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Using Metrics in the Research and Development Cycle

Most research and development (R&D) managers would say that they understand the concept of metrics but do not fully grasp how it can be practically applied. Among the challenges in implementing metrics are: where to start; how to ensure that changes are both initiated and sustained; how to achieve buy-in for change; and how to use the initial efforts as a starting point for internally generated improvements in the future. Alternatively, managers may admit they have attempted to introduce metrics and cycle-time reduction with little success. This article will explain why metrics are a key tool in improving productivity in today's R&D environment. Further, it will present keys to implementing metrics effectively and assuring long-term change. Finally, it will use real-life examples to illustrate pitfalls and problems, as well as solutions and key success factors.

Metrics in Research & Development

The use of metrics in R&D is important because of the sheer time and cost outlays involved. For example, pharmaceutical companies might see average costs of nearly $1 billion and a development timeline of well over ten years. Optimization of processes and timelines is a critical factor in saving both time and money. While costs and timelines are shorter in product manufacturing, market changes and competition make development cycle-time an important issue. Also, an earlier launch of product equals not only earlier revenue but a higher peak in overall revenues during the product's lifecycle. Establishing processes and metrics clears the way for focus on the science and quality of output. Tools that can be used consistently and with confidence allow better decision-making early in development. Consequently, more resources can be applied to productive development efforts. This can result in significant, quantifiable savings. At the clinical trials stage, it is well documented that over 80 percent of trials are not completed on time. A focus on reducing development cycle times and keeping trials on track can have a profound impact on not just R&D, but on the marketing timeline and the product's overall success.

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Navigating Your Organization's Future

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The practical value of an effective approach to R&D metrics can be quickly demonstrated by two pharmaceutical industry examples. At one site, a late reports backlog was worsening, increasing the potential for significant FDA problems. The problem was eliminated with a site-wide metrics approach — leading to a redesign of hand-offs and review stages, and renewed commitment to timelines. The internal team later successfully took on the challenge of significantly reducing study cycle times to become more aligned with industry standards.

In another situation, the pathology section had requested additional headcount to meet workload demands. A metrics assessment of time, process and productivity demonstrated there was a significant productivity issue in the current group. This was addressed with redesigned approaches to process and time usage. Factoring in the savings of not having to hire additional professionals, as well as the improved productivity of the current group, the metrics focus yielded significant results for this team.

What kind of organization benefits from process assessment and metrics/cycle-time reduction?

Regardless of size, today's successful organizations are geared toward strategic thinking applied to product development, production and marketing. In a larger, established organization, metrics issues arise because of size, lack of co-location and a status quo mentality. In a smaller or newer operation, the challenges often come from the need to establish systematic approaches to problem-solving. A company may have started out using an ad hoc approach to problem solving; an approach that becomes less effective as the company grows.

If there are such clear and demonstrable benefits to metrics in R&D, why is it not more broadly implemented? Consider the nature of the process. In manufacturing, process assessment, metrics and productivity improvement are used almost universally — but in this case, it is known what the final product should look like. In R&D, by its nature, the end product is somewhat of a mystery. However, in R&D metrics, the focus becomes process, not final product. One might wonder how quality will fare as a result of this approach. Quite well actually. R&D metrics is not about working faster: it is about optimizing approaches; reducing hand-offs and delays; lessening the burden of re-work; correcting scheduling issues; and otherwise enhancing process effectiveness. In reality, clear metrics support quality assurance.

It is important to note that metrics/cycle-time reduction are not meant to solve unrelated, underlying organizational problems. Building a organizational culture that supports metrics must be

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Did You Know?

Process Mapping Can Reduce R&D Paperwork!

As any R&D professional in an FDA-regulated company would affirm, documentation requirements can be time-consuming and burdensome. One major medical device company in New Jersey decided to use process mapping to see if its documentation processes could be streamlined and simplified.

First, the company formed teams within the R&D department to map the documentation processes involved for specific product lines. Then, the teams evaluated process steps, hand-offs, approvals, delays and cycle-times. Each team also identified "should be" and "could be" opportunities. "Should be" solutions clean up existing processes, and "could be" solutions require new processes and/or technology investments.

Several procedural changes were then made to existing processes, thereby immediately reducing paperwork and administrative tasks. Likewise, a new electronic document system was evaluated in an effort to promote additional gains in productivity.

In the end, the company reached several conclusions about its R&D administrative processes:

- *The processes themselves were not as complex as initially thought. Instead, it was the existing procedures associated with each process that caused confusion.*
- *Utilizing charts and maps during training can help people understand the entire R&D system, thereby preventing errors and inefficiencies.*
- *Some approval steps could be eliminated outright, without damaging the quality of the process.*
- *A lot of document copying and distribution went largely unused, and could be eliminated.*

Most notably, however, the company observed that the problem areas were not where management expected them to be, making the entire exercise that much more valuable. Without a means of mapping the entire process and clearly identifying weak areas, real and lasting solutions may not have been developed.

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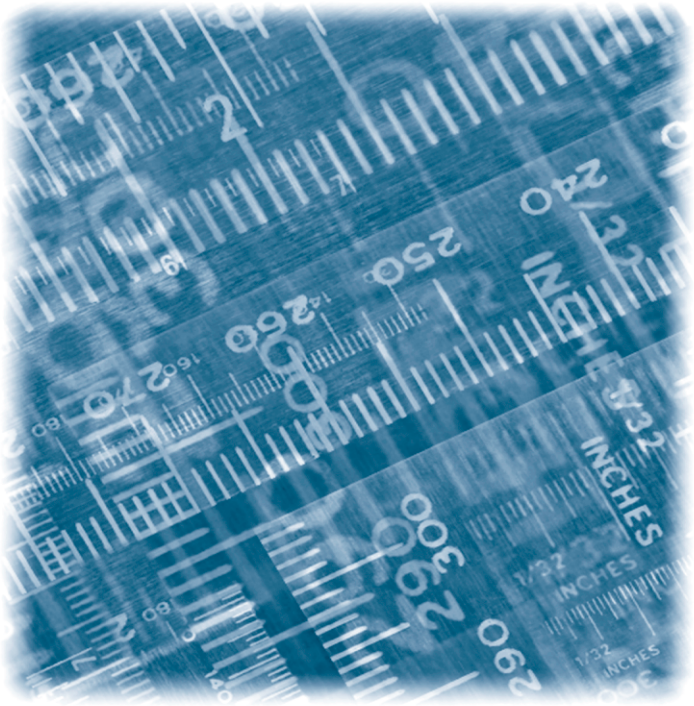

approached cross-functionally and must fit within the mission of the entire operation. Having an outside team come in to solve problems without broad-based internal involvement is an invitation to fail, since there is a process of unlearning and learning that has to go on for employees. Guided involvement of the internal teams in diagnosing and fixing their own problems is a big part of gaining buy-in. Expect some resistance, but also expect to see this diminish rapidly as successes are achieved and documented.

There are several key success factors in implementing and utilizing metrics, including:

- Understand and deal with other unrelated organizational and team issues as completely as possible before taking on a metrics project.
- Involve scientists and other product development professionals. In essence, they are mapping and improving their own processes. This generates ownership by the group.
- Keep the focus on process, not people. By stepping back and assessing processes and problems, we stay away from finger-pointing.
- Integrate across areas. Reducing cycle times and establishing strong sustainable metrics demands involvement of all groups that are involved upstream/downstream.
- Work small to large, and back. The total effort must include cross-functional operations. However, the most productive approach is to work through each area's assessments and proposed improvements, then look at the total group. If the integrated result require rethinking in a particular area, then that goes back to the originating group to reassess and agree.
- Establish a few key metrics to track (including at least one quality metric). No one pays attention to dozens of numbers, but two or three key indicators will attract and hold attention.

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New Two-Day Seminar: Measuring & Improving R&D Processes

Orion is pleased to announce the availability of our newest seminar offering designed to show how to increase productivity and reduce cycle times in R&D activities.

Led by Orion Development Group's R&D Process Consultant Dorothy Erlanger, this new seminar addresses where process and metrics fit within an organization; how to measure R&D processes; how to improve R&D processes; and implementation and ongoing improvement.

On the West Coast, this seminar is offered in conjunction with Cal State Hayward on November 2-3 in Oakland, California. On the East Coast, this seminar is offered in conjunction with Rutgers University on December 16-17 in New Brunswick. NJ.

For more information log on to http://www.odgroup.com/seminars/measure_rd.html.

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- Keep it public. Post results regularly to sustain momentum and also to get an early warning if there are any areas that are not achieving targeted improvements. A reassessment can quickly get a group back on track before major problems occur.
- Celebrate success. As targets are met and exceeded, recognize the team or operation involved.
- Don't rest on your laurels. After the first round of improvements, provide a timeline and forum to revisit and take the next step in improvements.

Metrics can be applied successfully in an R&D environment. The results are dramatic in terms of cycle time reductions and quality of work. The tools of process assessment, typically used in operational areas, work well in R&D. However, the approach and implementation include some special considerations relative to knowledge work and inherent uncertainty of results that are the nature of development. Effective process assessment has been demonstrated to produce long-term sustainable results in a range of R&D situations.

In the next issue of the *Orion Constellation...*

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