

In every NPD project, whether it is outsourced or not, three major parameters are to be controlled: Quality



The easiest way to maintain control is to simply constrain all three parameters for the team that carries out the NPD. This approach will only lead to satisfying results when the company has a complete and precise defined list of technical specifications available. Only in such a case, all resources needed to develop the product can be planned into full detail.

In reality, such a complete list is not available. It is more likely that there are only indicative user requirements defined like "easy to use", "low cost of goods" and "reliable". As a consequence, the planning of resources will be less accurate and, if no measures are taken to control the design requirements, the project results may be not as planned.

During a Medical Device & Manufacturing conference in 2004 the conclusion of a discussion around this topic was that, instead of constraining all three parameters, better results are expected when fixing only two of them and make the third parameter "floating" in a controlled way. The cases where quality and lead time where fixed, in combination with taking adequate measures to monitor the costs gives the best results regarding fulfilment of the business case behind the NPD project.

Business case

Before starting a NPD project the company should have a clear business case: the reason why this NPD project should be carried out. Per definition there will be uncertainties at start of the project. These uncertainties have to be identified and monitored throughout the project and measures should be defined on beforehand in terms of time buffers and financial resources in order to handle issues accurately when they occur. This all must be incorporated in the project plan and related to the business case.

When only focusing on the height of a development budget, a NPD project can be controlled easily during the development phase, however, it could also lead to extensive losses of potential turn over after the development phase when the product is on the market. Potential missed turnover is one of the main reasons why a business case is not fulfilled. For example, if a market introduction of four months later than originally planned, could lead to potential missed revenues in the same order of magnitude compared to the total investments for NPD project.

Literature

Millennium Research Group's Global Markets for Medical Device Outsourcing, 2006.

Faster, Cheaper, Better Products? Tips and tricks from insiders for freeing the product development logjam, Bill Evans and Lisa Scheinkopf.

Outsourcing of New Product Development: A decision Framework Luleå University of Technology Department of Business Administration and Social Sciences Division of Industrial Management 2007, Jonas Rundquist

Improving Outcomes in Outsourced Product Development: a Joint Consultant-Client Perspective, POMS 21st Annual Conference Vancouver, Canada May 7 to May 10, 2010, William J. Palm IV and Daniel E. Whitney

Managing Risk in Outsourced Product Development and Manufacturing, Proceedings of the SMTA International Conference, September 2006, Larry Fleming



F. Hazemeijerstraat 800 7555 RJ Hengelo The Netherlands

+31-(0)88-56 56 600 info@baatmedical.com www.baatmedical.com

DISCLAIMER: The information provided in this white paper is strictly the perspective and opinion of the author(s).