Going Process-Centric in the pharmaceutical industry

By Pete Caldwell, Alex Sifniotis and Tom Snoxell

1. Background

The pharmaceutical industry has long been protected from the need to drive down cost s, sheltered as it has been by innovative and patent-protected blockbusters. Many companies have grown complacent, allowing their direct and indirect processes to become bloated and bureaucratic. [Ref 1]

However, over the last decade, pressure on costs has risen relentlessly in this sector, fueled by aging populations throughout Western economies, increased patient expectations and the onslaught of cheaper generic alternatives to mature drugs. As a result of this and the decreased returns on R&D spending, the industry now has an urgent need to look for new ways of driving efficiency.

Moving towards a more process-centric organization is seen as one of the major levers, not only to reducing cost, but also to improving customer and employee satisfaction. However, there is no single correct organizational structure and companies must use a methodical approach to define what is right for them.

This article presents Tefen's renowned 8-step approach as a way of navigating through the difficulties and pitfalls of organizational redesign, so that companies can succeed in redesigning and implementing their new structures successfully and reap the substantial benefits that are available to them.

2. Examining the cost crisis

In a bid to reduce costs, healthcare providers are beginning to scrutinize manufacturers' prices with growing intensity. Since the proportion of GDP spent on healthcare in first-world countries increases year-on-year (costs now exceed 17% of GDP in the US), the primary focus is set firmly on finding the best value for money, leading to aggressive tender-based purchasing strategies and more limited formulary lists.

Coupled with this scrutiny, the stringent regulatory framework that surrounds the pharmaceutical sector is placing heavier demands on development, sales, procurement, production, quality assurance and administration functions than in other manufacturing sectors.

It has never been more challenging for pharmaceutical companies to stay competitive in this evolving environment. Suppliers are battling to minimize the cost of running a compliant operation, without jeopardizing the healthy flow of desirable new products into the marketplace.

To achieve this, companies need to streamline their operations, minimize unnecessary tasks that waste time and money, and structure their organizations around the key processes that add value to patients and users.

3. The effect on organizations

The lack of competition and cost-scrutiny in the past has allowed pharmaceutical manufacturers to enjoy impressive margins despite their high fixed costs, low utilization and low productivity. In the US, the pharmaceutical sector as a whole was still averaging net profit of 17% in 2002, outperforming the Fortune 500 five-fold. [Ref. 2]

This attractive level of revenue has encouraged a certain type of organizational structure to evolve, which is common throughout the pharmaceutical sector. As business units were given the authority to recruit at will to meet demand, they tended to build large-scale 'silos' of resources and expertise. Natural fluctuations in demand meant that although this aggressive recruitment strategy was ideal when the market was on the way up, the workforce was not adjusted to the same extent during downturns. This was particularly true for indirect functions, which are typically less easily scalable. [Ref. 3]
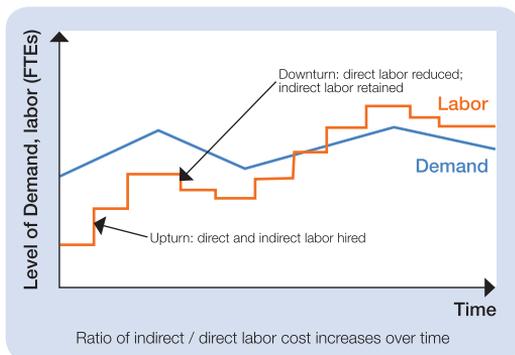
On top of this, manufacturing sites did not regularly reevaluate and redesign their structures to keep pace with site requirements in terms of size, shape and flexibility.

These cumbersome organizations often seen in the sector have become too complex and slow, leading to misaligned objectives, multiple handoffs between process steps, delays and increased costs. Managers lack an awareness of operational practices, while staff display confusion and poor co-ordination between functions. A failure to communicate ideas makes decision-making processes difficult and those concerned experience an atmosphere of stress and conflict.

This environment offers plenty of scope for restructuring measures from which substantial and wide ranging benefits can be reaped. According to Tefen's organizational benchmarks for 2004 and 2007, a typical pharmaceutical manufacturing site often has at least 600 staff, of which on average 45% (ranges from 15% to 74%) are involved in indirect operations, meaning that they are not directly involved in the making or testing of the product and therefore do not directly add value to the customer. In this landscape, there are significant opportunities to reduce costs by releasing indirect resources. [Ref 4]

If an average site can address 10% of its direct workforce and 40% of its indirect workforce, it could release 150 staff and approximately $10M per year (based on blended European salary rates). This step could be taken while simultaneously increasing the amount of effort spent adding value to the product. [Ref 5]

4. Transforming to a lean structure

Over the last decade, the concept of lean manufacturing has been heavily applied to the pharmaceutical sector. Initially, the focus was mainly on technology, outsourcing and shop floor improvements, and in some cases on administrative processes. It was rare for sites to conduct wholesale, site-wide organizational restructuring to realign their corporations to the actual needs of processes.

Ratio of indirect / direct labor cost increases over time

Recently, as sites have exhausted traditional efficiency options, redesigning the organizational structure has taken a more prominent position. The tide has turned away from conventional, function-based companies to more agile and empowered „process-centric" organizations.

The customer-oriented and highly responsive nature of these new structures has given the companies that have made the change an important advantage over the competition. Improved alignment with process specifications means that customers' needs are also better catered for and products are manufactured in line with market requirements. According to Hammer, 2007; Harmon, 2007; Hinterhuber, 1995; Melan, 1989; Reijers, 2006, an organization which has adopted the process view exhibits the following characteristics:

1. Process-centric organizations are able to define and therefore design their processes to match business needs more closely
2. Process-centric organizations tend to drive more involvement in operations and change from senior management, thus releasing an organization's full potential
3. The existence of process owners is the most visible difference between a process enterprise and a traditional organization. These owners are able to drive process performance as they have end to end responsibility for each process
4. Process-centric organizations can apply the concept of process performance measurement. By focusing measurement on processes rather than functions, alignment and common focus across separate organizational units can be achieved

A process-centric approach also has a positive effect on corporate culture (e.g. teamwork, readiness to change, and customer focus), IT systems (which seamlessly support business processes), HR systems (e.g. existence of an incentive system emphasizing the process needs) and the ability to coordinate interrelated process projects.

5. Implementing organizational redesign

Although it may seem a daunting task, the rewards from redesigning organizational structures and processes can be substantial and will impact the entire manufacturing site.

However, as we indicated at the beginning of this article, there is no single right answer and the process harbors many pitfalls. It is essential to apply a standardized, holistic approach to guarantee a customized structure that meets the needs of the specific business, regardless of its circumstances.

Tefen has developed a clear 8-step implementation program to optimize the structure of manufacturing sites in the pharmaceutical industry. This approach has been honed through many successful organizational transformations over the last ten years.
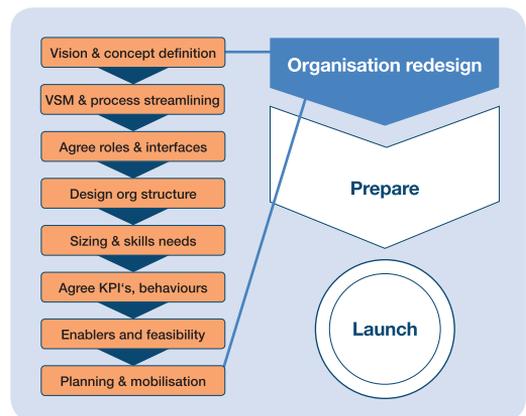
Step 1: Site strategy and organizational concept definition

Before any structural changes can be made, it is essential to clarify the corporate strategy of the site and define an organizational vision. Any decisions made during the following steps will depend heavily on the critical success factors and structural concept chosen. These elements are typically specified by the head of the site and a core team, based on corporate input. This concept should answer three main questions:

1. Where do you want to apply process centricity in your organization? Do you want to limit it to a small area of production or extend it throughout the company? A truly process-centric organization has an end-to-end span and stretches right from the initial planning and purchase of raw materials up to final customer care operations.

2. How process-centric do you want your organization to become (within the parameters defined in question 1). In the pure sense of the term, process-centric involves embracing all activities relating to supply within one exe cution team. The challenge of forming end-to-end teams increases when product receipt, manufacturing, testing and warehousing operations take place in different buildings. You should also be aware that tasks such as planning, buying, making, testing, repairing equipment, storing, shipping, invoicing and answering customer queries could all be included within the 'manufacturing' process if this process-centric approach is taken.

3. How many layers do you want? Some companies reduce the layers from 7 down to as few as 3 or 4; meaning that each manager makes many more direct reports and decisions are made closer to the operation. It also reduces the opportunity for upwards career development.

Step 2: Value-stream mapping & process streamlining

For an organizational structure to be successful, it must be based on appropriate, value adding processes. The value-stream mapping step identifies processes that themselves add no value, or are not linked to other processes; the process streamlining step focuses on the most critical 10-20 processes and reduces non-value-adding steps within them. Once the processes are streamlined, the structure can be designed to surround them and optimize their output. During this step, benchmarks and best practices from high-performing comparable sites should be assessed and incorporated where suitable.

Step 3: Agreeing roles and interfaces

In this step, current roles and interfaces are assessed and new ones defined; job descriptions are documented based on the new processes defined in step 2. The concept of plan-do-review is built into each process, so that wherever possible, the process owner is responsible for planning and measuring the process. Special care has to be taken in this step in countries with strong labor agreements.

Step 4: Designing new organizational structure

The organizational vision is taken into account at this stage. Decisions on end-to-end span, process-centricity and layers are taken. The new roles must then be assembled into a new structure. Frameworks such as the frequency/complexity matrix are used to help decide whether roles should sit within the manufacturing execution team or in 'centers of excellence'.

Step 5: Sizing & skills needs

The output from the process streamlining step is used to resize the organization. It is during this step that cost savings are secured, as non-value-adding steps have been eliminated and tasks better allocated to processes. The skills necessary for each role are defined incorporating the required knowledge and personal attributes for each position. All these changes must be identified and addressed through a training/recruitment roadmap.

Step 6: Agreeing KPIs, behavior

Based on the new organizational structure and processes, new KPIs need to be agreed and enforced in order to properly monitor process outputs. We recommend using the balanced scorecard approach specified by Kaplan and Norton in the 1990s, as they encourage predictive and real-time metrics as well as historical outputs.

Step 7: Enablers and feasibility

In this step all key constraints and enabling projects are identified to prepare for and ensure a successful structure launch. Each enabling project is prioritized according to cost and benefit.

Step 8: Planning and mobilization, ready for launch

Detailed work plans should be developed for the implementation of the new organization; work-streams, responsibilities, timescales, objectives and implementation resources for all activities must be outlined in the roadmap. It is acceptable to define a staggered or pilot approach to implementation if the proposed design is radically different from the current state.

Post go-live:

Identifying the right organizational structure and forming the right vision of how the company should operate is only the first step. In order to reap the full benefits of the optimal structure, companies must successfully implement their ideas and concepts. More often than not, it is during implementation that companies encounter the most significant issues and make the largest compromises that jeopardize the success of the site.

6. Conclusion

Although the pharmaceutical industry has been slow to adopt the benefits of organizational redesign, companies stand to benefit substantially by aligning their organizations more closely to the process. Inefficiencies born as a result of evolution can be rectified and eliminated if the 8 steps are completed thoroughly.

The process of organizational redesign should not be entered into lightly and there are significant challenges involved with implementing changes of this nature. Each organization is different and there is no 'one size fits all' solution. However, those companies that have redesigned their organizations testify to the potential improvements to be achieved and many have been re-vitalized by the change.

As the industry becomes more and more competitive, increasing numbers of companies in the industry are looking to replicate the improvements made by forerunners such as Novartis and MSD. The „organizational redesign" approach looks set to become a major efficiency driver of the future.

Two case studies

Companies that have addressed the issue or organizational design head-on cite it as one of the critical success factors of their operations:

Novartis launched a lean initiative in 2002 to reduce cycle times by 70% and spending by 40%, piloting in its Suffern plant. Every process and role at the pilot site was scrutinized and reengineered, and process-oriented teams without first line supervisors were created. This project has since been rolled out to almost all Novartis sites globally.

The result is a flatter, process centric organization. Gone are the traditional, vertically-focused departments of most pharmaceutical companies. In its place, Novartis adopted a product-based team approach, eliminating the supervisor role so that engineers, operators, and support staff such as IT, mechanics and maintenance, report directly to one team leader.

Tom Van Laar, Vice President of pharmaceutical operations has claimed, "In every case, we've seen at least a 40 to 50 percent reduction in the work required for each area, because that work was non-value added". [Ref. 6]
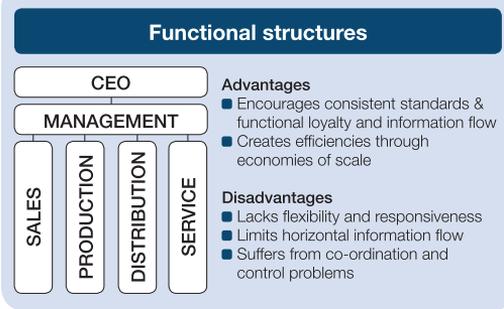
Merck revolutionized its structure when Richard Clark became CEO in 2005 to combat the impending loss of patent protection worth $7B annually. The company moved from a traditional pharmaceutical model of vertical silos responsible for functions across value streams to a "disease centric model", matching resources to business objectives and value streams.

Similar to Novartis, Merck did away with the functional silos traditional to the pharmaceutical industry and replaced them with process and product centric teams. Richard Clark once explained that bringing teams together "is the way work should get done in companies. It's not up and down. You need people to work together".
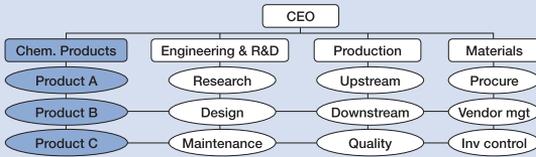
He has also warned that „the value proposition has to be from the payer's perspective. If you don't listen to your customers you're going to wake up someday and not have them anymore". [Ref. 7]

Alternative structures

Organizational redesign is not a trivial task, not least because there is no single optimum solution. Each company has different objectives and approaches, and various structures are feasible, each with its advantages and disadvantages.

Functional structures

CEO

MANAGEMENT

SALES | PRODUCTION | DISTRIBUTION | SERVICE

Advantages
- Encourages consistent standards & functional loyalty and information flow
- Creates efficiencies through economies of scale

Disadvantages
- Lacks flexibility and responsiveness
- Limits horizontal information flow
- Suffers from co-ordination and control problems

Matrix structures (functional bias)

CEO

Chem. Products — Engineering & R&D — Production — Materials

Product A — Research — Upstream — Procure
Product B — Design — Downstream — Vendor mgt
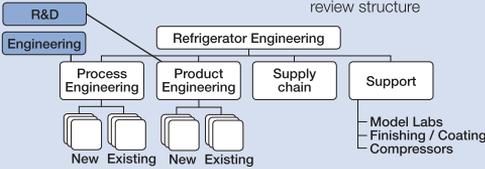Product C — Maintenance — Quality — Inv control

Advantages
- Relatively flexible
- Strong problem-solving focus
- Creates vertical and horizontal information flow

Disadvantages
- Inherent conflict between functional & project managers
- Lacks clarity in reporting lines
- Increased costs that are harder to manage
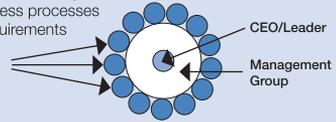
Matrix structures (project bias)

Advantages
- Matches skills to business objectives
- Promotes employee empowerment and encourages skills development

Disadvantages
- May not have appropriate skills to fill roles
- Continual requirement to review structure

R&D
Engineering
Refrigerator Engineering

Process Engineering — Product Engineering — Supply chain — Support

New Existing New Existing

— Model Labs
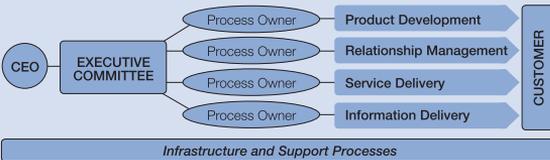— Finishing / Coating
— Compressors

Entrepreneurial network structures

Advantages
- Eliminate functional silos
- Increase in co-operation and co-ordination
- Reduction in response time
- Increase in accountability
- Aligned business processes with market requirements

Disadvantages
- Loss of economies of scale
- Staff disenfranchised between projects
- Chaotic and hard to manage

CEO/Leader
Management Group

Process structures

CEO — EXECUTIVE COMMITTEE

Process Owner — Product Development
Process Owner — Relationship Management
Process Owner — Service Delivery
Process Owner — Information Delivery

CUSTOMER

Infrastructure and Support Processes

Advantages
- Eliminate functional silos
- Increase in co-operation and co-ordination
- Reduction in response time
- Increase in accountability
- Aligned business processes with market requirements

Disadvantages
- Often requires redesign of facilities
- Culture change required
- Requires rethinking of traditional vertical career paths
- There is potential for creating "horizontal silos"

A comparison of alternative structures is shown in the following table. The scores represent the ability of the organizational structure to enable and achieve specific targets on a scale of 1-5 (1 low, 5 high).

		Increasing process-centricity					
		Functional (silo)	Matrix (functional bias)	Value-stream with COEs	Matrix (project bias)	Product & Process oriented	Entrepreneurial network
Customer focus	Focus and feeling of accountability towards end-customers	1	2	4	4	5	5
	Info flow & activity handover between departments	1	2	4	3	4	5
	Easy of customer needs multiple products and services	4	3	2	3	4	5
		2,0	2,3	3,3	3,3	4,3	5,0
Flexibility, creativity	Flexible responding to problem-solving & customer needs	1	2	4	3	5	5
	Conducive to innovation	2	3	3	3	4	5
		1,5	2,5	3,5	3,0	4,5	5,0
Economy, efficiency	Creates efficiencies through economies of scale	5	3	2	2	2	1
	No duplication of business processes	5	4	3	3	5	3
		5,0	3,5	2,5	2,5	3,5	2,0
Functional excellence	Consistent standards & functional loyalty	5	4	1	3	2	2
	Clarity of roles and relationships	5	2	4	2	3	4
	Easy coordination of specific issues	3	3	5	4	4	5
	Ability to measure productivity/quality	3	3	4	3	5	4
	Simplifies training	4	3	3	2	2	5
		4,0	3,0	3,4	2,8	3,2	4,0
Clarity	Simplicity & harmony between functions & processes	5	2	3	2	4	3
	Expedites vertical information flow	5	4	2	3	1	4
	Allows for product cost tracking	1	2	5	2	3	5
	Customer knows who to contact regarding process	5	3	2	2	4	4
		4,0	2,8	3,0	2,3	3,0	4,0
Motivation	Reinforces professional identity and transferable skills	5	4	2	3	4	3
	Staff enfranchised between projects	5	4	2	3	4	2
	Enriches jobs	1	4	3	4	3	5
	Traditional vertical career paths still valid	4	5	2	3	2	1
		3,8	4,3	2,3	3,3	3,3	2,8
Project/ problem	Creates strong problem-solving or goal focus	4	3	4	4	4	5
	Results in clear and visible project objectives	2	3	4	4	5	5
		3,0	3,0	4,0	4,0	4,5	5,0

[Ref 1] Kaplan, Porter: The Big Idea: How to Solve the Cost Crisis in Health Care, HBR, Sept 2011
[Ref 2] Congress Watch: Hefty Pharmaceutical Company Margins Dwarf Other Industries, http://www.citizen.org/documents/Pharma_Report.pdf, June 2003
[Ref 3] Kaplan, Anderson: Time-Driven Activity-Based Costing, HBR, 2004
[Ref 4] Caldwell, Bublitsky, Glass: Tefen Benchmark Surveys, 2004, 2007
[Ref 5] Average Salary Ranges for Pharmaceuticals jobs, http://www1.salary.com/Pharmaceuticals-salaries.html, 2011
[Ref 6] Novartis goes Lean, www.pharmamaufacturing.com, 2004
[Ref 7] Is Merck's medicine working? www.businessweek.com, 2007

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