

DOI: <http://doi.org/10.32750/2024-0128>

УДК 658.012.32

JEL Classification: G11, O32, M210

Oksana Kazak

PhD in Economics, Associate Profesor
Associate Professor of the Department of Finance
Borys Grinchenko Kyiv Metropolitan University
Kyiv, Ukraine
ORCID ID: 0000-0003-2088-9022
e-mail: o.kazak@kubg.edu.ua

Serhii Riabyk

Master of Economics, Master of Business Administration
Deputy Director for Development, UKRMEDTEXTILE LTD
Cherkasy, Ukraine
ORCID ID: 0009-0001-8126-3763
e-mail: sergey.ryabik@ukrmedtextile.com.ua

MODERN ASPECTS OF BUSINESS PLANNING OF MEDICAL PRODUCTS MANUFACTURING COMPANIES FOLLOWING THE REQUIREMENTS OF INTERNATIONAL QUALITY STANDARDS

Abstract. The article investigates the current problems of bringing new products to the market by enterprises engaged in the production of medical devices. The main factors of restrictions are identified as regulatory changes related to the need to comply with international quality standards in the integration conditions of medical device manufacturers. The essence and requirements of the international standard ISO 13485 for the design and development of new products are analyzed. The author clarifies the differentiation between the need for manufacturing companies to comply with the requirements of this standard and the consideration of the most important factors for drawing up thorough business planning as the main tool for determining the company's strategic goals and ensuring its stable and efficient operation. The article presents the essence of business planning in the system of strategic management of a company and defines it as a systematic process of making effective management decisions by allocating resources and choosing the best course of action from alternative options, aimed at assessing the feasibility of the chosen direction of the company's development, as well as formalizing the decision-making process for project implementation. It is proved that the optimal tool for evaluating the most effective projects is carried out using investment analysis tools. The methods for evaluating investment business projects are outlined: methods based on discounted estimates and methods based on accounting estimates. The main aspects of investment analysis are defined: functions, evaluation tools, and factors of influence. The project cycle of strategic business planning of the company's activities is presented. The analysis of the attractiveness of the business idea and the analysis of the business plan as a whole are defined as the main components of the expert analysis of the business plan before its implementation. In particular, the author identifies the criteria for express assessment of the prospects and feasibility of a business idea and the main parameters for assessing a marketing plan and marketing strategy, technological analysis, analysis of an organizational plan, and financial and economic analysis for business planning. Special attention is paid to the analysis of project risks. In particular, the classification of project risks is presented, the expediency of applying the Markowitz portfolio theory to form a campaign investment portfolio for optimal asset selection based on the required return/risk ratio is substantiated. The experience of applying business planning standards by leading international and national institutions in the field of investment and business consulting, such as UNIDO, TACIS and the EBRD, is reviewed and systematized. The use of automated analytical tools Wrike, Microsoft Project and Microsoft Dynamics 365 is proposed for making decisions on strategic business planning tasks. It is established that the introduction of activities related to the use of modern methods and automated programs for business planning and project management, the creation of a system of staff motivation during business planning and implementation can bring medical device companies to a qualitatively new level for successful integration into the Global System of Medical Devices Manufacturers.

Keywords: business planning; strategic management of the company; quality management system; investment analysis; project risks; project management.

INTRODUCTION

Statement of the problem. Business planning at an enterprise is one of the important processes since planning its activities allows you to determine the most promising areas of development timely and will allow the company to build the right strategic goals in the long term. The current economic and political challenges have generated many additional factors affecting the activities of any business entity, especially companies engaged in the production of medical devices. The COVID-19 pandemic and the full-scale Russian invasion have actualized the need for medical devices in the market. While the impact of COVID-19 has provoked a significant increase in the volume of the medical devices market in both physical and monetary terms compared to previous years, during the period of martial law, Ukrainian medical device manufacturers have experienced negative changes in their operations under the influence of internal and external factors, such as the outflow of specialists abroad, the impact of government reforms and public procurement on companies' operations, supply chain efficiency, demand for innovative technologies and the production of high-quality devices, government policy on That is why business planning in today's environment is becoming a universal tool for identifying possible solutions to problems arising in the course of companies' operations to ensure their stable and efficient operation.

Analysis of the latest research and publications. Any company carrying out commercial activity, regardless of the size or scope of the business, must plan its activities to determine the most promising ways of development. This is always related to long-term planning, which is also called strategic planning, and is most often related to the determination of specific vectors of the direction of the enterprise's activities.

Many Ukrainian specialists in the field of enterprise economics, including S. F. Pokropyvnyi, S. M. Sobol, H. M. Tarasiuk, H. O. Shvydanenko, O. S. Svitlychna, O. H. Derevianko, V. V. Makedon, etc. [1]–[4]. A significant contribution to the study of this economic category was made by foreign researchers, including C. Barrow, A. Volosky, B. Ford, D. Borystein, R. Brown, P. Pruett, etc. [5]. At the same time, approaches to the interpretation of the definition of business planning and its main components differ depending on the role and expectations of the company. In particular, I. Kulinich defines planning as one of the management functions, the process of choosing goals in making management decisions [6]. At the same time, L. Galko [7] notes that business planning is aimed at finding new opportunities to use the company's resource potential, since "the purpose of a business plan is not limited to attracting financial resources for business development. It allows you to form a new trajectory of the company's development, model a business management system, maintain communications with suppliers and consumers of products, identify obstacles to the implementation of a business idea, and reduce the risks of entrepreneurial activity". According to O. Kazak [8], "...business planning is a mechanism for coordinating and specifying goals, strategies and specific actions to ensure sustainable growth and strengthening of the business".

Therefore, planning is a systematic process of making effective management decisions by allocating resources and choosing the best course of action from alternative options.

The purpose of the article is to study the current peculiarities and problems of business planning at enterprises engaged in the production of medical devices and to identify its universal tools.

RESEARCH RESULTS

It can be assumed that in the current situation, the Business Plan [7] is probably a universal tool for business planning and is designed primarily to assess the appropriateness of the chosen direction of development, as well as to formalize the decision-making process for project implementation. In developing this document, the main attention is paid to the relevance, the possibility of implementing the project based on the selected company, the volumes and sources of financing are determined, and the expected financial results are assessed. At the same time, there are distinguished business plans developed for internal use, as well as investment plans for attracting financing from the outside, that is, a potential investor. In any case, we are talking about a document with the help of which it is possible to plan the direction of the company's development and, most importantly, to form strategic goals.

Many companies dealing in the medical device manufacturing industry as part of their commercial activities face restrictions on entering new products into the market. Key restrictions include challenges due to regulatory changes. These changes are mostly related to medical device approval procedures and getting certain documents and registrations as some markets like the US Food and Drug Administration (FDA) have requested additional clinical data to support the claims of safety and efficacy of medical devices. It is the potential loss of revenues for companies-manufacturers of medical devices due to delays in product releases, and additional costs incurred due to stringent approval processes put a strain on investments relating to new product developments, affecting the growth of the medical devices market. Because domestic manufacturers of medical devices undergo an integration process into the International Global Market of Medical Devices Manufacturing results focus exclusively on strict international standards regulating the activities of companies producing medical products.

This is currently an international standard is ISO 13485—Medical devices—Quality management systems—Requirements for regulatory purposes [9]. In point 7.3 Design and development is established in order of the new medical devices development and implementation. The requirements of the standard should be entirely accomplished for the successful medical products to the market issuing and the future audits passing.

ISO 13485 is an internationally agreed upon set of standard quality management system (QMS) requirements for any company involved in the design, production, installation, servicing, and manufacturing of medical devices. ISO 13485 is the medical industry's optimal medical device standard, which ensures that all medical devices meet the proper regulatory compliance laws and customer needs.

As a result, while paying close attention to compliance with the requirements of the standard for the design and development of new products, the companies, as a rule, do not take into account the most important factors for making a scrutinized business planning, namely, an initial analysis of the business idea (new product) is not carried out to determine the feasibility of development the product, the investment volume and ways of raising funds, market research is not carried out or not enough serious attention is paid through marketing investigation and commercial expertise on the possibilities of implementation.

The difficulty lies in the fact that the standard requirements for medical devices do not always, but most often, constantly differ from the requirements of the commercial department and a marked demand. This applies to consumer properties, quality characteristics, packaging design, labeling, etc. Therefore, companies of this type develop products based not on market needs, but on the capabilities of technological equipment and the requirements of regulatory documentation. This often leads to the fact that the manufactured products do not have unique quality characteristics, could have an unrepresentable appearance, and, as a result, do not have the required demand. All these factors have a negative influence on the financial indicators of the project, mostly the payback period and the volume of investments.

The implementation of any of the projects requires financing, which means attracting investment funds necessary for its successful implementation. In other words, the project is a proposal for changes in the company's activities, formulated in some way, aimed at expanding the product portfolio or other possible changes, the main goal of which should be obtaining additional profit for the company. It is obvious that companies must have a system for generating and evaluating such projects. At the same time, the assessment of the most effective projects is carried out with the help of investment analysis tools.

It is completely clear that investors and/or main stakeholders aka owners are prioritizing all the investment operations involved these days, which guarantee the security of capital and a

sufficient level of income, so they are faced with the need to accept investment decisions based on the selection of key concepts of financial management.

In general, we can agree with the author Viktor Levitsky, whose article, Investment Analysis, proposes two methods for assessing investment business projects [10]. They are:

Methods based on discounted estimates:

- net value method.
- return on investment index.
- method of calculating the internal rate of return.
- methods based on accounting estimates.
- method of calculating the investment payback period.
- method of determining the accounting return on investment.

Whatever method is chosen as the main one for investment analysis, the main thing is to systematically evaluate the disadvantages and advantages of investment projects. This can be done with the help of the following measures:

- data collection and analysis.
- determination of investment priorities.
- consideration of alternative options.
- analysis of problems and consideration of various aspects of development and implementation of financial management solutions.

The main functions of investment analysis can and should be implemented through:

- development of an orderly structure of data collection, which will ensure effective coordination of measures during the implementation of investment projects.
- optimization of the financial decision-making process based on the analysis of alternative options, determination of the order of execution of measures and selection of optimal technologies for investment.
- clear definition of organizational, financial, technological, social and environmental problems arising at various stages of investment project implementation.
- assistance in making competent decisions regarding the expediency of using investment resources.

The importance of conducting an investment analysis is determined by several factors, namely:

- the market situation, the environment in which the company is located is exposed to the permanent influence of external factors, which are often impossible to predict or resist.
- the financial stability of the company, namely the ability to implement similar projects in the existing realities.
- choosing the most promising ways of activities or product portfolios for their successful implementation.
- assortment analysis and selection of the most promising products that will ensure the planned sales volume.
- determination of requirements for production technology and the nature of technological equipment necessary for production.
- determination of the break-even point, determination of the minimum sales volume at which production costs are covered by income.

These and many other questions are considered at the stage of strategic business planning of the company's activities, which are most often formed into some kind of action system called the project cycle.

At domestic companies, the project cycle can have the following stages:

- 1) Generation of a project idea, the author of which can be any employee of the company, but which has passed mandatory processing and has been assigned the status of promising. The final decision to verify the feasibility of an idea is usually made by the general director or the owner—the main stakeholder of the company.
- 2) Development of a business plan to assess the economic feasibility and the company's ability to implement it.
- 3) Considering the business plan and deciding on a project implementation.
- 4) In the case of a positive decision, an analysis of the business plan is carried out, which involves an examination by the project manager of the received information with the involvement of experts in each of the business plan sections.
- 5) Implementation of the project by processing a business plan.
- 6) Achieving planned indicators and closing the project by transferring it to the current activities of the company.

The design process is shown schematically in Fig. 1. This scheme is relevant if a positive decision is made at each stage of project development and implementation.

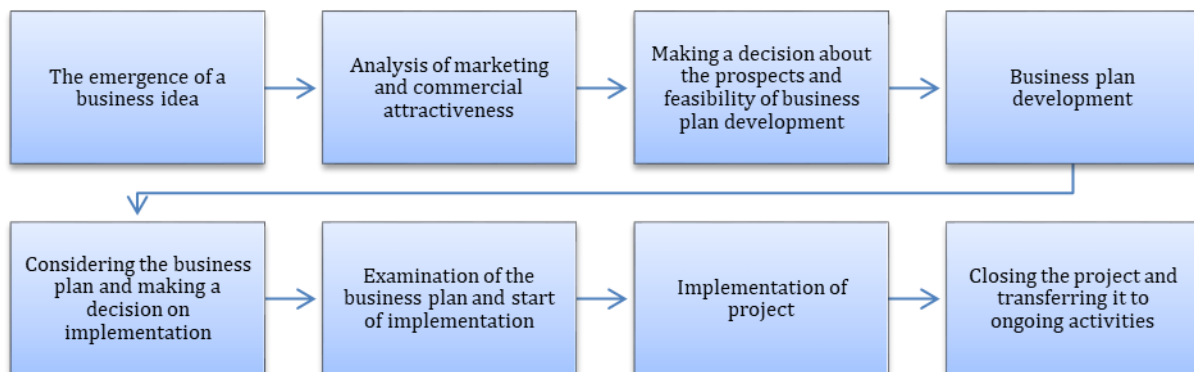


Fig. 1. Project cycle of strategic business planning for a company's activities

Source: compiled by the author

One of the key determining processes is the expert analysis of the business plan before its implementation. Such a process must be organized and carried out by an expert group or project team, which will subsequently implement it. The responsible person here is the project manager, who is appointed by a separate order for the company immediately after a positive result in considering the business plan. Thus, the analysis can be divided into two main sections:

1. Analysis of the attractiveness of a business idea. At this stage, an express assessment of the prospects and possibility of implementing this idea will be carried out according to the following criteria:

- availability of quality characteristics of the product (sample, analysis, standard).
- knowledge of production technology.
- presence of competitors, market size.
- the need for product registration (GOST, TU, ISO).
- availability of necessary raw materials and auxiliary materials for production, free access to them.
- the need to purchase new equipment and its cost.
- expenses for researching and passing the product into current manufacturing.

- the volume of necessary calculations for the implementation of a project for the production of new products.
- possible production capacity.
- will the new product be able to compete?
- risks of a business idea implementation.
- own or joint project.
- approximate cost of the project.

Based on the results, an analytical note is usually prepared with a brief feasibility study and recommendations for deciding on its prospects.

2. The analysis of the business plan in general is carried out according to the following main parameters, which must be properly prepared and provide comprehensive information for their assessment:

2.1 Analysis of the marketing plan and marketing strategy [11]. The proposed business idea for any new product design may only be successful if the product finds a consumer. For this reason should be collected and systematized information about the market environment. This data in the further is known as the marketing plan which consists of:

- potential consumers of future business products, their requests, and unsatisfied needs.
- technical, operational, and consumer qualities of similar types of products and their prices.
- peculiarities of the promotion of this group of products to the consumer market and other information characterizing the future business market.

One of the most important components of a marketing plan is the marketing strategy. When developing a marketing strategy, it would be most significant to assume several versions of changes in market factors and, accordingly, the company's position in the market. With this approach, the company will be prepared for negative, positive, and natural (neutral) changes in market factors. Therefore, companies usually develop several strategic alternatives and several scenarios of market behavior. The issue of developing strategic alternatives is most relevant when introducing a new product to the market.

In the case of a new product launch, the possibilities of developing market segments are considered as strategic alternatives. In this case, the most attractive segment will have priority for development. Thus, a new product is first introduced to a priority market (the most interested customers for whom it has the highest value) and then introduced to other markets with a lower priority for development. Entering additional markets is the basis for sales growth and business scaling. This analysis is usually carried out by the commercial director, who checks the relevance and adequacy of marketing information regarding the market situation, the selected product range, price positioning, and also verifies the chosen sales strategy and confirms this section of the business plan. In the future, during the implementation of the project, the sales function and all related tasks will be delegated to the commercial director or head of the sales department.

2.2 Technology analysis. Being conducted by a team of technician specialists. This group of experts confirms that the information in the business plan is true and the company has certain skills, equipment and a production personnel is technologically and technically ready to implement the project.

2.3 Analysis of the organizational plan. This section is the most labor-intensive and requires the involvement of a large group of experts from different departments of the company. First of all, this is the HR department, which checks the possibility of providing the project with the necessary human resources and confirms its readiness to staff it according to the requirements. The need and feasibility of obtaining appropriate licenses, permits and

certificates is controlled by the Standardization and Quality Management Department. It is difficult to overestimate the importance of this confirmation, since in the medical device industry, design, purchasing, production and sales of products are regulated by strict international ISO requirements.

2.4 Financial and economic analysis for business planning. An important direction of financial and economic analysis at the stage of business planning is the assessment of the adequacy of project financing sources and the determination of their optimal structure [12]. If the project cannot be fully financed by internal and external sources of funding, there is no point in further analyzing performance indicators. At the same time, such a structure of financial resources is considered optimal, which will provide cash flows for all stages of the implementation of the investment project. It can be noted that the financial and economic analysis is the most time-consuming and important stage of the pre-investment stage from the standpoint of decision-making regarding the feasibility of investing in a specific project. Its essence is a preliminary assessment of future benefits, costs, profitability of investments and risks during project implementation. The main tasks of the financial and economic analysis at this stage should be determined: analysis of the current financial state of the company and substantiation of the priority directions of its development; analysis of investment intentions and their compliance with the company's investment opportunities; situational analysis of existing alternative investment options; sufficiency and structure of investment sources; detailed analysis and examination of the business plan; analysis of the financial feasibility of investing in this project with determination of future income, expenses, profit, profitability and payback period of the project; analysis of investment risks. When conducting a financial and economic analysis, one should take into account not only the economic effect of the investment project, but also the social effect associated with improving the working conditions of employees, raising social standards, and forming the corporate culture of the company. Such an analysis should take into account all the financial consequences of the project both from the point of view of investors, customers, and from the point of view of the company implementing the project. The final stage of the feasibility of implementing an investment project necessarily involves summarizing, analyzing and evaluating the achievement of goals and the economic, financial and technological tasks set before the project. At this stage, the economic feasibility of the adopted investment and technological decisions is analyzed. The final analysis of the mistakes made and the correct decisions is an important basis for the development of further strategies for the development of the company's financial and economic potential, the choice of methods of attracting investment funds, the growth of culture and the improvement of the efficiency of project and investment activities. When making decisions about investing in a specific project, both external factors and internal characteristics of the investment object, which determine its investment attractiveness, must be taken into account. A similar approach is used in the comparative analysis of the effectiveness of alternative projects. Analytical substantiation of the feasibility of participation in the project is carried out from the standpoint of the interests of all participants in the investment process: the investor company, external creditors (banking institutions, credit unions), the state.

Analytical assessment of its economic efficiency, which is carried out in the process of preliminary analysis at the pre-investment stage of the project's life cycle, is of decisive importance for the acceptance of the project by the investor. It is the economic efficiency of the investment project, the criteria of which is the maximization of the profitability and profitability of the investing company's activity, that serves as a primary condition for making decisions about investing in this particular project. With all the variety of methodological approaches to assessing the investment attractiveness of projects, their essence is determined by comparing the future

economic benefits from their implementation with the amount of invested funds. Main performance indicators from project implementation: payback period, NPV, IRR, P&L report etc.

2.5 Project risk analysis is one of the main directions of investment business planning and is mainly aimed at assessing the probability of the occurrence of unforeseen negative events that can affect the terms, budget and quality of implementation [13]. A group of experts is studying a pre-prepared register of risks, which reflects the types of risks, their impact, probability of occurrence, and measures to reduce their impact. Risks are classified into systematic—which cannot be eliminated through diversification and non-systematic, the impact of which can be reduced through diversification. Unsystematic lines are usually classified as:

General project risks that can have an overall negative impact on the project. For example: absence of qualified specialists, low qualification and/or general lack of initiative of personnel; the risk of incorrect forecasting of the situation.

Risks of supply chain troubles, related to the provision of the project with fixed and working capital for the successful implementation of the project. First of all, it can be:

- the risk of not receiving raw materials, components, and auxiliary materials.
- low supply discipline, failure to meet raw material supply deadlines.
- low-quality raw materials.

Production—technological risks, related to the manufacturing of finished products. May be associated with problems in the operation of technological equipment, inconsistencies between the planned indicators of the volume of production and the actual ones, and a higher cost of the finished product compared to the planned.

Commercial risks are one of the key ones and are primarily related to non-fulfillment of the planned sales plan, lower margins, dumping by competitors, and other market surprises.

The company needs to take these risk events into account. In particular, you need to assess the volatility of a key financial and commercial indicator.

Volatility is a quantitative indicator that reflects risk. Volatility is usually expressed as a percentage of the spread of annualized returns. The higher the volatility, the greater the risk. The highest volatility means the highest risk.

Back in the 1950s, Harry Markowitz developed a methodology for forming an investment portfolio, aimed at the optimal selection of assets based on the required return/risk ratio.

Markowitz's portfolio theory is an approach based on the analysis of expected averages and variations of random variables.

The birth of Markowitz's portfolio theory is considered to be the article "Portfolio Selection" published in the Financial Journal in 1952 [14]. In it, he first proposed a mathematical model for the formation of an optimal portfolio and presented methods for constructing portfolios under certain conditions. Markowitz's main contribution was to propose a probabilistic formalization of the concepts of "return" and "risk," which made it possible to translate the problem of choosing an optimal portfolio into a formal mathematical language.

After the formalization carried out by Markowitz, from a mathematical point of view, the problem of forming an optimal portfolio was a quadratic optimization problem under linear constraints. This class of problems is one of the most studied classes of optimization problems, for which there are a large number of effective algorithms.

To construct the space of possible portfolios, Markowitz proposed using an asset class, a vector of their average expected returns, and a covariance matrix.

Based on these data, many possible portfolios with different return-risk ratios are constructed.

Since the analysis is based on two criteria, the manager selects portfolios:

Searching for effective or unimprovable solutions. In this case, any other solution that is better than those found in one parameter will necessarily be worse in another.

Choosing the main criterion (for example, profitability should not be lower than a certain value) using the rest only as criterion restrictions.

By specifying a certain super criterion, which is a superposition of these two (for example, their function).

Note that short-term financial policy has worked well for small companies.

Financial damage from the realization of risk is defined as a negative impact on financial performance in terms of Free Cash Flow (FCF; operating income—capital expenditures). For unification, a valuation horizon of 12 months is used. As a basis for assessing financial damage, budgetary indicators of income and costs are used, and then it is calculated how much, in the event of a risk being realized, the value of these indicators may differ from the budgeted values. The degree of deviation from budget indicators is determined by experts with the participation of specialists in the relevant fields. Historical data, if available, is also taken into account.

In this regard, when calculating the financial model of the project, three scenarios are considered to make a decision: optimistic, basic (average) and pessimistic. Usually, a pessimistic scenario is accepted: the lowest price, minimum sales volume, and high costs.

For the preparing of business plans and project management, there are no universal models and methods that would be applicable to every company as analytical tools for business planning, but first of all, it is necessary to pay attention to such approaches to business planning that are used in the activity influential international and national institutions or recommended for practical use by leading companies in the field of investment and business consulting.

It is recommended the following basic business planning standards for consideration [15]:

- UNIDO standard (United Nations Industrial Development Organization, abbreviated UNIDO—an organization whose purpose is to promote the industrial development of countries with a market economy).
- The TACIS standard (Technical Assistance for the Commonwealth of Independent States, a program offered by the European Union to assist the CIS countries).
- EBRD standard (the European Bank for Reconstruction and Development was founded in 1991 with the participation of 60 countries of the world and many international organizations as an investment mechanism to support the market economy in the countries of Central Europe and Asia).

UNIDO—an organization fighting for global prosperity, supporting the industrial development of developing countries and countries with economies in transition.

UNIDO provides various assistance to countries with transition economies and developing countries in adaptation and development in the conditions of globalization of the economy and the world as a whole. The organization collects knowledge, information, experience, and technologies, transfers them to countries in need, and thereby contributes to the development of a competitive economy and an increase in the level of employment. The standard has the following features:

- the most simple and clear, suitable for startups, and small and medium-sized businesses, has a clearly defined organization “by-products”.
- it is used most often as a basis for formats required by banks and for various competitions.
- used in specialized programs for developing business plans—Project Expert.
- the most popular in the countries of the former CIS.
- if there are no other requirements, it is recommended to use this standard or formats based on it, as it is the most common and recognizable in the territory of the former CIS.

From the practice tests, the UNIDO and EBRD business planning standards, as well as corporate methods developed by experts from international companies such as KPMG, BFMGroup, Goldman Sachs & Co, Ernst & Young, and others, remain the most popular [16].

It is important to understand that business planning and project development is a complex process that covers many stages and, first of all, requires the presence of highly qualified management personnel to solve problems of this level.

In this regard, analytical tools can be divided into types depending on their application. These are primarily tools for investment analysis, which are used to calculate the financial model of an investment business project and programs used to automate business in general.

The use of analytical systems is aimed at solving the following types of problems that are related to business planning:

- linear programming models used to implement strategic planning tasks.
- method of calculating the critical path and PERT for operational planning, based on network models.
- methods of regression analysis, time series analysis, and procedures for processing expert assessments are used to forecast potential demand and other similar studies.
- linear programming methods are used to plan production volumes and forecast sales volumes.
- methods for constructing network graphs and diagrams to form project schedules.

For business planning, automated analytical tools are actively used, intended primarily for making decisions on strategic tasks. Requirements for this kind of software are developed based on the need to make decisions in a “development” mode. The general requirements can be characterized as follows:

- carry out an assessment analysis of the company’s business to identify weak links and bottlenecks, according to the theory of constraints.
- conduct an expert assessment and comprehensive analysis of the business plan of an investment project.
- prepare a feasibility study for raising borrowed funds for possible external financing of the project.
- assess the degree of influence of external and internal factors on the project.
- carry out a comparative assessment by analyzing the elasticity of demand to select the most promising project options.
- maximum automation of calculations of project indicators and the preparing of a ready-made investment document for presentation to financial institutions.

The above-stated requirements can be fully or partially implemented using the following software:

Wrike is a project management app that doubles as a collaborative work management tool and works well for businesses of all sizes and activities. Besides its general project management app [17]. Wrike offers customized software for some industries and team functions with pre-configured templates for tasks, workflows, and communication. It has a user-friendly dashboard with enterprise-grade tools that can be used to manage both one-time projects and ongoing tasks.

Microsoft Project is one of the best ERP project management software products, developed and sold by Microsoft. It is designed to assist a project manager in developing a schedule, assigning resources to tasks, tracking progress, managing the budget, and analyzing workloads [18].

Microsoft Dynamics 365 in the program resolved the complexity of various CRM and ERP systems, and created modern modular business applications that work together on one platform [19].

The benefits of implementing such automated systems in an enterprise save time and resources, and also make it possible to consistently implement individual modules for company resource management.

CONCLUSION

In the process of business planning of the majority of Ukrainian enterprises producing medical devices, it is possible to identify a general deficiency that is inherent in most companies that conduct commercial activities, and this is the lack of a process approach to the development and introduction of new products to the market.

This is most often recognizable factors:

- the process of appointing the project manager, project team and their representatives is not formalized.
- the process and algorithm of project implementation actions after the adoption of the business plan are not prescribed in sufficient detail.
- the process of distribution of roles and areas of responsibility in the project is not specified.
- the business planning procedure in companies, mostly directed to the formal fulfillment of the requirements of the ISO standard, than to the quality business planning and effective implementation of the project.
- the motivation system of the project team for project implementation is not defined.

From the research, arguments, scientific approaches and assumptions presented in this article, we can conclude that there is no more universal tool for business planning than an investment business plan. Companies, regardless of their industry, need to use this tool to create a solid basis for the development and implementation of new product projects, assessing their own investment opportunities, permanently monitoring the market situation and the general competitive environment.

For companies whose activities are subject to strict regulation by industry standards, in the process of business planning, it is naturally necessary to focus on their strict compliance. This study deals in particular with the ISO 13485 standard. However, carrying out business planning in accordance with modern requirements and trends will be a necessary and only correct practice aimed at obtaining truthful information that will allow assessing the correctness of the chosen decision regarding investment activities of a company.

In the modern realities of the Ukrainian economy, which has been in a state of war for three years and is waging a desperate struggle for its existence, the medical device production industry is one of the few that remains afloat and shows positive indicators of financial and economic activity. Accordingly, performing commercial activities in modern conditions requires special attention to all business processes that operate in the company. Clarity and speed of decision-making will be the key and perhaps even the only factor in business survival. Companies must respond to market needs by introducing new products (increasing demand for hemostatic agents, reorienting to modern types of dressings, targeted delivery, etc.) adequately assessing their capabilities in terms of investment and human resources.

Most companies producing medical devices have an organizational structure that is a weak matrix with limited powers of departments involved in business planning represented by project managers. This most often leads to negative consequences, namely failure to meet business planning and project implementation deadlines, untimely financing, and resource shortages. Therefore, some specific features associated with changing the classical organizational structure in companies, aimed towards a project-based one—a strong matrix, will expand the powers of project managers. This, in turn, will make it possible to strengthen the priority in the bringing of additional funds by companies and attract resources to business

planning and project implementation in the required quantity and on time. The introduction of activities related to the use of modern methods and automated programs for business planning and project management, the creation of a staff motivation system during business planning and implementation, can bring companies that produce medical devices to a qualitatively new level for successful integration into the Global System of Manufacturers medical devices and getting into the TOP 10 Global Medical Devices Manufacturers in the next 10 years.

REFERENCES (TRANSLATED AND TRANSLITERATED)

1. Pokropivnyi, S. F., Sobol, S. M., Shvydenko, H. O., & Derevianko, O. G. (2010). *Business Plan: Development and Justification Technology*. Kyiv: KNEU.
2. Tarasiuk, H. M. (2006). *Business Plan: Development, Justification, and Analysis: Educational manual*. Kyiv: Karavela.
3. Karpov, V. A. (2014). *Planning and analysis of entrepreneurial projects*. Odessa: ONEU.
4. Makedon, V. V. (2009). *Business Planning: Textbook*. Kyiv: TsUL. https://dut.edu.ua/uploads/1_1340_36766043.pdf
5. Barrow, K., Barrow, P., & Braun, R. (2005). *Business Plan: A Practical Guide (4th ed.)*. Kyiv: Znannia.
6. Kozachenko, G. V., Ponomariov, V. P., & Lyashenko, O. M. (2003). *Economic Security of the Enterprise: Essence and Mechanism of Provision [Monograph]*. Kyiv: Libra.
7. Economy & Society. (2022). *Business planning of company development: Organizational and methodological aspects of implementation*. <https://www.economyandsociety.in.ua/index.php/journal/article/view/1836>
8. Kazak, O., & Myhailenko, O. (2022). *The essence of the role of business planning in the system of enterprise management. In Research on Financial Institutions and Instruments for the Development of the State, Theory and Subjects of Government: Theoretical, Methodological and Practical Aspects*. Odessa. https://elibrary.kubg.edu.ua/id/eprint/43408/1/O_Kazak_O_Myhailenko_REFTDSTE_2022_FEU.pdf
9. International Organization for Standardization. (n. d.). *ISO 13485 – Medical devices — Quality management systems — Requirements for regulatory purposes*.
10. Levitskyi, V. (2017). *Investment Analysis in Financial Management*. Retrieved from <https://echas.vnu.edu.ua/index.php/echas/article/view/143/88>
11. Kotler, Philip. (1984). *Marketing Essentials/Philip Kotler*. New Jersey: Prentice Hall.
12. Dankiv, V., & Veselovska (2019). *Collection of theses NAU 15-17.02.2019*. https://dspace.uzhnu.edu.ua/jspui/bitstream/lib/26092/1/%D0%94%D0%B0%D0%BD%D1%8C%D0%BA%D1%96%D0%B2_%D0%92%D0%B5%D1%81%D0%B5%D0%BB%D0%BE%D0%B2%D1%81%D1%8C%D0%BA%D0%B0_%D0%97%D0%B1%D1%80%D0%BD%D0%B8%D0%BA_%D1%82%D0%B5%D0%B7%D0%B8_%D0%9D%D0%90%D0%A3_15-17.02.2019%20%D0%A8%D1%82%D1%83%D0%BB%D0%B5%D1%80.pdf
13. Sosnovska, O., & Dedenko, L. (2019). *Risk management as a tool for ensuring the sustainable functioning of the enterprise in conditions of uncertainty*. <http://doi.org/10.32750/2019-0106>
14. Markowitz, H. M. (1959). *Portfolio Selection: Efficient Diversification of Investments*. Yale University Press.
15. Kvasha, O. S., & Fomina, V. V. (2017). *Business planning in the activity of the organization: European standards, basic methodological approaches and basic procedures*. *Economy and Society*, 12, 268–275. https://economyandsociety.in.ua/journals/12_ukr/45.pdf
16. Proboyov, O. A. (2019). *Conceptual approaches to the process of developing a business plan for the development of domestic enterprises*. *Black Sea Economic Studies*, 39–2, 12–16.
17. Shweta, Cassie Bottorff. (2024). *Wrike Review (2024): Features, Pros & Cons*. Retrieved from <https://www.forbes.com/advisor/business/software/wrike-review/>
18. PMO Team. (2024). *Microsoft Project vs Monday.com: Which Project Management Tool Is the Best?*. https://clickup.com/blog/microsoft-project-vs-monday.com/?utm_source=google-pmax&utm_medium=cpc&utm_campaign=gpm_cpc_ar_nnc_pro_trial_all-devices_tcpa_lp_x_all-departments_x_pmax&utm_content=&utm_creative=_____&gad_source=1&gclid=Cj0KCQjw3ZayBhDRARIsAPWzx8o7nXEwDo2DNfAgfkbYjsxCY22NtxrHkGyE1FQ83aoEINMc6nbUBU4aAoY9EALw_wcB
19. *Business performance planning for Dynamics 365*. (2024). <https://learn.microsoft.com/en-us/dynamics365/release-plan/2023wave2/finance-supply-chain/dynamics365-finance/extended-planning-analytics-dynamics-365-finance>

Казак Оксана Олексіївна

кандидат економічних наук, доцент
доцент кафедри фінансів
Київський столичний університет імені Бориса Грінченка
Київ, Україна
ORCID ID: 0000-0003-2088-9022
e-mail: o.kazak@kubg.edu.ua

Рябик Сергій

магістр економіки, МВА
Заступник директора з розвитку, ТОВ «УКРМЕДТЕКСТИЛЬ»
Черкаси, Україна
ORCID ID: 0009-0001-8126-3763
e-mail: sergey.ryabik@ukrmedtextile.com.ua

СУЧАСНІ АСПЕКТИ БІЗНЕС-ПЛАНУВАННЯ ДІЯЛЬНОСТІ КОМПАНІЙ З ВИРОБНИЦТВА МЕДИЧНИХ ЗАСОБІВ У ВІДПОВІДНОСТІ ДО ВИМОГ МІЖНАРОДНИХ СТАНДАРТІВ ЯКОСТІ

Анотація. У статті досліджено сучасні проблеми виведення нових продуктів на ринок підприємствами, що займаються виробництвом виробів медичного призначення. Основними чинниками виникнення обмежень визначено нормативні зміни, пов'язані з необхідністю дотримання міжнародних стандартів якості в інтеграційних умовах діяльності виробників медичних товарів. Проаналізовано сутність та вимоги міжнародного стандарту ISO 13485 щодо проектування та розробки нової продукції. Уточнено диференціації між необхідністю дотримання компаніями-виробниками вимог даного стандарту та врахування найважливіших факторів для складання ретельного бізнес-планування як основного інструменту визначення стратегічних цілей компанії та забезпечення її стабільної ефективної діяльності. Представлено сутність бізнес-планування в системі стратегічного управління компанією та визначено його як систематичний процес прийняття ефективних управлінських рішень шляхом розподілу ресурсів і вибору найкращого варіанту дій з альтернативних варіантів, спрямований на оцінку доцільності обраного напрямку розвитку компанії, а також формалізацію процесу прийняття рішень щодо реалізації проекту. Доведено, що оптимальним інструментом оцінювання найбільш ефективних проектів здійснюється за допомогою інструментів інвестиційного аналізу. Окреслено методи оцінки інвестиційних бізнес-проектів: методи, засновані на дисконтованих оцінках та методи, засновані на облікових оцінках. Визначено основні аспекти здійснення інвестиційного аналізу: функції, засоби оцінювання та фактори впливу. Представлений проектний цикл стратегічного бізнес-планування діяльності компанії. Визначено аналіз привабливості бізнес-ідеї та аналіз бізнес-плану в цілому як основні компоненти проведення експертного аналізу бізнес-плану перед його реалізацією. Зокрема, визначено критерії експрес-оцінки перспективності та можливості реалізації бізнес-ідеї та основні параметри оцінки маркетингового плану та маркетингової стратегії, технологічного аналізу, аналізу організаційного плану та фінансово-економічного аналізу для бізнес-планування. Окрему увагу приділено аналізу проектних ризиків. Зокрема, наведено класифікацію ризиків проекту, обґрунтовано доцільність застосування теорії портфеля Марковича для формування інвестиційного портфеля компанії задля оптимального відбору активів на основі необхідного співвідношення доходності/ризиків. Проаналізовано та систематизовано досвід застосування стандартів бізнес-планування провідними міжнародними та національними інституціями у сфері інвестиційного та бізнес-консалтингу ЮНІДО, TACIS та ЄБРР. Для прийняття рішень щодо стратегічних завдань бізнес-планування запропоновано використання автоматизованих аналітичних засобів Wrike, Microsoft Project та Microsoft Dynamics 365. Встановлено, що впровадження діяльності, пов'язаної з використанням сучасних

методів та автоматизованих програм для бізнес-планування та управління проектами, створення системи мотивації персоналу під час бізнес-планування та реалізації, може вивести компанії, що виробляють медичні вироби, на якісно новий рівень для успішної інтеграції в Global System of Manufacturers Medical Devices Manufacturers.

Ключові слова: бізнес-планування; стратегічне управління компанією; система управління якістю; інвестиційний аналіз; проєктні ризики; управління проєктами.

Стаття надійшла до редакції 03.06.24

Рецензовано 13.06.24

Опубліковано 28.06.2024 р.



This work is licensed under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License.