



Transforming Businesses from Good to Great !

*By Dr. Shruti U. Bhat, Director Lean Innovations and Continuous improvement Innoworks Inc.
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My column *Transforming Businesses from Good to Great!* is a multiple article series with a Pharmaceuticals, Medical devices and Healthcare industry backdrop. It focuses on creating ‘Organizational Excellence’, ‘Design Thinking led Innovation’ and ‘Strategic Continuous Improvement’ for start-ups and mid-sized expanding businesses. Further, it aims to recommend ways, how companies can stay healthy and grow despite rapid changes such as regulatory or poor economy undermining them.

Over the past seventy-odd years, the pharmaceutical industry globally, has evolved grossly and developed processes to ensure that patients receive high-quality products.

Yet, we witness rising numbers of 483s issued to pharma companies by the US FDA. Severe adverse effects and even deaths reported with drug products under-going clinical studies or at times after commercialization, which is extremely alarming! This is more so when drug-delivery platforms and their pharmaco-dynamics get more complex. Now more than ever before, there is a dire need to overhaul ‘pharma business operation processes’.

Another quandary is, to shift mindsets across this industry that has focused predominantly on compliance, rather than on truly knowing the root causes (and effects) of quality/ business process issues. Very often, we notice failures easily tagged to individuals, rather than being objectively investigated and/or tracked to process or systems issues. *Clearly, something more is needed, but, what?*

In my view, pharma industry executives should ask themselves some key questions, such as-

1. Does my company have at least one process that is world-class?
2. What would 10X better performance look like in a process that is part of my business operations today?
3. Which fundamental design choices do I need to set right?
4. What can pharma companies learn from other industries?
5. Is my organization connected to the best-in-class management thinkers and operations experts?

Because, *Operational Excellence* is a hard-won skill and a primer for creating ‘Organizational Excellence’.



A logical question is- *How do we achieve this Operational Excellence?*

A standard response I often hear is- “By everyone doing their best” … that, by the way, is a wrong answer!

Just doing your best won’t work. In fact, we should be thankful that not everybody is doing his or her best. Imagine the chaos it could create at your work site- everyone bumping into each other trying to be ‘best’ and working with cross-purposes.

The correct answer is- *You have got to know what to do, then do your best.*

Meaning, everybody works together with a common goal about how to achieve it. Not just with what seems to be brilliant ideas, but, *with a robust ‘Process Improvement technique’ targeted to create the desired Operational Excellence* and acknowledging that, *it is ‘People’ that create this value.*

When people become fully engaged in the process improvement campaign, understand ‘the why’ behind ‘the how’; they become empowered to act independently and to take initiatives. One successful improvement followed by another and then yet another, unleashes an enthusiastic commitment and continuous flow to the ‘Operational Excellence’ wave.

You Can't Control or Improve a Process You Don't Understand- Dr. Deming.

For starters, a helpful checklist with following questions can facilitate to understand processes -

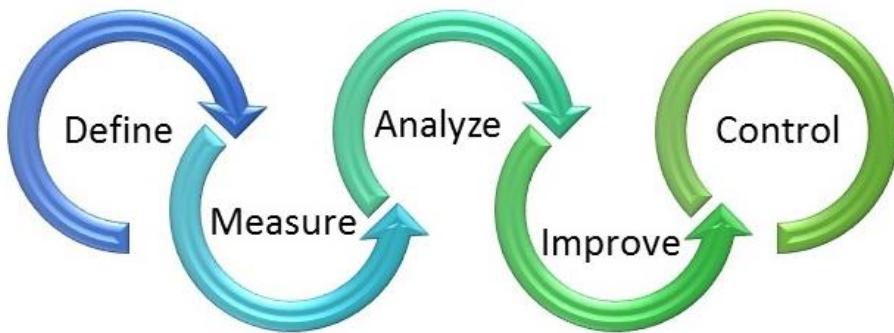
1. How does our company’s value stream (map) look like?
2. How do we manage innovations?
3. How does our company reduce waste?
4. How do we do our jobs?
5. How is our (business) process undertaken?

As obvious as these questions seem, it is amazing to see, how many companies forge ahead without answers!

Secondly, one needs to have the existing business operation landscape, the vision of what the business ought to be and the methodology to get there and make it happen!



Like any other transformation, you need to create the core team and its leader. Then, initiate an intensive training program or ‘Boot camp’ to rapidly build the team’s capabilities. Once this preparation phase is completed, use the five-step approach of DMAIC (Define, Measure, Analyze, Improve, Control) to get the most from your company’s value chain.



Every race begins with a small step.

The ‘Define’ stage of process improvement, usually germinates from one or more of following four streams –

1. Innovation in products and services.
2. Innovation in the process that creates products and services.
3. Improvement of existing products and services.
4. Improvement of the existing (business) processes.

In course of this article series, I shall expand on ‘Define’ phase and explain remaining stages of the DMAIC cycle.

In God we trust, all others bring data

I present few glimpses of success stories with DMAIC process improvement campaigns-

- A Medical device manufacturer reduced errors in product history records by 26%.
- A Pharmaceuticals company reduced ‘Change-over’ time from 64 to 27 hours on its operations line and completed nearly \$2 million worth of backorders.



- A filtration component manufacturer for biopharma applications, created 50% improvement in its product quality and 98.5% increase in ‘On-time’ deliveries.
- An Equipment manufacturing company improved working of its legal department, reduced waste from its import management process and created a 500% increase in work efficiency.
(More case studies are available at www.DrShrutiBhat.com/blog)

A point to remember is that, despite the strict vigil for compliance, no pharmaceutical manufacturer has yet succeeded in claiming the industry equivalent of Toyota’s “Quality Crown”. I hope that the global pharma industry can indeed shift its paradigms to achieve a performance that is close to flawless.

There are over 25 different time-tested process improvement methodologies that pharma/ medical devices and healthcare organizations can choose from, in order to achieve increased efficiency with their business operations and derive exponential profits.

In this string of article series, I shall touch upon each of these methodologies- concepts, advantages, limitations and situations where they could be successfully applied to your business.

The next article would feature about *Lean*, a Business Process Improvement method that made Toyota, Ford, Nike, Intel and many others, the industrial giants they are today!

Further, *Lean* advocates that, change and continuous improvement is a top-down process. Meaning it has to start from the company’s top executive leadership and percolate to the organization’s grass root levels. One of the important benefits of *Lean* methodology is that, it propels cost-effective innovations & manufacturing; thus providing companies with an ‘Early-mover’ advantage.

Set your business up for success ...

I love being part of an organization that has its roots in dynamic operations, people recognition, fast product launches and continuous improvement. *What about you?*



About the author:

Dr. Shruti U. Bhat is Strategic Innovations & Business Improvement Thought Leader.

Shruti has a PhD (Tech) in Pharmaceutical Sciences and MBA. She is an authority on anti-cancer, tuberculosis, cardiac health, diabetes, pain management and neurodegenerative disease therapeutic research. She specializes in Design Thinking & Innovation Management using DFSS (design for six sigma) principles that lead to defect-free products, mistake-proof processes and bring products first-to-market.

Shruti is also Lean Six Sigma champion, Innovation Management and Continuous Improvement Advisor to pharmaceutical companies worldwide. She employs Lean, Kaizen, Total quality management, Agile and Hoshin Kanri process improvement techniques to improve business efficiencies. She has turned-around failing companies to successful enterprises, helped solve cash flow problems, improved operations, line capacities, productivity and service levels of businesses worldwide.

Shruti is Director Training at *Shifting Paradigms Institute of Executive Education* focused on Transforming Businesses Good to Great!

Shruti is Chief Operations Officer, *Innoworks Inc. a Canadian Management Consulting firm* providing Innovation Management, Continuous Improvement and Business Transformation solutions, to pharmaceuticals, natural products, medical devices, cosmetics, engineering, biotech, chemicals and healthcare organizations.

Shruti is also Board Member and Programs Co-Chair of *American Society for Quality* (ASQ) Vancouver section.

Shruti is an invited speaker at several international conferences & workshops. She has 25 patents to her credit, over 90 publications in peer-reviewed journals and has authored *four* books on Business Process Management and Continuous Improvement.

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Note: In case you have a question about Process Improvement and/or Organizational Excellence, please drop me a message and I shall respond to it in my forthcoming column. I also look forward to hear your comments.