

The Brand New Idea of Disposable Bioreactor Production in the Hungarian Laboratory Market (A Case Study for Exponential Marketing Strategy)

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Abstract: The current study is presenting a strategically new idea of investigating in manufacturing locally a single-use disposable laboratory device with scalable and suitable technology on the research and development (R&D) laboratory market field in Hungary, where non-profit (universities, academic) – and for-profit (private research and contract labs, pharmaceutical laboratories) laboratories are equipped with well-known, international laboratory instruments and devices, except for consumables, which can be purchased directly from local producers, savings retail-chain transaction fee. Thus, those Hungarian manufacturers for small plastic and glass lab consumables have found the niches on the laboratory market to cover the general needs of local laboratories on a reasonable price. The paper mainly focus on the production plan of the implementation of manufacturing locally a microbiological and enzymatic as well as wastewater management for sustainable energy consumption, membrane bioreactor (MBR) lab equipment as the tool of biotechnology for the market. As technology innovation is the main driver on this closed, narrow scientific market, the best feasible plan must be connected to new innovative scientific approach, creating yet uncovered niche market, where brand new opportunities and possibilities are warmly welcomed to set unknown research directions. The implementation of the investment contains detailed production calculation as well as applies for funding supports partly. Besides presenting a brief overview of the most important aspects based on the efficiency of the use of EU development resources towards sustainable economic growth in research in the EU Member States, highlighting Hungary.

Keywords: sustainable, bioreactor, EU development resource, laboratory market, feasible plan

Introduction

The laboratory market is a small, narrow segment with high price-sensitivity. Purchases are made through mainly public procurements, even for small consumables, where price and references are the most relevant factors to be taken into consideration. There are around less than a hundred distributors representing the well-known international manufacturers, mainly on an exclusive-base right, as sole agents in Hungary, but no local manufacturers for laboratory equipments exist up till now. R&D development and cost reduction for laboratories through innovative, cost-efficient single use lab device can be a solution for many operational difficulties laboratories are facing continuously. EU funded project for technically developed price sensitive, disposable lab equipments' such as single-use bioreactors (SUBs) versus robust stainless steel bioreactors production can cover the growing needs of laboratory researches. Junne and Neubauer pointed out in 2018 that although the scalability of stainless steel bioreactors has been investigated for more than 50 years, and many methods for the characterization of these bioreactors have been evolved, the investigation of scalability of single-use bioreactors (SUBs) contains several new challenges.

The disposable bioreactor is a state-of-art quality single-use system mainly used for pharmaceutical field in cancer research or new drug application production in medicine. Disposable bioreactor is used for modern cancer research to produce agent against cancerous cells by gaining antibody from a cured host body and transposes into the mammalian cells (Lopes et al., 2015) Membrane bioreactor (MBR) is also a well-established, mature technology with many full-scale plants around the world treating municipal and industrial wastewater (Meng et al., 2011). The recent R&D advances in MBR technology with regard to energy demand reduction is being the technology key challenge and important aspect of MBR functioning (Naessens et al., 2012). These R&D efforts and continuous interest in MBR technology has led to an increased number of academic publications and MBR-related reviews in the recent years (Krzeminski et al., 2017). Key challenges facing the developers and end-users of single-use bioprocessing technologies include their limited scale, the restricted diversity of options, the lack of standardization, and some remaining performance issues that can be addressed by further research and development (Gottschalk, 2010), which must be overcome during the planning of implementation.

The current case study introduces a local trading company, who intends to implement the production of single-use, disposable bioreactor, is on the laboratory market representing several international companies on an exclusive-base trading

right for almost 30 years, but has not had its own production on lab equipments such like any other similar Hungarian distributor companies. The company has realised and come to the idea, using its long years experiences and deep market knowledge that there is a good opportunity arising on the market to manufacture an outstanding laboratory device, but market research has to be done by gathering relevant information prior to the preparation of the project, mining only relevant data and insights concerning and supporting a successful execution.

The scrutiny provides detailed destination plan with financial background for the implementation of a biotechnological tool used frequently in microbiological laboratories. The growth of single-use manufacturing technologies is anticipated to reduce biopharmaceutical manufacturing costs and several recent innovations have facilitated the implementation of integrated manufacturing facilities based entirely on single-use technologies. Schukla and Gottschalk (2013) anticipated that all these areas will expand significantly in the years to come, bringing disposable technologies to the forefront of biopharmaceutical manufacturing in both clinical and commercial manufacturing settings.

EU funds support

The European Union's latest growth strategy, Europe 2020, called 'An European strategy for smart, sustainable and inclusive growth' contains targets for public and private R&D investment in order to provide a stimulus EU competitiveness, as the main objective of country's development, with the key indicator of efficiency set to ensure the strategic goal of 3% of GDP. According to the publication of Gorzelak (2016) the 2014-2020 period could be the final phase of substantial Cohesion Policy (CP) transfers to the CEE, and this programming period has an increased focus on innovation and R&D support. Petrariu et al. (2013) reveals in their study that development level of a country is the engine of innovation, allocating funds to research and development is the main source of support offered in this respect. The CEE countries had a rapid economic growth, but a growth not based on the innovation process. Innovation is in a catch-up process, related to the growth rate (Petrariu et al., 2013). In Hungary, grants paid from EU Structural Funds related to the 'Science and Innovation Program' of the New Széchenyi Plan, co-financing innovation activities was EUR 680 million over the period of 2010 to 2013. One of the most important components of innovation-specific EU-funds supports higher education institutions' research and research infrastructure development expenditures. (Eurostat statistics, 2018 March) With these funding's supportiveness can be a background for the implementation of the R&D tool.

1 Methodology

The authors attempt to use the concept of Exponential Marketing Process for planning the new direction by producing disposable – single-use bioprocess mixing system - bioreactor locally on the Hungarian laboratory in the aim of a long-term success, instead of the usual standard, 'old fashioned', 'unproductive' marketing process for a non-sustainable business result.

Methods will include the following

- Destination planning
- Value Diagnostic
- Brand architecture
- Fully integrated communication

The planning starts with a current evaluation of the laboratory segment. The market evaluation is carried out by multiple research methodology, where the process of discovering customer needs is done by specific scientific directions. Unfortunately, advertising agencies cannot come into terms, while creativity is not functioning on this market in the common sense, only scientific knowledge.

Currently there are no local manufacturers in Hungary for high-tech laboratory devices, only for small lab consumables. All general laboratory devices or specific analytical instruments are being produced by international manufacturers leading back to some thirty, forty to sixty years of history with great scientific and technical experience. Taken the present market situation into consideration, there is an outstanding opportunity for Hungary, situated in the centre of middle-east Europe, to find a niche segment in the laboratory market, where there is an intensively growing need for specific laboratory equipment, for setting up a small production facility, manufacturing a certain kind of laboratory device.

It is not easy to identify the right niche, which needs are not yet served and fully covered by international supplier and still gives enough potential possibilities for long-term strategy. As high-tech analytical instruments or complex specific devices cannot be competitive besides the experienced international suppliers, the right decision had to be made by 360 degree of market valuation from all known suppliers as well as customers. The market research has to be carried out concerning not only American and West-European laboratory equipment's manufacturers, but also the emerging market; especially China has to be considered from this aspect. The aim was to find a niche market for specific research area where local laboratory products can be launched into the market, beating the currently available laboratory devices with a brand new idea on an international level and skim price-wise the market segment.

First step of destination planning was to find an idea to break through the presently available scientific equipment after carefully examining the whole laboratory market from research and development aspects. To be able to brainstorm new ideas on this special market, one needs many years of market knowledge and experience both on demand and supply. Western countries suppliers are way ahead in innovation technology, which is the most relevant key factor in this market. Besides in the last decade, the market is restructured by Chinese manufacturers' price- and also quality-wise. At the beginning of 2000, Chinese manufacturers mainly copied technical specification of western-made products, but nowadays they put more and more investment into R&D, which might mean presumably a threat to the Western World on long-term.

The process program has to be a strategic guide towards business growth in its meaning by achieving sales volume as well as the set profit goals for the company and its targeted customers. Also it must deliver clear communication and sales strategy in alignment with the set objectives. And lastly it is important to be defendable that the strategically idea and methods of success should not be acquired or copied by competitors. The production has to be protected by technology patent.

The three processes have to comply with the following tasks:

Meaningful: finding the gap for special needs of the customers by examining the scientific research fields, where new applications and validation methods can be discovered by a supporting new design with compelling value proposition.

Deliverable: messages as well as set strategic objectives have to be delivered by the right types of communication channels to reach out for the right target group. It has to be a long-term concept with integrated multiple campaign and consumer touch points that can be easily understood to the target group. Investments have to be well-balanced by the expected and calculated sales goals as part of the future growth plan.

Defendable: as it is a scientific special product, with a secret know-how production technology supported by a protected market or even patent, the gained success cannot be acquired by competitors on the segment. Material to be used for the laboratory device is under strict FDA and EU regulation control, same compliance as for medical devices; therefore production is highly protected and not easily copied by manufacturers.

The main aim of effectuate a successful business through investments is by putting great focus on development of a customer-focused products by constant, up-to-date technical service, instead of functional benefits only.

The ideal objectives must contain a top-down reflection of the company's mission and strategy, addressing current future success, as the whole planning is rather forward-looking. The targeted market is one of the main profitable and highly

driven by the latest research results, the pharmaceutical industry field is a promisingly developing research background for the future. The planning also includes and integrates external and internal measures to examine trade-offs between performance measures in the past and future success prospect.

Value Diagnostic

As the product was already introduced in the planning section, it is a brand new idea of a disposable, single-use system, proactive and very useful in the laboratory pharmaceutical, microbiological and wastewater management market. Therefore lots of data has to be gathered as well as collected for value diagnostic customer value driven concept. The customers' scientific knowledge and research experience is essential for setting up the production technology to be able to give the professional end-users the solution they require for their application methods. While it is proved to be a technology-specialized, innovative and product-focused scientific market, where international, well-known companies are competing with each other. Determining requirements of the laboratory market the continuous technological improvement which often targeting to satisfy customers' latent demands. It could be useful to consider implementing well assembled Quality Function Deployment (QFD) functional system based on customers' needs and share its measures and results with the manufacturers continuously during the product development process. In the centre of development quality assurance shall be essential. QFD system complies with both the declared and latent demands of the customers and its main target to produce a quality product focusing on the satisfactory of the clientele.

In this project the authors attempt a diagnostic approach on the laboratory equipment market and execute the whole process to enable to break through with a new idea which is unknown to the local laboratory market. Taken the international market into consideration disposable, single-use system for a laboratory device is not a common solution yet, but the needs for single-use system starts to accelerate in the laboratory market.

a. Value Diagnostic Results – Identify Key Growth Opportunities

- Target Consumer Assessment:
- Target Buyer Assessment:

These two can be considered as the same target group in this case, as conventional consumption in this sense is not a relevant term. Buyers are end-users here, working in laboratories and carrying out professional scientific researches, which can affect human lives and common future towards sustainability. So business success simply lies on scientific decision.

- Brand and Product Portfolio Assessment

Brand positioning is always easier if the manufacturer's background is leading back to several decades of experience and having significant reference lists world-

wide in its sales history. In the present project the company has to face difficulties concerning production knowledge, which has to be overcome by professional customer value driven approaches, such as demo-unit availability and application consultancy. The product portfolio will be considered as an outstanding product possibility. Advantages cited for single-use system, such as increases in batch success rate, eliminating potential cross contamination, more rapid changeover between campaigns, reductions in water and waste water requirements, and eliminating clean-in-place (CIP) and stream-in-place (SIP) validation (Barnoon et al., 2008).

- Related Product Assessment

Related product from the customer's aspect is assumedly professional scientific education on this research field, while from the product's point of view is disposable plastic, single-use products are becoming more and more popular in everyday life, and so as in the laboratory segment concerning consumables. They are easy to use, practical products, but it has to be emphasized that the lifecycle approach does not always have positive effect on sustainability, especially environmentally.

- Current Performance Assessment

The company is well running business enterprise, already with a good reputation in the laboratory market. It has promising opportunity in production area as the first mover in this field. Detailed calculation for investment will be presented shortly. Also the net present value (NPV) saving will be introduced for single-used system versus conventional device implementing a scientific article for such purposes.

- Competitive Assessment

There are several international bioreactor manufacturers worldwide, but most of them are not specialised for disposable bioreactor, while its operational field is narrower, than stainless-steel conventional bioreactors, but extremely useful and can be profitable from the producer's point of view. Local competitors are not existing yet and only a couple of international ones (Sartorius Inc., Solida Biotech, Eppendorf) can be found worldwide. No Chinese manufacturers so far, which is very positive fact for the execution of the local production. Western competitors will be easier to be skimmed price-wise.

b. Some Key Value Diagnostic Questions

What are the current customer attitudes towards the brand? Are there any limitations?

The only limitation on the laboratory segment is the specified niche market to be targeted concerning the research field, where the product can be successfully used. For pharma field single-use system supports the best practise with high value in this field. The advantages are much more significant and incomparable to the

conventional bioreactor. The success on the market lies on the efficient marketing communication towards end-users by highlighting the main factors. Single-use systems have large positive impact on the layout of a facility and also may affect automation strategies, clean utility requirements, floor-to-floor heights, project timelines, procurement schedules and even area classifications like heating, ventilation, and air-conditioning (HVAC) design. Facilities that use only single-use processing sometimes realize substantial advantages over conventional designs, but tend to be limited in scale. Space is a commodity in laboratories. Some steps have to be taken to reduce the amount of space needed.

What are the different usage purposes for specific brands? How does that differ from the rest of the portfolio? What are the main differences?

Conventional stainless steel bioreactors are designed for more extend usage for several other industrial fields, such as food and beverage, pharmaceutical, cosmetics, etc. Those manufacturers, who produce single-use systems, all have the same technical specifications (specs). Laboratory devices cannot stand out or to be differentiated by application methods or in this case designs. They could vary in control units in software and automation technologies.

What are the possible competitive reactions?

Once single-use system achieve the expected reaction and proved to be economically sufficient, other international manufacturers will be awoken and taken by the opportunity that the business idea is excellent. The targeted niche is small and specific, but the scientific background, cancer research is so up-to-date and increasingly important for the future, so the market is expanding continuously. Pharma as a for-profit company, is financially a strong player on the laboratory market.

What is relevant to communicate?

Professional research applications must be clearly communicated at conferences and exhibitions. Also professional application consultancies can be made through personal visits. Providing demo-units for trying out for a few weeks can be also advantageous. Not only visibility is important, but physical usage in laboratorial circumstances. It has to be emphasized that the product is innovative bioprocess equipment, providing outstanding bioprocess solution on the market.

Brand architecture

Brand positioning is highlighting the benefits and product differentiation in customer value on the laboratory segment, targeting pharmaceutical field. The distinctive advantage, so called competitive advantage, is the perceived difference in the customer value. Awareness is irrelevant concerning the product on the market. The aim of brand architecture and brand positioning at the company, is achieving customers to understand brand's value, delivering customer value.

During the process of brand positioning more efficient and effective brand communication tools have to be implemented.

Marketing is a science from this aspect, so using the right kind of tools combination is essential for the business success. Positioning is not some miracles done with the product, is how to position into the customers' heads. As bioreactor is a research product, it has to be approached by scientific knowledge and professional application consultancy.

The single-use system has several advantages versus the conventional stainless steel bioreactors. Single-use systems reduce capital cost, but the right targeting is the most important as in many cases life cycle costs can be increased. A scientific article proved in BioPharm International by Barnoon et al. in 2008 that in many applications, capital savings are offset by increased operating costs. Another scientific article states by Gottschalk in 2012 that the environmental benefits of the reduced energy demand can be said to outweigh the increase in solid waste generated by the disposal of single-use devices.

Functional benefit is very important in this case. Actually is even more important than service, as repair and maintenance do not come into picture for the disposable unit. For other laboratory devices, equipment service is a highly value added product.

Brands are containers for the total crucial experience of customers (zip of values). The brand new brand is very promising and provide special experience, furthermore develops relationship between the sales team and the customers for longer-term.

What makes a great band? It has to be creditable, delivering promises and well-educated towards researchers on this market. Creditability is one of the main concerns in research field. All factors and circumstances must meet the FDA, EU regulations requirements and has to be ISO standard proven.

Once the brand architecture is successfully built on the laboratory market and the device launched in an appropriate way. The company's aim is to consistently enhance the reputation and integrity of its clients in the segment. As laboratory market is a very closed, small and specific field 'word of mouth' will spread rapidly. The more references the product achieve, the easier it will be to strengthen its position. It would provide a free way to public procurement, which is the most common purchase source, especially for low-budget non-profit sector.

Fully integrated communication

Fully integrated marketing communication is needed with immense capacity to provide bespoke and premium 360 degree communication and marketing solutions to the customers. The company is passionately and irrevocably committed to satisfactorily delivering high-impact results to all its clients. As the product is

serving a scientific research field, traditional tools do not always bring success. Messages have to clearly forward to customers.

Creating marketing content to the related market segment:

- Brochure
- Application Notes
- Battle Cards (Internal documents)
- Video on educational purpose
- Customer testimonial.

Best practise is personal visits in this market. Direct marketing can be used to be informative, such as:

- └ Company's own database,
- └ Webinar,
- └ LinkedIn,
- └ Application Notes,
- └ Leaflets
- └ e-Blasts.

Marketing communication can be made through EDM, E-Alerts and Application Notes. Printed advertisements can be published in the following papers:

- Technology Networks
- Eurolab
- Analytical Scientist
- Separation Science
- LCGC Europe

Multiple research methodology can be implemented to find out customers' needs for the product. Content is more important than anything else in this scientific market. The aim is to build up long-term loyalty, which lies on creditability and trust in the product. Highlighting Functional benefits is the main concern in this matter; however the product's launch has to include also some emotional aspects, even though it is a purely scientific product for research and development purposes. The emotional part could cover certain empathically feeling for cancerous diseases and other kind of sicknesses. Researchers are deeply committed to the subject with high-level of emotional intelligence. Through emotional approach great value can be delivered to the customers.

In this field ‘above the line’ (ATL) and ‘below the line’ (BTL) marketing communication are rare approach to be successful on a scientific market. Concerning ATL tools only scientific publications can be mentioned and their effect are being measured as results. Media spots and internet banners have no relevant roles in this market as the target group is relatively small. For BTL only e-Blast and flyers can be counted as possible marketing communication tools, but sales goals cannot be accounted to these kinds of promotions on a bigger scale. However, Integrated Multiple Consumer Touch points have to be implemented during the marketing process through conferences attendances, demonstration instruments, scientific workshop, trading shows as well as technical application consultancy, as an exponential-based concept. Giving out demo-devices for testing is essential for the end-users to have the opportunity to try the product out in their own laboratories for research purpose. Personal experience can built loyalty. Once the product has some positive feedback from end-users’ own research experience, it can be communicated as references on the market, which is the main step of the so called ‘Persuasion Hierarchy of the Motivation Architecture’. Thus scientific collaboration with key-account customers is suggested to develop methods.

2 Performance Alignment

The very first milestone is the idea to be born to be a market product at a later stage, as Value Proposition of setting plans. During the planning and construction phase controlling panels and milestone goals are set.

For the financial implementation credit has to be borrowed. After careful consideration and market research, Széchenyi Loan of 25 million HUF, will be the solution. It has an extra handling cost and transfer fee of 500,000.00 HUF, which is already built in the Investment cost calculation. Another possibility is to apply for EU funds supporting R&D innovation technology for a more efficient research.

As profit margins for membranes are lowered but as the overall MBR market itself grows, it is expected that many more mergers, acquisitions, and divestitures will take place. (Krzeminski et al., 2017). The economic benefits of disposable technologies are becoming more important because biopharmaceutical manufacturers are facing increasing pressure to reduce product costs while maintaining product quality (Walsh, 2010).

Table 1. describes the cost savings based on a scientific article by Barnoon et al. published in BioPhram International in 2008, for a conventional, stainless steel bioreactor versus a single-use system. It can be detected that the savings are significantly huge, more than 8,000 Euros, which can convince costumers for certain, taken all the positive factors into consideration as extra advantages.

Equipment deleted				
QTY	Description	Price (USD)	Lange factor	Total (USD)
4	100L buffer hold tank, portable	70.000	1,5	420.000
4	300L buffer hold tank, portable	105.000	1,5	630.000
2	400L buffer hold tank, fixed	100.000	4,0	800.000
4	600L buffer hold tank, fixed	120.000	4,0	1.920.000
2	2000L buffer hold tank, fixed	150.000	4,0	1.200.000
1	500L buffer prep vessel, agitator, vent filter	90.000	4,0	360.000
1	1000L buffer prep vessel, agitator, vent filter	105.000	4,0	420.000
1	4000L buffer prep vessel, agitator, vent filter	125.000	4,0	500.000
2	CIP skid	350.000	3,0	2.100.000
Subtotal deletions				8.350.000
Equipment added				
QTY	Description	Price (USD)	Lange factor	Total (USD)
8	2000 L fixed bag holders w/load cells	20.000	1,3	200.000
20	500 L portable bag holders	3.000	1,3	75.000
35	100 L drums w/ dollies	300	1,0	10.500
Subtotal additions				285.500
Total equipment savings (USD)				8.064.500

Table 1.: Capital savings for single-use buffer bags based on the scientific publication by Barnoon et al., 2008

In Table 2., operation costs can be observed for disposable bioreactors. Same effects can be observed for every day working costs, as in Table 1. demonstrating equipment expenditure for buffer bags and hold tanks. It is clearly depicted, that single-use system proved to be economically more favourable. Not to mention the advantage concerning laboratory space, as it is always one of the main issue in laboratories shorten in space.

Item	Cost
Validation labor rate (USD/h)	50
Maintenance cost, % of direct costs (QA)	3,0%
Water used per buffer CIP (L)	2000
Buffer preps per batch, base case	7
Buffer preps per batch, single use	3
100 L bags used per batch	5
500 L bags used per batch	3
1.000 L bags used per batch	1
1.500 L bags used per batch	2
3.000 L bags used per batch	1
Labor hours per CIP	1
Labor hours per SIP	1
Labor hours per bag set up	1
Labor hours per buffer prep	8
Commission hours saved	3.652
Qualification hours saved	3.712

Table 2. Rates and quantities used to estimate operating cost savings for single-use systems: Items which are assumed to be constant or which only affect the first year based on the scientific publication by Barnoon et al., 2008

3 Results

Once the Value Proposition is done and ready to be accomplished, Delivery Promise of how to reach the target has to be implemented. Goal realization has a strong financial implication to be calculated.

Profit Calculation for a Single-Use System:

Revenue:

The market price of a pair of single-use system:

Euro /1,000.00

Investments:

The production price for 2 pieces is around:

Euro /450.00

Technical development engineering of the system:

Euro /15,000

(min. 60% of total prototype investment)

150 pcs of Prototypes for launching, testing:

Euro 33,750.00

Labor cost, bank credit cost:

Euro 25,000.00

Marketing costs:

Conference attendance (local) as exhibitor:

min. Euro 500-1,000

Conference attendance (international) as exhibitor:

min. Euro 1,500-3,000

(Depending on the rented square meters)

Brochures (500 pcs)

Euro 500

Total expenditure (for launching, start-up period)

min. Euro 78,000

(Minimum investment is calculated for only one international and local conference attendance, excluded personal visits and labour force costs)

Target group:

- 5-6 big pharmaceutical companies (Teva, Richter, Egis, Sanofi, Mylan)
- several (around 40-50) small private pharma laboratories

Calculation for Return-on-Investment equation

$$78,000/1,000 = 78$$

Minimum 78 orders have to be received for returning the starting investment in to the project. The goal is to reach at least 10-20 orders for the first year and 30 more for the year after. Investment has to be returned by the 5th year to be successful, concerning normal profit with positive NPV calculation.

Within the near future (in 5 years) increasing or stable growth of EBIT margin allow for further investments. Expanding sales activity towards the Central East European countries (CEE region) followed by some successful trial period in Hungary. Export activity based on a single-distributor channel, where there will be solely one representative appointed to be responsible for a certain region by achieving yearly sales goals to be set.

Conclusion

Product efficiency has to be evaluated, by questionnaires and deep interviews with the end-users prior to the production. During market research Outdoor communication can be opened with gather all relevant information for customers' needs to be integrated into the technical specification of the product. Producing laboratory instruments for demonstration goals can lead to loyalty by Indoor communication for setting up a supportive reference background. Feedbacks must be gathered and followed-up by customer's opinions to be successful in the laboratory market. End-users' personal research experience and knowledge have to be spread and shared in this scientific niche market segment.

Single-use technologies began as an innovative alternative to fixed equipment. In Schluka and Gottschalk conclusion remarks in 2013 the increasing pressure on capital and operating costs, the risk of product cross-contamination, and the cost of cleaning validation all conspire to push manufacturers away from fixed equipment and to embrace the significant advantages of disposable processes. The growth of single-use manufacturing technologies is anticipated to reduce biopharmaceutical manufacturing costs. Several recent innovations have facilitated the implementation of integrated manufacturing facilities based entirely on single-use technologies. The authors anticipate that all these areas will expand significantly in the years to come, bringing disposable technologies to the forefront of biopharmaceutical manufacturing in both clinical and commercial manufacturing settings.

References

- [1] Barnoon I., Bader B. (2008) Lifecycle Cost Analysis for Single-Use Systems, BioPharm International.com
- [2] Gorzelak G. (2016): Cohesion Policy and regional development, in Bachtler J., Berkowitz P., Hardy S. and Muravska T. (eds.) (2016) EU

Cohesion Policy: reassessing performance and direction, Abingdon, Routledge

- [3] Gottschalk, U. (2010) Disposables in downstream processing, In *Advances in Biochemical Engineering/Biotechnology* (Vol. 115), pp. 171–183, Springer
- [4] Jacquemart R, Vandersluis M, Zhao MC, Sukhija K, Sidhu N,
- [5] Stout J: A single-use strategy to enable manufacturing of affordable biologics, *Comput Struct Biotechnol J* 2016, 14: 309-318
- [6] Lopes AG (2015) Single-use in the biopharmaceutical industry: a review of current technology impact, challenges and limitations, *Food Bioproducts Process* 2015, 93:98-114.
- [7] F. Meng, S.-R. Chae, H.-S. Shin, F. Yang, Z. Zhou (2011) Recent advances in membrane
- [8] bioreactors: configuration development, pollutant elimination, and sludge reduction, *Environ. Eng. Sci.* 29 (2011) 139–160.
- [9] W. Naessens, T. Maere, I. Nopens, (2012) Critical review of membrane bioreactor models
- [10] *Technol.* 122 (2012) 95–106.
- [11] Pawel Krzeminskia, Lance Leveretteb, Simos Malamisc, Evina Katsou
Membrane bioreactors – A review on recent developments in energy reduction, fouling control, novel configurations, LCA and market prospects, *Journal of Membrane Science* 527 (2017) 207–227
- [12] Petrariu I.R., Bumbac R., Ciobanu R. (2013): Theoretical and Applied Economics Volume XX, No. 5(582), pp. 15-26)
- [13] Solida The Next Generation Bioreactor brochure material
- [14] Stefan Junne and Peter Neubauer, How scalable and suitable are single-use bioreactors?
- [15] *Current Opinion in Biotechnology* 2018, 53:240–247
- [16] Walsh, G. (2010) Biopharmaceutical benchmarks 2010. *Natinal Biotechnology* 28, 917–924
- [17] https://ec.europa.eu/eurostat/statistics-explained/index.php/R_%26_D_expenditure