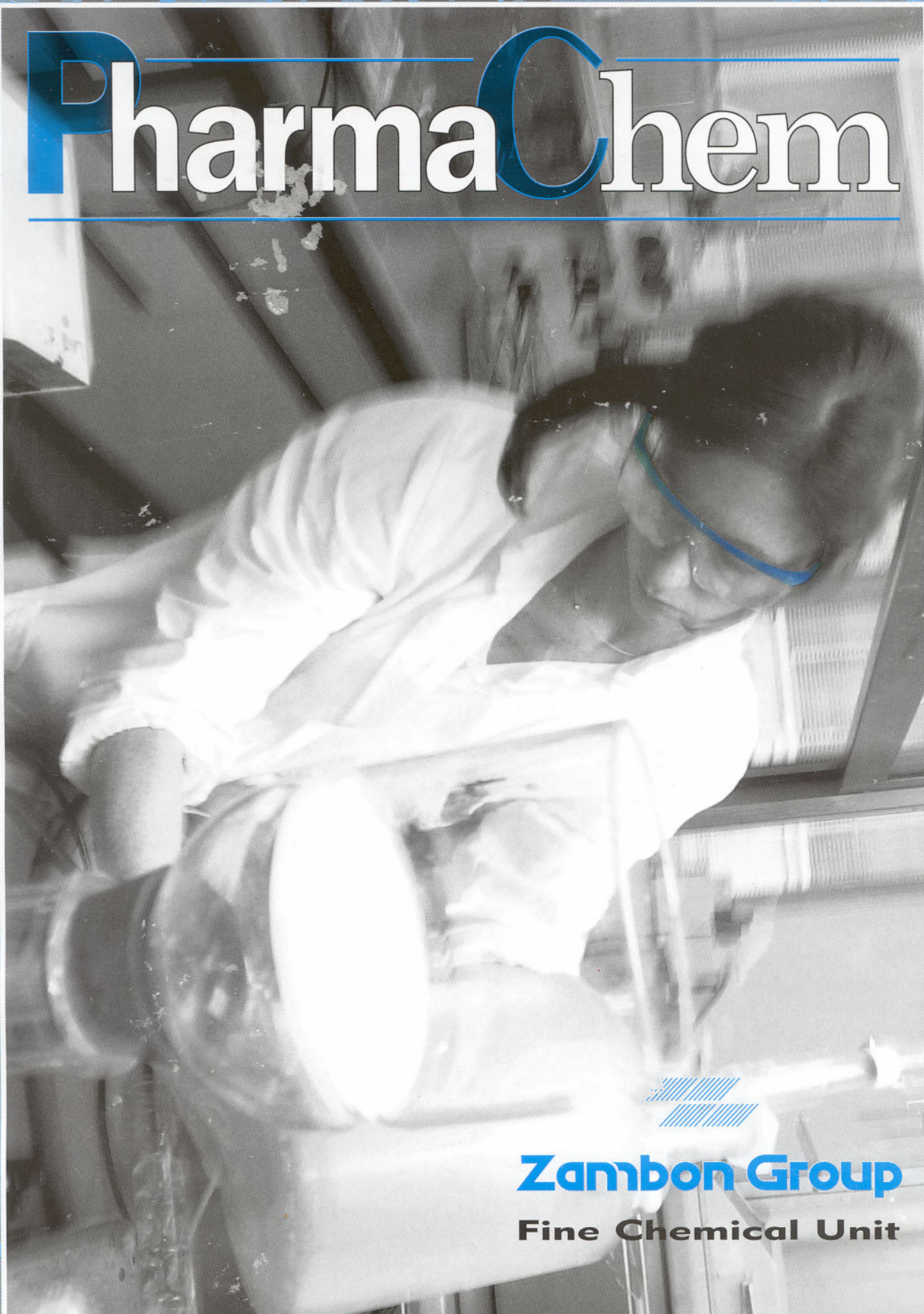


PharmaChem



Zambon Group

Fine Chemical Unit

The Lean Perspective

Design Engineering for Lean Operations

(The fifth in a 9 part series on Lean Enterprise and the tools and techniques employed to affect change) by **Lee Ducharme and Patrick Lucansky**.

The face of competition in today's business environment is requiring companies to dramatically change their strategic direction. The major challenge facing product development organizations is a global marketplace that is demanding more innovation, shrinking lead-times and improved quality at the lowest "total cost". This challenge strikes at the heart of the product development strategy that was pervasive throughout the 1980s and early 1990s. Product development organizations have traditionally undertaken design initiatives with the objectives of producing a required level of product functionality and features. Cost and quality often were given consideration after achieving product functionality. While product development methods have been narrowly focused on products, their associated processes have remained sequential, linear, and filled with non-value added activity.

The emphasis placed on the product development (PD) process over the past two decades has lead to a lack of support for design engineering. As a result, product development processes have traditionally been under the control of engineers not trained or skillful in lean thinking, six-sigma, or project management. Consequently, product development processes generate products and technical solutions without a link to lean strategy and market demands. While improvements in the area of electronic communications (i.e., e-commerce, Cad/cam systems, computer integrated manufacturing and virtual data technology) are increasing the speed (and efficiency) of design and development processes, most remain linear and sequential. A typical product development process includes several phases: idea generation/selection, design of requirements, development of specifications, prototyping, and release to manufacturing. Reviews, testing, inspection, acceptance, rework, and handoffs are normal occurrences that typically flow through the traditional PD process as depicted in the following 20 step melee (see also figure 1):

Step One – A product is identified.

Step Two – A plan is created for the development of products to meet specifications.

Step Three – Engineers begin the development of a product concept.

Step Four – Reviews are held to evaluate the design concept.

Step Five – Upon acceptance, development of a product design begins.

Step Six – Reviews and evaluations proceed to identify potential problems.

Step Seven – Problems are identified and more reviews are conducted.

Step Eight – Changes are made, review and acceptance processes continue.

Step Nine – Once the preliminary design is approved, detail design work starts.

Step Ten – Upon completion of detail work, engineers work on prototypes.

Step Eleven – Changes occur to finalize production/prototype requirements.

Step Twelve – Prototypes are tested.

Step Thirteen – Changes/review/acceptance processes.

Step Fourteen – Upon final acceptance, prototypes are ready for production.

Step Fifteen – Documentation is released.

Step Sixteen – Tooling and fixtures are designed/approved for production.

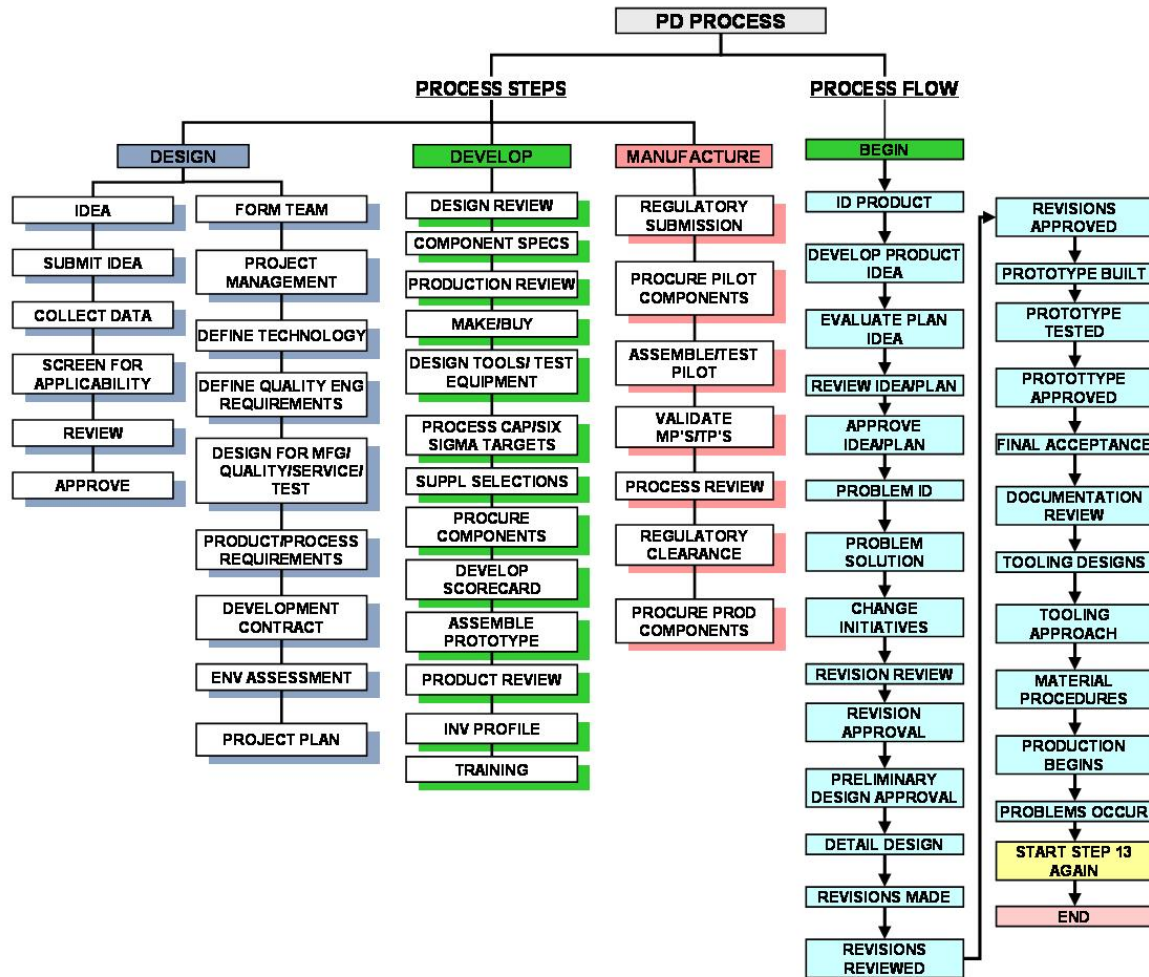
Step Seventeen – Floor layout is designed.

Step Eighteen – Materials are purchased/approved/inspected.

Step Nineteen – Production begins.

Step Twenty – Engineering changes begin (start step 13 over).

FIGURE 1: PD STEPS AND PROCESS



A meaningful start of the integration and improvements of development processes started in the early 1980s. Quality initiatives shifted the focus from product requirement planning to process performance. The “total quality” approach helped define product development standards of performance in terms of internal and external customer expectations. Cross-functional teams were trained to understand lean manufacturing, six-sigma and their role in the product development process. A significant shift from a fire-fighting, problem-solving, reactionary approach was transformed into a proactive, quality, customer-driven, team-oriented approach that recognized the importance of the *value vs. cost*. In the early 1990s, lean thinking introduced value-added, value stream (Womack and Roos), and the customer-driven approach. This heightened level of performance placed a great deal of focus on time to market, total cost, and the elimination of non-value-added activity. Rethinking of the traditional product development process now considers a method of conducting business that optimizes value, primarily through customer service and flow. Lean thinking defines its primary goal as “creating an uninterrupted flow of value to customers”. The four basic principles of Lean are identified as:

Value: The customer’s definition of product and service characteristics.

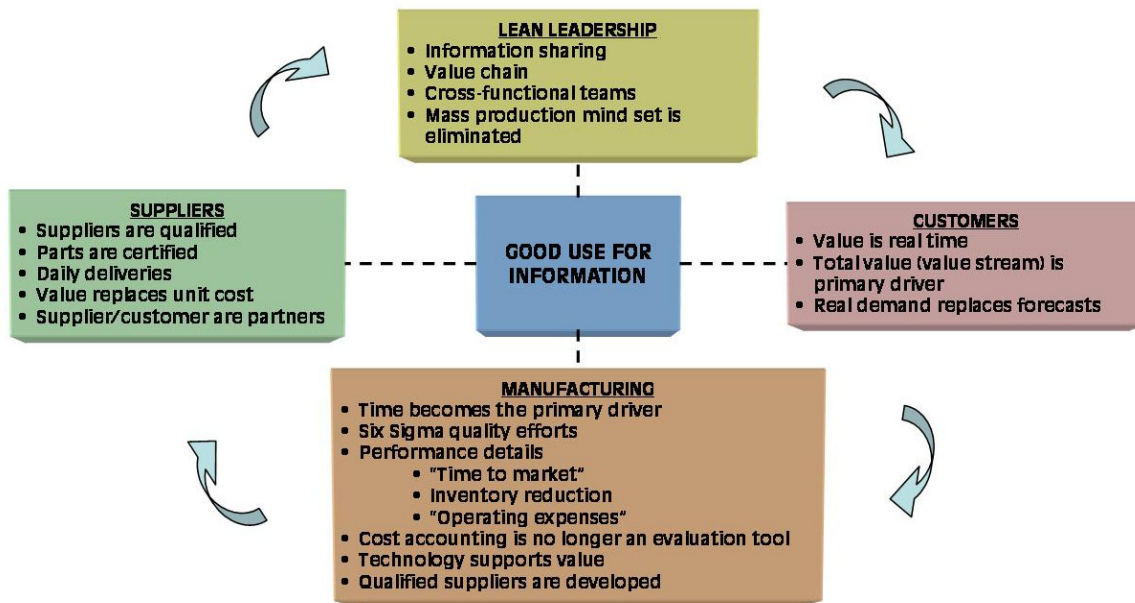
Value Streams: All activities required to support the creation of value.

Flow: The delivery of value without interruption, scrap or rework of products/services.

Demand Pull: Step-by-step authority within a value stream to create value.

In today's market, lean thinking is the most visible movement influencing companies to operate more effectively in a global business environment. As the performance bar to deliver value has risen, senior executives strive for process excellence in every aspect of their business's. Lean practitioners such as Dell, Toyota, and Kawasaki have overhauled their entire product development strategy and approach to meet business objectives. All functions in the supply chain play a supportive and vital role in the transformation to a lean strategy. (See FIGURE 2).

FIGURE 2: LEAN STRATEGY



STRATEGY

The strategic importance of the product development process is clearly expanding. Notwithstanding, the major effect on the bottom line, cost, quality, and time to market are critical success factors that rival the importance of product functionality. Under pressure to meet these critical success factors, product development organizations have revised their strategy and methodology to align with a strategic lean supply chain approach.

Product cost is sensitive to the type of equipment, material, and technology in the design concept. Design of manufacturing/assembly is the primary Lean approaches affecting total cost and efficiency. Simplifying activities such as manufacturing, handling, and assembly of components specifically reduces production cost. Value mapping provides the technique that help identify non-value added activity. Activity based costing provides the tool for understanding the cost related to non-value added activity. Identifying and costing activities such as handoffs, rework, testing, inspection, paperwork, inventory, space, and scrap are important factors that helps transform a design process into a flexible, agile, and capable process that meets time to market and total cost objectives. The risk associated with the choice of new and existing technology and products is minimized when non-value-added activity is eliminated in the design process. The ability to manage a design process that is lean becomes more responsive to customer requirements and may capture a larger share of the market. At the same time, lean techniques have a direct impact on the elimination of sequential processing and the reduction of linear non-value added steps that add unnecessary cost and lead-time to the

FIGURE 3: PRODUCTION DEVELOPMENT STRATEGY

TRADITIONAL	LEAN THINKING
<ul style="list-style-type: none"> • Flood products and goods in niche market 	<ul style="list-style-type: none"> • Achievable world-wide growth
<ul style="list-style-type: none"> • Manufacture products with engineering-driven specifications 	<ul style="list-style-type: none"> • Products ‘MRP-based’ on customer-driven requirements
<ul style="list-style-type: none"> • Products designed against rigid/ inflexible engineering requirements 	<ul style="list-style-type: none"> • Products are innovative, agile, and flexible
<ul style="list-style-type: none"> • Decision-making is top-down engineering-driven 	<ul style="list-style-type: none"> • Cross-functional teams are robust and empowered to make decisions as needed
<ul style="list-style-type: none"> • Product-focused only 	<ul style="list-style-type: none"> • Balanced customer product, process-focused
<ul style="list-style-type: none"> • Regional and stratified decision-making 	<ul style="list-style-type: none"> • Global decision-making
<ul style="list-style-type: none"> • “Bells and whistles” approach 	<ul style="list-style-type: none"> • Common product base
<ul style="list-style-type: none"> • Increased number of SKUs remain in production 	<ul style="list-style-type: none"> • Reduced number of SKUs
<ul style="list-style-type: none"> • NPD process is functional and disjointed 	<ul style="list-style-type: none"> • Cross-functional teams are institutionalized
<ul style="list-style-type: none"> • Functional support is mostly administrative and lagging 	<ul style="list-style-type: none"> • Appropriate functional and supplier interaction is concurrent

product development process. Lean techniques reveal the need to restructure product development organizations and incorporate goals and objectives reflected in a complicated and innovative marketplace. Rethinking of traditional product development process requires that organizations involves changes in approach and methodology to lean business strategy beginning with purchasing of raw material to delivery of products to customers. (See FIGURE 3 for a comparison).

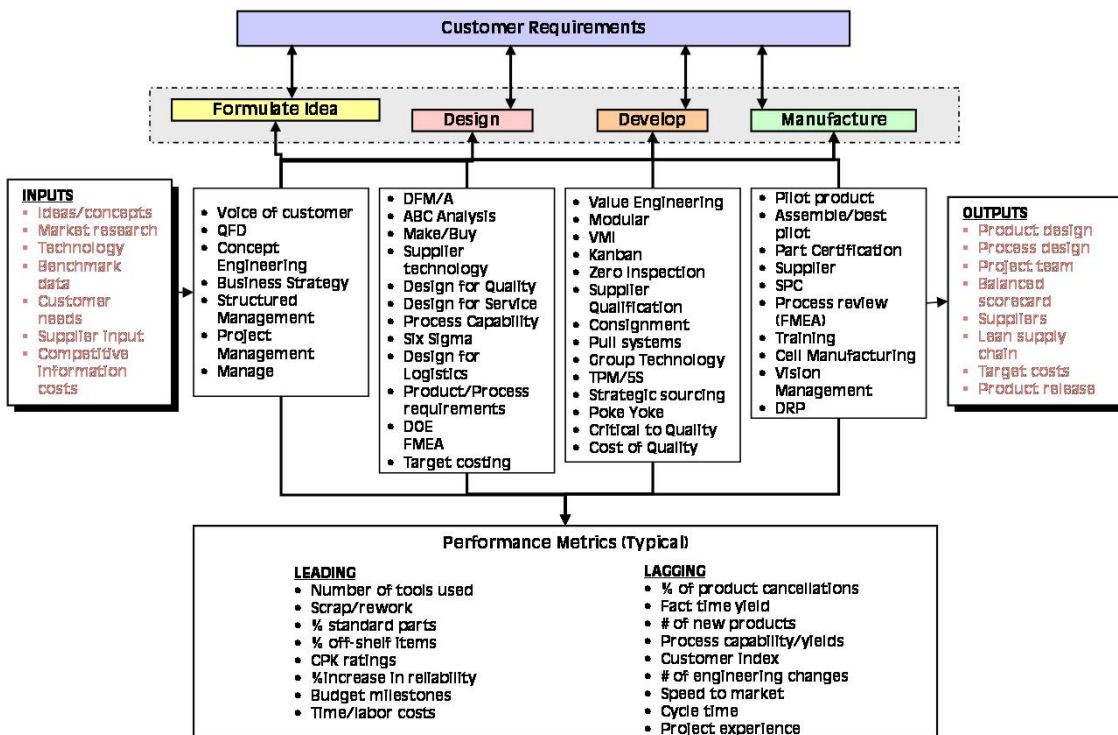
PROCESS/TOOLS

In an integrated product development environment, the design process begins as the idea generation/selection phase takes shape and potential features are identified. At this point, creating the manufacturing process for a product should be part of the design. The need to wait until the design activity is complete is too late to determine how a product or service will be produced. This requires an early and extensive level of involvement from manufacturing, procurement, and quality to introduce lean techniques such as cost of quality and design for assembly and manufacturing. Modifications to the design of products and services that arise from these techniques should be incorporated very early in the process.

Cost of Quality is the sum of all costs incurred throughout the development process. Poor quality is defined as “products not having perfect quality the first time”. The cost of quality is usually expressed as a percentage of sales, consisting of four types of quality costs – internal failure costs, external failure costs, appraisal costs, and prevention costs. Internal failure costs are categorized as scrap, rework, engineering changes, and design work not required by customers. External failure costs occur after the product is delivered to the customer and is rejected or returned under warranty or field liability. This also results when products are delivered prematurely to market to gain “first to market status.” Appraisal costs measures quality and performance of activities such as inspection and process monitoring. First time quality, training, and supplier/part certification are categorized as prevention costs. Not addressing or recognizing these cost activities can translate into a loss of as much as 20% of sales revenue. Accurate product and process costing are at the core of quality decisions for new and existing

products and services. Design for Assembly reduces cost and time by simplifying products and processes by reducing the number of parts, simplifying assemblies, handling, and testing. Design for Manufacturing is oriented to individual parts and components. Both techniques aim to eliminate costly and unnecessary features that increase production complexity and difficulty. When combined into DFM/A an organization realizes a cumulative effect to the benefits achieved. (FIGURE 4 outlines some other techniques)

FIGURE 4: LEAN PROCESS AND TOOLS



Lean philosophy defines non-value activity as waste. In the product development process waste contributes to long lead-times, unnecessary handling, paperwork, space, inventory, checking, testing, inspection, rework, and scrap. If waste is not minimized or eliminated during the design process, it subsequently permeates the entire supply chain and often finds itself imbedded into SOPs, GMPs and work standards. Clearly, when this occurs, an organization finds itself in a markedly difficult competitive position.

In the lean supply chain, suppliers play a greater role in the product development process. A well-aligned design process with supplier's harnesses key resources and optimizes value. Results reached through external resources typically include the use of pre-established technology, proven processes and products, concurrent development of testing, designing, and production of components, sub-assemblies, and final assemblies. The direct benefit in the design process is the reduction of lead-times, early refinement of specifications, features, manufacturing cost, value engineering, and manufacturing capacity. Industry leaders have defined and configured product development processes as part of an extended lean supply chain. As part of the value chain, design activities are required to conform to processes intended to support volume production. These product development organizations now must maintain dual objectives to deliver prototypes and volume ramp-up to meet targeted time to

market and total cost. The following checklist (See FIGURE 5) is helpful in determining a supply chain's ability to produce and design products.

FIGURE 5: PRODUCT DEVELOPMENT CHECKLIST

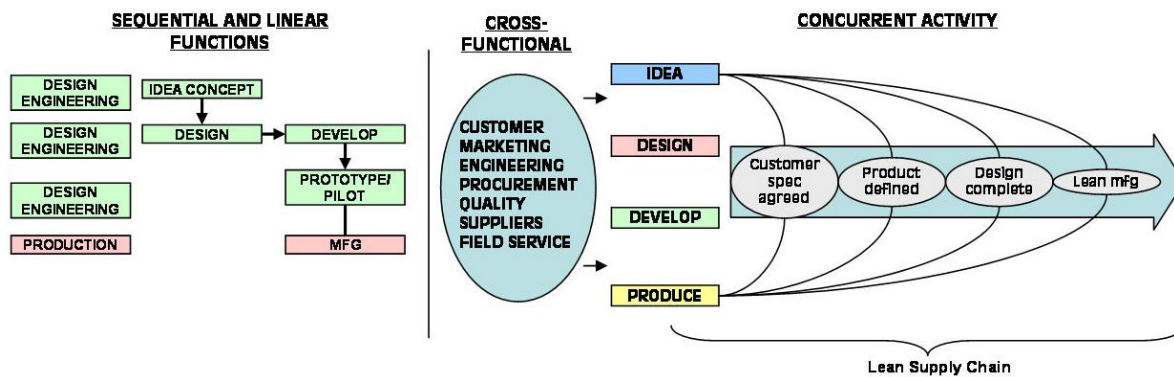
PRODUCIBILITY	PRODUCT
<ul style="list-style-type: none"> • Producibility constraints • First article acceptance • Component costs • Pre-production control • Lead-time requirements • Make/Buy • Plant layout • Handling requirements • Test equipment • Standards • Purchase of tools and dies • Quality specifications • Documentation release • BOM data • Item master data • Modular BOMs 	<ul style="list-style-type: none"> • Specification • Reliability • FMEA • Fault tree analysis • Risk analysis • Design of experiment • SPC control • Test requirements • Value Engineering • Field tests • Competitive analysis • Cost effectiveness • FMEA process • Design • Field environment test • Stress test • Packaging • ESD • Self diagnosis • Software requirements • Reliability

ORGANIZATIONS

Product development organizations are slowly moving from sequential and linear processes with the help of cross-functional teams. Cross-functional teams are making informed and timely decisions throughout the PD process. Starting with the idea generation/selection phase; marketing and sales organizations are feeding customer requirements and features into the system. Advanced design organizations utilize tools like, "voice of the customer" or quality functional deployment to sort and refine marketplace information. During the design and development phases, a robust discussion of design models and specifications takes place among additional functional groups. Procurement and suppliers offer value engineering methodology,

while manufacturing and production engineering lead the discussions regarding design for manufacturing/assembly. Finance and quality provide the invaluable tasks of identifying cost related to products and associated activities as the interaction among functional groups grows more robust and real-time. The move away from sequential and linear steps is accelerated by this concurrent approach as seen in Figure 6).

FIGURE 6: CROSS-FUNCTIONAL CORE TEAM



Typical cross-functional activities that maintain a robust product development process include some of the following:

DEPARTMENT	FUNCTION
Engineering	<ul style="list-style-type: none"> • Supplier Quality Assurance • Process capability • Target costing • Project management
Quality	<ul style="list-style-type: none"> • Cost of quality • Supplier/part certification • Testing
Marketing/Sales	<ul style="list-style-type: none"> • Forecast • Customer requirements • Market segmentation
Manufacturing	<ul style="list-style-type: none"> • Cell Manufacturing • Modular build • Kanban (pull system)
Procurement	<ul style="list-style-type: none"> • Critical costs • Value Engineering
Suppliers	<ul style="list-style-type: none"> • Design specifications • Product specifications • Delivery packaging • Sub-assembly manufacturing • Value Engineering

Leading companies now view lean thinking as an important part of their business approach and marketing objectives. The lean strategy demonstrates the importance of product development to design and launch products that meet or exceed customer requirements in the shortest time and lowest total cost. Lean tactics provide product development organizations with the tools and methodology to focus on cost, quality, and time to market. Balanced with an approach to product functionality, product development organizations are recognized as competitive marketing weapons. Under the Lean umbrella, product designs, while simple and standard, meet all of the marketplace requirements for product marketplace innovation and agility. Best in class organizations which have incorporated product development in their supply chains have created a clearly defined product development process that meets all of the global ever-changing customer requirements.

Part 6 of the Lean series, **Procurement, “fuel for business growth”**. For question or comments relating to the article or lean tools and techniques, please email authors.

VIP is an operations improvement consulting firm specializing in the delivery of value through implementation of Lean Manufacturing and Supply Chain Management tools and techniques in a variety of industries from discrete parts to continuous flow, from distribution to assembly, from aerospace to pharmaceuticals. We have enjoyed equal success deploying these tools and techniques in non-traditional settings like offices, regulated environments and retail settings. Visit our website at www.vipgroup.us.

Patrick A. Lucansky is President of Value Innovation Partners, Ltd, a Certified Management Consultant through the IMC, teaches operations/ lean courses at the BA/MBA levels and can be reached at plucansky@vipgroup.us.

Lee Ducharme is with Ducharme and Associates.

*This article was originally published in the April Issue of PharmaChem Magazine through B5srl.
<http://www.b5srl.com/>*