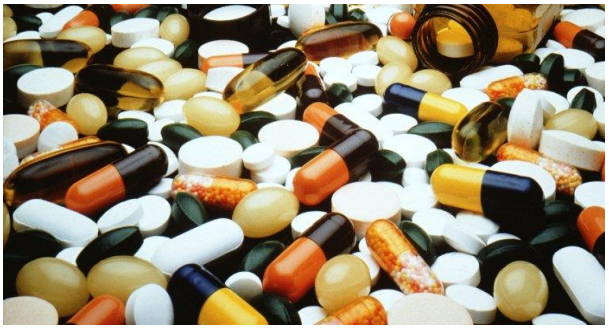
CUTTING DRUG COSTS - BIOTECH AND PHARMA ARE INVESTING IN PATIENT HEALTH

There is a lot of talk these days about putting pressure on the pharmaceutical and biotech industry to work towards lowering drug costs. This is not a new concept. The industry is way ahead of the politicians on this. We have been striving to this end for decades. But because the details are wrapped up in technical issues, it is difficult for the press and the politicians to make good sound bites out of it. The consumer has been led to believe that the industry is not looking out for them. It just is **not** true.



Each year an increasing number of innovations are focused on making the patients' lives better and drugs less expensive.

It is all about innovation. The game is about being able to turn around the batch, the process and the facility in an efficient and safe manner.

So how do you do that?

Turn Around the Batch

The pharmaceutical industry is making moves towards continuous processing. The pharmaceutical industry is one of the last hold outs that is finally looking at continuous or simulated continuous processing. Why we are still dragging our feet? It is all about the definition of "THE BATCH."

The definition of the batch is what allows the industry to protect the patient. We define the batch. We control the batch. We monitor the batch. We test the batch. We package the batch. We label the batch. We release the batch. And if something does show up later that is wrong, we recall the batch. Because we know so much about the distinct batch, we can account for each dose on the market. Changing to continuous processing is a little different. If it is continuous, then how do you define what the batch is so that you can ensure safety of the patient?

Progress has been made recently in defining "the batch" for continuous processing and this definition along with intense innovations in monitoring instrumentation will enable us to provide the kind of protection needed for continuous processing. This will mean that for the same amount of drug product, the manufacturing site will require smaller process equipment, smaller facility, and therefore smaller production costs. This will result in better pricing on better drugs for the patient. The industry is not there yet, but *be assured that there are a large number of companies and much research being done to provide a lower cost AND safe drug for the patient.*

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Turn Around the Process

Many processes were once single product processes. Millions of dollars were once spent for one process to be placed into one facility to make one drug. That facility and process became obsolete once the drug patent ran out. The tide has turned and the process has changed. Most processes are being designed as modularized process steps that can be changed as the process changes. The great growth in single-use technologies has allowed companies to build a modularized process with less infrastructure; so when a process needs to be changed, it is more easily changed. The process can be evaluated in a different space and then moved into place. This is an oversimplification of course; there is a *LOT* of analysis and calculations and evaluations that go into these decisions. Single-use technologies are not right for every application, but this technology has changed the design thought process and has brought about the more modular process approach for even traditional equipment.

Turn Around the Facility

The rooms and buildings wrapped around the processes that are used to make drug product are going through changes, as well. Facilities have to morph into something new as the process changes. Facility changeover has to happen faster. Retrofits must happen faster. We have seen a growth in ideas and equipment that enable this. Modular cleanrooms along with advanced methodologies for room decontamination are enabling a faster turnaround of facility spaces. Modular cleanrooms allow the facility changes to occur faster and easier. Construction can be done off-site and moved into place. These are not the modules of the past, but a more thoroughly designed and tested turn-key approach. Advanced technologies for room decontamination is being used in new and innovative ways to allow for faster facility cleaning and decontamination. It allows for a more thorough way of consistently and efficiently decontaminating biological organisms from those rooms.

Look to the Future: New ideas continue to move us to leaner and more productive designs that will help the patient who, at some point, might be you and me.

About the Author

Christa Myers is a Senior Pharmaceutical Engineering Specialist at CRB with 20+ years of experience providing clients with insight as to how innovative technologies apply to process and facility designs. Her involvement starts with the strategic concept and continues through construction and startup of projects.

With an extensive background in the design of fill-finish facilities, chemical kilo labs, pilot plants, API research and manufacturing facilities, bulk pharmaceutical chemical facilities, highly hazardous compound containment, and biotech process facilities, Christa's broad range of expertise benefits her clients in the design of their facilities.