Waking up to Waste

Waste can present an untapped source of substantial savings when practices are thoroughly examined and updated – a realisation that is beginning to bear fruit for the more forward-thinking and proactive companies in the sector.

By Lee Petts at Remsol Limited

Lee Petts is Founder and Managing Director of Remsol Limited, a company specialising in waste, resource and environmental management. He has over 15 years’ experience in the waste management business, gained at UK-based companies such as North West Water, UK Waste and P&R Group. During this time, he developed an interest in managing waste from pharmaceutical manufacturing sites, leading him to set up Remsol in 2002. In the last five years, the company has expanded its expertise in the pharmaceutical sector, helping a number of companies to produce less waste, recycle more of the waste they produce and keep costs under control.

Times are changing fast. With an increasing number of the world’s best-selling drugs due to come off-patent in the next couple of years, paving the way for even greater competition from the generics market, and with fewer blockbuster drugs in the pipeline to replace them, the pharmaceutical giants of old are boosting their efforts to cut costs in order to maintain their respective competitive positions. Pfizer, for example, recently announced plans to save $2 billion worldwide, with some of the savings expected to come from shedding up to 10% of its global workforce.

Despite these efforts, the cost structure of many businesses is increasing. Energy costs, for example, have continued to rise on the back of unsettled conditions in the Middle East, pushing oil prices to record highs in recent times.

Waste management, too, is an area in which costs are generally increasing. In the UK and Europe, tougher laws dictating the disposal fate of many wastes produced in the pharmaceutical sector have led to a rise in demand for incineration capacity, prompting increases in the unit rate costs of disposal. This has been made worse by the need to upgrade many existing incineration plants to meet strict new emissions limits, with operators seeking to pass on these infrastructure costs to their customers.

Yet, paradoxically, waste can often present an untapped source of substantial savings when practices are thoroughly examined and updated – a realisation that is beginning to bear fruit for the more forward-thinking and proactive companies in the sector, particularly contract manufacturing organisations (CMOs).

CURBING WASTE OUTPUT AND COSTS THROUGH PROCESS REVIEW

Historically, the pharmaceutical industry has generally been perceived as an extravagant consumer of energy, water and raw materials. Whilst this may not be entirely fair, there is an element of substance in the claim; this has been borne out by the record profits announced by the world’s larger groups, and by what has appeared to be a lack of enthusiasm for invigorating operations with waste reduction and resource efficiency programmes.

With the costs of bringing new drugs to market increasing, and thought to now average $1 billion for a blockbuster. However, these same companies are switching on to the savings that can be created by reviewing their manufacturing processes to find ways of reducing waste or producing waste in a form that makes it easier to recycle rather than dispose of. Working with Remsol, one CMO in the UK recently identified that between 15% and 45% of production waste consigned for expensive incineration could be safely disposed of by much less expensive means through simple source segregation. It is expected that savings of up to £32,000 per year will be realised as a result.

In another example, a manufacturer of sterile injectables was able to reduce its exposure to the high costs of waste incineration after it was found that a substantial quantity of the production waste it discarded every year was nothing more than glass vials, which are now recycled into fibreglass products free of charge.

Whilst it will always remain possible to reduce waste bills through direct negotiation of market rate costs with a company’s chosen suppliers, the evidence suggests that there is no substitute for tackling the issue at source. Businesses need to focus more on eliminating or reducing waste in all its forms – not simply relying on better characterisation and segregation.

Water use is an area that is often overlooked in the pharmaceutical sector, particularly because of the way it is used so extensively for cleaning in place (CIP). In a recent case, one company found that its CIP practices, which were developed fifteen years earlier, had become so outdated that they were regularly wasting on average 15,000 litres of expensive water for injection (WFI) every day. Needless to say, they are now in the process of changing this practice.
Once-through systems that use water to cool product in jacketed vessels are still incredibly common when — instead — used cooling water should be processed through a heat exchanger so that it can be re-used continually (allowing for evaporative losses) and thus reduce water consumption. There is a tendency in developed countries not to view water as a resource worthy of enhanced protection because it is generally widely available, but this may not always be the case — particularly if predictions concerning climate change are correct and water shortages become more common around the world.

Unfortunately, because businesses inevitably focus their resources on what they exist to do (and are best at doing), opportunities like these are often missed and are not identified without the benefit of outside assistance — someone who can see the wood despite the presence of all the trees.

**RISING DISPOSAL COSTS DRIVING TECHNOLOGICAL CHANGE**

With much of the waste that arises in the pharmaceutical sector being in some way “hazardous”, the options for disposal have for a long time been limited. Incineration remains the most favoured option, particularly for rejected finished product in consumer packaging, but this is increasingly expensive – whether operating an in-house facility that is in constant need of maintenance or relying on merchant capacity.

It is said that “necessity is the mother of all invention”, and so it is that novel new methods for dealing with leftover, non-recyclable waste are being sought in a bid to reduce exposure to uncertain market costs, driven by supply and demand. At Remsol, for example, we are currently involved in developing a physico-mechanical treatment system for the disposal of drugs presented in blister packs. It is expected that this will significantly reduce dependency on incineration as a final disposal method by as much as 6:1, whilst still ensuring that primary packaging and the drug itself is effectively “destroyed”. The system is being designed so that it can be incorporated at the point-of-production too, greatly reducing the demand for vehicular transportation of waste to remote disposal locations, thereby lowering costs – and the associated carbon emissions – for manufacturers that don’t operate in-house incineration.

Others are focused on pursuing high-tech solutions to more complex chemical waste problems, with great hopes being placed on Plasma Arc and Gasification as a means of breaking down the molecular structure of intractable hazardous wastes, and thus rendering them non-hazardous. Whilst these technologies and others are still in their infancy, their scope for reducing business waste costs in the pharmaceutical sector cannot be ignored and must be watched with interest.

**PVC PACKAGING**

Concern about product contact with PVC packaging has been growing for some time, in both the food and pharmaceutical industries. Whilst, generally, businesses seem to have reacted slowly to this concern, there is now an added incentive to seek alternatives: doing so could help to boost the recyclability of unwanted production residues such as ‘grid waste’ from tablet blistering and bottles used to contain eyedrops and so on.

PVC has always been somewhat tricky to recycle owing to the potential for chlorine to be liberated during any downstream reprocessing operation, but it also hinders recycling opportunities in other areas. For example, many of the aluminium foils used in sealing blister packs are actually a multilayer laminate that consists not just of aluminium but also of paper and PVC. Were it not for the presence of the PVC, it is very likely that the aluminium reprocessing industry could accept such wastes for recovery; the paper content would rapidly (and without hazard) “burn off” in the smelting process, as would other plastics which, without the associated chlorine problem, may also not cause aluminium smelters any real difficulties. And, even were this not to be viable option, substituting PVC with less environmentally hazardous plastic products would almost certainly open up greater access to the burgeoning waste-to-energy market for materials such as grid waste.

**DRAWING THE LINE ON QC TESTING**

In our work with the UK pharmaceutical sector, we have found several CMOs conducting QC testing of finished product only when it has been dispensed into its final packaging. For example, in once instance, a company manufacturing antibacterial nasal drops was observed to check product sterility once the finished product had been filled into 15ml bottles and these then packed into cartons. No sterility testing of the bulk liquid product was undertaken upstream.

Performing these and similar tests to ensure the correct composition or potency at a much earlier stage in manufacture can immediately reduce wastage in two main ways in the event that such testing fails a batch: first, the time taken to complete the filling and packaging of product can be avoided; and, second, the primary packaging, outer cartons and patient information leaflets can also be saved as, once QC testing has been completed and a batch failed after filling, these are typically disposed of along with the drug or therapeutic product itself.

Determining where and at what point destructive testing is carried out needs to play a more important role in licensing and manufacturing in order to help curb waste at a much earlier stage in the production life-cycle. If it is possible to perform these functions at this early stage with regulatory approval, then it is an approach...
Innovations in Pharmaceutical Technology

that must surely be embraced by any pharmaceutical manufacturer that isn’t already doing so.

DESTROYING THE DESTRUCTION MYTH
Most pharmaceutical manufacturers insist that unwanted, obsolete printed primary packaging materials and reject finished product are destroyed by incineration. It seems that this requirement has its roots in the Orange Guide (in the UK) and the Code of Federal Regulations 21 (CFR21), both of which convey the need for such materials to be destroyed in order to prevent counterfeiting and black marketing. However, neither the Orange Guide nor CFR 21 is actually so prescriptive as to dictate the method by which this destruction should be achieved; there is no mention of incineration to be found anywhere. It is implicit that the ‘destruction’ requirement is aimed at putting such materials beyond economic recovery – not making them cease to exist altogether.

A simple shredding operation can achieve this same aim for paper and cardboard packaging, for instance, allowing such materials to be recovered for recycling into new products, rather than wastefully being disposed of with no further commercial value at a time when it is increasingly recognised that we need to do more to conserve our natural resources.

The challenge for the modern pharmaceutical company is to confront wasteful practices that are undertaken under the misapprehension that they are a cGMP requirement, so that more value can be extracted from waste and exposure to expensive incineration can be reduced.

WASTE BEYOND THE FACTORY GATES
Beyond the waste challenges that companies are faced with inside the confines of their production facilities, the pharmaceutical industry will at some stage have to tackle the wider environmental issue of the wastes it is responsible for once its products have been consumed by patients. Excreted after passage through the body (human, or animal in the case of veterinary pharmaceuticals), it is inevitable that at least some residue of drug will enter the water environment at some stage. In what quantity and with what effect is not well understood.

There is already concern about the after-effects of the female contraceptive pill, with some claiming that the presence of elevated oestrogen levels in rivers is affecting reproduction in some species of fish and that this is being caused by the release of synthetically produced hormones into the water environment via sewerage and sanitation systems.

With a noticeable trend towards increased environmental awareness amongst the general public, there will surely come a time when consumer pressure is brought to bear on the pharmaceutical industry in one form or another, forcing increased research into the environmental effects of post-patient drugs.

The presence of unknown and as yet undiscovered reactions of drug chemistry in the environment – with who knows how many substances entering the human food chain and leading to long-term adverse effects – is a prospect that the pharmaceutical industry, with its foundations in promoting human health, can surely not continue to contemplate without action.

At some stage in the near future, greater research into these potential environmental effects needs to become a mainstream activity, possibly conducted as part of – or at least in conjunction with – clinical trials, so that we can better predict the likely impacts and develop strategies to avoid or, at the very least, mitigate them.

CONCLUSION
The waste challenges facing today’s pharmaceutical company are many and diverse, ranging from the need to reduce operating costs to remain competitive to a greater need to conserve natural resources. Even waste that is created indirectly poses a problem for the industry to deal with now and in the future.

Identifying beneficial process changes to eliminate or reduce waste at the point-of-origin, and finding ways to improve resource efficiency by getting more out of what is put in, will become the pursuit of all companies in the pharmaceutical sector in the next few years. However, designing-out waste at the new product development (NPD) stage and before manufacturing processes become operational is the key to successfully minimising waste in all its forms, as well as associated costs, in the long term.

Pharmaceutical companies and their regulators, such as the US Food and Drugs Administration (FDA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA), need to work together more closely to identify and eradicate those practices and restrictions that exist misguidedly to ensure cGMP compliance, and in particular to open up greater opportunities for in-process re-use and recycling of some raw materials (where it is clear that product safety will not be compromised).

Emerging waste treatment and disposal technologies will help to solve some of these challenges, but it will be the resolve, attitude and ability to adapt inwardly that will reap the most rewards for companies in this sector. Regardless of the approach taken, engagement with important stakeholders – and in particular staff – is key. A failure to listen to and learn from those whose daily work is intrinsically linked to the processes that give rise to waste will hamper efforts to reduce waste and cut costs.

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