Pharmaceutical Waste Handling and Disposal

by Lise Andreassen and Nigel A. Fletcher

This article focuses on waste management and disposal issues as they pertain to the pharmaceutical industry. It classifies waste into three areas: research and development, primary manufacturing and secondary manufacturing. It further discusses ways to achieve efficient and effective waste handling and figures legislative issues into the final equation.

The pharmaceutical industry is not a homogeneous industry producing one product, but a set of interconnecting industries dependent on the products of preceding parts. The basic subdivisions are: the primary sector; the secondary sector; and the research and development sector. Associated with each of these is a whole array of other manufacturers that produce solvents and basic raw materials through to packaging materials, vials, needles, etc., and the other trappings of the "industry" with which consumers are familiar. Research and Development (R&D) also consumes vast amounts of high technological equipment such as NMRs, HPLCs and many other items. All this is well known to many inside and outside the pharmaceutical industry, but what is perhaps less well known is what happens to it all. In fact much of it ends up as waste, since the end products of the industry are often small in volume and weight. Figure 1 lists types of wastes produced by the industry.

The three main sectors can be placed in order of "wastefulness" as represented by the approximate percentage of raw materials entering against 'products' leaving the gate as seen below:

1. Research & Development - 99.99%
2. Primary Manufacturing - 60%
3. Secondary Manufacturing - 30%

Obviously these figures are not true for all situations, but are presented to rank the three sectors. R & D simply does not have any real 'products' except ideas. R & D pilot plants do produce some products in the form of clinical trial material, seed quantities of organisms and small samples, but this is small in the wider scheme of things. Generally, everything that enters an R & D site leaves as waste; however, the ideas generated on paper might be considered R & D's one real product. The amount of paper involved in this is quite considerable since it includes drug registration documents, trials data, process details, etc. However, when the quantity of compounds investigated and rejected is realized, even at quite late stages, the final successful candidates take very little paper with them to the production stages.

When it comes to primary manufacturing, the considerable use of organic solvents in synthetic work and the vast use of water in the fermentation of antibiotics (much of which is waste) leads to its coming number two in the above list. Obviously, the main purpose of primary manufacturing is the production of bulk active ingredients and this is produced in considerable tonnages. The main sources of waste from such a facility are liquids and solids, in that order.

The final category, secondary manufacturing, is probably the least wasteful of the three main sectors. Apart from actives, it imports excipients and packaging materials substantially converting them to dosage form pharmaceuticals. However, as in any process, there is waste such as off-spec product, unusable or contaminated packaging and lesser quantities of solvents and other chemicals. In parenteral manufacturing, considerable amounts of water are used for washing and water for injection (WFI), which in its own right produces a large volume of 'waste water'. Cleaning agents contaminate some of this water, but the majority is sent to the sewer with little serious contamination. This water is true waste; however it is unknown how much a threat it is to the environment.

Sources of Waste

Research & Development

One of the primary wastes is trade effluent or dirty water resulting from a variety of sources that include boiler and cooling tower blowdowns, and, most significantly, from research laboratories. Here it gets contaminated with solvents, chemicals, drug entities, drug by-products and a certain amount of general dirt. Certain laboratories also discharge low levels of radioactive substances. Each laboratory or building on the site gives rise to trade effluent of a slightly different composition but, as all these separate sources are mixed prior to discharge, these differences are insignificant. This mixing often takes place in a large tank where the trade effluent is accumulated for some form of treatment.

As required by law, all sites will have a discharge consent from their local sewerage undertaker or the National Rivers Authority which lists the maximum quantities of substances the site can discharge and also those substances whose discharge is prohibited. However, few companies monitor the trade effluent accurately and treatment may be simply pH adjustment. This means the company may have no clear idea about what it is discharging.

One of the secondary wastes generated by the R & D sector is glass. Glass is widely used in laboratories for flasks, retorts and the usual laboratory paraphernalia and in the usual course of research becomes dirty; broken or both. Then it can be cleaned and/or discarded. Discarded glassware is usually considered to be dangerous due to either chemical contamination or simply because it has sharp (broken) edges and it is, therefore, generally put into a skip for landfilling. This also is the usual fate of empty reagent bottles and solvent Winchesters.

A better destination for this type of waste may be recycling, where minor chemical contamination ceases to be a problem in the heat of the glass furnace. Obviously pathogenic contamination must be inactivated and in some cases there is no alternative but incineration to deal with a particular problem. This example has a direct parallel in the local community, where glass banks are a common sight outside supermarkets and so the infrastructure for recycling of this material is in place.

Primary Manufacturing

Parallels like this for waste from other sectors of the industry are harder to find, particularly for solvents, one of
the main wastes of primary manufacturing. Chemical syntheses, extractions and solvent interchanges all use large volumes of solvents. These volumes are of course kept to a reasonable level as dictated by the particular processes to prevent premature crystallization, product dropout, maintenance of suspension and correct reagent concentration.

Solvents are commonly recycled in dedicated processes with wash liquors being sent back to earlier parts of the process to become the mother liquor. This form of recycling is impossible when the solvent becomes contaminated with other solvents during a solvent exchange or with water or with other materials such as color compounds, by-products and solids. At this point two options exist: recovery in-house or disposal. The choice of route is then invariably guided by cost and the environment is given very little real consideration (eg, by waste minimization).

If the solvents are cheap and easy to obtain then disposal is often the preferred option. However, the term cheap is used in a relative sense as today's pharmaceuticals are so costly to produce that solvent costs can only be marginal compared to the overall production cost. This is simply because pharmaceutical prices arise from the huge investment of manpower and resources needed in getting the drug to the market. This may be the crux of the problem ie., the prices of pharmaceuticals are composites of a large number of different sources of costs, most of which taken individually are marginal resulting in there being insufficient financial incentive for the introduction of less wasteful strategies.

The disposal of waste solvent is determined mainly by price and secondly by the hazard it may represent. If the material contains highly active substances hazardous to humans, or if some uncertainty exists as to what it may contain, then incineration is usually the preferred disposal route. Once again; however, recycling is a possibility. Recycling by distillation may be a possibility, but not necessarily back to pharmaceutical manufacture, due to GMP considerations, but to third party use. Distillation can certainly clean up the vast majority of solvents to the standard required by, for example, the manufacturers of paint stripper, a common ingredient of which is methylene chloride. Comparable uses exist for other solvents.

Typical secondary wastes from the primary sector are filter aids and charcoal. Here the problem is somewhat more intractable as the reuse of these materials is not so easy.

Charcoal can be regenerated by heating in a furnace to evaporate the adsorbed components, but this is not practicable if those components are metals of low volatility. Even more to the point is the fact that these materials are used in very small quantities which also makes the recycling option to be less practicable. In this case it is difficult to see any other course open except disposal, by incineration or landfilling.

Secondary Manufacturing
The last of the three pharmaceutical industry sectors to consider is terms of wastefulness is secondary manufacturing.

The first waste to be considered from this sector is water. Water is fast becoming a scarce material and its price is set to climb. One commentator recently said that the idea of a world in which water costs as much as oil is one which should not be dismissed too lightly. The production of high quality water to the WFI standard is a very expensive business, not to mention the huge amounts of water which get rejected as waste in the process of its production.

Reuse and recycling of water may be forced upon this industry.

Recycling of packaging, another main waste of the secondary sector, is not one which is easy to tackle but it is close to the hearts of the EC bureaucrats. Most businesses should now be aware that the EC position on packaging materials is that much more will have to be recyclable. This will inevitably affect the whole industry, but be most felt by secondary manufacturing.

There has been a considerable move, in recent years, towards the use of original package dispensing for a variety of sound reasons, not the least of which is improved self administration by the customer/patient. However, this form of packaging is wasteful, with quantities of plastics and cardboard being generated. It also is indirectly wasteful as original packages occupy seven times the volume compared to bulk packages, increasing waste in the areas of transport, warehousing and handling. This type of waste will have to be minimized and possibly the only way to do this will require a return to the days of the bulk packaging and the local pharmacy issuing medicines in recyclable glass bottles.

This is not the case for parenterals; however, where single use vials and ampoules is probably the best for the patient and is, practically, the only option for freeze-dried pharmaceuticals. In fact, the use of parenteral products is generally less popular so the pressure is on the pharmaceutical companies to produce oral versions of the products. This is to be encouraged as the production of the parenteral wastes water and energy.

This article has demonstrated that there are areas in each of the main sectors of the pharmaceutical industry where wastes could be minimized, mainly by recycling although the possibilities for source reduction are fairly substantial. It is at the R & D stage that source reduction is most effective and it is essential that future R & D work does start to consider the environment. One of the major pharmaceutical companies has started on this approach and has had some success giving rise to a marked reduction in waste emissions.

It has not been the pharmaceutical industry in particular that has given rise to the great environmental debate, more so the major producers of power and heavy industry. However, the debate is now under way and the fall out from it is going to affect this industry.

Waste handling and disposal is now a topic of hot debate in regulatory circles, journals, the press and industrial societies. Although much spoken and written about, this interest has often not filtered down to the site level.

Company policy statements on the environment are also rife, particularly so for the more sizeable companies, but this in itself does not necessarily reflect an improvement in the manner in which waste is managed.

The first necessary step to take after making a company commitment to improving waste management is to establish what the current situation is at the working level. This is frequently the reason for undertaking a waste audit.

A waste audit is typically comprised of:

- a review of the waste management structure
- an inspection of the generation, handling and disposal of waste
- an assessment of compliance with existing legislation
- an assessment of the implications of forthcoming legislation

It is not the intention of this article to detail how a waste audit should be conducted, since there are numerous recent publications on this subject from which to choose. Instead, a selection of the commonplace findings that result from such audits are listed and discussed under the following sections:

- Waste Management
- Waste Storage
- Waste Generation/Disposal
- Waste Disposal Costs
- Waste Minimization
Waste Management

- Policy statements exist, but have not been translated into effective procedures.
- Procedures exist, but do not set out the requirements clearly or designate responsibility for actions.
- A timetable for producing and implementing the procedures is non-existent or incomplete.
- Procedures exist, but are not distributed.
- Little or no training towards procedures is undertaken.
- Procedures are based on legal requirements of other countries and are not directly applicable or understandable locally.

The proliferation of company commitments and policy statements concerning the environment, including waste, is certainly encouraging at first sight. All too often, however, this may be where the new enlightened thinking ends. A policy statement is of only superficial value unless it is translated into working methods that are effective at site level. In addition, adherence to the stated policy, and to the procedures that are derived from it, must be mandatory and in accordance with a realistic implementation schedule.

The lack of working procedures, including those relating to waste management, is a common occurrence throughout industry. Information on working methods is often passed on verbally with no reference to a written standard. This approach can lead to outdated attitudes and methods, possibly based on requirements which have long since changed.

Diffused and uncoordinated management of waste

There is often no central figure responsible for waste management. On any one site, for example, there may be separate persons responsible for special waste consignments, contractor derived waste, radioactive waste, trade effluent and non-hazardous waste.

Where there is little coordination or communication between such persons (which might occur where they report to different line managers), waste management suffers from duplication of effort, oversights and misunderstandings. Another consequence of such scattered management may be that there is no central file or system for recording waste generation and disposal.

Interphex93

Utrecht
The Netherlands
26-28 October

Exhibition & Conference for European Pharmaceutical & Cosmetics Manufacturers and their Worldwide Supplying Industries

Why visit Interphex '93?

An exhibition targeted on your industries
Meet exhibitors from 15 countries offering a consolidated overview of new developments and new products
A senior-level conference, addressing topics of current interest, has been organised alongside the exhibition

The implementation of the Duty of Care requirements should go some way to providing a centralized recording system for solid and containerized liquid wastes.

- Lack of coordination between company sites

The existence of a number of company sites with little effective coordination may lead to inconsistent approaches to waste management, where varying standards and practices are employed. This situation will make it more difficult to adopt common procedures but it can also provide an interesting selection of approaches from which the best can be chosen to form the basis of any new universal procedure.

Waste Storage

- Uncovered, unsegregated, unbounded, unlocked storage areas for hazardous waste
- Poor labelling of drummed waste
- Forgotten waste

Adequate labelling of waste containers may only take place just prior to transportation off-site. Thus, in the event of an emergency situation or spillage on-site, personnel may have little
idea as to the nature of the contents and therefore of the optimal actions to be taken. Comprehensive labels, detailing the hazardous characteristics and constituents of the waste, should be laced on the waste containers as soon as possible after filling.

- Lack of waste disposal licenses for specified special waste storage areas

A waste disposal license needs to be obtained from the waste disposal authority if special waste is stored on-site in quantities above specified limits. Situations where it is required are when:

- liquid special waste storage quantities exceed 23,000 liters
- non-liquid special waste stored in secure containers exceeds a total of 80 cubic meters
- non-liquid special waste stored in a secure place (or places) exceeds a total of 50 cubic meters

Companies may not have considered whether special waste storage quantities on-site warrant a license, if indeed they are aware of the existence of the license itself.

Lack of waste disposal licenses for specified special waste storage areas

- liquid special waste storage quantities exceed 23,000 liters
- non-liquid special waste stored in secure containers exceeds a total of 80 cubic meters
- non-liquid special waste stored in a secure place (or places) exceeds a total of 50 cubic meters

Partial trade effluent monitoring is conducted.

Trade effluent monitoring is often restricted to pH and visual assessments. Comprehensive, regular monitoring of all parameters on the discharge consent is commonly not undertaken by either the discharger or the sewerage undertaker (where the discharge is to sewer). In such instances, compliance is not definitely known by the discharger, but is assumed by the lack of contrary data i.e., compliance is assumed by default rather than by verification.

In addition, companies rarely monitor for substances not listed on their discharge consent. Changes in plant operations that are likely to impact on the nature or volume of trade effluent are required to be reported to the sewerage undertaker (as stated on the discharge consent). This enables the sewerage undertakers to ensure that discharge limits are placed on the consent for substances of concern that are likely to be present.

Due to the lack of such reporting by companies, discharge consents may reflect site operations of 10 years ago or earlier.

Sewerage undertakers may only take effluent measurements for charging purposes (i.e., volume, chemical oxygen demand and solid level determinations) unless they suspect there is a problem. Such a problem may only come to light when the receiving sewage treatment works is adversely affected or the water utilities themselves contravene a discharge consent level as set by the National Rivers Authority. In such instances, the first indication a discharger may have of a compliance problem may come in the form of a prosecution, with the associated unfavorable publicity.

- Partial information is kept on solid and liquid waste generation.

This information is typically restricted to that stipulated by legislation (e.g., information on radioactive waste, special waste and controlled waste). The data collated to comply with the relevant legislation will generally cover consignments of waste and their desti-

BULLETIN 90 WILL HELP YOU SELECT THE FILTER YOU NEED

Call or write for your copy

BULLETIN 90 and BULLETIN EM-86

Ertel Engineering Co.
P.O. Box 3358
Kingston, N.Y. 12401
914-331-4552
800-553-7535
FAX 914-339-1063
<table>
<thead>
<tr>
<th>Description</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Solvents</strong></td>
<td>Solvent Extractions, Pilot Plants, Laboratories, Laboratory Instruments</td>
</tr>
<tr>
<td><strong>Clinical Wastes</strong></td>
<td>'Biological' Work, Animal Testing, Formulation Work</td>
</tr>
<tr>
<td><strong>Paper</strong></td>
<td>Filters, Laboratory Filter Paper, Pilot Plant Filters, Cardboard/Paper Packaging, Disposable Clothing</td>
</tr>
<tr>
<td><strong>Glass</strong></td>
<td>Laboratory Breakage, Solvent Winchesters, Chemical Bottles, Pilot Plant Equipment</td>
</tr>
<tr>
<td><strong>Plastic</strong></td>
<td>Laboratory Syringes/Pipettes, Disposable Gloves</td>
</tr>
<tr>
<td><strong>Metal</strong></td>
<td>Pipe, Redundant Equipment, Needles</td>
</tr>
<tr>
<td><strong>Radioactive</strong></td>
<td>Scintillation Solvents, Animal Tissue, Fume Cupboard Exhaust, Disposable Clothing, Disposable Laboratory Ware</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td>Insulation, Waste Oil, Surface Water System Sludge, HVAC Filters, Chromatographic Column Packing, Spillage Clean-up Material, Silica Gel, Redundant Furniture/Fittings</td>
</tr>
<tr>
<td><strong>Atmospheric Emissions</strong></td>
<td>Plant Ventilation, General Extraction from Workshops, Offices and Kitchens, Boilers, Incinerators, Pumps, Fugitive Emissions (Noise)</td>
</tr>
</tbody>
</table>

*Figure 1. Sources of waste.*
nation, as opposed to details on where in the facility the waste was initially produced. To obtain such information, it is advisable to introduce a procedure for compiling data on waste from the point of generation to the point of treatment/disposal i.e., a waste inventory procedure.

Without a good knowledge of waste generation (toxic characteristics, emission levels etc), it is often difficult to predict the impact that changes in legislation will have on a process.

- Complete information should now exist on waste disposal routes used.

Prior to the introduction of the Duty of Care,$^{1,2}$ comprehensive information on waste disposal routes may only have been held for radioactive waste, special waste, trade effluent and atmospheric emissions. Now, the disposal of all controlled waste (household, commercial and industrial), which is covered by the Duty of Care, has to be documented, including information on the waste carriers and waste disposal contractors (WDC) employed.

Before the implementation of the Duty of Care requirements, and possibly in those companies who have yet to comply with the new duties, a common situation was as follows:

- For non-hazardous waste, the waste carrier would be selected, but the selection of the WDC would be left to the waste producer. The name and address of the final destination of the waste may not have been held by the waste producer.

- For hazardous waste (including special waste), the WDC would be selected, but the selection of the waste carrier would be left to the WDC and the waste producer would not know who it was going to be until the time of collection.

**Waste Minimization**

- Minimal recycling is undertaken.

- Minimal effort is given to reducing waste generation from industrial processes or research and development establishments.

- Waste minimization targets are set without a detailed knowledge of current waste generation.

- Waste minimization is not undertaken at an early enough stage i.e., R & D.

Once waste generation has been detailed, targets should be set for waste minimization. 'Target' areas should be placed in a priority list where top of the list are areas where maximum reductions in waste generation can be obtained by the minimum degree of effort.

**Disposal Costs**

- Information on overall costs for waste disposal to external WDCs is comprehensive.

The external waste disposal cost records are, as might be expected, relatively complete. For example:

- For non-hazardous waste collected in skips on site, companies are charged for the size of skips and the number of skip changes.

- For special waste, each load is separately costed.

- For trade effluent discharges to sewer, periodic bills are received.

The exception to this trend, is when a contractor is employed to provide more than a waste disposal service e.g., demolition/building contractors and asbestos removal firms. In such instances, the cost of waste disposal is usually included in the overall service charge, but it is a simple matter to request that such information be provided separately.

Overall waste disposal costs for a site should take into account monies received or costs saved by waste recycling and other waste minimization schemes. It is rare to find waste disposal costs allocated back to the generating departments or projects on-site. Once a waste inventory and internal waste tracking system is in operation, and all disposal costs are known, a company can allocate a budget to the various departments and then charge back all waste disposal costs. In this way, personnel will come to understand the cost implications of their actions (or lack of) concerning waste. Consideration may also want to be given to 'hidden' disposal costs such as the manpower used to transport and manage the storage of waste on-site, and the cost of any in-house waste treatment facilities.

**Summary**

The approach to waste management is often disorganized and incomplete. It is still seen as the "dirty job" on-site and the people involved are not given credit for the work performed. For example, at R & D sites, the attitude may be that you cannot expect research personnel to consider the waste aspects of a project, the implication being that they have more important aspects of the project to consider and that waste considerations should be left to someone of lesser capability.

Generally, comprehensive information on waste generation (including emissions) only exists where it has to be collated under law. The first waste audit undertaken may highlight just as much missing data as existing data. The findings of a waste audit will often form the impetus for initiating a waste inventory procedure. Once a firm understanding of waste arisings has been obtained, objectives for waste reduction can realistically be set. Setting such reduction targets prior to obtaining an understanding of current waste generation is meaningless as there is no base data with which to compare.

Currently, the implementation of more stringent legislation (e.g., Duty of Care, Integrated Pollution Control (IPC) and various voluntary schemes (e.g., Responsible Care, ECO-Audit), BS 7750) has placed more emphasis on waste management.

Since the late 1980's, the requirements of the COSHH Regulations have filtered through to educational establishments, where it can now be found as an integral consideration in laboratory experiments. Students are taught to assess the need to use hazardous substances and the need to minimize exposure to such substances. In the 1990s, it is hoped that, as with COSHH, aspects of waste management (including minimization) will be considered automatically and routinely by all those involved, through R & D to full-scale development. It may be too late to get traditional and veteran industrialists and scientists to take waste seriously, but the teaching of its importance from school level onwards will ensure it is ingrained in the next generation of scientists.

**References**


This article was published in *Pharmaceutical Manufacturing International*, 1996 edition.