*Written by Ken Hunter, APR*
*khunter@PowerStationComms.com / 908-295-8946*

# Pharmaceutical Resolutions for the New Year: Solve Problems Before They Occur

By Michael Curran-Hays
Global President, General Enterprise
Kepner-Tregoe Inc.

Last year was filled with a myriad of issues that the pharmaceutical industry has had to combat and rise above. However, with the implementation of a few proactive programs to address lessons learned while applying foresight to industry trends, the inevitable issues that will arise next year can be solved or mitigated even before they occur.

## Hot Topics From the Year

### Product safety recalls

Without a doubt, safety recalls were the greatest concern to pharmaceutical companies. The most notable recalls were for antidepressant drugs (linked to suicidal thinking and behavior in young adults), anemia drugs (linked to heart problems) and vaccination contamination. In addition to affecting company perception and revenues, at the plant level, recalls affect manufacturing schedules, labeling and other functions, creating line downtime and other delays. Plus, these issues affect profits.

Lesson learned: quick recall action is a necessary response, but diligent troubleshooting will restore confidence with employees, stockholders and the public.

### Quality concerns

Anticipating the potential for product contamination is a continual expertise being refined at pharmaceutical companies. Contaminated batches are very costly - not just to profitability, but also in its effects on public perception, increased FDA scrutiny, and recreating processes to identify culprits.

Lesson learned: instill a company-wide culture that treats troubleshooting as a required skill.

### Offshore manufacturing

Pharmaceutical companies are often challenged with the opportunity for lower costs in an offshore manufacturing facility offset by the distance from experienced oversight, different "local" manufacturing philosophies, and divergent cultures. Companies that develop strong process management skills, while continually analyzing how they are being implemented in an offshore location, will be able to overcome these issues.

Lesson learned: treat offshore manufacturing as a process where you assume nothing.

*Written by Ken Hunter, APR*
*khunter@PowerStationComms.com / 908-295-8946*

**Adopting world class manufacturing practices such as Lean Manufacturing and Six Sigma**
Pharmaceutical companies have been implementing these practices for several years, and have seen dramatic improvements in manufacturing. However, manufacturers are falling short on the people management aspects of these practices in the drive to attain "flow" with "zero" waste.

Lesson learned: bring the people that are responsible for sustaining these programs to the forefront and better manage them in the process to decrease variable and unpredictable process improvements and business results that can't be maintained.

## Issues of Importance for Next Year

**Pressures to cut manufacturing costs/reduce waste**
This is a double-edged sword, where changes in the process can have wide-ranging effects that may not bring the benefits anticipated. Also, answers become less obvious as a supposedly winning process becomes entrenched.

Resolution: approach cost and waste changes with a skeptical eye on outcomes. The more proof you can gather to convince your team that a change will be beneficial, the better the change.

**Quality concerns/improvements**
As the industry saw this year, pharmaceutical manufacturers will need to stay ahead of the problems that can lead to contamination, recalls or other negatives that can affect the entire enterprise.

Resolution: be thoroughly consistent in your review of the manufacturing process so that you can more easily identify unusual situations that can throw your process into turmoil.

**Regulation and compliance problems across global operations**
A good guideline to follow is the further from the home base, the more potential for problems.

Resolution: create a manufacturing culture that will better educate overseas floor personnel on Lean and Six Sigma drivers so they can better identify process problems and improvements to offset the issues brought by international manufacturing.

**Patent expiration and cost pressure**
Patent expirations continually affect the pharmaceutical industry. But manufacturers need to continually mitigate the effects of these revenue hits. Unlike contamination concerns or safety recalls, these events are known well in advance, and that allows ample time to develop cost responses.

Resolution: begin planning earlier and smarter to better replace lost revenue streams with improvements in manufacturing processes.

*Written by Ken Hunter, APR*
*khunter@PowerStationComms.com / 908-295-8946*

**How Companies Will Be Addressing These Issues:**

1) Pharmaceutical companies will continue to implement Lean principles, including Lean Office techniques in the non-manufacturing areas such as research and development, marketing, sales, etc., and will address ways to improve manufacturing performance and cut costs. Changes we are likely to see:

a. Equipment: companies will increasingly develop and implement reliability-centered maintenance plans.

b. Human behavior: project management training will expand so pharmaceutical teams can optimize performance.

2) With compliance remaining a necessity in the pharmaceutical industry, we will see pharmaceutical companies focusing more now than ever on Corrective/Preventive Action (CAPA) programs that institutionalize a global, standardized approach to troubleshooting and written investigations.

CAPA programs offer these benefits:

- Reduce recurring problems
- Reduce time to locate the root cause
- Reduce time to close investigations and take corrective and preventive actions

When implementing a CAPA program to address compliance issues, heed these tips:

- Develop and analyze investigation success factors and be sure to quantify their impacts
- Determine the performance-gap causes
- Create solutions that can be quickly implemented

**A Key Tool to Implement Next Year:**

There will always be pressure in the pharmaceutical industry to keep maintenance costs to a minimum, and through reliability-centered maintenance plans, this can be accomplished. Managers need to see solid evidence of the likely return these programs will generate through factors such as money, downtime, quality, safety, and compliance in order to prove that their equipment is properly maintained for the least cost.

A strategy Kepner-Tregoe developed and frequently applies is the creation of a comprehensive and robust Asset Management program, which becomes an "owner's manual" for bridging the gap between an organization's strategic and production objectives, and the maintenance policies and modification decisions for critical assets. This Kepner-Tregoe proprietary tool is called Asset Performance Management Concept (APMC).

On its most basic level, the APMC provides a clear description of what a manager needs to do and when. On a more advanced level, this “owner’s manual” provides analysis,

planning, and actions needed for effective plant and facilities management. An APMC also should determine the financial consequences of equipment failure and maintenance actions within defined parameters of problem and risk. In addition, an APMC documents the logic and value of maintenance activity, and consequently, provides work orders for an appropriate level of maintenance.

**Here are the Steps to Implement an Effective APMC:**

- **Define Standards**

Before an analysis of maintenance requirements or actions is taken, production and strategic objectives must be defined with requirements or actions to take. Additionally, requirements for acceptable safety, environmental, regulatory, and other standards need to be established and prioritized as "Musts" and "Wants."

- **Assess Failure Moves**

By asking the right questions in a rational order, you create a structured and unambiguous list of potential failure modes, their likelihood of occurring, and all their effects.

- **Understand Alternatives**

An AMPC needs to be configured to help you identify and monetize actions that reduce or eliminate the probability of a failure mode occurring while comparing alternatives using annual costs.

- **Plan Effectively and Efficiently**

Decision trees should be built into an APMC to guide the actions that achieve the lowest total annual costs and eliminate ineffective actions. Built-in calculations help determine the financial consequences of each action within well-defined parameters.

- **Focus Analysis**

Identifying which assets should require an APMC is best determined using value-driven maintenance analysis. This ensures that the APMC will provide significant value. An APMC for new equipment is a useful tool when initiated during the engineering phase.

- **Respond to Change**

An APMC should be flexible to help pharmaceutical management make rapid maintenance decisions in response to sudden changes in market conditions, production performance, government regulations, or other variables by incorporating new data into the APMC template and recalculating based on the new weighted objectives, performance measures, or costs.

- **Capture Knowledge**

APMC models for key assets should serve as repositories for all information relating to performance. This makes APMC especially valuable to organizations with an aging workforce or high employee turnover.

*Written by Ken Hunter, APR*
*khunter@PowerStationComms.com / 908-295-8946*

With the variety of problems pharmaceutical companies are likely to face in 2008, one strategy should remain constant: develop a plan to address the problems in quality, production and maintenance before the problems occur. This philosophy will save pharmaceutical manufacturers expense, time and effort, while positively affecting profitability and even public perception. Your new year's resolution should be to take control of the situation before it even occurs.

***About the author:***

Michael Curran-Hays directs Kepner-Tregoe Inc. general enterprise operations in the U.S., Canada and Europe. Mr. Curran-Hays provides executive leadership for all consulting and training services in the region including client-specific, integrated teams of Kepner-Tregoe professionals.

Mr. Curran-Hays joined Kepner-Tregoe in 1998 as a consultant specializing in analyzing organizational processes, facilitating issue resolution, designing and implementing project management systems, and transferring critical thinking skills in client organizations. His expertise is in cost management, operational improvement, and strategy formulation. Clients he has worked with include Bayer AG, Pfizer, Johnson & Johnson, Bristol-Myers Squibb, Novartis, Abbott, Glaxo Smith Kline, Boston Scientific, and Tyco (Covidien). Mr. Curran-Hays holds a Bachelor of Arts degree from the University of Arizona. He resides in Camp Hill, Pa.

# # #