



Management of Mix Up Prevention: Reality or Myth?

One of the most common causes of recall, and also a frequent GMP failure, is where material from one batch of product is inadvertently mixed with a different batch of either the same product or a different product. This might range from a single tablet found on a packaging line, to a drum of excipient labelled as a different material. Many companies involved in GxP activities have a 'mix up prevention' programme, either running as a defined project, or as an ongoing part of the business.

But where does mix-up prevention start and end? In the author's opinion it starts not in manufacturing, nor in packaging, nor in the warehouse, nor in the goods received area. It starts with design. Design of your manufacturing facility and the equipment employed. The layout of a facility, to facilitate good material flow can be extremely successful in preventing mix-ups, for instance. The use of equipment that is easy to clean and check that it is clean will also reap real benefits. It also starts with the design of your product (should we use a blister pack, should the ampoule have coded markings, should this tablet be white?). And what does mix-up prevention include? As well as the obvious areas of manufacturing, packing, and warehousing, it also includes fundamental systems, such as training, supplier selection and approval, documentation design, maintenance programmes, artwork control.... And it never ends, as continuing to manage performance criteria, changes within the facility, continuous improvement initiatives, new products, audits, self inspection... all bring fresh data and new challenges...In short, mix up prevention touches every aspect of the business and is a continuous process. It is not something that can be 'flavour of the month'. It must be something that is a key part of your business. It is vitally important to keep mix up prevention as a high profile activity.

How do we therefore 'Manage' mix up prevention? The key is to risk assess the operation, by reviewing the history of mix-ups and by reviewing the status of all areas of your operation, including design, system and operational aspects. The programme should then prioritise the higher risk areas, which are reasonably practical to improve. It may not be possible to re-design your facility, but if the processes employed can be improved, or if simple design improvements, such as the lighting in an area, can be enhanced, then fewer mix-ups should result. The profile of mix up prevention must always be high. 'Visual Factory' style techniques are extremely powerful for maintaining that visibility.

One of the major areas for concern is the packaging floor and packaging equipment. The author has been involved in a global programme concentrating on this aspect of mix up prevention and it is amazing that simple improvements (often highlighted by the operational staff involved) to older facilities can reap real benefits, not only in GMP, but also in staff morale. On one packaging line several simple changes, costing less than a few thousand pounds sterling, made a tremendous improvement to the operation of that line.

Of course, there are also some obvious areas, which require continual monitoring. How many times have you seen two different batches of the same product/material being stored next to each other, with inadequate security/packaging. Bulk unlabelled vials in unlocked, open

containers is a common audit finding and the transportation of such materials around a manufacturing site is often found as the root cause during failure investigations of mix-ups.

Mix-Up prevention is a reality, it can be successfully managed and if successfully implemented and maintained, will lead to improved GMP, less recalls and most importantly, greater patient safety.

About This Article

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A Chartered Chemist, Alan Smith has worked in a number of key positions for global pharmaceutical companies. He has been a Qualified Person for the last 10 years and has experience of all the major pharmaceutical forms. Alan has led the Q.A. activities for a number of major projects and is also a successful project manager.

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