14
THE PACKAGING LINE

I.H.Hall

Introduction

In this chapter there is a discussion of the practical requirements of operating pharmaceutical packaging lines. This includes *all* the requirements of the packaging line including, where necessary, the staff required.

The objectives of any pharmaceutical packaging line can be simply described as filling, closing, identifying and protecting the product safely to a predetermined specification and at an economic cost. Unfortunately the design and operation is more complicated in reality.

Other requirements are:

- high consistent output
- zero downtime due to stoppages
- no rejects or wastage
- consistent quality
- low services, labour and maintenance costs
- high integrity, i.e. no risk of mix-ups
- high level of hygiene
- minimum depreciation
- minimum wear and tear
- regular and effective maintenance
- effective operator and maintenance staff training
- provision of safety for staff.

The typical pharmaceutical packaging line needs only:

1 materials—product and packaging materials supplied to agreed specifications
2 services—electricity, compressed air, etc. to agreed standards
3 personnel—effectively trained operators, engineering, QC and other support staff.

The activities of a typical packaging line may be broken down into the following broad steps, which form the backbone of this chapter:

- bringing the materials (both product and packaging) onto the line
- packaging line services required to make the line operate
- filling the product into the prime container
- closing the package, i.e. prime container
- labelling or identifying the prime container
- leaflet addition
- cartoning/display outers application, i.e. secondary packaging
- collation, casing and palletisation for warehousing and distribution
- on-line testing
- provision of motivated and trained production and support staff.

The filling and packaging operations may take place on one piece of machinery or be split across several machines, namely form fill and seal—e.g. blister packs where the product is filled, closed and identified on one machine—whereas a bottle of liquid

medicine would need unscrambling, cleaning, filling, closing and labelling as separate linked operations to reach the same state of completion.

One of the most important considerations is that of the speed of the packaging line, which can be expressed as:

- design speed—the speed of the line running under no load and optimum conditions
- capacity—the upper sustainable limit of acceptable product passing a point on the line prior to warehousing
- running speed—the instantaneous operating rate
- output—the exact quantity of acceptable quality product which passes from the line, under load conditions, to the warehouse in a standard time.

There appears to be no pharmaceutical industry standard for measuring the efficiency of a packaging line. Line efficiency has been defined as the ratio of output to input, but a better measure is the ratio of the actual operating time (the actual time producing acceptable product) divided by the available time (when there is work available for the line) expressed as a percentage.

Looking at a typical complex packaging line, the most critical operation usually operates at around the required output speed. In most cases this is the filling operation. The other machines upstream and downstream should be designed so as to operate faster than the critical machine so that there is as little queueing of unfinished packaging as practical, for example as shown in Table 14.1.

There also may be a requirement to have accumulator tables upstream and downstream of the critical machine(s), each holding about one minute's worth of product. It should be noted here that the faster a packaging line goes, the greater is the need for higher quality packaging materials with lower, i.e. tighter, tolerances.

Bringing the materials to the packaging line

It is necessary to bring together the product and packaging materials at the head of the packaging line in order to pack them. It is sensible to discuss the various storage and cleanliness conditions first, so that the optimum conditions can be designed.

The major requirements of the proposed pack should be identified, e.g. is the line going to fill and close and pack the product in one or more operations?

Is the product particularly susceptible, e.g. sterile, moisture sensitive, oxygen sensi-

Table 14.1 Packaging line operations

Running speed (cpm)	*Machine function*	
113	Unload packaging materials	upstream
110	Unscramble containers	
105	Clean containers	
100	Filling the product into the prime container	
105	Closing the prime container	downstream
108	Labelling the prime container	
110	Cartoning/leaflet addition (usually the same machine)	
115	Collation of a standard quantity of prime containers	
117	Casing of a standard number of collations	
120	Palletisation to a preset stack pattern of cases	

cpm=containers per minute.

tive? Are special environments required and what level of cleanliness is required for the particular product, e.g. is the product dusty, or is the unscrambling of packaging materials a ready source of particulate contaminations?

There may only be need to fill, close and identify the primary container, e.g. many sterile filling operations store the filled prime containers for later packaging. This creates many problems, e.g. identification, storage of part finished packs (costs and specialist work in progress (WIP) stores etc). Having said this, the following general comments apply whether the pack is completed in one or more stages.

All the materials for a particular filling and packaging order should be brought together in a secure collation area, away from the filling and packaging line and fully checked against an authorised specification for identity and quantity, by a competent appointed person. It is essential that the co-operation of the planning, purchasing and stores departments is obtained in order to complete this detailed operation ahead of the scheduled packaging time.

The product should be closed as soon as practical after filling. The only major exception is freeze drying, where the container is filled with liquid, partially closed, freeze dried, then the closure operation is completed.

Sterile conditions produce their own problems where the primary packaging materials and closures are to be pre-sterilised and fed into a sterile area for aseptic filling and closing, or with filling and closing of the pack for terminal sterilisation e.g. sterile dressings with beta or gamma irradiation. In the first of these cases the secondary packaging would probably be done at a different time and in a different packaging area, whereas in the second case the pack could be completed to secondary packaging and only require separate tertiary packaging.

Note that *all* sterilisation procedures on packaging materials, e.g. heat, irradiation, do have an effect on the physical and sometimes chemical properties, e.g. plastics tend to go more brittle upon beta or gamma radiation. The sterilising of packaging materials is a specialised subject dealt with in Chapter 12.

The conditioning of containers or reel materials needs special attention, e.g. low temperature of storage containers brought into a warm moist atmosphere will induce condensation, thereby making the product damp and negating the adhesion of labels, due to the water film on the container. Storage of reels of material that are either stood on edge forming flats or in too moist or dry conditions giving 'dumb-bell' shaped reels should also be noted. Those packaging materials that are to be in direct contact with the product, e.g. containers, reels, wadding materials and closures, should be supplied in packaging that prevents contamination, is easy to clean, is easy to unload onto the packaging line, sheds as little contamination as possible, and is easy to store and recycle.

Open containers, e.g. securitainers or bottles, should always be inverted, blown with clean dry, oil-free compressed air injected by a dip tube from the base and vacuum sucked to remove as many particles as possible.

Unscrambling techniques have generally to be used for containers, closures, wads, etc., as they are of fixed shape and need to be manoeuvred into a queue and/or oriented for presentation to the filling/closing process. The ever-present problem is one of vibration and movement which attracts/sheds particles into the vibratory bowl or other moving parts of the unscrambler. No container should be allowed to be filled without going through some form of inspection for dirt or positive cleaning immediately prior to filling.

Reel-fed components are different in that they are usually fed through pre-set guides onto the machine main bed and the contact surface is usually on the 'inside' of the reel, thereby attracting less contamination.

Packaging line services

The packaging line cannot operate in isolation. It needs essential services, e.g. clean, dry, oil-free air, electricity, gases (nitrogen, oxygen), cooling water, vacuum, removal of waste material(s), removal of finished packs.

The services have been divided into three convenient headings, and should be considered before building the line:

1 atmosphere, sterility, level of cleanliness, environment, removal/disposal of waste
2 line layouts, operators, loading points
3 specifications, maintenance, planning, inventory control, testing off-line and QA/QC support.

The first consideration about general services is what atmosphere is to surround the line, is it to be clean or sterile, or are there requirements to isolate one section of the line, e.g. cartoning kept apart from filling as the cartons will shed fibres. This sort of requirement defines the level of cleanliness required in the packaging area. There should be, even in all non-sterile packaging areas, a good and efficient air-conditioning system with the ability to vacuum extract waste or contaminated air from the points of most contamination, e.g. container cleaning, unscrambling, cartons.

The solutions to the cleanliness problem may include the following.

1 Isolate the filling and closing operation in a GMP classified area (e.g. European class A or B; FDA class 100). In this case remember that *all* materials going into an aseptic area must be sterile. The output of the sterile area i.e. the closed sealed container, *must* be identified in some secure manner if it is going to be taken off the line and not labelled immediately.
2 For non-sterile situations build a floor to ceiling partition between the filling/closing equipment and the secondary packaging operations, and restrict the movement of fibre shedding materials.
3 Strip off all the fibre shedding incoming packaging materials in the collation area and send the materials to the line in internally recycled (plastic) containers and an aluminium pallet.
4 Keep the fibre shedding materials away from the immediate vicinity of the product contact materials.
5 Provide special closed container(s) for solid waste, e.g. cases, and cleaning cloths, plastic coverings, etc.
6 Special instructions for the recovery/reworking of reject packs produced on the line to minimise contamination.

The items in this section are contained in the later sections on ‘On-line testing’ and ‘Operators and training’.

This section deals mainly with the external departments that have an influence on the line services and their operation, e.g. specifications, maintenance, planning, inventory control, testing off-line and QA/QC support. (Specifications of the packaging materials, product and final pack are essential, and are fully described in Chapter 4.)

Planning and inventory control have the task of ensuring that for any given order:

1 the services in the production building will all be available for the time needed for the order completion, e.g. heating, ventilation, air conditioning (HVAC), power
2 the requisite passed materials are available for the job
3 the requisite labour is available, including scheduling of line changeover; engineering, QC, etc. presence is available
4 there is internal transport, warehouse space, etc. available for the finished goods.

General principles of product filling

The following points are the major ones needing consideration when designing a packaging line.

1 How to unload the delivery of materials from the collation area, e.g. is there easy access to loading points on the line? All loading points, safety off switches, controls and warning panels should be on the operator side of the line. Operators should not be expected to crawl under, jump over or run around the line for routine topping-up of materials.
2 The physical state of the product will lead towards the design of the filling technique:

- gas—liquefied or pressurised
- liquid—sterile, viscosity, volatility, frothing
- semi-liquid—viscosity, separation, phasing into layers
- solid—powder, granule, tablet, capsule, regular or irregular shapes, free flowing or sticky or fragile.

3 The mechanism of filling may be achieved in one of several ways:

- volume—cups, pockets, auger filling, pump piston
- weight—one shot, dump and trickle
- level—vacuum, pressure, gravity
- arrangement—blister or column
- count—recessed cylinders, slats, regular objects queued then breaking a photocell beam.

The cleanliness of the chosen filling technique should be considered for potential contaminations, e.g. drips, product seepage, powder agglomeration. There therefore needs to be control of the following filling problems:

1 aeration of liquids, semi-liquids and powders, usually caused by excessive highspeed stirring
2 compaction, dusting, powder explosion risk
3 separation of liquids, semi-liquids and powders into phases
4 dusting and break-up of tablets and capsules due to being vibrated for too long in hoppers etc.

Common filling methods used for the various phases of product

Gas

This is usually used in the liquefied gas form as propellants for aerosols. Filling liquefied gas is usually by volume using a specialist high-pressure pump on a time or flow basis, usually filled backwards through the aerosol valve. Alternatively the aerosol container may be open in a highly refrigerated area, where the liquefied gas is dosed by a piston pump then the container is quickly closed.

Using gas as a flushing medium usually only requires a small volume of low-pressure gas, e.g. nitrogen or CO_2 to clear air out of the container, by means of a timed valve opening operation.

Liquid

With liquid filling the sterility, viscosity, volatility, and frothing characteristics of the product will eliminate some of the potential filling methods. Liquids may be filled by the following methods.

1 By volume, using a volumatic cup, a timed distribution from a pump, or by a piston in a sleeve dosing the correct amount. It is usual to use dip tubes which retract with the level of the fill to control the drips and reduce turbulence and frothing.
2 By level, where the liquid is pushed into the container and the excess liquid removed by vacuum, or pressure which forces excess liquid out through an overflow pipe or with gravity supplying the force required.

Semi-liquid

With semi-liquids the following physical criteria must be considered: viscosity, separation, phasing into layers. Sometimes too much stirring, or any stirring at all (in the case of creams), during filling can have adverse effects on the product.

Semi-liquids are usually dosed by volume using either an adjustable rotary pump or a piston and sleeve valve filler. Again the dip tubes which retract with the level of the fill help in controlling the amount of spillage.

Solid

Solids come in many forms, and the product form and speed of operation will determine the method of measurement.

There are probably more ways of controlling the various solids than any other pharmaceutical form.

1 By volume of powder using cups, pockets, and particularly by auger filling.
2 By weight of any solid form but most commonly using an auger fill either with one shot, or dumping the greater part of the product and trickle feeding the remainder. This latter is very accurate but usually needs an expensive feedback weighing system.
3 By level using either gravity or auger fill to a predetermined level in a transparent container.
4 By arrangement, e.g. in blisters, or columnar in the case of roll wrapped tablets etc.
5 By electronic count of regular shaped objects, e.g. tablets and capsules, using recessed cylinders, or slats, or regular objects queued on a rotating table then breaking a photoelectric cell beam to give a count.

Line fill checks include check-weighing, level of fill by light or X-ray or alpha radiation, pattern by artificial vision or feeler systems.

The two major forms of filling, i.e. with pre-made containers and with those that are form fill and sealed, will now be considered in more detail.

Container-based filling

The containers must first be unscrambled by various means depending on the shape, size and material of the container. Major risks are induced dirt from friction and static electricity from dry conditions and movement of plastics. Most containers used for sterile filling (ampoules, vials, bottles and collapsible tubes) are fed directly so that the operation of unscrambling should not be necessary. There are also certain types of precleaned bottles which are supplied in clean layers, where the outer plastic protection may be removed and the above unscrambling operation may be excluded.

The non-sterile containers *must* in most cases be cleaned in line, e.g. invert; blow with clean, dry, oil-free, compressed air. The resulting dislodged particles are then sucked away from the container while withdrawing the air probe, but beware of induced static.

The objective is to have all the containers presented and fed to the orientation devices correctly, so the containers will next require queueing and orientation. Here the design and tolerances of the container are critical for high-speed filling.

Figure 14.1 shows containers that will queue well and therefore fill at high speed. Figure 14.2 shows containers that will have problems in orientation and presentation to the filling heads.

The containers may be presented to the filling apparatus in one of three ways:

1 gated—a preset number of containers are allowed through a feeding gate on a moving conveyor and stop by hitting a preset output gate positioned so that the container(s) are directly under the filling heads

2 scrolled, i.e. fed on a moving conveyer belt through a tapered screw so that the containers emerge evenly spaced on the conveyor infeed to the filler
3 placed, i.e. fed or placed into a ‘puck’ or bucket (usually used if the container is unstable, e.g. collapsible tubes).

The filling then takes place, usually by the methods mentioned above, prior to the container being closed.

Form fill and seal packaging systems

The types of pack that are sealed straight away on the filling line include blister packs, strip packs, pillow packs, ampoule filling and Rommelag/ALP form fill and seal systems.

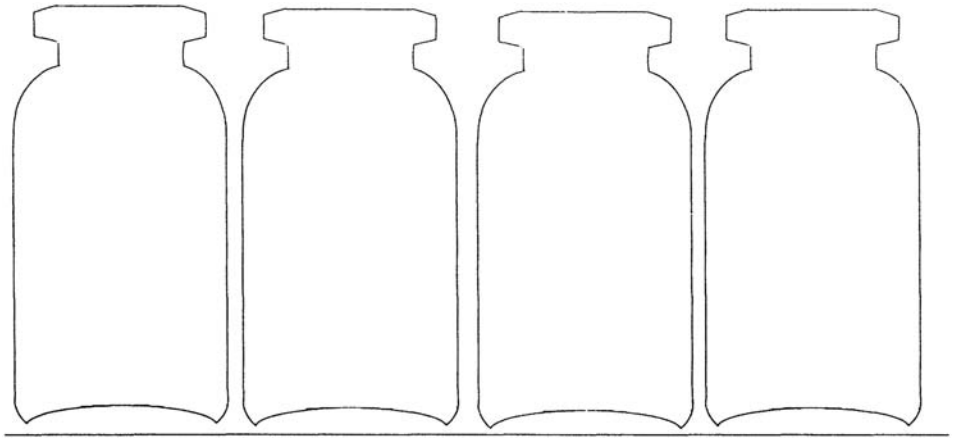

Figure 14.1 Good containers

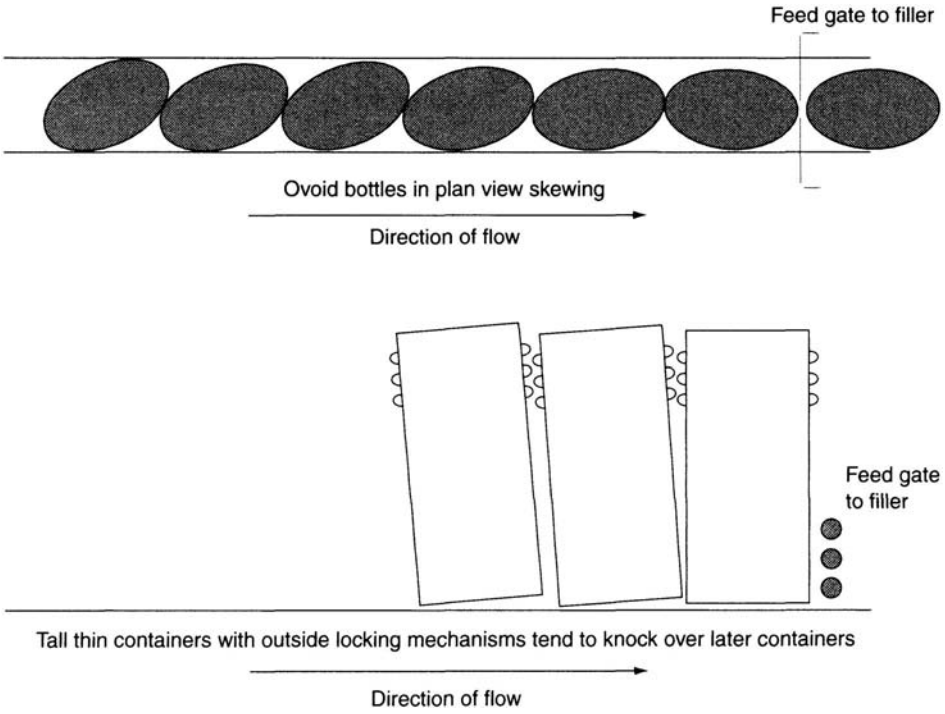

Figure 14.2 Problem containers

Blister packs

Two basic types exist, i.e. hot formed and cold formed. The filling and closing operations are covered in detail in Chapter 13. Most blister packs will need to be collated and cartoned, with a leaflet, as they are not robust enough to survive the rigours of transport and distribution unprotected.

Strip packs

Usually two laminates of paper, soft temper aluminium foil and various plastics. Again the filling and sealing details are considered with the materials descriptions.

Sachets

These are usually a laminate with aluminium foil as the centre core and a heat sealable plastic as the product contact material. They can be made from either a single feed reel or twin reel feed. Firstly the carrying pouch is formed, then dosed with product, then hermetically heat sealed so that contamination is reduced to a minimum.

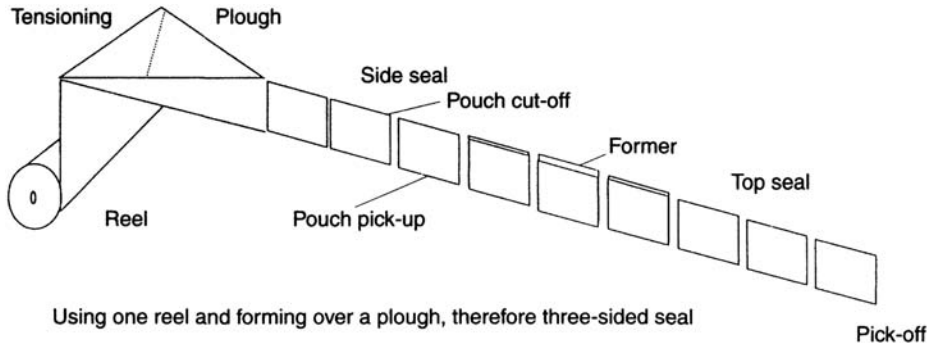

Figure 14.3 Single web pouch operation

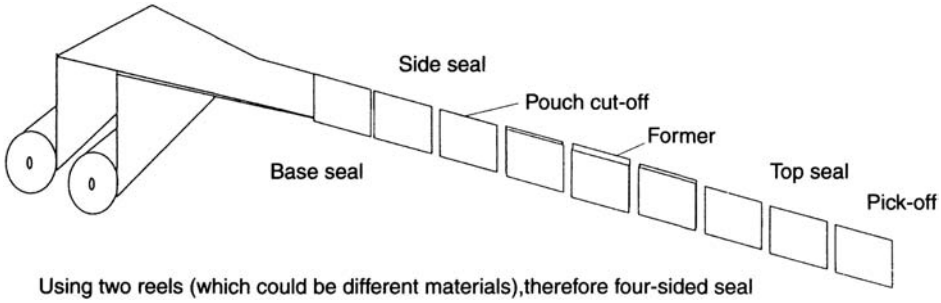

Figure 14.4 Double web pouch operation

There are two basic ways of using the form fill seal process with laminates, films or sheets in reel form:

1 use only one stock reel of double the width but 'centrefold' it, the fold forming the base of the pouch (usually used in horizontal form fill seal operations) (Figure 14.3)
2 use two stock reels to form the two sides of the pouch; could have two different materials as the front and back of the sachet (Figure 14.4).

Both methods have been used for powders, granules, suppositories, liquids, pastes, and creams usually in the horizontal reel feeding mode. The control of the position of the print on the sachets is by the 'eye' mark and electronic registering method.

Pillow packs

These today are usually used for added protection as a secondary pack. In many respects they are similar to single reel sachet packs, but the product forms the outline of the pillow pack which is usually heat fin sealed up one edge and heat lap sealed/guillotined on each end.

Ampoules

These are in many shapes and sizes in glass, but have the common feature that they are always closed as soon as possible, by the use of gas/oxygen flames, after filling. Plastic ampoules are discussed under Rommelag/ALP systems below.

Glass (of whatever type) ampoules may be designed in different ways:

1 single ended
2 double ended
3 supplied with the end(s) open
4 supplied with the end(s) closed.

There are two ways to fill ampoules:

(a) by a dip needle dispensing the correct amount of fluid
(b) by using a tray and vacuum system, whereby the liquid is drawn into the open ampoule by vacuum.

In the case of single ended with end open and (a) above, there is just the closing of the aperture by heat to consider; in the case of double ended with ends open and (b) above, it is usual to have one end of the two-ended ampoule already closed, giving a heat closure to one end only; in the case of single ended with end closed and (a) above, the ampoule has to be first opened and then closed by heat.

The major problem with all glass ampoules is that when glass is cut there is a phenomenon of glass particle shedding. It is also difficult to fill any heat sensitive product when the temperatures might be >1000°C locally in the neck area.

Rommelag/ALP systems

Both Rommelag AG (Germany and Switzerland) and Automatic Liquid Packaging (ALP) in the USA produce very specialised equipment, under the name 'bottlepack' or blow, fill seal. Each produces filled sterile products starting with dry granules of plastic.

The process which enables a sterile product to be produced operates as follows. The plastic material is fed into an extruder from which a round or oval tube (parison) emerges. For LDPE this typically involves heating to around 165–175°C for about 3–4 min, where the bioburden is destroyed. The tube or a series of extruded tubes is fed into open single or multicavity cooled moulds which then close around the tube(s), sealing the base but leaving the top open and an extension which retains sufficient heat for welding. At this stage the 'bottles' are extended to the full mould size by either sterile compressed air (large containers) or vacuum (small containers), then filled with sterile, usually aqueous, liquid (achieved by double terminal filtration).

The top of the mould is then sealed using the residual heat in the above mentioned extension and is taken away from the machine to a final punch trim operation, to remove any waste. In the filling and closing stages the base of the mould remains cool, thereby adding little heat to the product. The forming and filling area is usually shrouded in a laminar flow cabinet. Prior to start-up the machines have all contact parts sterilised (automatically) by pressurised steam with a sterile wash through, i.e. SIP. The machine has to be regularly validated by microbial challenge.

Some regulatory authorities request that certain types of product, e.g. IV solutions, be subsequently subjected to terminal sterilisation. However, there is still an advantage in that a cleaner product is achieved, as the container is made, filled, sealed with the minimum of exposure and handling. Virtually all the risk is related to machine stoppage, clean-down after operating and the start-up period.

A range of machines are available with outputs from 800 units per hour (1 l+fills) up to 22,000 units per hour (0.2–2 ml fills). The latter are usually presented in 'sticks' of eight to sixteen units per stick. Certain machines have been designed to have the capability of inserting other sterile components, e.g. rubber stoppers, which are secured by the final top welding operation.

Materials used for the containers are LDPE, LLDPE, HDPE, PP, PVC, etc. The machines need a dedicated sterile area, so the capital costs for both machine and associated area vary from £1.5 million to £5.5 million. This would have to be justified, usually by 24 h operation.

Closing the package

Closing techniques are covered comprehensively in Chapter 11. All that needs to be said here is that the various methods of sealing listed below are critical to the whole of the integrity of the pack for three major reasons:

1 the closure is the weakest point in the pack design
2 the pack will have to be opened and may be reclosed
3 the closure may also have to act as a dispensing device.

There are two basic methods of closing the pack:

- integral sealing of the prime container, e.g. heat sealing of sachets, ampoules, etc., or by cold sealing techniques, e.g. pattern coating
- addition of individual closures, e.g. roll-on closures, screw closures.

Where vibratory bowl feeds are used for the separation and feeding of closures, it should be noted that the closures may pick up dirt and static electricity unless the feeding system is properly controlled. There is a case for ensuring that this type of feed has a vacuum extraction incorporated to remove as much of the induced contamination as possible.

Labelling or identifying the contents

Labelling techniques related to paper-based materials and the whole question of overprinting are covered comprehensively in Chapter 5. This leaves the need for a few comments on other forms of labelling, mainly involving plastics in the form of films.

Plastics are used in two ways as labels.

1 As a direct replacement for paper, i.e. used as sheet fed and applied adhesive (usually hot melt) or pre-coated with heat sensitive or pressure sensitive adhesive. The same application techniques are used for plastic labels as for paper, except that the presence of a clear plastic label can be difficult to detect on a labelling machine. This is overcome by either using 'eye marks' or adding a fluorescing material incorporated in the print or adhesive—reading with a UV sensitive reader. Another problem associated with 'plastic' labels is that, in general, they tend to be thinner than paper and have the property of picking up static electricity as they move in a dry atmosphere. Anti-static additives should be used in the plastic film as well as earthing the labelling machine.
2 Using the peculiar properties of plastic to be applied by either the shrinking or the stretching route (see below).

Stretch and shrink plastic labels

Most stretch and shrink labels are added to containers in a tubular form, generally relying on the stretch/shrink tightness of the material to retain label position for the life of the product. An additional feature is that the label may be extended over the closure to form a tamper-evident seal on suitable packs.

Stretch labels are unusual to date in pharmaceutical packaging but have the advantage of not requiring heat or specialised artwork to achieve a professional finish. However, they are difficult to use successfully on anything but regular shapes.

Shrink labels are used in the form of a full label or in the form of an additional label added for tamper-evidence, or both. A heat shrink tunnel is needed and, as the tube is fed loosely over the container and tightened, there is potential distortion of the print. This is catered for by distorting the artwork so that the finished shrunk sleeve copy is visually correct.

The materials used are generally LDPE, LLDPE, PP, OPP, or PVC in thickness ranging from about 30 to 100 μm.

A few additional general points on all labelling need to be stressed. Many form fill and seal styles of pack (e.g. blisters, sachets) use reel-fed preprinted materials which *must* conform to the same labelling/leafleting regulations as container labelled packs. Even though these reels may be thought of as labels, there is no independent action of labelling.

The shape of the container, its material and the closure type to be labelled all have a major influence on the choice of labelling machine. Cylindrical containers are the easiest to label, provided that they are clean and parallel sided with no protrusions anywhere on the plane to be labelled. Any other shape increases the difficulty of label placement and wipedown. If the closure of the container is of the dispensing type, e.g. aerosol valve, holding the container by means of top pressure during labelling will actuate the aerosol.

The particular labelling machine chosen for any particular job *must* be capable of easy cleaning so that full reconciliation of the label quantities can be achieved.

Other requirements

Leaflet addition

This is dealt with comprehensively in Chapter 5.

Cartoning/display outers

There are two basic types of equipment, loaded either horizontally (usually automatic) or vertically (which might require an operator).

1 Intermittent motion, achieved by a Geneva movement, works with lower speeds up to about 90 cartons per minute, but is more tolerant of poor cartons and robust.
2 Continuous motion—higher speeds up to 200+ cartons per minute, but requires tight toleranced cartons.

Collation, casing and palletisation

Overwrapping, stretch wrapping or shrink wrapping materials may be used on single items or bundles of 5, 6,10, 12, 20, 24, 25, depending on the marketing preference. This is covered in more detail in Chapter 9.

Bundles may be cased and palletised: details are given in Chapter 15.

On-line testing

It is assumed that the incoming packaging materials have been supplied to an adequate authorised specification, quality controlled in an approved manner so that the materials arriving at the packaging line are known to be within the parameters of the specification. Therefore the testing that follows is that associated with putting the elements of the pack together.

There are some testing procedures that are essential to the correct functioning of the line, such as those that detect that the pack is incomplete:

- no container (or film)—no fill
- no container, no ullage filler—no closure
- no container—no label
- no container—no carton
- no leaflet—no carton.

This means that if any part of the total pack structure does not feed to the line, the feeding mechanisms for the subsequent materials will not be activated. It is also essential, as detailed earlier, to ensure that the correct fill of product has gone into the primary pack by whatever method is used.

Another essential area is the testing of the seal integrity of the closure:

- level/tilt position of applied closure
- inert gas 'sniffing' of form, fill and seal packs.

A fourth area considered essential for checking is ensuring that the correct identification is on the primary pack, i.e. bar code read or optical character verification (OCV) of the primary pack, label, leaflet, carton, outer casing or outer label. Bar codes and reading are dealt with in Chapter 5, but the techniques of optical character reading (OCR) or OCV are described below.

The OCR/OCV techniques have only become economically comparable with bar code reading in recent years. They are defined as follows.

1 OCR means that each individual character of text is compared with a preloaded series of type fonts, the results of the comparator output fed either to a display or to an accept/reject mechanism.
2 OCV means that a short series of printed characters is electronically compared with a short series of stored characters. It is therefore very much quicker in operation than OCR. Note that the same rules of loading the string of characters apply as are used for preloading bar codes, i.e. the information must be independent of the packaging material being delivered to the packaging line.

When one is contemplating the use of OCV, either OCR 'A' or OCR 'B' type fonts should be used, as they have been specially designed to minimise the problems of misidentifying characters. Some of the problem characters are:

2, Z; 1, I; S, 8, 9; 0, D, 8, 9; 5, 6, b

The comparator in the 'black box' is programmed to look very carefully at the problem characters, emphasising the differences between like characters by a high 'loading' of the scores of compatibility in the small differences area. Speeds in excess of 150 strings of 50 characters per minute have been achieved. The benefit of OCV over bar coding is that the already printed component item code, part number (or whatever it is called) may be used rather than the extra printing of a special security bar code.

Lastly, the product might need to be tested on line for the presence of unwanted metal objects, i.e. metal detection.

Operators and training

Packaging line operators should be encouraged to report any minor health hazards, e.g. cuts, minor skin infections, so that informed decisions can be made as to their suitability for working in controlled areas.

They should also have been formally trained on the particular machines that are in use on the packaging line, particularly in safety and observation, and have a thorough knowledge of how the marketable pack should look at all stages of its packaging. There should be SOPs for codes of dress, discipline, line processing, clean-down, etc. Training records should be archived.

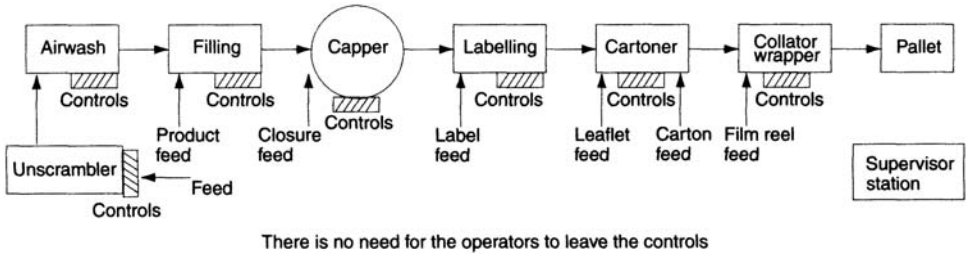

Figure 14.5 A good compound line layout

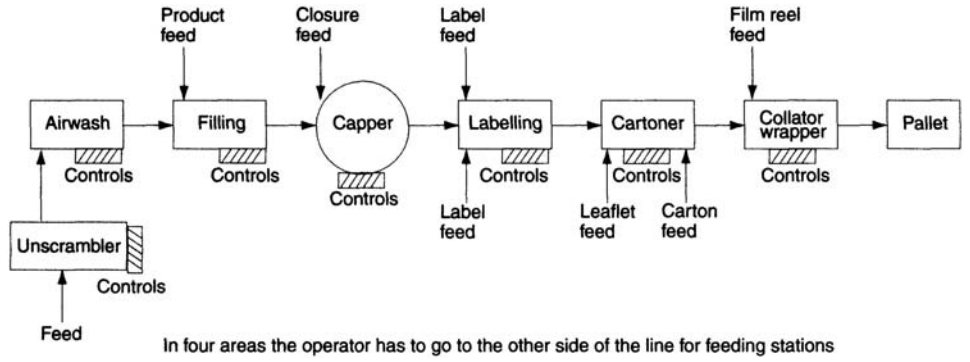

Figure 14.6 The same line as in Figure 14.5, thoughtlessly laid out

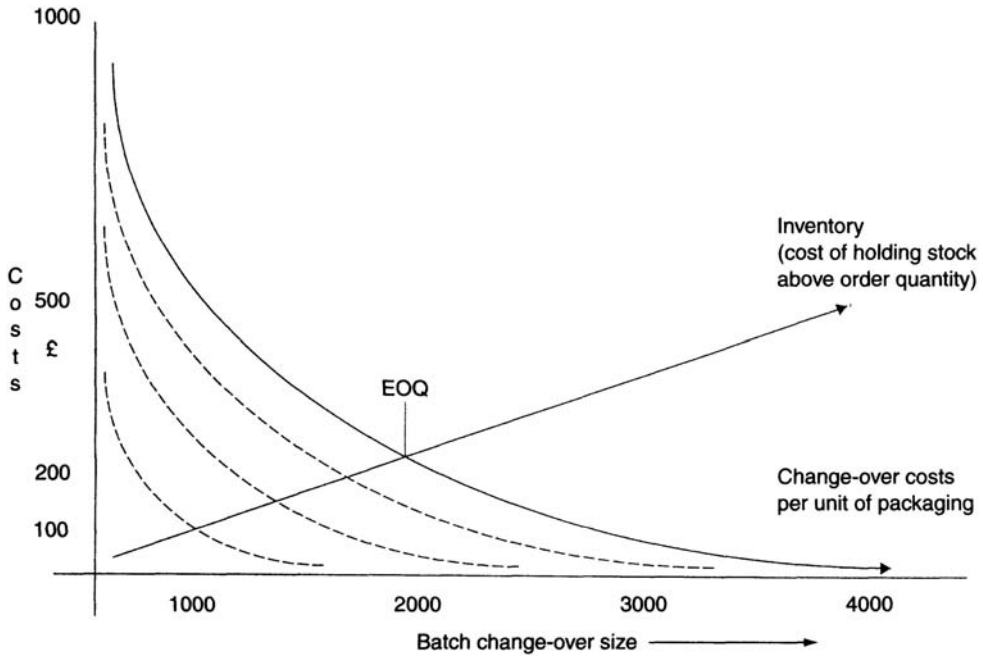

Figure 14.7 Economic order quantity (EOQ) graph

The packaging line should be designed in such a way that the ergonomics gives the operator the least amount of time away from watching the line while loading additional components. Figure 14.5 shows a line designed to help the operator and the engineer; Figure 14.6 shows a badly designed line.

There must be planned routine maintenance, change-overs planning with the engineers, schedule planners and marketing in particular to maximise the economic order quantity (EOQ). The EOQ is defined as the point at which the cost of change-over equates to the cost of holding the extra inventory, by increasing production order quantities (Figure 14.7 shows a graph of EOQ).

All the time a packaging line is not producing finished packs it is consuming fixed overheads for no financial return. It is therefore essential that the downtime of the packaging line is minimised. This means that the EOQ becomes an important

factor in the scheduling of work to the packaging line, as it has been calculated that a line with an output of about 100 pieces per minute, when materials and orders are available, costs about £20+ per minute to run. It therefore costs about £20+ per minute for the line to be standing still when it is scheduled to be operating. Companies cannot afford this, and must be aware of the need to programme and control all aspects of the process.