

# manufacturing CHEMIST

Volume 88 Number 6 June 2017

THE LEADING JOURNAL FOR THE PHARMACEUTICAL INDUSTRY

## ADAM COVITT

Adam Covitt, Vice President of Federal Equipment Company, explains "OEE," overall equipment effectiveness for oral solid dose manufacturing pp 44-45

**Federal Equipment**  
Company

## CONTAINMENT

Room to manoeuvre and the case of the faulty valve

## SERIALISATION

The EU-FMD compliance project: is Europe ready?

## FORMULATION

The use of parallel screening to overcome bioavailability issues

**Focused on measuring equipment availability** and reliable, as-designed functionality, OEE principles focus on “losses” that can be generated from a whole host of issues related to equipment. At a macro level, OEE focuses on availability loss, performance loss and quality loss; it also takes into account idling and minor stops, one of the Six Big Losses that affect OEE performance (Table I).<sup>1</sup>

In a 2014 *Industry Week* article, Senior Consultant Ellis New, Business Practice Leader for Productivity Inc., explained: “OEE assigns a numerical value to improvement opportunity. It factors in the availability, performance and quality of output of a given piece of equipment and asks you this: How much right-first-time product did this machine produce compared with what it should have produced in the allocated time?”

In other words, the question and answer is as follows: Is a piece of equipment effective within its value stream? Does it let you meet present or future customer demand? If not, says New (and this is critical), OEE helps you analyse the reasons why, so you can address them systematically.<sup>1</sup>

Acquiring pharmaceutical processing equipment and successfully integrating it into operations is not as straightforward as it may seem. Whether used or new, everything is up for consideration and evaluation, including vendor, type, specifications, performance, reliability, capability, service life, price and, importantly, availability. Oral solid dose (OSD) manufacturing, especially at commercial scale, is particularly dependent on the operational efficiency of a familiar but increasingly complex train of processing equipment to mass-produce tablets and capsules. The efficient production of OSD products relies on operational excellence and the ability to deliver high-performing, variation-free processes.

## Strategic equipment acquisition

Without sounding too simplistic, the primary reason why pharmaceutical manufacturers

purchase production processing equipment is to meet present or future demand for its products. Beyond that, there are hundreds of business and competitive drivers prompting equipment acquisition, and it's safe to assume that the better a company is at acquiring and integrating equipment into operations, the more economical, efficient and flexible those operations can be. Given speed to market, response to market demand, competition and all the other factors involved, OSD pharma processors are increasingly looking to head off OEE's six big "losses" as early as possible, boost equipment value as soon as possible and, by necessity, earn its keep for years to come.

Pharma manufacturers operate some of the most intensive processing environments and, after 40 years in the business, we understand that customers engage with us and return to us because we've developed a business model that provides a range of resources — we not only optimise equipment selection, but its acquisition, installation and process implementation.

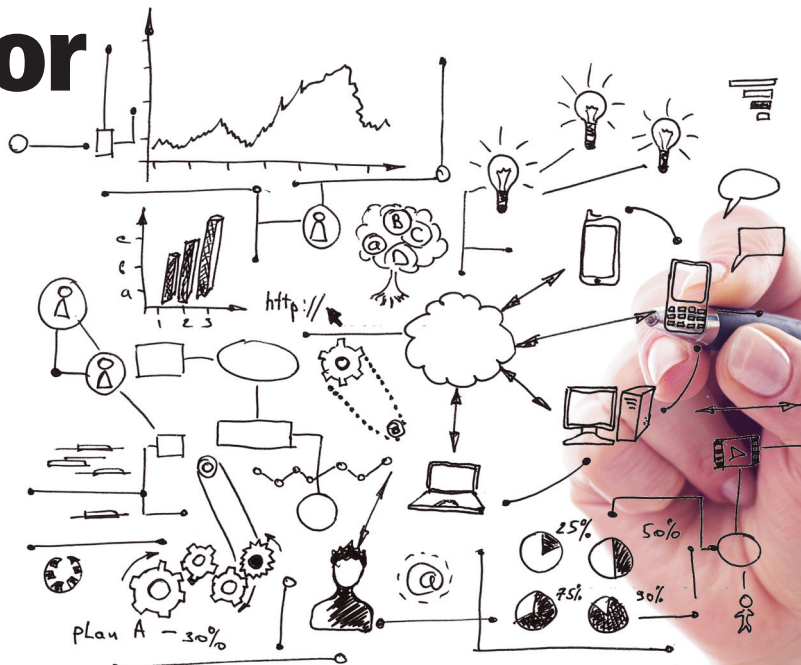
The process and manufacturing community understands that OEE offers a solid foundation for measuring or scoring operational excellence. It also offers a guide to how we marshal company resources and key partnerships to support our customers' equipment acquisitions and integrations. Whether choosing from the extensive inventory of used OSD equipment that Federal Equipment Company maintains, or selecting new technology from prominent OEMs — many of them partners — we've created a unique equipment buyer's journey built around key equipment supply chain relationships — relationships that effectively support equipment acquisition strategies for some of pharma's most prominent branded, generic and contract OSD manufacturers.

As mentioned, there are hundreds of reasons that prompt an equipment purchase; but, first, you must find the equipment. Acquiring the right

“OEE offers a solid foundation for measuring or scoring operational excellence

# Overall equipment effectiveness for oral solid dose sourcing and integration

Measuring the operational performance of process equipment has evolved with time, and the methodology to determine overall equipment effectiveness (OEE) is gaining in popularity





**Table 1:** The six big losses

|                         |  |
|-------------------------|--|
| Availability (downtime) | Equipment failure (breakdowns)                     |
|                         | Set-up and adjustment                              |
| Performance (speed)     | Idling and minor stoppages                         |
|                         | Reduced speed of operation                         |
| Quality (defects)       | Process defects (scrap, repairs)                   |
|                         | Reduced yield (from start-up to stable production) |

machine for the job at the speed of business and within often-severe financial constraints has frustrated many a process engineer under pressure to extend a line in a hurry. New equipment is one answer, but manufacturers' timelines and other constraints can disrupt or delay critical equipment/process-related project timelines if delivery won't fit the schedule. The dynamics of the secondary equipment market can offer relief, and working with an experienced and knowledgeable equipment dealer who can locate and source affordable access to a particular machine or system will help you to meet challenging project goals and deadlines.

In OEE circles, 100% performance means equipment in the manufacturing process is running at its theoretical maximum speed while operating. There are so many things that contribute to process performance (or the lack thereof) and, like any complex technical endeavour, requires a comprehensive approach. Applying OEE strategy and a GMP-like process to equipment purchasing, uptake and acquisition is best practice. Because product quality is so tightly linked to equipment performance, pharma OSD manufacturers must be masters of all aspects of formulation, equipment condition and proper operation and maintenance. However, not every pharma processor has the resources to accomplish this internally.

### Process and equipment education

OEE philosophy is centred on finding improvement opportunities. As Federal Equipment Company's experience with equipment acquisition has continued to grow, it became apparent that good customer experience and success with an equipment purchase is closely associated to how well an organisation understands all the improvement opportunities that might be associated with their equipment purchase.

Addressing this knowledge gap and helping pharma's OSD manufacturers institutionalise better operational practices (in an effort to foster a more transparent and effective understanding of equipment and solid dose process) has been technical consultant Mike Tousey's mission for decades. Under the Techceuticals banner, Tousey has been schooling OSD equipment suppliers, pharma processors and operators on the finer points of tablet and capsule processing. Years of client referrals and co-operation created synergies that our mutual customers increasingly find valuable.

Federal Equipment Company's long experience of selling used equipment is similar to new equipment vendors: pharma's OSD manufacturers want to get the most value out of every dollar spent on capital equipment

In 2012, Federal Equipment Company extended its relationship with Tousey, colocating Techceuticals classrooms and labs adjacent to new environmentally controlled equipment staging and storage facilities acquired in a recent expansion. Combining lectures and hands-on training, Techceuticals provides a perfect venue to address gaps in OSD process optimisation and conduct equipment evaluations as part of a comprehensive equipment acquisition strategy.

Tousey explains that not every company understands exactly what equipment or process specifics will suit their needs best or understand how to optimise formulation/equipment to curtail quality excursions and other things gumming up operations. The lab creates an opportunity to explore and evaluate alternatives and options without the financial commitment. The lab currently houses some of the most advanced solid dose manufacturing equipment now offered by the industry's biggest names, including Glatt, O'Hara, Korsch, Fette, Globe, Vector and similar, popular OEMs.

Recently, Glatt installed two of its latest wet and dry granulators at the Cleveland lab, part of an ongoing relationship with Techceuticals, Federal Equipment Company and the pharmaceutical manufacturing industry. Quality OSD equipment can have an extended life (especially once it moves into secondary markets) and whether acquired new or used, the closer equipment vendors can be to its users the better.

"Our commitment to customers doesn't end with delivery," said Ed Godek, Process Technology Manager for Glatt. "We want to connect with our users in meaningful practical ways; central to that effort is our direct support of Techceuticals' training and optimisation mission. Beyond that, we offer factory support to Federal Equipment Company's buyers of used Glatt equipment — the relationship creates great synergies that all our customers value." According to Tousey, the Techceuticals lab provides a real-world processing environment wherein students can evaluate the performance of their current and proposed formulations in machines they are looking to specify and acquire. "We provide the training and the equipment necessary for anyone looking to get better performance and quality from the solid dose products they manufacture," he says.

### Operational excellence

Acquiring equipment and implementing it effectively is becoming a strategic imperative that no pharma manufacturer can avoid. Equipment performance metrics such as OEE can provide guidance and frame a best practice acquisition strategy. The synergies between Federal Equipment Company, Techceuticals and equipment OEMs form a nexus for operational excellence and provide the means to effectively evaluate equipment, explore process optimisation tactics to make equipment acquisition more strategic and extend the value of every equipment dollar spent.

### REFERENCE

1. E. New, "OEE – Learn How to Use It Right," *Industry Week* (19 August 2014).

### FOR MORE INFORMATION

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