

Operations Excellence in the Life-Sciences

The new reality causing pharmaceutical, biotech, and medical-device companies to rethink the way they operate

The life-sciences industry is under pressure from the decline in the discovery of blockbuster products, aggressive strategies from the generic manufacturers, the emergence of competitors from the Far East, and the global economic downturn. These factors are causing pharmaceutical, biotech, and medical-device companies to rethink the way they operate.

Growth is no longer the mantra of the life-sciences industry; it is survival and maintaining a competitive advantage. The ability to supply products in the most cost-effective manner through efficiency initiatives has become necessary just to survive. Over the last five years, this has led life-sciences companies to embark on Operations Excellence (OpEx) programs, based on Lean, Six-sigma and other improvement methodologies. This paper summarizes research conducted by Tefen Ltd. in 2008-2009 on these OpEx programs and how they have reshaped the way life-sciences companies develop, supply, and even sell their products.



The Decline of the Blockbuster

Historically, the “big-pharma” model was based on the development of blockbuster drugs that provided billions of dollars in revenue. This model traditionally meant that when small-scale niche products were found, they were discarded or sold to smaller companies where lower operating costs ensured the profit margins generated made them profitable to develop. However, as the number of blockbuster drugs being discovered started to diminish, and the investment needed to gener-

ate new drugs increased, the big-pharma model started to look untenable.

What happens when this model for development no longer works? Investment is now being poured into previously ignored industries and technologies. The bio-pharma and biotech sectors do not have a great deal of direct competition, since most of the drugs have been developed for small, rare conditions that had historically been ignored by big-pharma. With the growth of investment in these sectors, this situation is changing. Consumer interest in biotech

Industry

By Pete Caldwell and Liam O'Donnell

and bio-pharma products that target specific medical conditions should keep the industry commercially viable.

The Rise of Generic Competition

The emergence of generic manufacturers has become a bigger challenge for big-pharma. These companies are preying on the blockbuster drugs even before they come off patent, causing severe declines in revenue for the big-pharma companies. Generic manufacturers, with their lower operating costs, no research investments, and small marketing budgets, are able to quickly enter the market with cheaper products, thus gaining 88 percent of the market share within two years.

The investment required to develop new drugs, together with the pricing structure of generics, is causing large-scale revenue loss for big-pharma, which in turn reduces its ability to invest in new-drug discovery. As a result, a new trend among big-pharma is to partner with, or acquire, biotech companies with solid

pipelines and relatively long patent life on existing products, to provide protection against generic exploitation.

Competition From the East

The emergence of cheaper, rival products from companies based in the Far East, including India, China, and Singapore, is not a new challenge for big-pharma. For over a decade, leading pharmaceutical companies have been buying into established companies or building sites of their own in the Far East to remain competitive. They tend to be much larger than their traditional Western counterparts due to tax breaks and cheaper labor. These strategies enable companies to transfer their existing products from American and European bases to reduce the production costs and, when balanced with increased transportation and distribution costs, enable bigger profits. The recent growth of the Chinese and Indian markets has provided an interesting opportunity for pharmaceutical companies. Their presence in

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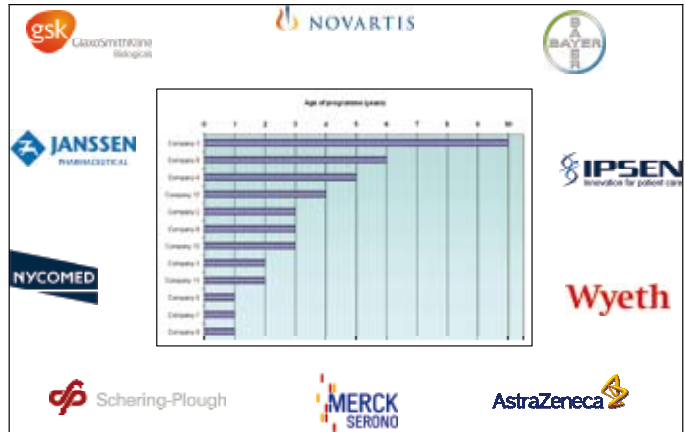
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this region will enable them to supply their previously unaffordable products quickly, with low distribution costs to the fastest growing economies in the world.

However, as their economies grow, so will competition, and soon the marketplace will be flooded. The regulations governing quality and ethics in medical products in these regions have typically been poorly maintained, and the market has been monopolized with cheap, ineffective, and sometimes dangerous copies. To change this trend and win the consumer over to the more expensive big-pharma products, further operating-cost reductions are required. The size of the emerging markets makes them impossible to ignore, and so it is imperative for pharmaceutical companies to undertake these cost-reducing initiatives.

The Credit Crunch

While the current economic crisis is affecting the pharmaceutical industry, there are several factors that reduce the negative impact of the "credit-crunch." Historically, big-pharma is cash rich and can continue to invest in product development and acquisitions. Secondly, the necessity to purchase pharmaceutical products to prevent illness ensures a reliable source of income, especially for products that are provided by national medical services. However, revenue from many non essential product lines



has been hit, and most pharmaceutical companies have announced site closures and job cuts. It is clear that cost reduction is on the agenda.

OpEx: The Answer?

“Operations Excellence is when each and every employee can see the flow of value to the customer, and fix that flow when it breaks down.”

— The Institute of Operations Excellence

The state of Operations Excellence (OpEx) is therefore that in which no activity performed in the company is wasteful, its products are made or supplied only when needed, and its employees are authorized, trained, and motivated to make positive change to support its customers. This means that customers are happy, costs are minimized, and the company triumphs over its competition. If Operations Excellence is the destination, pharmaceutical companies are using structured programs to make the

journey. The use of techniques such as Lean or Six-sigma allows companies to combat the root causes of waste and variability and make their way toward OpEx. These techniques have evolved over the last 10 to 20 years and are seen as being applicable in the pharmaceutical sector, where process reliability and efficiency is becoming a source of competitive advantage. Lean manufacturing, based on the Toyota Production System, is a set of tools and techniques for reducing waste within any process. Waste can be unnecessary activities such as waiting, delays, and storage. Six-sigma, which was originally developed by Motorola, is a set of techniques for measuring, identifying, and reducing variability within processes. Process deviations and failures, human variations, and flow and demand fluctuations are a small example of variability that can be tackled using Six-sigma methodologies.

Tefen conducted research on AstraZeneca, Bayer Schering, GSK Bio, Ipsen, Janssen, Merck Serono, Novartis, Nycomed, Schering Plough, and Wyeth during 2008 and 2009 through consultancy engagements and interviews with OpEx leaders on life-sciences OpEx programs. These companies' programs ranged from 10-year-old programs to just one year old.

Operations-Excellence Goals: People As Well As Numbers

The current operational priority faced by many life-sciences companies is to reduce the cost of goods sold. Forty percent of the companies that participated in this study stated this as the main aim of their OpEx program. Secondary objectives such as improving process reliability, releasing cash, and becoming more flexible to customer needs were also highly important. All of the participants stated the need to increase the speed of product flow. Some companies use their OpEx programs to solve challenges specific to them (i.e., to harmonize practices and cultures following a merger).

What is apparent with these companies, which have been running OpEx programs for more than a couple of years, is that there slowly emerges a greater emphasis on people. This becomes more apparent as leadership effectiveness, people development, improvement culture, and performance metrics such as cost and

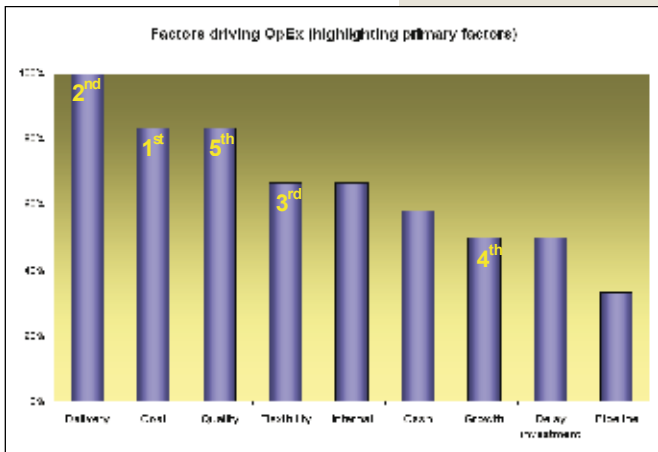
delivery become the focus of attention. If OpEx means “everyone can see the flow of value to the customer and fix it when it breaks,” then people must be empowered and trained to make their own process changes and recognize they are part of a larger team serving the customer and have authority to make changes in others' areas. They also must recognize that leaders have to be prepared to relinquish some control and trust their subordinates to make change.

Operations Excellence Should Not be Measured by Financials Alone

Without proactive and relevant metrics, investment in OpEx can go to waste. The three traditional key metrics of cost, quality, and delivery feature most highly. Capacity absorption and cost avoidance is imperative to companies that are experiencing growth. Working capital is popular for companies that lack cash. More mature OpEx programs

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turn their attention to the attitudes and maturity of their organizations as they recognize the true meaning of Operations Excellence. Measures that are typically used are number of employee suggestions implemented, number of people trained, and number of teams initiated. These programs have their measures integrated into the sites' general performance metrics. Seventy-five percent of life-sciences companies researched have already done so, while the rest are not far behind.

Operations-Excellence Benefits From a Lean and Six-sigma Approach

Of the improvement methodologies, the most commonly used by pharmaceutical OpEx programs is Lean (every company researched used Lean Manufacturing in one way or another), followed by Six-sigma. They both have advantages and disadvantages. Lean can be perceived as purely a headcount-cutting technique and as a potential contributor to quality problems caused by cutting corners. Conversely, the heavily data-reliant and statistically based approach of Six-sigma is seen by some as over-intellectual, uninspiring, with limited applicability. In addition, an over emphasis on tools rather than people driving the change can damage the program. Hence, it is recommended to use a hybrid Lean/Six-sigma approach. If well-designed, this will incorporate a structured, simple problem-solving approach, run by cross-functional teams working together to identify and

eliminate waste. Eighty-five percent of life-science companies use a hybrid approach, and not one company researched uses Six-sigma alone.

The theory of constraints is only deployed by a minority of companies and only where growth is a key objective of the program. However, Goldratt's "Five Steps to Continuous Improvement" are not used in any company as an overarching methodology. Peripheral methodologies such as Design for Six-sigma and Business Process Re-engineering are sometimes employed where needed.

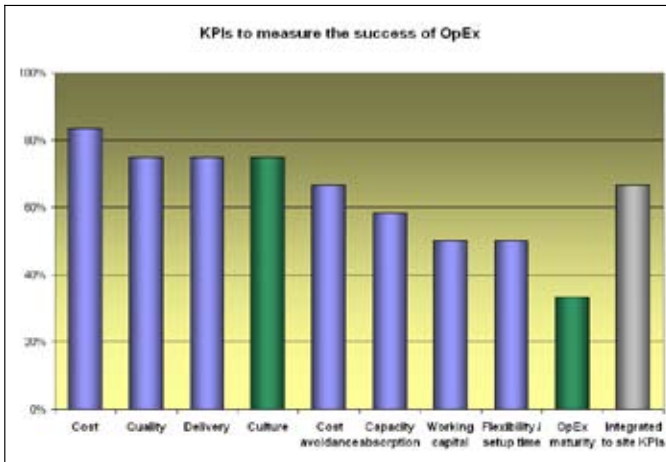
Operations Excellence: Moving From Program to Way of Life

An OpEx program should be like any other program and include a sponsor, a charter, a steering committee, etc. It should be driven as a top-down, directive program with a clearly defined scope, rather than a philosophy which may be up for interpretation. OpEx programs are typically given a name, a budget, and a great deal of focus. Most programs are called Operations Excellence, OpEx, or OE. A few companies use the term Excellence or Business Excellence. There are a collection of other names, such as Continuous Improvement, Lean, or Best in Class. Early-stage programs should have a defined suite of "work streams," each with their own group of experts to help coach along the way. As the programs mature, they transform in nature and

become a way of life. Mature companies have managed to drop the program's name and work streams, and the tools have become embedded in peoples' daily working routines. This is enabled by added effort of training, improving resource skills, and embedding the language of OpEx within the organization. In the early stage of OpEx programs, there is a lot of emphasis on standardizing training material, problem-solving techniques and tools. A more evolved OpEx program focuses on standardizing the company's philosophy and ensuring flexibility in the approach and use of tools. At whichever stage possible, companies should strive toward a common philosophy and language.

Operations Excellence Throughout the Organization

OpEx has wide applicability and is relevant beyond the four walls of manufacturing. However, there is an inclination for companies to confine their programs to manufacturing and supply operations, as it provides the most tangible benefits in terms of cost, quality, and product flow. Some companies have incorporated Development and Sales operations into their programs. Doing so is imperative because approximately two-thirds of the overall cost is in R&D (sales and marketing). Furthermore, product-development cycle times are long, and altering product specification during its commercial life is



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difficult due to regulatory constraints. Therefore, great value can be derived by optimizing products and processes so that they are well-aligned with customer requirements, are cheap to manufacture, and are effective across many therapeutic needs.

Another significant contributor to cost and lead-time lies in the support functions (HR, Finance, IT, QA, and so on). OpEx programs can be adapted to address these areas and overcome such problems. However, almost half the companies do not plan to include these functions within the scope.

Operations Excellence Can Benefit From the Pilot Roll-out Model

In any improvement program where there are risks involved and the company can afford the time and resources, it is practical to conduct pilot trials before replicating the improvements everywhere. This enables companies to learn from new practices

that work well in their environment and those that should be modified or discarded. Even in cases where the problem-solving process has been creative and thorough and trials have been well-managed and monitored, there are two main potential errors that companies make:

Roll-out of improvements without regard for lessons learned:

Once a standard improvement has been rolled out across an operation, it is very difficult and costly to modify it. Companies often implement an initiative simultaneously across all areas, or they simply stagger the implementation across sites without adjusting based on trials. This gives the appearance of a pilot-rollout approach, but is simply a resource-constrained expansion.

Forgetting to Roll-out the Process:

There were instances in many organizations (particularly in Quality Control) where initial projects had been successful, but the intent to roll the processes out to other areas had

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been forgotten along the way. Consequently, the effort and expense of trials and modifications was not exploited.

Operations-Excellence Sponsors Need to be Visible and Supportive

During an OpEx program's early life, people need to know its importance. The sponsor should be at the SVP level and must show great interest in the bottom-line benefits that the program provides. It is critical that he/she provides visible, vocal support and resources the program adequately. This demonstrates a commitment to its success. In two-thirds of the companies researched, the sponsor was deeply involved, helping to define the methodology used and the direction taken. The program leader should have high stature within the organization, typically reporting to the SVP of Operations. In some cases, the leader reported through a functional department, such as the qual-

ity or finance function. This arrangement is not recommended, as the program can become de-prioritized or over-focused toward the function's day-to-day objectives.

Operations-Excellence Benefits From Effective External Support

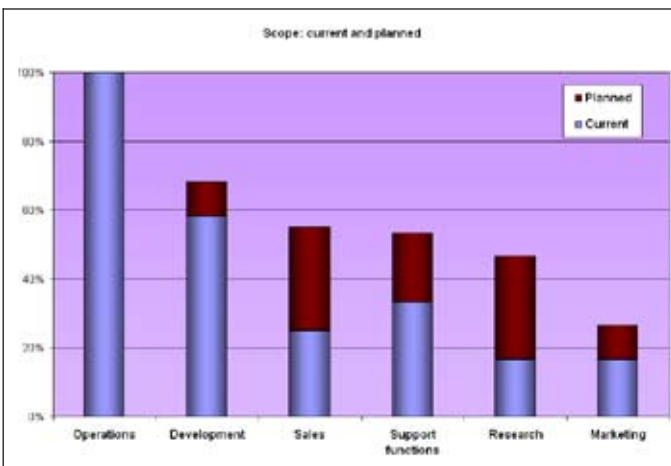
The company's maturity and objectives often determine the way external or corporate support should be used. In general, investment in consultancy services delivers the most value at the direction setting, setup, initial training and coaching of the program. Most of the coordination, governance activity, auditing, and knowledge management should be performed at the corporate level, and implementation should be assigned to the local teams as soon as possible. The philosophy underpinning OpEx is that employees be empowered and authorized to make positive change from within. Hence, over time, coaching and training must be

passed from the consulting team to the company.

Careful Management of Operations-Excellence Programs

Many companies find that the benefits of OpEx programs do not initially live up to the expectations. It might be expected that individual work streams were unable to deliver their anticipated benefits. However, this has not been found to be a major cause. More common causes are:

- Work streams start to lose stride. This is typically symptomatic of a dwindling sponsorship, re-diverted resources, and a haphazard attitude toward risk management. Although many work streams do eventually deliver the projected benefits, the cumulative effect of these delays appears as a shortfall in benefit realization.
- Often local deliverables are achieved, but there is no formal feedback through the budgeting process, so the financial benefits do not flow through to the bottom line.
- Occasionally projects are selected that have clear operational deliverables but do not affect end-customer or financial performance. Examples include widening non-bottlenecks and shortening lead times of processes that are not in the critical path.
- Successful OpEx programs deploy a range of management and governance techniques to guarantee benefit flow at the desired level and



rate. The program and its projects must be thought out, with project charters used to specify scope, deliverables, time scales, and resources. Steering processes at corporate and site level should be followed to ensure external changes are considered, progress is monitored, and action is taken. Mechanisms to track milestones, operational benefits, and financial benefits should be employed. Risk management is an area that tends not to be as structured as it should be and is a significant reason for delays in benefit realization.

Use of formal change-management principles, as advocated by Kotter (8 steps), Lewin (unfreeze-change-refreeze), and others, is generally low in many OpEx programs. Moreover, simple techniques to drive cultural change are often not well-understood or deployed. The topic is seen as important, and terms such as communication, culture, awareness, and

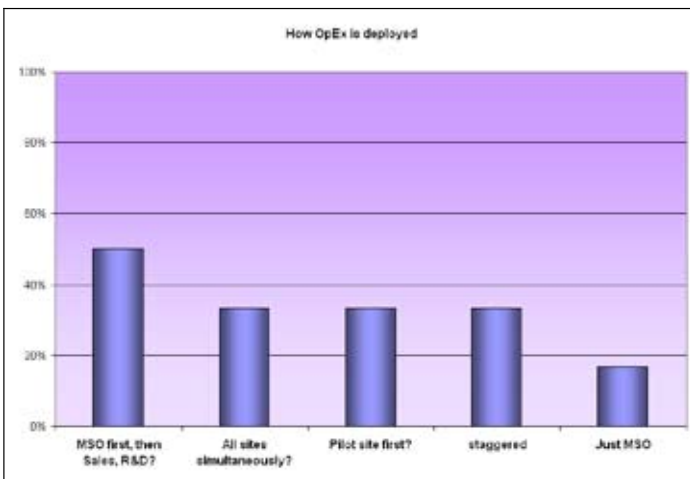
change are often mentioned during steering meetings. However, change theory is not valued enough to reach the training curriculum, and many senior managers regard it as common sense rather than a legitimate management science. Therefore, it is often the case that the OpEx message does not find its way down to the shop floor, and the capability of supervisors to champion projects is not maximized. Many programs use employee-accreditation systems (ASQ's Six-sigma Belt qualifications), though more mature programs tend to disband these in favor of site-driven personal objectives and training plans.

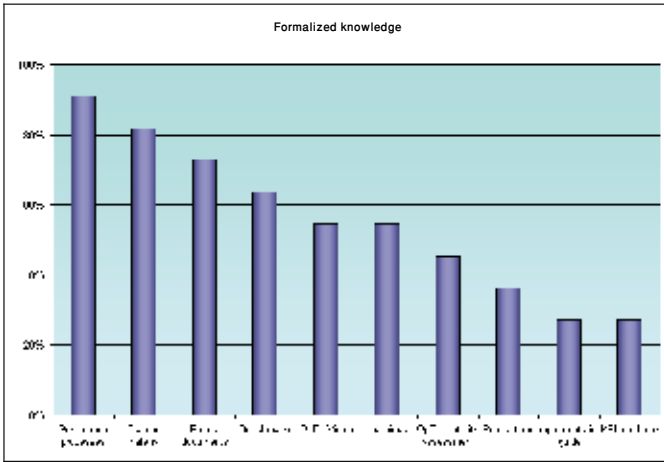
Communal Knowledge and Operations Excellence

Most companies recognize that the way they manage the knowledge surrounding their OpEx program is sub-optimal. Knowledge capture is often not proactive, and knowledge sharing can be poorly driven and

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coordinated. This results in multiple approaches across sites and the risk of confusion when teams are brought together. Most of all, it is the experiential data that is lacking – the know-how of what worked well and what worked poorly. Seventy-five percent of companies feel that most of the knowledge concerning Operations Excellence is too tacit to be formally laid down.

One company researched, whose program was a year old, had not instituted knowledge-sharing processes. The knowledge tended to reside in a small core of people, and this represented a lost opportunity for people lower down in the organization to learn from past mistakes.

Half of the companies interviewed have a statement that describes their OpEx vision. The younger programs have not formalized their vision, but it is typically on the agenda. Companies that are more than two years into their pro-

grams tend to use a six-month or annual OpEx assessment to highlight areas that need more focus.

Successes in Operations Excellence

Almost all companies researched have a lot to be proud of:

- First-wave projects produced a success rate nearing 75%-110% of targeted benefits. This is due to the enthusiasm and dedication of the first pioneers and to the internal competition to show better results. The real challenge is to maintain these results in the medium to long term.
- After a couple of years, the first results can be clearly seen in the operational cost or CoGS figures. This is a critical success factor and, especially in the early stages, is perceived as the main benefit of the program.
- During the deployment of the program a new improvement attitude and language can be

recognized within the companies. Lean and Six-sigma idioms and slogans become part of the company language. Often new roles are created to embed the new attitude in the job descriptions.

- Continuous improvement processes (if not culture) have been successfully installed. Often many continuous-improvement projects have started outside the program.

Common Concerns

Many companies have experienced similar issues in the evolution of their programs, particularly in the first 18 months. With the benefit of hindsight, OpEx leaders tend to highlight similar problems and solutions for others starting on the same journey:

- Insufficient corporate sponsorship and promotion is often found; communication of the importance and direction of the program from the business leaders is vital in reinforcing any messages coming from OpEx teams. If this is missing or misunderstood, it is extremely unlikely that the OpEx program will really “live and breathe” on a site. The method and wording of communications is critical to ensure OpEx methodologies are not treated as new cost-cutting initiatives, but rather the foundations for effective business.
- Insufficient buy-in and understanding within middle management is a recurring theme, leading to cynicism, delays, and low performance. Often, local priorities are given

precedence over the OpEx projects.

- Choosing the wrong projects and carrying out excessive analysis are seen as common pitfalls. Projects that fail to provide any material benefits will ensure a future lack of resources. The allocation of resources is never a simple task; when spare capacity is provided, any perceived waste of resource will hamper future support. The value obtained from the projects and training should always be greater than the investment required.
- Benefits derived from individual work streams are often not taken advantage of.
- Poor governance, inflexible leaders, and concept pilots that are too large can also hinder progress. Large pilots can be too cumbersome and soak up resources, causing the benefits and learning from the trial to be lost.

The Golden Rules

What is apparent is that all the companies researched view Lean and Six-sigma as the way business needs to be conducted from now on. An OpEx program is a critical undertaking for any organization, impacting the way the company will do business in the coming years. None of the OpEx programs researched has an end date. Therefore, one must conclude that the intent is to move from a program to a way of life. Even though many companies experience difficulties along the way, this should not be seen as a deterrent but as

a learning opportunity. Companies in the early stages can benefit from these lessons and correct the mistakes made by others. From Tefen's research, certain key messages have emerged that have been distilled into 10 Golden Rules (below). If OpEx programs live by these rules, the chance of success is very high and the potential rewards are great.

1. Operations Excellence is about people as well as numbers.
2. Operations Excellence should not be measured by financials alone.
3. Operations Excellence benefits from a Lean and Six-sigma approach.
4. Operations Excellence should move from "program" to "way of life."
5. Operations Excellence should be exploited throughout the organization.
6. Operations Excellence can benefit from the pilot rollout model.
7. Operations-Excellence sponsors need to be visible and supportive.
8. Operations Excellence benefits from effective external support.
9. Operations-Excellence programs need careful management
10. Operations Excellence is defined by communal knowledge.

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