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### EUROPE



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# Reducing Cost

## by Automating Laboratory Workflow

In laboratories the automation of operational procedures does not only concern practical-analytical tasks but also documentation and control. The common keywords for extensive automation projects are: quality assurance, optimization and acceleration of procedures, reproducibility of results and the reduction of error ratios. Automation's intention is to provide the laboratory personnel with more time for its core tasks. From an economical point of view automation is a means of cost reduction. That economical and innovative criteria concerning laboratory techniques go well together shows a current project of automating operational procedures in a relevant laboratory. A medium-sized pharmaceutical company can expect millions of Euro cost reduction due to their intended automation project.



### Acceptance

The starting point of introducing automation techniques in the chemical industry is repetitively as follows: Automation asks for high investments that go with a high risk. How much it may reduce costs is not clear and the reaction of the laboratory personnel are never indifferent. Automations that create transparency or seem to cut individual responsibilities are often harshly criticized. But if instruments make the staff's work easier and avoid the problems above, innovation is warmly welcomed.

Often certain staff members claim exclusive rights on certain equipment so that further equipment is bought although the utilization ca-

capacity of each device is low. For example the utilization capacity of HPLC-instrument is currently under 50% on average. From the perspective of cost efficiency this phenomenon is an indefensible situation. The acceptance of an automating procedure by the laboratory personnel is therefore an essential success factor for these investments. Therefore it should be considered right from the beginning.

The question is how these requirements can be met and realized cost efficiently. This objective is definitely not softened by the fact that work routines and procedures in laboratories are highly complex. This dilemma can be solved with a business case that is built in cooperation of management and staff.

### The Business Case

In an exemplary case, for an investment of € 900.000, a business case for a pharmaceutical company was built within three weeks. This investment has to be seen in a connection with an overall benefit of € 3.816.900 over the time-span of three years (fig. 1). The ROI is therefore 324.1%. The potential for cost reduction is thereby clearly quantified. Are these numbers trustworthy? How can it be proved that this cost reduction actually improves the capability of innovation in the laboratory, and that the staff approves these changes? In order to answer these questions it is necessary to explain the underlying business case method.

A business case that offers a solid quantification of complex projects in respect of the company's specific challenges, consists of three working steps.

### Influence Matrix

First, an influence matrix is built in order to visualize and define the project. It structures the complexity of the project in the way that it can be embedded within the financial model.

A financial model is scrutinized on its validity by running a risk and sensitivity analysis. Its aim is to state the final result and the essential risk factors with statistical validity.

The influence matrix is a tool for the visualization of the entire project on a single PowerPoint slide (fig. 2). It comprises the complexity of the project with all relevant elements and their interrelations. In the influence matrix, technical and economical parameters are set in relation to each other, the result is that the first step of their necessary translation is achieved. The translation from technical into economical parameters is the prerequisite for a successful quantification of possible cost reductions by automating laboratory specific procedures. The influence matrix can be adapted to any given project. It consists of four main categories that create a very first

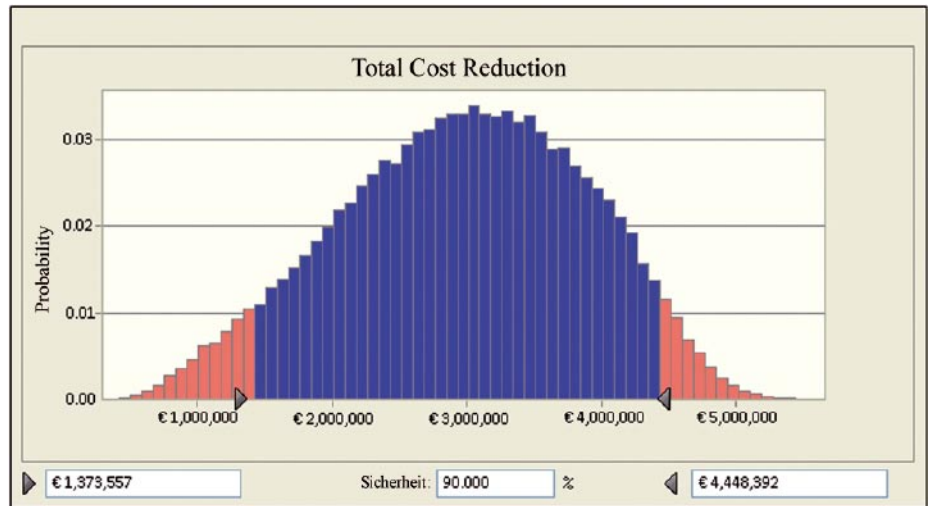


Fig. 1: Probability

structure. These categories are scenarios, decisions, uncertainties, and values.

### Scenarios, Decisions, Uncertainties, and Values

There are at least two scenarios in every business case. The first one is the scenario of keeping the current system. It considers the costs to be expected if no new automation procedure is

introduced. This scenario is compared with the scenario „automation project“.

Decisions on the one hand are everything that can be controlled. That is i.e. the date of starting the project, the selection of laboratories in question, and the scope of the automation.

Uncertainties on the other hand are everything that cannot be controlled. They are the reason why a business case is needed. Uncertainties are i.e. cost per analysis parameter, the



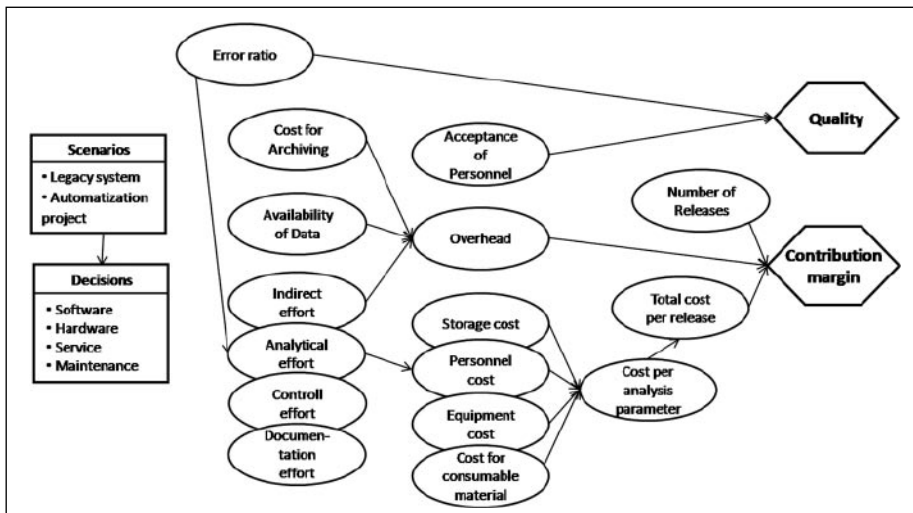


Fig. 2: Influence Matrix

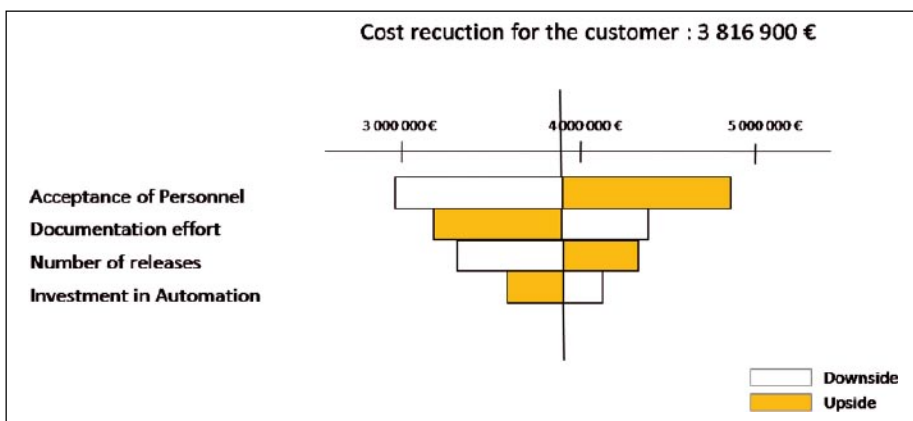


Fig. 3: Tornado Chart

error ratio, personnel cost, the acceptance of the personnel, number of releases, and the total benefit.

The value is the value that is supposed to be calculated with the business case analysis and is chosen with reference to the company's objectives. In the exemplary business case it is the contribution margin. In reference to the contribution margin the underlying economical question if an investment of € 900.000 was appropriate and the risk could be taken was to be answered.

### Financial Model

The financial model quantifies each element and its structure is based on the one of the influence matrix. The correct structure is as important as the quality of the data. Often non-available data is expected to be the problem when calculating a financial model. But this problem is easily solved and offers even an advantage that can be a success factor for the automation project. The needed data is collected by interviewing subject matter experts. The subject matter experts are the staff of the company and therefore are familiar with the operational procedures of the company, their technical conditions, and other necessities. They can judge the best for their specific area of

competence which possible changes are to be expected due to the automation project. These interviews not only provide high quality data, but also contribute to the acceptance of the project by creating consensus. Since point estimates are exactly wrong, data is collected by asking for range estimates. The experts therefore name a minimum, a most likely and a maximum value for each uncertainty. Through this procedure each uncertainty included in the influence matrix is assigned a numerical value. The interrelation of these values is captured in the financial model with which the expected contribution margin can be calculated. A business case is built in order to weigh short-term and long-term developments against each other. Therefore a solid statement concerning the investment cost asks for analyzing a time span of three years.

### Probability

With the calculation of the contribution margin the business case is not finished yet. Probability is not only taken seriously while collecting the data, but also when the results are evaluated. A meaningful statement concerning the contribution margin can only be made if it is known with which probability a certain result is to be expected. Possible outcomes are therefore calculated

by running simulations that allow the determination of the calculated result with reference to its statistical distribution. A simulation makes the following statement possible: a contribution margin of € 1.373.557 to € 4.448.392 can be expected with a 90 % probability. Diverse risk factors can cause a deviation of the calculated result. That is why the knowledge of the risk factors is a decisive prerequisite in order to reach the forecasted result as closely as possible.

### Tornado Diagram

A tornado diagram is the second tool within the risk and sensitivity analysis. It quantifies the influence of each risk factor on the final result. Thereby the biggest risk factors and how they may influence the final result positively or negatively can be seen. In the presented project, the biggest risk factor was the acceptance of the personnel that weighed € -823.350 and € +1.023.820. The costs for the investment into automation as i.e. Laboratory Information Management System (LIMS) and Electronic Laboratory Notebook (ELN) have a low impact on the final result (fig. 3).

### Conclusions

The business case is an economical decision tool in order to decide in favor or against a planned investment. It considers the argument of cost reduction or increase in productivity as the prior argument for the automation with respect to their clear monetary value. But the business case offers more than that. It is only by profoundly considering the specific conditions of the pharmaceutical company that the possible cost reduction can be quantified appropriately. Cost reduction is not to be achieved by reducing possible cost drivers such as personnel but by increasing the efficiency of the laboratory. The efficiency of the laboratory can only be described in qualitative terms. Quality standards and operational procedures are therefore crucial for quantifying the process effectively. That is achieved by breaking the qualitative elements down into their quantifiable elements such as error ratio and constancy of data, time spent on the laboratory journal, and reiteration of analyses. With numeral values such as 60–70 % less reiterations, 70–90 % less control and documentation effort there is much more information available as the one condensed in the value of the contribution margin. A business case is an economical motivated tool that answers a diversity of qualitative questions concerning laboratory techniques at the same time.

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