

Flexible and Agile Facilities of the Future

Synopsis

The health care sector requires more and more specialized products, which might only be used by a small groups of patients, and the regulatory authorities supports this trend by offering different kind of accelerated approval processes for this type of products. Topping this with an increased focus on reducing manufacturing costs and less predictability of the future demands for different products the increasingly expanding product portfolio, demands more flexible and agile facilities.

A broad range of tools needs to be activated to meet this requirement for a new type of facilities and manufacturing strategies, which include modular approach, Single Use technologies, continuous processing and new operational models.

Some of us are old enough to remember the good old days of pharma manufacturing, when the world was fairly predictable. Pharmaceuticals was a good investment and the performance was stable in most companies, and the only cloud on the sky was by the outlook to big patent expires, which however was quite a few years out in the future. Most companies had big investments in dedicated facilities or facility expansion for their upcoming products with blockbuster potential. The most far-sighted companies understood the value of a product pipeline, why large investments was directed to R&D activities, which mostly was done in in-house. However, some companies were also looking outside, searching for potential acquisitions targets to expand the number of potential blockbusters in their portfolio.

The new pharma reality

This was actually the situation only a little more than 10 years ago, but we now live in a new and different pharma reality. Some of the most profitable facilities from this past time are now "aging facilities". Some of those facilities are today causing the biggest cost in pharma manufacturing, as the companies struggle to maintain in regulatory compliance, while still keeping them efficient and reliable. The good news for the ones who have seen the writing on the wall, is that the new pharma reality is much more dynamic, global and



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harmonised. The bad news, and that is actually for everyone, is that making good predictions for the future demands and product mix, is not an easy task. The new pharma reality requires agility and flexibility, and it a major challenge to introduce this in your operation, if agility and flexibility are new words in your vocabulary.

The playground has also changed. Pharmaceutical manufacturing used to a centralized operation, done at few large facilities in US and EU. Today pharmaceutical manufacturing trends to be de-centralized and performed in a wide global network of facilities. Keeping several facilities, that might make same product, fully utilized and operating efficiently is a huge challenge. On top of this, the players have to accept the complexity of predicting future demands, due to increasing competition from generics and biosimilars, pressure on drug prices, reimbursement policies and uncertainty of the local/global political situation and associate requirements.

The old blockbuster products were mainly for big markets of traditional medicine. It was large volume products, with a relative low unit price. The key focus was to make the production as effective and robust as possible by using 24/7 operation with as few stops as possible. Due to the unit value of some of the new pharmaceutical blockbusters, they are produced in fairly small volumes, by complex processes. Several of the new products are quite expensive, why takes much lower production volume to produce enough for the sales mark of one billion US dollars. As a result of this, the same facility should preferably be able to produces several different products, why the key differentiator and focus area today, is how to make the change-over time as short as



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possible. Existing facilities might take weeks or even months to change the production setup from one product to another. The future winners of the manufacturing races, are right now designing and building facilities where product change-overs, are done in days or maybe even in hours.

Another aspect in the new pharma reality is that some of the new products are approved much faster than just a few years back. There are many factors behind this, both on science, regulations, technology and practical experience. So far only few companies have been able to cope with the fast approvals and market takeup of new drugs. The best examples on this are some of the newest products from the last couple of years that have made a huge difference for the patients they are targeting. Those products are well known, even by the general public that has been waiting for cures and treatments like this to finally show up. One example among many, are the recent advances within oncology treatments.

Those trends and changes in the pharmaceutical industry are requiring changes on many levels, and not at least on the manufacturing side, where this new pharma reality requires an increased focus on flexible manufacturing solutions. This goes for the facilities currently are being designed and built, but also for how existing facilities are operated and upgraded.

Flexible manufacturing solutions

The planning of pharmaceutical facilities requires new solutions to provide the necessary agility and flexibility for the new pharma reality. Intelligent automation being one. Modern pharmaceutical manufacturing is highly depending on well-controlled computer systems and much of the automation infrastructure is becoming old - not ready and fitted for the business and regulatory requirements of the future. A number of solutions are available that builds on top on the basic controls on equipment and process units. These are naturally important in a broader context to achieve high flexibility and intelligent integration, but they take careful planning in cooperation with specialists that knows the commercially available solutions and their benefits as well as the potential pitfalls.

Looking 10 years ahead, it is hard to imagine that the pharmaceutical industry that are not taking advantages of the development in the robot sector. In fact, the pharmaceutical industry is lagging far behind in the use of robot technology, compared to most other industries. Despite the fact that there are increasing numbers of industrial robots ready to be implemented in the strictly regulated pharmaceutical industry, the uptake of the technology is still far from impressing. Flexible solutions for aseptic processing, high potency substance handling, complex assembly processes etc. requires robots and offers huge advantages, which only few companies have realized today. It is also worth mentioning, that people

are the primary source of contamination of unwanted substances in pharmaceutical products. Minimizing the number of people directly involved in the manufacturing processes, will reduce the number of batch failures due to human errors and contaminations. Another positive side effect is the reduced requirements for expensive clean room facilities and all the time consuming and costly gowning procedures.

The overall system integration is also advancing a new and higher level - by some called Industry 4.0 - which is a central part of flexible manufacturing solutions in the new pharma reality. So far these technologies are so new that many consider them mostly hype with little reality, but the potential is there. As often the pharmaceutical industry might be expected to be a late adopter, but there is no doubt that it will come.

Single Use Systems for biopharmaceuticals

One of the key enablers to meet the requirements for increased flexibility has been the introduction and adaption of Single Use Systems (SUS) for especially biopharmaceuticals. SUS has proven flexible and scalable and is constantly gaining increased popularity and it is introduced in new areas. Like all other new technologies, SUS requires knowledge and good advice to on where to use SUS, and where not to move away from the traditional stainless steel solutions. A structured approach is highly advisable, and should minimally include assessment of; technical, business, product, process and implementation implications.

Thus, It is not sufficient to look through the technical solutions from the broad range of suppliers of SUS in order to plan for the manufacturing needs of the future. The real solutions required detailed planning and understanding of various technology opportunities and challenges in order to find the best combinations. SUS is definitely often an integral part of the answer, but it can rarely stand alone and does relaying on careful planning with future needs, scalability and maintainability.

Besides, SUS keeps on evolving. Nearly every week, one of the major suppliers of SUS or other equipment, announces new solutions based on single-use technology. Some include combination with stainless steel equipment and others are purely polymer based solutions. It all started with single-use bags for various liquids, followed by the successful introduction of single-use bioreactors and now, the technology is spreading into all other aspects of modern manufacturing. The drivers for this growth is not only cost of investments but not at least cost for flexibility, expansion capabilities and maybe most importantly, the reduction in change-over time.

The popularity is spreading from the upstream bioreactors

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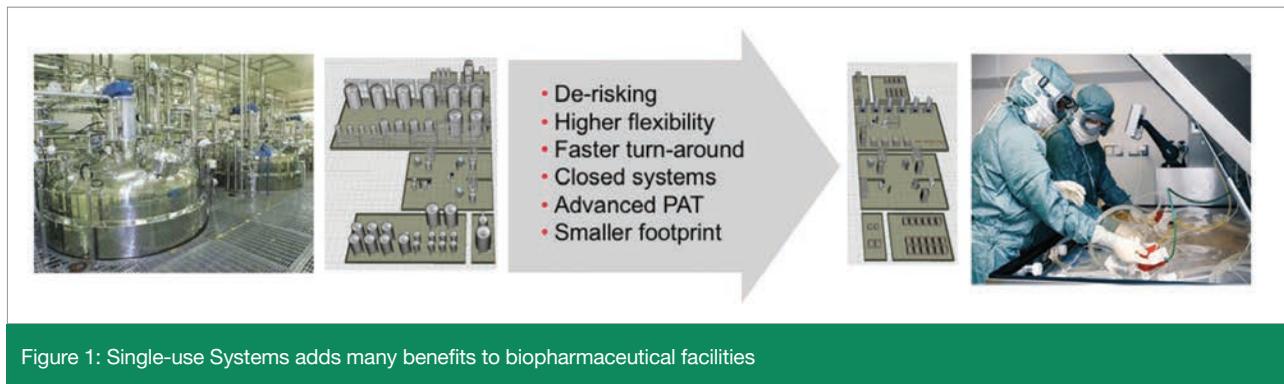
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over harvesting solutions to and increasingly widely use in the downstream operation, and even for formulation and filling of biopharmaceutical drug products. In the early days of SUS, the solutions were highly manual with low level of automation, but the new solutions typically include stand-alone control systems, smart sensors and transmitters for the single use application. This area is still undergoing significant changes but the trend is clear and these new technologies as well as their implication on support, maintenance and other life-cycle aspects should be taken into consideration.

Continuous Manufacturing

Many has considered SUS to be inherently batch-oriented manufacturing but this is no longer the case. Several SUS component are integral part of continuous bioprocessing covering the whole range of operation. Starting with supporting SUS perfusion technology in the seed train and the main bioreactor, over continuous chromatography to continuous operations in the fill and finish steps. This is only in its beginning and it is too early to predict the magnitude of the impact, but it seems likely that some applications will become widely accepted within a foreseeable future.

Related Product Focus - GE Healthcare Life Sciences

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The global biopharmaceutical market is in constant change. Yesterday, the main focus was on blockbuster drugs manufactured in large quantities. Today, the focus has shifted towards a larger number of products produced in smaller batches. With revenues under pressure, biopharmaceutical companies are facing increasing demands to develop new drugs at lower cost in an ever shrinking time frame.

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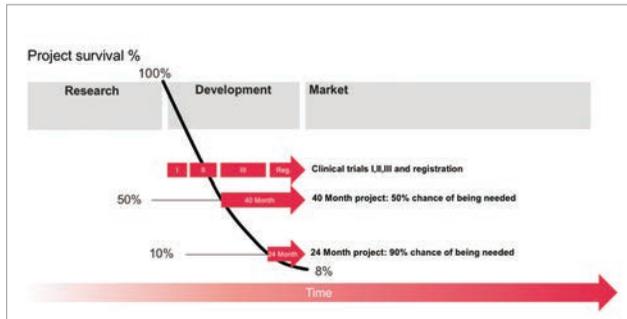


Figure 2: Time-to-market must be balanced against the change of the project survival of new a new product

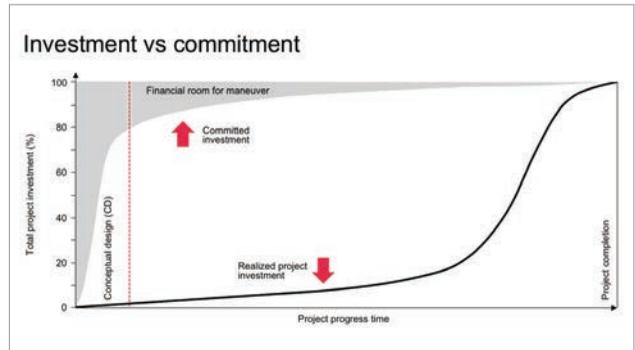


Figure 3: The early project decisions during conceptual design drives 80 percent of the project cost that are realised much later in the project

There is a significant regulatory push in the direction of continuous manufacturing, especially from US FDA but also other agencies are in favour of the advanced control strategies that are associated with continuous manufacturing. The updated European regulations on e.g. process validation and other GMP aspects are enabling this direction and it is becoming increasingly clear that industry is pushing on an open door when it comes to regulatory endorsement.

Within pharmaceutical manufacturing of OSD products such as tablets, it is becoming clear that a handful of most innovative suppliers are the enablers of industrial solutions of continuous manufacturing for commercial use. The biopharmaceutical part of the pharmaceutical industry seems a bit less mature and there is still room for the most significant players to show what the most feasible technologies will be.

Modular Manufacturing Facilities

Another key technology supporting agile and flexible solutions, are modular facility design principles. This technology is a key enabler, even it is a complex technology that needs careful planning and considerations to be the future manufacturing platform. There are many different solutions on the market and here decisions needs to be made up-front. The modular approach is part of the full facility design and it must be part of the facility project planning, including the selection of vendors, involvement of partners and the overall project execution strategy.

Modular facilities did also exist in the old pharma reality

Related Product Focus - PYRAMID Laboratories, Inc.

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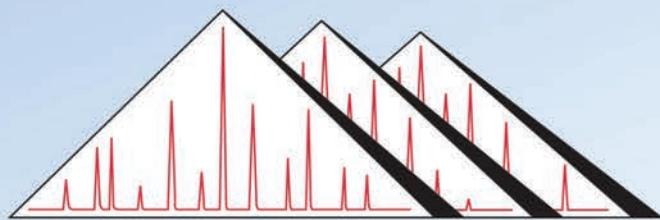
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PYRAMID Laboratories, Inc. is located in Southern California, United States. Our facilities are housed in three buildings covering approximately 70,000 sq. ft. The combination of our manufacturing facilities, analytical laboratory and new state-of-the-art product storage and distribution facility allows PYRAMID to offer the pharmaceutical and biotech industry expertise from start to finish. The new facility includes cGMP labeling, controlled temperature storage, and distribution service capabilities for parenteral drug products. PYRAMID's Warehouse and Distribution Center is located in a customized 27,200 sq. ft building next to PYRAMID's clinical and commercial manufacturing sites that include aseptic fill/finish for vials and syringes.

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and although it has been an area that has been explored in different ways, it has been remarkably to follow the recent year's development. The new generation of modular facilities includes advanced technologies that enables virtually "out of the box" cleanrooms, utility buildings or even manufacturing facilities for continuous manufacturing. These makes a lot of sense and there has been a number of successful applications based on these different modular solutions.

However, modular facilities are also a mindset and a concept. Even traditional facilities can be planned in a modular way that enables flexibility and provides highly effective execution in parallel across equipment of work-packages. In that regard the modular solutions and the many types of equipment that are available as "skid-mounted" solutions together forms a highly effective way of doing facility projects which enables high agility and flexibility - and short time to market.

Dedicated Facilities vs. flexibility and fast-track?

In the new pharma reality there is an increasing dilemma between fast-track and flexibility. The fast-to-market pressure that increasingly drives investment decisions also drives towards simple and dedicated facilities, sometimes even as copies of existing facilities or concepts from previous facility designs. This drives towards difficult decisions that balances the dilemma of fast track and flexible. Although technologies such as SUS or modular facilities can support the flexibility in the decision making, they are not sufficient to solve the time-to-market challenge.

This dilemma will increase as breakthrough products gains faster and faster approvals. In fact it has always been difficult to find the optimal decision point for new investments in facilities for new drug products because of the uncertainty of product approvals. However, this challenge is increasing when products

are approved in fast-track and time-to-market becomes the bottleneck for the business potential of a product. The challenge as well as the importance of being able to build fast and flexible are illustrated below, where the relation between the survival rate of a drug product during its development from research to market introduction is compared to the potential timeline of the facility project. It is possible to solve through the right conceptual planning, but it is not an easy task and it

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needs to be addressed already during the development phases of the product, but before a large investment decisions on e.g. building or long-lead equipment items are made.

Besides, new regulatory expectations and requirements for containment, cleaning validation and other cross-contamination measures adds to the challenges of flexible facilities in a time-line perspective. The safe decision is to make dedicated facilities just like the normal of the old pharma reality.

This is a proven concept and normally the cheapest solution in the short run, at least from an investment point of view. However, from the perspective of the life-cycle of the facility, it is often a too short term solution and frequently the dedicated facilities becomes both more expensive to operate, due to the inflexibility, or they are subjected to frequent changes and downtime in order to do unavoidable changes to the

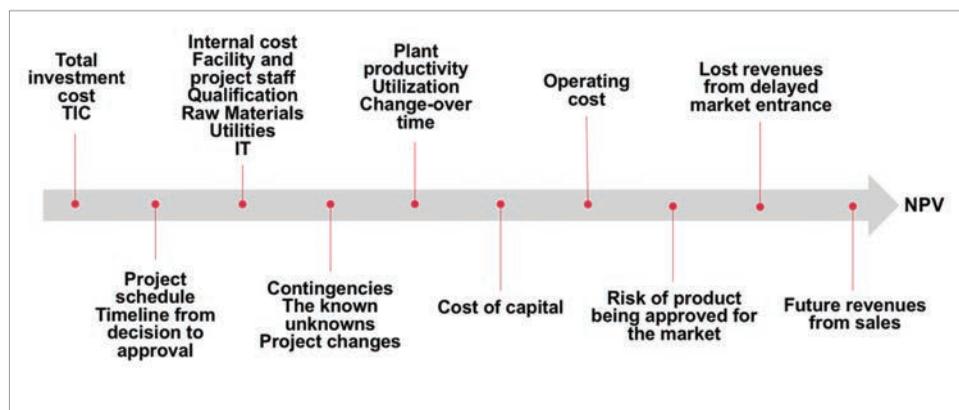


Figure 4: The cost drivers for the Net Present Value (NPV) of a facility investment

facility. Typically, changes to the product or process or there are new product variants to existing products that needs to be implemented in the dedicated facility and then the saved investments or time may be significantly challenges. The history is unfortunately full of expensive examples of facilities where a new product or just a new variant of a product have challenged the existing capacity during expansion projects, resulting in significantly negatively impacted timelines, cost and production capacities.

The answer to the dilemma of dedicated facilities must be seen in a larger context and as part of the flexibility strategy of the facility. It is possible to design for flexibility through appropriate planning right from the conceptual design stage and it is significantly more cost-effective to design for flexibility and keep the scope than to adjust the scope later. Many studies have shown that there is a curve of the relation between the cost of a facility project and the introduction of changes, as shown figure 4.

Facility investment in a life-cycle perspective

It is recommended to make the decisions on facility investments from a life-cycle perspective. Although it is a classical challenge and it is being discussed in almost all facility projects, this is

often given too low priority, leading to short-sighted decisions that pays back later in the lifetime of a facility.

One challenge is to be clear on what to include in the life-time cost of a facility. A good tool is a NPV (Net Present Value) calculation of the lifetime costs. The calculation should including all the significant components of the cost drivers of the facility, as illustrated below - not just the investment and the operating cost. The most visible components are naturally the Total Investment Cost (TIC) and the Operating Cost, but there are a number of other components that should be considered, such as the project schedule time from decision to approval, the internal cost of the facility from support staff such as maintenance functions, qualification staff, technical utilities, IT and others.

In larger facility projects, new as well as expansion projects, the contingency is significant to cover what can be called the "known unknowns". They are different in new facilities compared to expansion projects in existing facilities, but they must be counted in and estimated as a separate element in the calculation. The future plant utilization should also be estimated, even it might be difficult to predict. The plant utilization has a huge potential impact on the overall NPV of the facility, due to the differences in productivity, change-over time and equipment downtime expectations between different technical solutions.

Related Product Focus - Finesse

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Furthermore a number of financial elements should be included in the NPV, such as the cost of capital, the potential lost revenue in case of late market entry for the product in case the project runs into delays. Finally, the potential risk of delayed or failed product approvals in certain markets and - last but not least - the projected revenue from sales once the product is into commercial production. This last component is probably the hardest to predict, due to the uncertainty of the market penetration. Anyhow, it might be the most important

NPV components, due to the impact throughout the lifecycle of the facility.

The manufacturing network in the new pharma reality

Facility investments are typically not made in isolation. A new facility fits into a network of facilities, locally or globally. Most

Related Product Focus - Sartorius Stedim Biotech

SARTOFLOW® Smart

Sartorius Stedim Biotech presents new crossflow filtration system for process development
The ideal solution for scaling studies and low volume ultra- and diafiltration operations

Sartorius Stedim Biotech (SSB), an international leading supplier for the biopharmaceutical industry, announces the launch of SARTOFLOW® Smart, the smart and easy benchtop crossflow system for optimized ultra- and diafiltration applications. It can ideally be used in many downstream processes, such as purification of vaccines, monoclonal antibodies and recombinant proteins. The system is suitable for flexible use in laboratory environments for process development and clinical trials as well as for cGMP environments.

The brand new system is equipped with a low shear 4-piston membrane pump that enables highest product yields to be achieved. In addition the pump provides a wide range of flow rates allowing to choose between membrane surface areas from 50 cm² to as much as 0.14 m².

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"SARTOFLOW® Smart is a milestone development in the landscape of small crossflow systems. It combines outstanding technology with options that are normally only available with process systems. With an exceptionally wide working range of membrane surface areas, the system is the perfect tool for both R&D optimization trials and cGMP production," stated Dr. Marc Jenke, expert for benchtop crossflow filtration systems at Sartorius Stedim Biotech.

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pharmaceutical companies have international manufacturing site strategy and the trends seems to move towards a more complex and global oriented manufacturing network. Pharma companies are generally facing a pressure to establish local facilities in countries as a condition to serve the market or as part of the price negotiations. This adds to the complexity of the investment decisions and the challenge of finding the right solution to flexibility.

New facilities for local countries might typically be designed as clones of existing facilities elsewhere, which however often end up being an expensive solution. Most of the existing facilities were built in the old pharma reality and they are not made with flexibility, scalability and all the other modern requirements for pharmaceutical manufacturing in mind. This has led to a trend in the market, where companies decided to make a different design for facilities to be deployed locally in countries that are not normally part of their manufacturing network. These new concepts may be used as reference design for a number of facilities and they may contain some of the elements mentioned above, such as SUS, modular construction elements or even continuous manufacturing in order to gain the needed flexibility for the local market needs.

The important aspect of this is that facility investments can be seen in the light of the overall manufacturing network strategy. Only the largest pharmaceutical companies have a truly global manufacturing network strategy, but even small or mid-sized companies will benefit from establishing a strategy in which perspective the specific facility investment project decisions should be seen. Mid-sized companies might use those new concepts for local manufacturing facilities as their “new normal” of facilities in the new pharma reality. Because one thing seems to be constant across the old and the new pharma reality. The needs of the future are getting increasingly hard to predict and the safest approach is to prepare in order to expect the unexpected. This becomes increasingly true when operating a manufacturing network across many countries and regions in the ongoing globalisation trend.

Conclusion

The new pharma reality requires new manufacturing systems and for many companies this is more than an upgrade of the existing plants. It has to be planned for. Acceptance and adaptation of technologies and solutions supporting a more agile and flexible pharmaceutical manufacturing sector is key to meet the future challenges. The next generation of specialized pharmaceutical products

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requires a new type of manufacturing and must support faster product approvals as well as investment decisions with high uncertainty in forecasting and high dependency on flexibility.

It is possible to plan and design for the flexibility, even it is not trivial. All new technologies should be considered, supported by a structured risk based approach and include through NPV calculation covering of the whole life cycle of a facility. Additionally, global trends requesting local manufacturing and other aspects related to the international manufacturing network should be included in the strategic planning. Based on this approach, it should be possible for the pharmaceutical industry to meet the challenges of the new pharma reality.

Author Biographies

Morten Munk joined NNE Pharmaplan in 2015 as Global Technology Partner, supporting all aspects around biopharmaceutical development and manufacturing. In 2001 Morten co-founded CMC Biologics A/S, and prior to founding CMC Biologics, Morten held a position as principal scientist at Novo Nordisk.

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