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Technically auditing a factory producing cosmetics

Assessing a factory to see whether it is suitable for manufacture of cosmetics and toiletries is a vital and important part of any client's responsibilities, especially if intending to export to a foreign market like Europe.

Technical/legal preamble

The manufacture of cosmetics and toiletries is more regulated than the food industry but not to the extent of the pharmaceutical industry. The comparison between the production of pharmaceuticals in terms of GMP (Good Manufacturing Practice) and the cosmetics and toiletries industry reveals a number of similarities.

In Europe, the USA and Japan the laws are quite specific and though these three regions strive to achieve parity, there are still many differences between the various legislative documents, particularly in the area of sun care, antiperspirants and toothpaste.

The EEC has Council Directive 76/768/EEC up to the 27th amending Directive 2003/15/EC and including the previous 26 amendments and this has to be translated into the language of each member state. In the UK the law is Statutory Instrument 2004 No. 2152 The Cosmetic Products (Safety) Regulations 2004 (107 pages).

In addition, products must not infringe the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, a very common infringement with today's eagerness to have "alluring" pack copy. The Regulations provide that, unless exempt, any "medicinal product" to which Chapters II to V of Directive 2001/83/EEC apply must not be placed on the UK market unless it has a marketing authorisation (product licence) granted by the European Commission or by the UK Licensing Authority. The Act similarly provides that, unless exempt, any other "medicinal product" must not be sold or supplied without a marketing authority. A marketing authorisation or product licence is only granted for a product which meets statutory standards of safety, quality and efficacy.

The status of many products on the "borderline" between medicinal products and food supplements, cosmetic or medical devices can be difficult to determine. The MHRA has produced a Guidance Note 8 document to explain how and on what basis the MCA decides whether products are medicines or not. It includes guidance on the statutory procedures in Regulation 3A of the Regulations introduced by the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2000 (S.I. 2000/292).

There is also the requirement to ensure that claims made on the packaging comply with the Trade Descriptions Act 1968, Control of Misleading Advertising Regulations 1988 (as amended). Products must also comply with the Weights and Measures Act 1985, and certain categories (e.g. insect repellants and products that contain this property) may also be subject to the Statutory Instrument 2003 No. 429 The Biocidal Products (Amendment) Regulations 2003.

Compliance with these laws is mandatory in Europe and many countries have adopted them with little alteration. This is the shape of things to come and most countries are in the process of harmonising and adopting these legal safeguards. Any company that does not react ahead of the inevitable is going to find it an arduous and almost impossible task to implement in the time frames that are normally allowed for full compliance.

Even in countries where the laws do not apply, retailers are beginning to expect their products to be the best.

Technical audit

The initial part of any audit is to assess the capability of the staff and to examine in detail the organisational structure. It is also useful to examine their existing supplier base and product portfolio.

Audit forms

Many auditors have a check list of the areas they are going to review and have a tick sheet of things that they must remember to probe and examine. The use of a camera is useful to record those things that are good and also to capture those things that are in need of amendment or need to be repaired or rectified. A good resolution is also important, since with a resolution of five million pixels or more, you may photograph key documents and labels etc.

Audit trails and traceability

Traceability is vital. It should be possible starting with the batch code on the bottom of a product to go right back to the actual delivery and lot number of every single raw

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material used in the production of that product. It should also be possible to follow that same product back through to the Research & Development laboratory and find the full development details including the stability testing results and microbiological challenge test data.

Outside perimeter and storage

The best way to measure the factory's capabilities is to follow the arrival of the raw material from the goods inwards reception through to the finished goods warehouse. The outside perimeter of the factory is normally a good measure of the factory's commitment to good housekeeping and attitude to their attention to detail. In most cases, the things that they do not wish to be seen are hidden outside of the factory building and carefully stored out of view.

Warehouses

Goods coming in to the factory should be booked in and held in quarantine pending a review by the quality control department. They should be stored in a totally distinct area away from normal production and storage pending a pass or fail sticker being applied to each carton or pallet by Quality Control. All warehouse racking space should be off the floor (at least five inches), and there should be a clear gap between the racking and the wall to discourage rodents setting up "rat runs". Rodent control should be installed and regularly inspected with a record of the inspections kept on file.

The raw materials

Raw materials should be stored carefully. Examine pallets for dust, stock rotation, and cleanliness. Check the factory records to see whether they have been booked in correctly, check to see whether lot numbers have been recorded. Are the MSDSs (Manufacturers Safety Data Sheets) kept in an easily accessible location? Are hazardous materials kept separate from those that are innocuous and are they correctly labeled? Are staff trained in the handling of these materials?

Many materials can be corrosive or emit fumes that are not beneficial to health and it is important to check that proper ventilation and safety equipment is available for the handling of these materials. In the case of dangerous materials (like preservatives) the stock should be identified as hazardous.

Packaging materials

Packaging materials should be stored carefully and neatly. Stock should be segregated to keep the bottle, caps, cardboard and labels etc in distinct areas.

Once again a complete set of records should be maintained showing goods received and goods issued against production orders. Returned balances from production should also be booked back in to stock.

Finished goods warehousing

Finished goods should be stored in a clean and well-ventilated environment. Slow moving stock should be covered or on cling-filmed pallets to protect against dust.

Production area

The production area should be clean and well-ventilated, with good quality flooring. The presence of wood or cardboard is a source of microbiological contamination and should be discouraged. Open doors and open windows are not allowed. The ingress of dust, insect and other flying vermin is to be avoided. Mosquito nets may be used on open windows, but become unsightly after a year or so and require difficult cleaning. Insectocutors should be installed wherever open product is present.

Ask to see a copy of the company's code of Good Manufacturing Practice.

Dispensary

The cleanest and most sensitive area is the dispensary where batches are weighed out. The equipment must be scrupulously clean and should have regular cleaning protocols and balance checks and calibration written into the standard operating procedures (SOPs). Cleaning equipment must be clearly colour coded as specific to this area and not allowed to leave the room for any reason. This area must be totally scrubbed down at the end of each day using a tried and tested cleaning protocol. Drains should be inspected at least once a week and the area microbiologically swabbed to check for cleaning efficiency.

Batches should be weighed up using the production formula. All raw material lot numbers should be recorded on this sheet. Sensitive materials like preservatives must be counter-signed by a second member of staff.

All raw materials should be weighed out into clean containers or bags and clearly marked. They should be stored on a plastic or stainless steel pallet ready for delivery into the manufacturing or mixing room.

Staff must wear clean overalls and follow a rigorous hand cleaning protocol before handling any raw materials. Head protection and gloves must be worn at all times. Breathing masks should be available for powders and other respiratory irritants.

Demineralised water

There are many standards for the water used in the production of cosmetic and toiletry products. All water should be filtered at source to remove any particulate impurities. At the very least the water should pass through a water softener. Other products may then pass this softened water through a demineralising plant that employs two exchange resins to remove anions and cations. In the best

An example of a perfect bottling line.

systems, this water is then passed through a reverse osmosis unit to further rectify the water to a higher standard. Many manufacturers then go down through a series of filters (down to as low as 0.2 µm) to take out impurities as small as microbiological contamination.

The water is then passed through an in-line UV lamp (sometimes as many as three) to kill off any other opportunistic spoilage organisms. The lamp also helps to reduce the possibility of algal growth. The life of the UV lamps is finite and a log book should be kept of the number of hours that they have been used and then replaced once they have been burnt for their operational period. The lamps and their assembly should also be regularly stripped down to ensure that the glass window between lamp and water has not become dirty or suffered build up of any microbiological residues. All parts of the system should be part of a continual assessment, clean down, regeneration and measurement of the conductivity and microbiological integrity. Comprehensive records should be available.

The water is stored in a continuously circulating loop that includes filters and UV lamps. The major source of product contamination and failure can be attributed in most cases to poor water quality.

Manufacturing room

The manufacturing floor and its mixers is the second most sensitive area in the factory. Staff must wear clean overalls, head protection and gloves. Breathing masks should be available for powders and other respiratory irritants. Every tank should have a cleaning protocol and a sign telling the manufacturing operator its state of cleanliness (when it was last cleaned and when it has to be re-cleaned). Each tank should have a regular maintenance schedule, so that seals, bearings and other sensitive areas can be inspected for mechanical safety and hygiene reasons.

Hoses are a particular source of contamination and should be regularly replaced. The use of string, adhesive tape and other materials is to be banned from this area, especially cleaning rags and other cloths. Hoses must be stored with no minima (i.e. humps not troughs), pumps should be regularly inspected and stripped down. Peristaltic pumps are much less of a microbiological risk than other pumps with moving parts and hidden cavities.

Drains are a continual source of potential contamination and must be regularly opened up and thoroughly cleaned. All of these systems must be written into standard operating procedures.

Floors must be free of cracks, or any sort of damage. The best floors are constructed of screeded concrete coated in numerous coats of two pack polyurethane composite which gives a continuous surface with no place for bacteria to harbour.

Cleaning procedures

Cleaning should be with a proven surfactant system (e.g. Tego 2000) and the use of neat alcohol prior to each production batch is effective. A two-bucket cleaning system should be employed where clean water is taken from a blue or green bucket, but the mop is wrung out into a red bucket which is only for disposal. This greatly reduces the chance of spreading any contamination from one part of the floor to another. Once again, the colour coding of the utensils used in this area should be unique. These cleaning tools must not be used in the dispensary or be allowed out of the mixing room into the filling hall.

Production equipment

Record the year, make, capacity and model of every piece of equipment as it will enable the production capacity to be calculated later. Inspect the machine for its service record, reliability and state of repair.

All equipment not in use should be sealed and covered. Check all empty ports, inlets and outlets are covered with clean plastic bags to prevent the ingress of dirt.

Production capacities

It is important to assess the efficiency and capability of the factory under audit. It is a laborious task, but run through the annual production of the lines produced in the machine. It is important to know how many days a week the factory operates and for how many hours the machine runs. It is important to know whether the factory operates a shift system in the manufacturing area. It is all very well having the right equipment, but not if there is no spare capacity to prepare your products.

Breakdown of production

In many cases a factory will have more than one choice of suitable machine, and it is important to take into account every possible machine that could be used to produce your products.

Cooling water

In hot countries the batch time may be seriously compromised by the time it takes to cool down the batch. How does the company cool its batches?, check for water chillers, in-line heat exchangers or simple mains water running to waste (not very environmentally friendly).

Filling room

The filling room should be clean and tidy and once again there should be cleaning equipment specific to this area. Work in Progress (WIP) should have a position

on the filling floor with packaging (bottles, labels, caps, cartons and other items) booked in to the filling hall prior to filling commencing. Check to see if there is a WIP storage area. Check to see whether staff are briefed on the production line, and whether they have a standard on line. Quality control should have an in-line check weighing balance and results form on line, there should also be a go/no-go set of tolerances for label positions and other critical quality standards. Check also that batch codes are being applied.

Check filling equipment for suitability and that it is regularly serviced. Some filling jobs are complicated by small run sizes and awkward shapes etc. A basic manual line might not be a bad thing, but check that staff are being used efficiently. A check of volumes filled per day versus the declared filling rates at the filling head is often illuminating and often totally different. Calculate the efficiencies based on similar production.

The filled stock should be passed and certified by Quality Control before being sent to the finished goods warehouse for booking in.

Filling room equipment

Record all filling equipment according to age, model, filling rate, operator line size and calculate man hours per 1,000 units. It is often useful to compare different machines employing different line operator line sizes and looking at the efficiency figures. Also check the frequency of maintenance inspections, in particular that the line is clearly marked according to its cleaning status.

Filling room capability

Once again it is a very long and intensive task, but it is useful to know how much capacity the filling room has spare. The only way to be certain of the capacity is to go through every filling machine and examine the volume of products that it is running. Once again, it is important to determine the number of days per year that the factory is open and the working hours per day of the factory. Check whether they need to use overtime or operate a shift system.

The quality control laboratory

A well equipped and well-run quality control laboratory is essential to any successful factory. Check that there are records for all incoming raw materials and components. Determine whether they do any analysis checks or whether they rely on certificates of conformance. Look at the record keeping for these materials, if this data is computerised, then check that they have back up systems in place.

Check the retained sample store for finished goods as well as for raw materials and components.

R&D laboratory

Not all companies have their own R&D department, but the facility to design new products for a range or work closely with a client to develop new ideas is a bonus.

Systems for product development and testing are vital, so a full check of equipment, incubators, refrigerator and related equipment like viscometers, pH meters and other kit is vital.

Microbiology laboratory

The microbiology laboratory is an intrinsic part of every factory and should be involved in monitoring factory hygiene, checking each production batch (total viable count), raw material integrity, laboratory samples, water quality and staff hygiene training.

Paperwork and systems

The paperwork and ability to trace the documentation is vital. The key documents should be kept as controlled documents. The ability of the company to produce, control and retrieve their information is something that the auditor must assess.

Conclusions

A thorough audit takes around two days to complete and the auditor should issue a full report that shows the areas where the company was in compliance, but more important where the company was under performing. The action points should be agreed and a time frame agreed in which the company may achieve the improvements. PC