



Pharmaceutical Manufacturers Set Sights on Best-in-Class Operations Performance

Benchmark Study Reveals Practices of Top Performing Manufacturers

Executive Summary

Pharmaceutical organizations, large and small, face unprecedented pressure to balance innovation with operational excellence. In the past it was much easier to achieve margins acceptable to Wall Street, given the high margins and relatively low cost of goods of the times. Consequently, operational performance was never an issue, and never received attention ... until now, that is. Today's pharmaceutical manufacturers face expiring patents, stiff competition and price pressure from generics and FDA initiatives for process innovation, not to mention that manufacturing costs now exceed R&D operations. These and other factors compel pharmaceutical companies to focus on operational excellence - and it's now gaining strong attention from the executive suite.

The focus on operational excellence has:

- Forced companies to better utilize plant assets, people and materials;
- Caused plants to increase flexibility - enabling more products to be produced; and
- Created interest in looking to other industries to expand best practice knowledge.

From January to June 2007, Informance studied 50 pharmaceutical packaging lines worldwide. Researchers used the Informance Enterprise Manufacturing Intelligence Suite (including patented analytics), and IMPACT Advisory Services to collect data, derive insight and discover correlations to operational success of tactical and strategic actions.

Key Findings

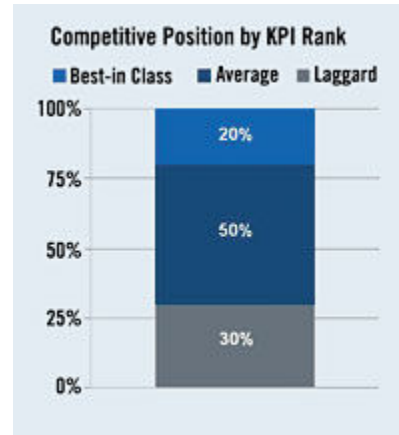
- Best-in-class pharmaceutical manufacturers exhibit 87% more availability than laggard performers
- Best-in-class performers reduce loss due to changeover at a factor 4 times greater than laggards
- Equipment failure is a significant contributor to lost capacity; however, best-in-class pharmaceutical manufacturers attribute 7% of lost capacity to equipment failure, versus laggards that experience a staggering 26% of capacity lost due to equipment failure.

Definition of Best-in-Class

To determine a manufacturer's competitive position, we use overall equipment effectiveness (OEE) as the top indicator of performance. We rank each manufacturer by OEE and view all other key performance indicators (KPIs) in context of this order. The average of the top 20%

of each KPI denotes best-in-class performance for that KPI, the average of the middle 50th percentile represents average performance, and the average of the bottom 30th percentile represents laggard performance.

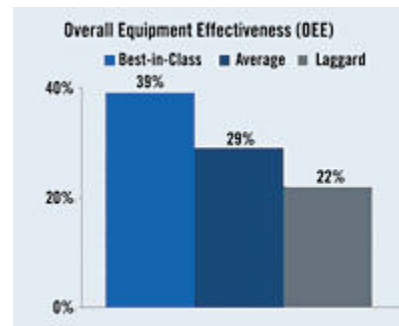
During this study, researchers also compared the performance of pharmaceutical manufacturers to those in the consumer packaged goods industry. Why this cross-industry comparison? Pharmaceutical packaging operations have a great deal in common with CPG manufacturers in terms of volume, packaging equipment, frequency of changeover, frequency of minor production interruptions, and maturity of lean and six sigma initiatives. Pharmaceutical packaging operations differ only in length of changeover time, due to activities mandated by regulation. By examining performance within and across industries, we can begin to identify potential areas for improvement by correlating the practices of best-in-class manufacturers, which companies eager to improve performance can then use as a starting point to set realistic improvement targets and develop an action plan.



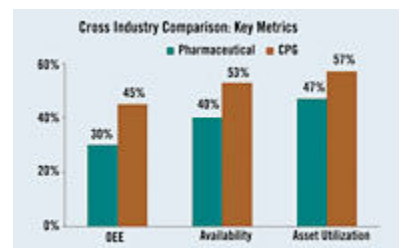
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Best-in-Class Differentiators

At first glance, best-in-class pharmaceutical manufacturers excel in Overall Equipment Effectiveness (OEE) over average and laggard counterparts. At 39%, best-in-class OEE is 17 percentage points higher than the 22% exhibited by laggards. Conversely, best-in-class consumer packaged goods manufacturers are 32 percentage points higher than their laggard peers, at 70% and 38% respectively.



Why do best-in-class CPG companies outpace laggards in their own industry at an astonishingly higher rate than best-in-class pharmaceutical companies over their own laggard peers? When comparing performance to consumer goods companies, we discover that pharmaceutical packaging operations lag far behind in not just OEE, but also other key metrics like availability and asset utilization - both of which have a significant impact on OEE.



(Click images for larger versions.)

OEE: The 1% Rule

Before we continue the journey exploring best-in-class differentiators, it's important to understand why so many organizations focus on OEE as a fundamental indicator of performance. Most of the manufacturers we studied are capacity constrained - producing more product equals more

The 1% Rule, (Pharmaceutical Manufacturing)

Value Lever	Value Potential	Financial Statement Lever
Labor Savings	\$423,077	COGS / SG&A
Inventory Savings	\$333,013	Inventory / COGS
New Revenue Margin Contribution	\$462,962	Gross Profit
Expanded Revenue	\$1,851,851	Revenue
One-Time Increase in Working Capital	\$2,220,088	CapEx/Assets
Total Impact: 1% Increase in OEE	\$6,510,048	

(Click image for larger version.)

revenue. While top-line revenue objectives typically drive initiatives to improve OEE, bottom-line benefits present strong justification for these efforts. A one-billion dollar pharmaceutical manufacturer quantified the financial effect for each percentage point improvement in OEE as at least \$6.5 million. The "one percent rule" creates value contribution in areas like cost of goods sold, inventory, gross profit, revenue, capital expense and assets.

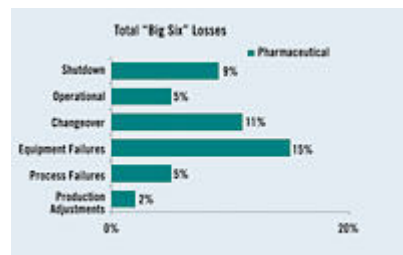
Big Six Losses

For this study, researchers categorized downtime in standard capacity loss buckets, known as the "Big Six", popular among most TPM practitioners. Across all of the pharmaceutical manufacturing lines in this study, almost one-half of capacity (47%) was lost due to the "big six." Best-in-class companies lost 33% of overall capacity to the "big six" while average and laggard performers lost 46% and 62% respectively. The "big six" disparity between best-in-class and laggards presents additional focus areas to help drive OEE performance.

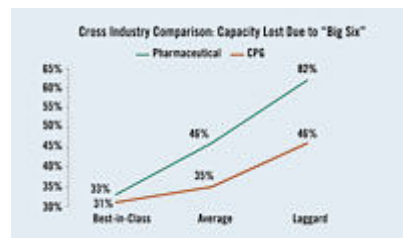
Definition of "Big Six" Losses

Shutdown	Preventative maintenance, breaks and lunches, training exercises, other miscellaneous production stops
Operational Downtime	Adjustments or related equipment losses that are not direct failures during scheduled run time
Changeover	Changes in material, equipment or product
Equipment Failures	Equipment unexpectedly becomes dysfunctional or inoperable
Process Failures	Changes in defective raw material
Production Adjustments	Time spent on changes in supply and demand that require adjustments to production plans

Turning again to the cross-industry comparison with CPG, researchers found that while best-in-class pharmaceutical manufacturers lost 33% of capacity to the "big six", their best-in-class counterparts in CPG lost only 31%. At the best-in-class level, there is not a great disparity, but as overall performance decreases (for average and laggard performers), the gap in performance increases. Researchers conclude that these losses hit pharmaceutical manufacturers much harder, and have a greater impact on performance.



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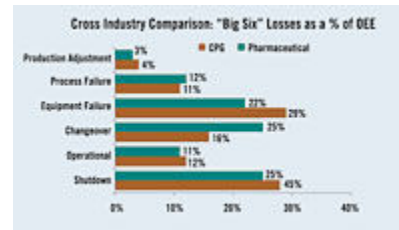


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Now that we have assessed and analyzed the "big six" as a percentage of overall capacity, it's helpful to dive deeper to understand how each of the loss buckets impacts performance. To prioritize these losses further, we evaluated the individual losses as a percentage of the "big six" and compared to loss buckets for CPG. Changeover and shutdown are tied as the largest loss area for pharmaceutical manufacturers, and is where researchers discovered the largest disparity between pharmaceutical and CPG companies. This validates the emphasis on changeover as a primary target of lost capacity for pharmaceutical manufacturers.

Looking specifically at changeover, we see that best-in-class pharmaceutical manufacturers maintain this loss category at 4% of capacity, in line with their best-in-class CPG counterparts. However, average and laggard performers in the CPG

industry significantly outperform their average and laggard counterparts in the pharmaceutical industry when maintaining loss from changeover. In fact, we see that even laggards in CPG significantly outperform average performers in pharmaceutical.



These findings indicate that changeover is possibly the leading cause of poor performance by pharmaceutical manufacturers - and their greatest opportunity for improvement. Since there is little difference between average and laggard pharmaceutical performers when it comes to maintaining loss due to changeover, yet we see outstanding performance from best-in-class, it is clear that world-class organizations have successfully reduced lost capacity from changeover, and maintain low or reduced cycle and setup times. In our experience, world-class firms do this by documenting settings, cross-training team members and utilizing quick changeover techniques.



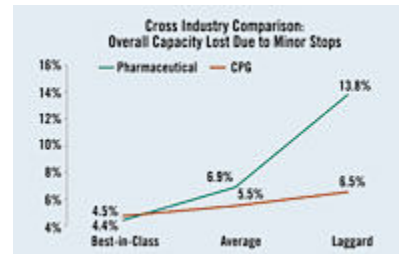
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Minor Stops

We define minor stops as interruptions with duration of ten minutes or less. The minor stop index is the number of minor stops per hour. While best-in-class performers in both industries maintain a low minor stop index, the large divergence in average and laggard pharmaceutical performers offers another opportunity for improvement. Certainly, the minor stop index for laggards in pharmaceutical is a shocking yet telling fact.



It is interesting to note that best-in-class performers in the pharmaceutical industry actually outperform their best-in-class counterparts in the CPG industry, 4.44 versus 4.74. As with previous gap analysis, we see a pronounced divergence in average pharmaceutical companies, and a much larger divergence, almost double, for laggard performers.



(Click images for larger versions.)

Recommendations

Average and Laggard Performers

- Minor stops, overall big six loss and equipment failures are areas proven by high performance organizations - a good place to start.
- Changeover, a key improvement opportunity, has been greatly reduced by best-in-class companies by cross-training team members, utilizing 5s and quick changeover techniques.

Best-in-Class Performers

- There is always room for improvement - with an average OEE of 39%, this holds very true.
- A "better-than-CPG" metric such as equipment failures suggests that TPM, or other proactive strategies are in place. Should organizations invest more in these programs? There is always a point of diminishing return, but at this time, the research suggests additional room for improvement.

What's Next in Achieving Operational Excellence?

Many operational improvement initiatives have a "bottom's-up" look and feel; they start at the plant and even line-level, and move through the enterprise. One flaw with this approach is that it's difficult, and often impossible, to propagate best practices between plants and throughout the organization. Since the average global enterprise has 22 facilities, forward-thinking companies view multi-site performance analysis as a key value generator for the enterprise.

With the ability to leverage composite metrics for many KPIs across a number of plants, organizations can better determine which investments, and which strategic and tactical changes will provide the greatest impact across the entire enterprise. For example a company can now ask, "Is there a small set of improvements that, if applied globally, will reduce downtime and improve performance across the enterprise?" Many times, the answer is "yes." But, without the right information and ability to effectively evaluate and quantify the financial impact of improvements, it is extremely difficult to find and justify the right combination of strategic and tactical changes for the greatest impact on performance.

About Informance Benchmark Studies

Informance benchmark studies demonstrate how practices of best-in-class companies impact manufacturing performance. Researchers use 5-7 months of real-time manufacturing performance data aggregated using the Informance Enterprise Manufacturing Intelligence platform. The highly granular and rich real-time nature of Informance EMI adds a new dimension for external and internal benchmarking initiatives. By correlating attributes of best-in-class performers across a variety of metrics, executives have the ability to gain insight and direction. Organizations can use Informance benchmark studies as a starting point to understand how they stack up against their peers and develop an action plan for operational improvement. Each year, Informance publishes a number of benchmark studies across manufacturing industries that include consumer packaged goods, pharmaceutical, food and beverage, chemical, and industrial products. Informance has forged new ground in cross-industry benchmarking, so that manufacturing executives and professionals can understand and apply best practices from peers in other industries.

To learn more about Informance benchmark studies, or to schedule a briefing or strategic assessment call (877) 464-6262 or email info@informance.com.

About the Author

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Sudy brings to Informance nearly 20 years of business process leadership, and was most recently senior analyst and vice president of global supply management research programs for Aberdeen Group. Prior to Aberdeen, he was a member of the management team of MINDFLOW Technologies, a leading strategic sourcing solutions provider. Sudy has also served in a variety of management roles spanning marketing, sales, product management, program management, and consulting at i2, Hewlett-Packard, Scientific Computing Associates and ParaSoft Corporation. First launching his career as a software developer, Sudy earned his B.S. in Computer Science from the State University of New York at Buffalo.

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