

An Inventive Roadmap To Success

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Pressures continue to build for pharmaceutical organizations in a constant balancing effort caused by increased competition, shorter patent lives, and profit pressures. The challenge, of course, is to control costs in a research-driven industry; develop and maintain high levels of quality in products, processes and services; meet regulatory requirements; remain competitive; and grow. That's a tall order, but there are solutions.

This article will describe how a new approach to meeting that challenge combines two revolutionary methods in a single integrated breakthrough process called Innovative Design for Six Sigma™ (I-DFSS).

for Six Sigma (DFSS) discipline with Ideation/TRIZ, another structured methodology, in a single coordinated process. This combination can lead to better and faster results that enable organizations to achieve extraordinary productivity gains.

Stronger data packages can be produced from R&D results to accelerate NDAs by the FDA, reduce the costs of poorly performing processes, cut rejects or errors, produce productivity gains, improve customer satisfaction, leverage all resources for growth in highly competitive markets, and increase the return on investment.

I-DFSS integrates concurrent principles with Six Sigma design and data organizing tools while stimulating innovative thinking. These disciplines enable users to: solve apparently insolvable problems; resolve contradictions in design requirements;

shorten lead times for developing new products, services, and processes; reduce rejects or errors; cut costs; improve customer satisfaction by creating user-friendly products that are competitive; and design next-generation products, services and systems based on evolutionary patterns.

The combined process expands the breadth of opportunities available to an organization by matching technological, product and service-oriented developments to customers and markets. The methodology can be applied whether the issue is

organizational; involves products, services and customer needs; or a goal to improve processes. It can produce results regardless of the state of the economy.

I-DFSS makes it possible to achieve Six Sigma levels of performance more quickly, efficiently and effectively than is possible with other methods individually. The new approach integrates cross-functional design involvement; uses process capability measures in making final design decisions; and anticipates and prevents process failures.

The two methods that comprise I-

DFSS, Design for Six Sigma (DFSS) and Inventive Problem Solving (I-TRIZ), become even more powerful when they work together synergistically as one process.

Components of I-DFSS™

DFSS is an established, data-driven methodology based on analytical tools that provides users with the ability to prevent and predict defects in the design of a product, service or process.

Making significant reductions in cost and cycle time requires a major departure from traditional design methods. Each DFSS project begins by identifying customers, doing a full analysis to understand their needs, designing innovative products, and putting in place the processes and services that will meet those needs. Statistical methods of analysis in the DFSS process result in data and the way to achieve Six Sigma levels of quality at all of these stages.

Focused on creating new or modified designs and processes that have higher levels of performance, the Design for Six Sigma procedure:

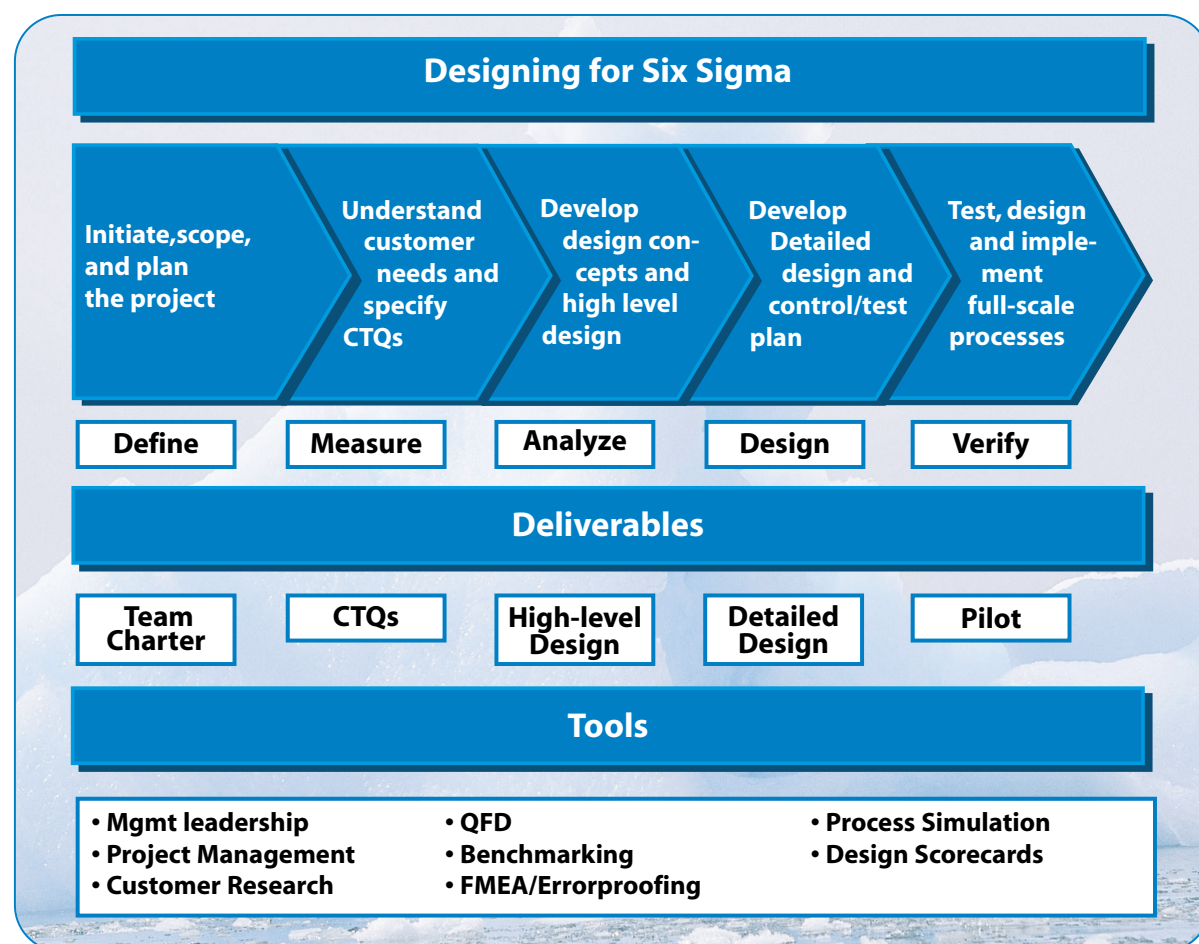
- Drives the customer-oriented design process with Six Sigma capability
- Predicts design quality at the outset
- Matches top-down requirements flow down by capability flow up
- Integrates cross-functional design involvement
- Drives quality measurement and predictability improvement in early phases
- Uses process capabilities in making final decisions
- Monitors process variances to verify that customer requirements are met

DFSS methodology follows a Define-Measure-Analyze-Design-Verify (DMADV) sequence. (see Figure 1)

Significant benefits from these methodologies have been achieved by many companies such as Johnson & Johnson and GE Medical Systems as well as for a wide range of applications at other companies in a variety of industries. These organizations are using variations of Six Sigma to achieve results with ROI ranging from 10:1 to over 100:1.

2. Theory of Inventive Problem Solving (I-TRIZ)

A highly structured methodology, I-TRIZ (pronounced "i-trees") stimulates innovative thinking while taking users step by step through a systematic process designed to help them resolve intractable problems, eliminate technological barriers, create new product features or services, and evolve systems



(Figure 1: Five-Steps of DFSS)

I-DFSS is a methodology that combines innovative thinking with the analytical tools used for designing products, services and processes into a single operation. The total endeavor provides one coordinated effort that reduces development and cycle time, targets zero-defect process delivery, and produces better overall results.

Design and development processes sometimes work independently of other functions within an overall organization. Now, a new approach for achieving strategic change combines the Design

(i.e. products, processes, services) to a successful next-generation level.

I-TRIZ is an advanced form of the Theory of Inventive Problem Solving, a science of invention rooted in the extensive analysis of over two million patents and other sources documenting mankind's creative achievements throughout history. This analysis revealed a set of regularities or patterns indicating how successful systems evolve, paving the way for creating analytical and knowledge-base tools to help users solve problems; analyze, predict and prevent failures; and advance a system to its evolutionary successor. Unlike other tools for enhancing creativity, which are based on psychological techniques, I-TRIZ is based on technology, and is capable of delivering reliable and repeatable results.

I-TRIZ: The Basics

I-TRIZ is built around the following core competencies:

- Inventive Problem Solving (IPS), which is applied to overcome tough dilemmas and technological roadblocks
- Failure Analysis, to identify the root causes of a failure or other undesired phenomenon occurring in a product, process, or service, and to correct it in a timely manner
- Failure Prediction, to develop an exhaustive set of potential failures in a product, process or service, then prevent or eliminate them
- Directed Evolution™, to develop successful next-generation products, services or processes.

Inventive Problem Solving

I-TRIZ Inventive Problem Solving uses analytical and knowledge-base tools to help analyze a problem situation and develop innovative solution concepts. The IPS process is organized into five steps:

- 1) Problem documentation and preliminary analysis
- 2) Problem modeling and formulation
- 3) Selection and prioritization of 'directions' for solving the problem
- 4) Development of solution concepts
- 5) Evaluation of results and revealing/solving problems that might arise during implementation.

I-TRIZ Failure Analysis

I-TRIZ Failure Analysis is a powerful process for revealing the root causes of an error, unsuccessful action, manufacturing failure, or accident; for developing effective approaches to eliminate associated problems; and for investigating unclear mechanisms related to any phenomenon or event. The approach used by the analysis is unique. Instead of asking the traditional question - "Why did the failure occur?" - the team asks instead: "How can we make the system

Suture Results With DE

Current Approach	Directed Evolution Approach
Staples of different sizes for different tissues/procedures	One universal, adjustable seam-making cutter
All staples in cartridge are of the same size	Seam can have variable attachment pitch
Limited number of staples in cartridge	Seam can be of unlimited, uninterrupted length
Disruptive replacement of cartridge is necessary in the case of a long seam	Straight and curved seams are possible

(Figure 2: Suture Results With DE)

fail?" By using this approach, failure analysis becomes an inventive task that can be addressed using the wealth of information and tools available to help inventors create a particular function, action, process, etc.

I-TRIZ Failure Prediction

I-TRIZ Failure Prediction is a systematic process for identifying beforehand - and then preventing - all dangerous or harmful events that might be associated with a product, process, or service. This is accomplished in a non-traditional manner. Instead of 'guessing' what failures might occur, the task is inverted to an inventive task of finding all possible ways to produce a failure in a given system.

Directed Evolution™

The I-TRIZ Directed Evolution (DE) process provides the means to proactively control innovation and growth without relying on traditional technological forecasting. Used to analyze and evaluate a system from technological and marketing standpoints, the process develops a comprehensive set of possible scenarios for future evolution, establishes a decisive course of action, secures intellectual capital, and defines a plan to create next-generation products, processes, services and technologies.

Directed Evolution is based in large part on the I-TRIZ Patterns of Evolution and their sub-patterns (called Lines of Evolution) revealed through the analysis of over 2 million patents and the history of technology, as well as applicable trends in society, markets, industries, technologies, etc.

Example of the DE process: Next-Generation Endoscopic Surgical Instrument

The following case study resulted from conducting an "express" DE process on endoscopic surgical instruments (linear cutter family). Valuable concepts for next-generation systems resulted, some of which will impact future surgical practices.

Today, there is a suture material to fit every surgical procedure. Also important is suture packaging, which serves as a sterile barrier and whose physical configuration affects suture performance.

Suture Options

Apparent directions for linear cutter evolution: In the evolution of linear cutters, the predominant direction has been toward an increased level of specialization. Patent research indicated that all cutter developers were following this approach.

Non-apparent directions of evolution for sutures. One of the Patterns of Evolution states that systems become more universal by becoming more dynamic, and by transitioning to the micro-level to realize its functions. This suggests that tissue interaction would be affected by a formless medium (liquid or jelly) that could take any shape, rather than by pre-shaped objects such as staples or sutures.

One of many possible conceptual designs for a future surgical instrument was developed by combining the benefits of sewing and stapling in accordance with the Pattern of Evolution describing a system's evolution toward the micro-level. With the development of this conceptual design, it is possible to create the next generation of surgical cutters which uses an "adhesive" (polymer) to close the wound, and functions according to the figure shown below.

Components would include a housing, closing anvil, and cartridge in the shape of a reservoir containing a liquid polymer. The reservoir has a nozzle and is connected to a pressure source. Under very high pressure, the polymer is extruded through the nozzle in a narrow knife-like stream which pierces the tissue and comes in contact with the anvil. Upon contacting the tissue, the polymer solidifies (polymerizes). Angular application in two directions forms a "V" on the underside. A continuous system of triangles holds the tissue together.

This device can be used with polymers already approved for medical applications. The polymer may contain additives that make the material stronger or more conductive. Magnetic or chemically reactive additives, for example, could enhance interaction with the tissue.

Different polymerization techniques can be combined with different homeostasis techniques (temperature, chemical or radiation protein denaturation in

the seam's proximity). Sewing may be combined with cutting, either by a mechanical blade or by a pressurized liquid (possibly using the same polymer extruded in the form of a continuous wall, thereby creating a layer of separation between the tissue).

The differences between the current approach and the approach described above are summarized in Figure 2.

In the actual process, numerous patterns and lines of evolution were applied to develop a set of concepts, making it possible to create a highly-effective patent fence.

What Six Sigma Achieves

The process produces ongoing breakthroughs by using the project approach. Dr. Joseph M. Juran, considered by many as the father of the modern quality movement and of the breakthrough process,

Here are two examples at companies where a broad range of results were achieved using a combination of traditional Six Sigma disciplines:

Johnson & Johnson

Patrick Noonan, Vice President, Process Excellence, Medical Diagnostics & Devices at Johnson & Johnson Corp., says the company's Process Excellence initiatives, including Six Sigma, have been an important contributor to productivity efforts that have helped Johnson & Johnson eliminate more than \$5 billion in costs over the past five years. The company now has over 1,800 experts trained in problem solving and making fundamental improvements. Noonan emphasized, "Process Excellence is mandatory throughout Johnson & Johnson. It reduces the time required to develop new products, gives us greater confidence in their effectiveness, and also cuts costs. We are convinced Six Sigma and our other initiatives make the company a stronger competitor at every level - and it drives both volume and profits."

General Electric

General Electric, an international role model in the implementation of Six Sigma, focused on reducing waste initially by concentrating on improving efficiencies and reducing variances in internal operations - from product development to manufacturing operations and financial services back rooms.

From efficiency, the company's operating system steered the initiative into design engineering to prepare products and processes for the future. Every GE product business and financial service activity is using Six Sigma in product design and fulfillment processes. It is the practice and language of every GE facility throughout the world.

An example of GE products developed by Design for Six Sigma methodology is at the company's medical systems business. DFSS-designed products currently account for more than 60 percent of sales by GE Medical. The power of DFSS is demonstrated, for instance, by a body scan system called Discovery LS PET/CT. It allows doctors in a single scan to see a tumor, confirm if it is cancerous or not, and determine the best course of treatment - eliminating the need for multiple examinations that may take weeks or months to perform.

To improve quality, speed and efficiency that is critical to healthcare customers, the medical business completed more than 3,000 Six Sigma projects focused on improving clinical processes at customer facilities during 2001. Those efforts helped GE customers save more than \$50 million. The company reported that Six Sigma-designed product introductions will increase by 25 percent in 2002.

All that is known for certain about the

Roadblocks To Innovation

Historical Mindset
Need for Instant Answers
An Impatient World
Resistance to Change
Change is Threatening
Poorly Defined Problem or Objective
'Not Invented Here' Syndrome
Habits
Past Experiences
Inability to Accept Risk
Peer Influences
Rejection of Past Ideas

(Figure 4: Roadblocks to Innovation)

future is that it will be different. Products, organizations, skills and attitudes that serve a business well today may have little relevance under the conditions of tomorrow. To survive, a business must change. The change must be timely and meet future customer needs. I-DFSS helps to accomplish these results.

The healthy and productive cultural changes I-DFSS™ brings about take time to complete. They are not free. Using the process requires a commitment to provide resources and employee training.

The overall benefits that result could be critical. They include:

- Productivity gains
- Existing capacity becomes available and new capacity unnecessary
- Innovative products, processes and services
- Higher quality levels in everything
- Improved customer satisfaction
- Increased market penetration
- Growth in revenue
- Reduction of capital spending
- Faster turn over of working capital
- Expansion in margins
- Greater employee career potential, satisfaction and pride
- Highly competitive enterprise that is profitable with significant ROI

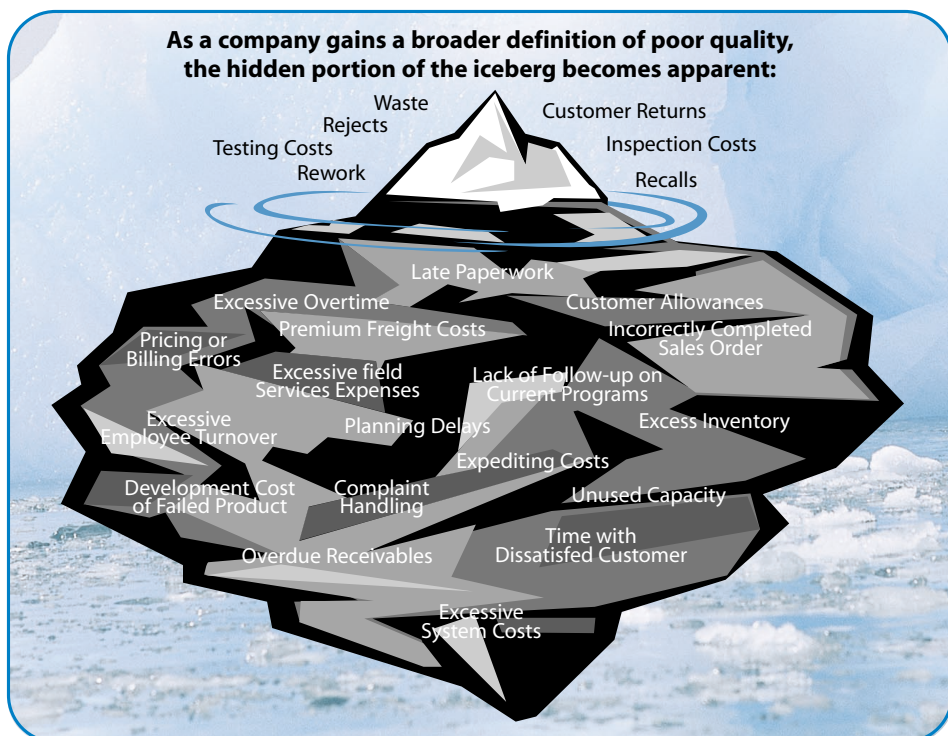
Training and consulting in I-DFSS is available only from the Juran Institute.

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Joseph A. De Feo is President and Chief Executive Officer of Juran Institute. The company provides companies worldwide with business solutions and organizational training to improve their effectiveness. Its services include Innovative Design for Six Sigma and all of the other basic Six Sigma methodologies that are applicable throughout an organization. Mr. De Feo can be contacted at jdefeo@juran.com

As a company gains a broader definition of poor quality, the hidden portion of the iceberg becomes apparent:



(Figure 3 - Cost of Poor Quality) (COPQ)

has stated, 'All improvement takes place project by project, and in no other way.'

Breakthrough improvement is essential for drastically reducing chronic waste, i.e. waste that is systematic to an organization's workings. This chronic waste, measured as cost of poor quality (COPQ), accounts for about 25 percent of annual sales for most companies. Most of this waste is hidden because traditional accounting systems do not measure waste adequately. What is visible and accounted for is the tip of the iceberg. (see Figure 3)

We now have clear evidence and results that the costs of poor quality can be reduced from 10 percent to about 5 percent quickly. Additional savings take longer, but are certainly worth pursuing.

Many organizations have made great strides in Six Sigma continuous breakthrough improvement programs. It is no surprise that these programs also drive market leadership and profitability in the pharmaceutical and health care fields.