

# Use of stainless steel in pharma flow & treat products will be shaped by innovation

The pharmaceutical industry needs innovations from flow and treat suppliers. The route to better products and higher profits will ultimately come from the Innovation-TCO-Profitability Causation Loop.

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## A growing industry

The pharmaceutical industry has grown much faster than other industry sectors. The pharmaceutical industry currently spends over USD \$10 billion on flow and treat products. For many years, stainless steel has been the predominant material of choice (see Figure 1).

This industry is also rapidly changing. New drugs can treat diseases, such as cancer, without harming patients. The challenge, however, is that these new drugs utilize the cells from within each individual patient to create a drug which can be used only by that patient.

Manufacturing these single-patient drugs has been a real struggle for manufacturers because the quantities are

small, and it is very difficult to switch from the previous batch to a new one without contamination.

This manufacturing difficulty is resulting in an increased use of single use technologies. The cleaning of conventional stainless steel equipment and the downtime are very expensive.

## Single-use technologies

There have been recent innovations that have been put to use that include disposable polymer-based materials. There have also been successes in innovations like combining stainless steel and polymer materials. The future market for stainless steel in the pharmaceutical industry will be based on the competition between these new designs.



An example of equipment that is used throughout the industry is a centrifuge. A centrifuge is a piece of equipment that uses centrifugal force to separate various components of a fluid. This is accomplished by spinning the fluid at high speeds inside a container, which separates fluids of different densities or liquids from solids. Centrifuges make liberal use of stainless steel materials for the housing and moving parts.

Companies like GEA, a leading provider of centrifuges, have entered the single-use separator market. The new design is said to combine the outstanding performance of larger stainless steel pharma centrifuges with the features and benefits that a single-use separator provides.

The TCO (total cost of ownership) factors will be different from process to process, and will change as the technology changes. For example, there are currently several different disposable sampling systems on the market. These systems make sampling quick and efficient, in most cases. However, they do have a limited number of samples that can be taken.

## Total cost of ownership of new innovations

Mark Embury of the American Society of Mechanical Engineers Bioprocessing Equipment (ASME BPE) and valve manufacturer, ASEPCO, recently pointed to innovative designs that could leverage stainless advantages.

"Let us say someone decides to use a bag sampling system that can only take five samples before it has to be replaced. At the same time, the process might require many more samples than five to be taken. By combining this sampling system with a stainless-steel valve, the number of samples can be unlimited by allowing the bag system to be removed and replaced after every five samples."

In a period of such rapid innovation, a new approach is needed to determine which alternative will provide users with the lowest total cost of ownership.

In the past, the leading manufacturer who had many successful installations could use their large market share to



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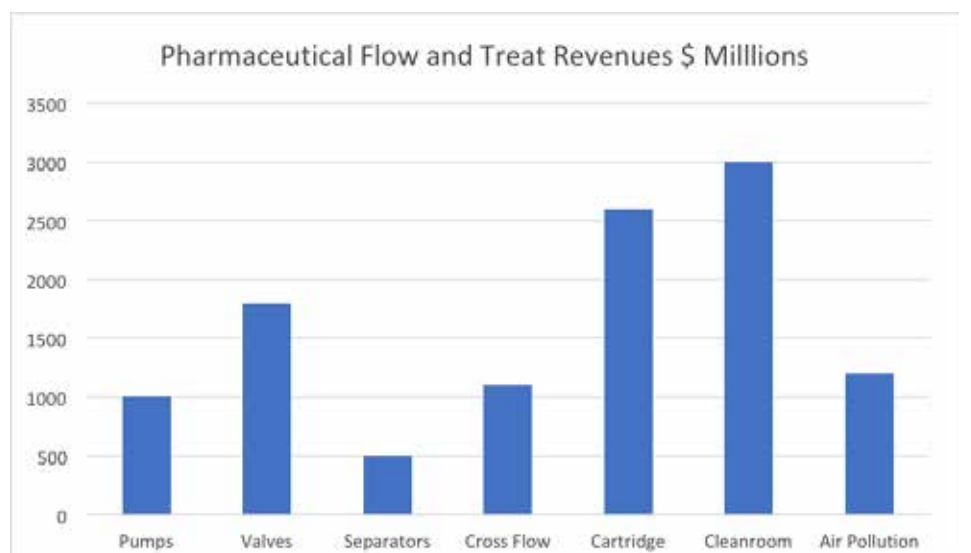


Figure 1.



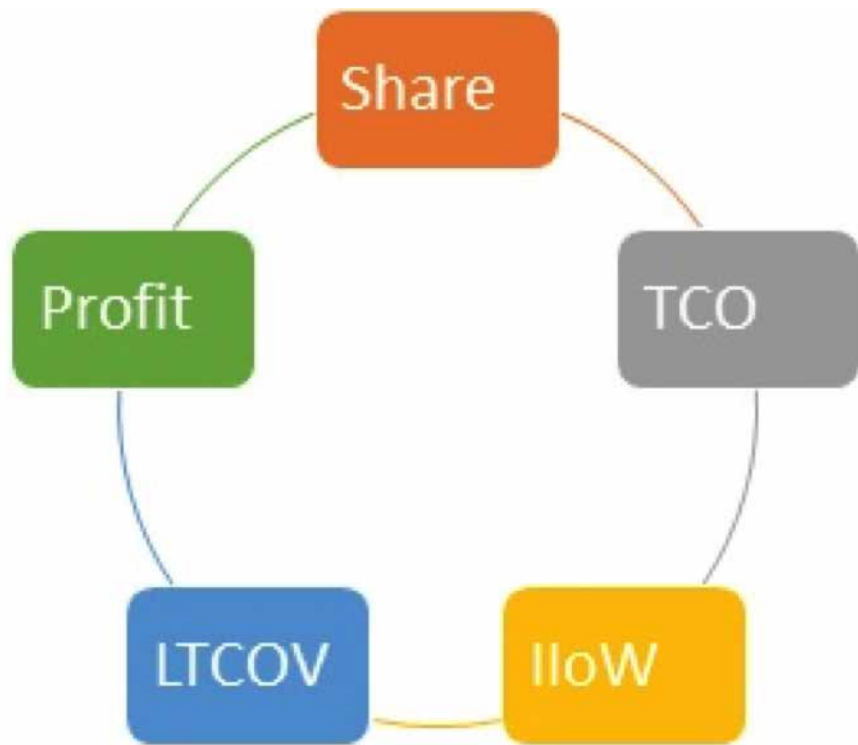


Figure 2. Innovation-TCO-Profitability Causation Loop.

validate their equipment. The argument had been, 'If all these users are finding it the best, so will a new purchaser'. However, in today's environment, purchasers want accurate cost of ownership evaluations to ensure they are finding new and better options.

The media, suppliers, and associations are all providing instant access to the latest product and technical information. In effect, an Industrial Internet of Wisdom (IloW) has been created, which allows the user to determine which product has the lowest total cost of ownership and will best suit their needs.

What is being created is an Innovation-TCO-Profitability Causation Loop consisting of:

- Market share,
- TCO for the innovation,
- Industrial Internet of Wisdom (IloW),

- Lowest TCO Validation (LTCOV), and
- Profit margin and total profits.

The TCO for the innovation can now be validated with IloW. The LTCOV convinces the customer to pay a higher price for the product. In turn, the higher price results in higher profits. Funds are then available for more R&D (research and development). This investment leads to newer and better products, and the cycle continues, as illustrated below:

1. Develop a better stainless valve for a bag sampling system through an R&D investment.
2. Determine that this valve reduces the total cost of ownership for bag sampling systems and quantify the lower total cost of ownership (LTCO).
3. With IloW, validate this LTCO even with higher gross margins than achieved with less novel products.

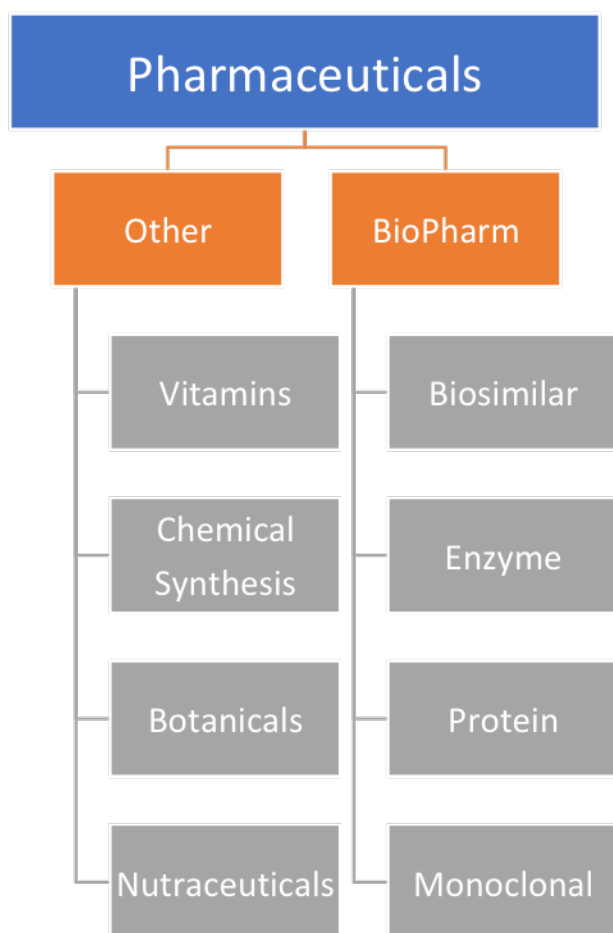


Figure 3.

4. Achieve a high market share due to the LTCOV.
5. The high market share plus the high margins will substantially increase profits.
6. A portion of this profit is directed toward additional R&D.
7. The R&D expenditures are made only with careful analysis of the potential to decrease TCO in market niches selected to maximize profits.
8. The successful development on the next new product results in the continuance of the causation loop.

rial for that product, can provide the potential for high profits in a niche market.

There are many potential niches for stainless steel flow and treat products in the pharmaceutical industry (see Figure 3). There are unique conditions, and therefore unique TCO factors, in each segment. The challenge is to quantify the market size and the LTCO in each niche.

The pharmaceutical industry is the leader with R&D expenditures averaging approximately 19% of revenues. The flow and treat industry averages 3%. The large investment in pharma has resulted in remarkable cell and gene therapy treatments and a vaccine for coronavirus.

## The advantages of stainless

There are a wide variety of types of stainless steels used in the pharmaceutical industry. The combination of a unique product design paired with a selection of the best stainless steel mate-

## Summary

Flow and treat suppliers need to keep pace with their pharma customers. The Innovation-TCO- Profitability Causation Loop is the recommended route.

## References

1. *Stainless Steel Markets* published by the McIlvaine Company.



## About the author

Robert McIlvaine is the CEO of the McIlvaine Company, which publishes *Industrial Valves: World Markets*. He was a pollution control company executive prior to 1974 when he founded the present company. McIlvaine oversees a staff of 30 people in the U.S. and China. <http://www.mcilvaine.com>

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