

## Project management for the development of a new breast milk pump (medical device)

### Client company environment and challenge

The Swiss medical technology company specializes in the development and manufacture of breastfeeding products and medical vacuum technology.



The company employs over 1,700 people worldwide, 440 of them at the Swiss headquarters. As the undisputed market leader, breast milk pumps are also sold in the retail market. The successful business development over many years hides the fact that the majority of the products are more than 10 years old. The company does not bring any innovations to the market in its core business. Aggressive competitors appear seemingly out of nowhere:

- Chinese manufacturers copy the successful products and sell them in Asia at rock-bottom prices.
- A well-known European competitor launches an attractive and innovative product on the market

The company responds by developing a new product. However, a new breast milk pump for the upper price segment has then been in development for more than three years. The project is making slow progress. The team, though, is showing signs of fatigue and demotivation. Finally, the project manager leaves the company.

### Task of the interim manager

The interim manager assumes the following tasks as project manager:

- Leading the development project based on the company's own innovation process, which meets the requirements of the quality management system for medical devices in accordance with ISO 13485
- Leading the project team with different disciplines:  
User Centered Design, Mechanical Design, SW/HW Design, Testing & Reliability, Global Sourcing, Global Product Management, Quality Management, Regulatory Affairs, Production Engineering, Supply Chain Planning and Production.

- Ensuring that the product meets quality and compliance requirements. The product is to be launched as a medical device (e.g. for USA, FDA) and as a household appliance (e.g. for Europe, CE)
- Leading the process of industrialization, production launch, and supporting the market launch

## Specific challenges:

- No new breast milk pump has been developed at the Swiss site for more than 10 years. Many processes of product development for medical devices according to ISO 13485 were applied by the team for the first time.
- The specific product development know-how has to be built up simultaneously with the development of the product, because large parts of the development had been outsourced for the previous products and because important key people (know-how sources) had left the company.
- For this very reason, it is crucial for the company and for the motivation of the employees that a successful product - a new flagship product - can be launched on the market again.

## Solution

- Conduct a project review, revise work packages, simplify interfaces
- Restructure the project organization, clear assignment of tasks
- Development of the master plan - introduction of an "Accelerated Scenario" to reduce the risk of a project delay (to create additional time reserves)
- Coaching of product developers and sub-project leaders, weekly progress meetings
- Management of the key supplier (external industrialization partner for an important assembly)
- Planning of product verification and process validation
- Install and lead two task forces
  - to fix a serious electronic defect
  - to ensure the timely production of the product software and integration tests
- Enforce field testing with a limited CE approval
- Create sales & operations plan as a team with product management and operations, including phase-out planning of the predecessor product
- Prepare and start the approval process for CE, FDA and CMITT (China)
- Preparation of the release documentation and handover to the project manager to support the ramp-up of production and country specific launches

## Results

- CE and FDA approval for medical devices was granted on time.
- The product is successfully launched worldwide. Unit volume targets were exceeded - five months ahead of schedule
- The product is produced in excellent quality:
  - the market organizations receive hardly any customer complaints
  - the production yield is already gratifyingly high at the start of production

The product served as the basis for the development of a lower-cost product version.

This entry product - developed together with a Chinese partner and produced in China - can be successfully launched on the market one and a half years later.

## Customer references

Director Project Portfolio Management:

"Mr. Strotz performed his tasks with determination, consistency and very efficiently."

Team Leader Electronics & Software:

"Without you, this would not have been possible at all...Your "business" thinking - instead of bureaucracy - served the project well."

CEO of the company:

„It passed the sales targets... full five months ahead of schedule after the launch of the pump... How was this possible? For one thing, sales exceeded all expectations. In addition to having a successful product and a steady supply of units for our customers, we are grateful to Team and the excellent teamwork displayed by all the departments and external partners involved."

## Keywords of the mandate

Client	A Swiss medical company
Industry	medical technology
Contract length	14 months / full time
Location	Zurich, partly Shanghai
Turnover	N/A
Employees	1700