Chapter 1

Process Simplification: Basic Guidelines

In today's competitive world it is necessary to have the highest-quality product at the lowest cost. In addition, products must be safe and environmentally friendly. Most manufacturing processes, even the best, can be improved to reduce cost and enhance product quality. At times process simplification/improvement may seem like a formidable task, but every step in that direction is a satisfying experience. Since we are trained to apply our knowledge and experience to achieve such objectives, these tasks should be easy.

Process simplification invariably results in the following:

- Improved product quality
- Reduced waste
- Reduced batch-process cycle time
- Reduced raw-material cost.

At times, process simplification can result in the development of an innovative technology that is superior to existing processes. It could be a better batch process or an improved continuous process. Such developments are the most rewarding benefit of the exercise. Each of the above reduces product cost and improves profitability.

Cost reductions are due to improved conversion of raw materials. They are also due to lower conversion cost of a finished product. Therefore, we have to make a continuous effort in each of these areas. A process of continuous improvement allows one to determine, design, and implement the best process for the product.

Cost reductions can also be due to the use of cheaper raw materials. Replacing an existing raw material with a lower-cost raw material has to be part of improving the continuous process effort. Many of the processes, especially active pharmaceutical ingredients, use multiple solvents in a process. Reduction to a single solvent has multiple benefits. Cycle-time improvement improves profitability in two ways: It lowers the conversion cost, and it adds production capacity at minimal or no investment.

If we are able to improve the conversion yield for any product, we are implementing an environmentally sustainable process. Sustainability means "meeting the needs of the present without compromising the ability of future generations to meet their own needs."[1] This is a good definition but I like to modify it to say "exceeding the needs of the present and giving the future generations ability to exceed their own needs." We have to strive to meet a higher goal if we are to be able to meet the expectations of future generations.

In the early seventies when I was at the Illinois EPA working on hydrocarbon emission standards, I recall that during the public hearings the standards were considered to be tough and were challenged by the industry. As the standards became law, industry benefited not only from the savings of raw materials but also from lower conversion costs, since the new regulations led to improvements of the existing processes and the development of innovative processes.

During my tenure at the Illinois EPA I had denied an operating permit to a chemical company because its operation exceeded emission standards of a potential carcinogen. The permit was granted after a reasonable control plan was submitted. About 16 years later I met one of the executives from the same company. He was thankful for our actions, as the company realized a return on investment in a much shorter time than had been anticipated. It had also allowed the company to implement the improvements throughout the operation.

Thirty years later the hydrocarbon emission standards of the early seventies are considered too lax. They were a start. Industry and government collectively have improved the environment. We still have significant opportunities.

Since we are going through a global energy crisis, it would be prudent to figure out how to improve process efficiencies including internal combustion engines so that we can all benefit for the long term. We have to challenge the status quo and strive for better methods. We should not be thinking that it can't be done but looking at what and how it can be done. The current global slump is the best time to rationalize and improve process efficiencies. The goal has to be "innovate, innovate, and innovate."

My purpose in this book is to share my experiences with readers and suggest how we can apply and use our educational and industrial knowledge to simplify and improve process development and manufacturing operations. Readers should not feel that everything has to be done just as I did it but should use this book as a guide for your applications and needs. I have used a few "basic rules of thumb" in my career. This list can be augmented and/or modified to include readers' own experiences. Some of my rules are worth reviewing:

1. There are no failures. Every experiment is a learning experience. These experiences add to our knowledge base and allow us to do a better job.
2. Every dollar we spend has to be earned. My basic rule has been that, under the standard business models, if we are able to increase revenue by $100, we should be able to spend after tax $10. If revenue increase is not the goal but we need to invest to improve the process, then we should save $2 for every $1 to be spent. I have used this benchmark. It may be considered a challenge, but it forces one to be innovative and creative in process selection. I consider this rule as my "breakeven rule." It can be modified to suit individual business needs.
3. We should never hesitate to look outside our business comfort zone for simpler ideas, and we should cross-fertilize. Industry A might be doing the same thing that you are doing but have figured out how to do it better.
4. We should keep in mind that we are dealing with chemicals that many times are alien to our body and our environment. Anything that is alien to our body and environment can be detrimental, as we do not exactly know how it will interact. Thus, it is important that we respect our body and sustain our environment. We will leave a legacy of our deeds.
5. Patents are excellent tools that show what is possible for processes and chemistries. They provide a wealth of information especially for the chemistries and processes that have been and are being invented. Many outline how a process is being executed in the laboratory. They also suggest how the process could be commercialized. Deciphering information can be a challenge but is worth the effort. We need to capitalize on these opportunities.
6. In chemical processes, mass and heat balance are true reflections of the thinking and vision of the developer and implementer or commercializer. They are great educational tools. An actual mass balance reflects the status of the current operation and is a starting place for improvement opportunities.
7. We must document everything we do. It is hard to do, as we are in a hurry to move on to tackle other challenges. Saying "No job is complete without the paperwork" is very apropos.

The above rules are applicable to any manufacturing industry. They are especially applicable to industries that use chemicals. This would include situations where chemicals are reacted to produce a new chemical entity and/or blended for an application to facilitate our lifestyle. In process simplification and operational problem solving, developing a checklist[2] might be helpful. All of us have our mental checklists, but we do not call them a checklist. An organized list on paper should be created and updated with time. It will not only improve the process, but will also result in a safe process and can be used as a training tool.

We humans are the best innovators. If we can go to the moon and come back, we can do almost anything. We want to make our jobs and lives easier so that we can enjoy them. We like to bask in our laziness. After we have enjoyed a good result, we move on to a new challenge.

In order to avoid any stalemate that develops in a project, I have always used a simple methodology of dividing the project at hand into the smallest pieces/steps. A review of all the process steps, allows me to improve each. Let us take an illustration.

Let us assume that a process has five steps: A, B, C, D, and E. We need to review each step individually and collectively. They do not have to be reviewed in the processing sequence. Random order can be used for the review. If process step C can be improved before the other steps, we should implement this improvement to gain its benefit. This not only gives us confidence but also wins over our colleagues. They help us more, as we have facilitated their job. Small wins lead to big wins.

Every manufacturing company has business components that relate directly to the produced products. These include research and development and manufacturing. Process development and process engineering are part of R&D. Maintenance is a critical manufacturing function, needed to keep operations humming all the time. Every other function, such as quality control, shipping, inventory management, sales, accounting, and marketing, are complementary functions of the total business process.

My "rules of thumb" can be applicable to different functions of any manufacturing operation. I will focus on process development, process research, and manufacturing functions.

APPLICATION AREAS

My focus is on specialty and fine chemicals, active pharmaceutical ingredients, paint, paper making, electronic and electroplating chemicals, adhesives, dyes, colors and pigments, and food. These products can be classified in the following two general categories:

- Chemicals that are produced through reactions and may be blended to produce a product
- Chemicals that are blended and applied.

Classification of products in these two general categories is an oversimplification. The fundamentals of chemical engineering and chemistry are applicable, thus there are many commonalities. This not only has allowed me to give a clear and clean view to the challenge at hand but also to cross-fertilize technologies and practices. Since there are commonalities of chemistry and application of engineering principles, compliance with different regulations and safety requirements is simplified.

As we graduate from universities and gain experience in an industry, we generally get labeled as expert in the industry of our first employment and are not considered suitable for other industries. I believe cross-employment has higher value as it offers a different perspective. I would like to illustrate this by the following example.

Organic and inorganic chemicals are reacted to produce a chemical. The created chemical does not know where and how it can be applied and used. If our fundamental knowledge of chemistry and unit processes and operations is strong, we should be able to produce a variety of chemicals for different applications, whether they are a reaction product or a blended product. In certain cases specific knowledge might be needed but that should come in the way of experience of the chemist and engineers.

This is illustrated with the following example. Common salt (sodium chloride) is used in food to enhance taste or treat roads during winter, among many other applications. This does not mean that to mine salt we need personnel with training for each application. However, we do need an engineer who can safely mine and an engineer who can process salt for the different applications.

Similarly, an organic chemical could be used as a flavoring, a UV initiator, a sweetener, a herbicide, an active pharmaceutical ingredient, or an additive by reacting with different chemicals. It is the ingenuity of the chemist and chemical engineer to have an optimal process to produce these chemicals. The chemist and/or engineer should not be labeled a specialist in application/product "B or C," but considered as an innovator who can deliver a quality product safely at the lowest cost. If we classify chemists and engineers based on their past experiences, we are depriving ourselves of their cross-creativity and innovation skills. Commonalities and cross-fertilization provide advantages as they reduce learning and process simplification time. They also bring new thinking in the development of products and processes.

We as chemists and/or chemical engineers need to learn and understand the physical properties of the raw materials and intermediates involved in a reactive and/or blending process. We also need to understand their interaction, reaction chemistry, and kinetics. This knowledge of the chemistry, components, and interactions gives us the capability to control and manipulate the processing conditions. We can be creative and imaginative in improving and developing new processes that will have the following characteristics:

- Economical
- Sustainable
- Quality product.

Knowledge and command of the process variables eliminate any process deviations. This knowledge can allow the development and implementation of continuous processes, which we know are economical and better compared to batch processes.

Use of acronyms such as QBD (quality by design), QBA (quality by analysis), DS (design space), CMC (chemistry, manufacturing, and controls), PAT (process analytical technologies), or any other used by various regulatory agencies to encourage companies to improve their manufacturing technologies become redundant as knowledge of the physical properties and reactions becomes the fundamentals of any chemical-engineering curriculum. Use of these acronyms creates confusion due to variable interpretation.

Imagineering, blue-sky dreaming, and ideation for process and technology enhancements are of considerable value. They lead to innovations. We need to capitalize on "out-thinkers."

Process simplification and innovation are always and will be a "selling" challenge at any company. In September 1973 during a job interview I was asked, "Are you a salesman?" My answer was that as a practicing process engineer I have no experience in sales. I was told that all of us are in sales whether we are a chemist, engineer, or manager, as we are always selling our ideas. The value of this advice has been insurmountable. Many times we are given advice by a colleague and/or in a good book but do not fully adopt it. We should.

REFERENCES

1. http://www.epa.gov/Sustainability/basicinfo.htm. Accessed November 8, 2008.
2. Gawande, Atul. *The Checklist Manifesto: How To Get Things Right*. Metropolitan Books, 2001.