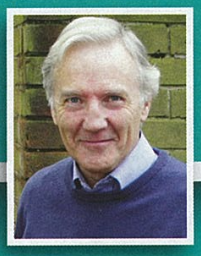
Plant reliability

How do managers in the pharmaceutical industry ensure that their plant performs reliably and safely? Michael Dixey and Pete Hibbs of GGR Associates explain some of the reasons for poor performance and suggest how these problems may be overcome.



Many pharmaceutical companies have invested heavily in recent years in new plant and equipment. Much of this equipment is running at higher speeds and for longer periods — often 24/7. Yet, despite this investment in equipment, plant performance may not be reaching target levels. Companies measuring overall equipment effectiveness (OEE) often find that plant reliability is little better than it was before the investments were made.

In response, some companies focus on increasing the amount of preventive maintenance being undertaken, particularly in response to failures. Some upgrade their computerised maintenance management system (CMMS) or focus on shop floor data capture systems. Others make organisational changes. These seldom make a significant difference. No wonder senior managers feel that they are 'between a rock and a hard place'!

Yet the civil airlines learnt that increased maintenance and improved systems do not necessarily improve reliability. Indeed, their research work showed that certain types of maintenance are counter-productive and reduce reliability.

Causes of poor performance

To understand why plant performance is poor, one needs first to look closely at the underlying causes. In many companies, most 'performance losses' are classed as downtime which, in turn, is equated with breakdowns. Breakdowns are viewed as being a maintenance issue.

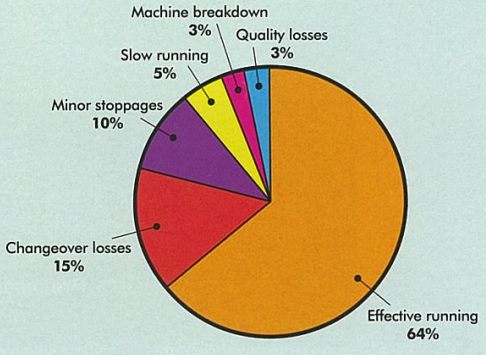
However, the reality is often very different. Most equipment in the pharmaceutical industry will run virtually forever if no raw materials, product or packaging are put through it. The majority of the causes of poor performance centre around the machine/material interfaces, and there may be many of these. For example, on a packaging line there may be several hundred of these interfaces.

A typical analysis of these losses for a packaging line which is achieving 64% efficiency is given in figure 1. Less than 5% of the losses are due to breakdowns. Most of the losses for a packaging line are likely to be caused by one or more of the following:

- Poor setting at start-ups or changeovers
- Raw material or packaging variations
- Process capability issues
- Equipment design limitations
- Poor line control philosophy
- Process control issues
- Incorrect or inadequate operating procedures
- Inappropriate intrusive preventive maintenance
- Operator 'adjustments'
- Inappropriate cleaning or hygiene procedures.

LINE EFFICIENCY LOSSES

Figure 1



Few, if any, of these problems can be solved with improved preventive maintenance. Even the causes of genuine breakdowns can often be traced back to problems at the machine/material interface. To leave it to the engineers to solve these problems on their own is clearly inappropriate. Yet this is exactly what many companies do.

Possible solutions

Many companies will have programmes such as Lean, World Class Manufacturing or Manufacturing Excellence. Within these programmes, they may be using one or more of the following methodologies for improving equipment reliability:

- Total productive maintenance (TPM)
- Reliability centred maintenance (RCM)
- Failure mode, effects & criticality analysis (FMECA)
- Single minute exchange of dies (SMED).

Each of these focuses on different aspects of performance.

TPM was developed in the Japanese car industry. It tends to concentrate on operator-related issues — 'ownership' of the equipment and the basic disciplines, e.g. the 5Ss (an approach to organising the workplace, keeping it neat and clean, and maintaining the standardised conditions and disciplines needed to do an effective job). It also puts great emphasis on the need for continuous improvement, and can be a driver for autonomous maintenance.

RCM is from the US airlines. It focuses on developing and optimising preventive maintenance routines. It also identifies where maintenance alone cannot deliver the required reliability.

FMECA comes from the off-shore oil and gas industry. It is now most widely used at the design stage for equipment, with the purpose of improving the design to eliminate potential failures or to mitigate their consequences.

SMED is from the press shops in the car industry. It focuses on reducing start-up and changeover times and losses. (In the authors' experience, over half the waste in the pharmaceutical industry can be directly attributed to poor start-up and changeover procedures.)

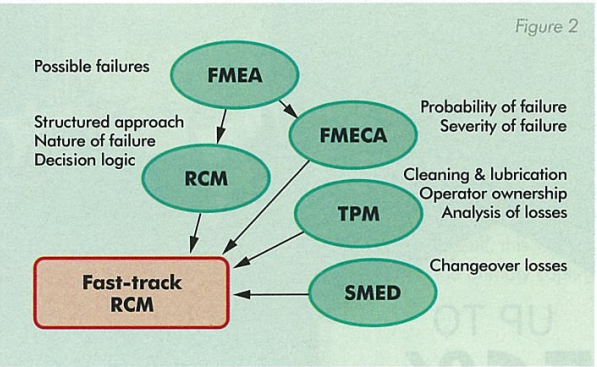
All four of these approaches have their strengths, but none address the complete range of problems which affect plant performance in most companies.

An alternative approach

Working with a number of household-name companies, GGR Associates have developed an approach to overcome these limitations. It is based on the structure of RCM but incorporates many of the best features of TPM, FMECA and SMED (see figure 2). This approach which is called Fast-track RCM has three stages:

- Failure analysis: An analysis of the ways in which the equipment can fail to perform together with the root causes. These are identified under seven headings, somewhat similar to TPM's six losses. The categories include more than 'breakdown' failure modes: they cover intermittent stoppages, slow running, quality and product integrity issues, low yields, start-up and changeover losses, material problems, access and maintainability issues, safety and protection, etc.
- Consequences and criticality assessment: The consequences and criticality of each of these failures are evaluated, including an assessment of both the probability and the severity of the failure modes (as in FMECA).
- Recommended actions: The recommendations are made with the help of a comprehensive logic diagram. The actions available are many and include cleaning and lubrication routines, preventive maintenance tasks (emphasis on condition-based maintenance), changes to operating procedures or setting and changeover routines, training, improved documentation (SOPs), changes to the specification of materials including packaging and its storage, plant modifications, necessary rectification work and spares recommendations.

Figure 2



The analysis is performed by a small team that knows the equipment well, working under the guidance of a facilitator — similar to TPM — and involves both operators and technicians as well as relevant specialists such as quality control. The focus is on improving overall plant performance and ensuring that product integrity is maintained at the very highest level.

Unlike TPM, Fast-track RCM is performed on a machine-by-machine basis, rather than as a site-wide initiative. This makes the approach much easier to manage. The approach is also quicker to use than 'classical' RCM (e.g., RCM2/MSG-3), typically taking about one-third of the time. Its application has led to step changes in performance levels in a wide range of industries.

Conclusions

Performance improvement initiatives are usually started with much enthusiasm but tend to be short-lived and have limited impact. This is often because the techniques and methodologies being used do not address the wide range of issues faced by production and engineering management.

The authors recommend that Fast-track RCM initiatives always start with one or more pilot projects to demonstrate the effectiveness and relevance of the approach. Once this has been established, it can then be rolled-out on a phased basis to all areas where there is scope for improved performance.