

On Economic Aspects of Engineering and Automatization in the Pharmaceutical Industry

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Abstract—The objective of the study is to reveal the parameters and key aspects of engineering and automatization processes; also to propose recommendations on the pharmaceutical industry's development perspective. The main goal of the study is to emphasize the complexity of this industry and the need of taking into consideration the specifics of the medicines' production before applying the templates inherent to other industries. The methods used include comparison, internet research, secondary data analysis; archival study; working with literature; formulation of hypothesis, and graphical representation. The key results of the research are: 1) the parameters and the conditions of automatization and an engineering application are determined; 2) the approach to automatization and engineering is provided; 3) the wrong templates for bringing about innovations are revealed. The result of the study shows that the core of development lies in in ability of decision-making, not technological advancements.

Index Terms—engineering, automatization, pharmaceutical industry, innovations.

I. INTRODUCTION

The modern pharmaceutical industry has generated in itself a huge potential for innovations. Whereas it faces new challenges, this potential finds its realization through different tools including automatization and engineering. The main trend is being able to flexibly switch to a new product according to the market demands. But still, several aspects need to be taken into the consideration – among which are choosing the right time for engineering and re-engineering; also, the turning point preconditions to carry out automatization are crucial. Determining the scale of automatization and engineering is the second aspect that needs a thorough approach. Moreover, choosing the right priorities for any pharmaceutical enterprise and according to them finding the right parameters of automatization and engineering is the main goal for the industry as a whole.

II. PHARMA MARKET COMPONENTS

Pharmaceutical production is quite a complex process that includes several aspects that cover not only the industry itself but also the whole market including consumers of drugs, infrastructure, etc. First, it is needed to mention that it is a long-term process – before a certain medicine is put into production, it takes up to 8 years from its concept – as a validation needed that the drug is safe – to launch its production, according to FDA [6]. The need to estimate the market size and other parameters found its realization in a pharma economics scientific discipline that uses the principles of economic evaluation [7].

As we see in the Fig., the USA takes 1st place, with the share exceeding the sum of five countries that stand after it. It is the base to refer to this country in the first place when analyzing this market. Correspondingly, its spending on R&D in this industry is the highest. However, there is no

evidence whether this results in more drug approvals, although it is difficult to conceive of a circumstance in which higher spending would not affect drug discovery [5].

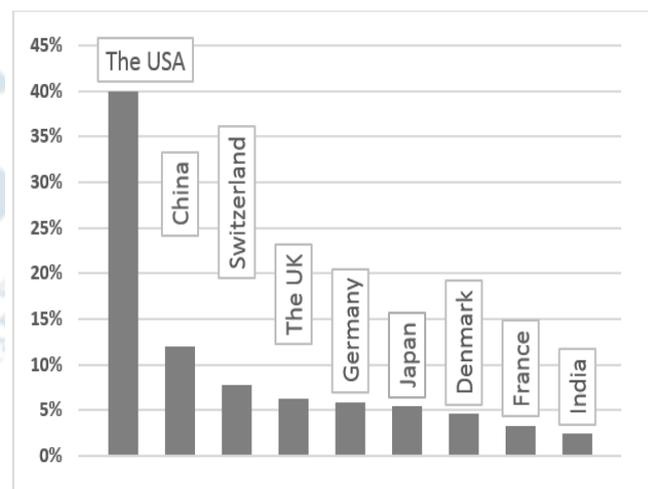


Figure.1 Value share of the pharmaceutical market worldwide as of November 2021, by country

Source: <https://www.statista.com/statistics/1246593/value-share-of-pharmaceutical-companies-worldwide-by-country/>

The main factor of production here is human capital; nevertheless, sufficient financial resources are required if we talk about this industry's main characteristic feature. The need to develop a new medicine is an obvious incentive for the industry's growth. However, the advances in research are the main impetus to the development and disregard the influence of demand considerations [1].

This industry holds about 19% of all the R&D spending worldwide [3]; additionally, the spending on R&D and corresponding productivity are correlated; but it is hard to determine any other pattern despite the increasing costs of R&D per drug [4].

III. AUTOMATIZATION AS A CURRENT TREND

Pharmacy automatization is not a new phenomenon — many pharmacies have integrated some degree of automatization since the 1960s. First automatization may be referred to as the process of counting tablets — when the Kirby brothers proposed a machine to perform this task — later spread to the bottle-filling option. An increased artificial intelligence and machine learning facilities, combined with the automated systems that become cheaper and available, made this a standard and a generally applied option.

Automatization has lots of benefits which include:

- Increased speed. Even the most experienced pharmacist or technician is slower than a machine. Automatization allows pharmacies to fill orders more quickly while freeing up human resources to do essential tasks that cannot be automated, like decision-making and maintenance; the intuition of a developer or any other specialist plays a nonetheless important role.
- Higher accuracy. Accuracy is a major concern in the pharmacy. Even the neatest and tidiest one is exposed to fallacy. Automating routine tasks can serve a big deal in the production process.
- Higher security and confidentiality. There are several aspects when contacting patients about their prescriptions or when following security protocols for drugs. For example, a pharmacy technician can leave too much information on a voicemail for a patient, whereas automated calling programs consistently only verbalize information programmed by the pharmaceutical company. Automatization can also eliminate possibilities for human errors.

The pattern nowadays is that various automatization options become more available for end-users in the aspect of becoming cheaper and giving the opportunity to even small enterprises which introduce them in their factories. What is a corner point here — the automatization in the scale of huge enterprises does really economize production as reduces costs; but what about the small industries — as their output is not as high as reaches the global scale, it is needed for them to try to avoid unnecessary inclusions — the only reason to introduce those technologies is the urge to bring certain improvements due to teething troubles. It is important to keep up to date, but, at the same time, improvements should not harm productivity. It is important to note that automatization and the related sphere are in danger of making the production process even more complicated.

Automatization not only covers the workspace — but also various applications — the so-called Optimization Sets (OpS) - approaches to automating the assembly of applications, putting them into operation, connecting and processing data, training AI/ML (artificial intelligence and machine learning) algorithms; organization of storage for storing artifacts related to algorithms, etc.

IV. FUTURE FRONTIERS IN PHARMACY AUTOMATIZATION

What about the future of automatization processes — of course, there is still much more to uncover as AI (Artificial Intelligence) developments allow to bring multivariate changes in the production process by various aspects.

The solution to the concern of whether to resist global automatization or to instantly introduce it into the production process can be seen as this: before applying automatization to the whole enterprise, we suggest to allot a department to fully introduce this automatization at work, process it for a certain period during which the personnel would be trained and the work-frame settled; then to be implemented on the whole enterprise. This is a better option rather than the gradual introduction of automatization to the enterprise which is quite wasteful. It is also good as develops specialists that work with the new technology, fully intake it, and use only the key features needed for the production.

The need for automatization to be limited to a certain extent is crucial if we talk about flexible and adaptive technologies — the system is a closed-loop without the possibility to change, add or exclude something. So, there must be no ambitions about automatization — only rational considerations on bringing those patterns into our life.

Talking about engineering in the pharmaceutical industry, we must admit that this is the key if we want to bring any industry to the level of high productiveness. Before talking about pharmaceutical engineering and the need to understand that the production process in the field of drug production or any other goods is a complex process including the various aspects related to the production line itself and the customer care, the business department, the laboratories, and all the corresponding infrastructure, we might admit that the way the workspace is established is crucial — this is the “formula” to obtain a better performance.

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crucial moments and cause further lags. The specifics of innovation processes lie in the fact that innovations should be convenient – they must be working. They are a solution – good, comfortable, and practical. Not an option or an alternative new format. Innovation must be considered as a product that was awaited – not the transition made according to the plan – this should be the core of any industry. The planned development is not effective – the substituted previous option may not be fully uncovered being replaced just according to the plan.

There must be a department in the companies that is responsible for studying the market's proposed innovations – what new solutions are suggested; what they bring about, and to instantly produce its solution according to the algorithm to “detect missing aspects and wrong patterns the competitors have” and suggest the product that might alter those deficiencies. The process must get started by informing the staff of the company of the competitors' products and – which is a very crucial thing – waiting; not launching the production immediately. Because an innovation that competitors suggest might not bring the expected effect, or may even generate a negative opinion. So, the factor of time has various opportunities in different prospects. Time management must be the top priority. It can be used as a certain approach that works in any relation – do not take all the new things or innovations, give them time – use just the sparks of the fire – not the flame.

When talking about pharma engineering, it is very essential to mention such an organization as ISPE (International Society for Pharmaceutical Engineering) — this organization is formed on a noncommercial basis – for the knowledge and experience exchange in the pharmaceutical industry. Famous engineering firms (in Germany – BilfingerTebodin) specialize in a wide range of engineering services in various directions, including pharmaceuticals production.

It is not greeted to approach engineering as “the key to have things done the right way”. There is no template or a particular architecture that, once applied, might transform the whole production process. The only rule of how engineering works is – allowing to meet a functional goal of optimization. That must be a two-iteration process which means the transformation, once planned, must be negotiated with the staff; after all the procedures are clarified and the main plan determined, the engineering can be launched.

The other aspect is the time to apply reengineering in case of a fallacy or while implementing preventive maintenance. The thing is that the failure is the reason to look at the problem in the aspect of bringing about any possible improvements – and it is quite possible that the analysis might detect the need of not simply repairing a certain chain but the technical rehabilitation of the whole production line – in this case, it is needed to use this opportunity.

To conclude about the automatization of the pharmaceutical industry, we must admit that it should not

fully cover the production site because the machines cannot take the place of a human.

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