Improving line clearances -

packaging line efficiency

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Overview

Overview

- **Packaging Instructions should normally include, or have reference to the following:**

- * (f) *Special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin."*

  - EU Guide to Good Manufacturing Practice for Medicinal Products: 4.16 - Packaging Instructions

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Overview

- Packaging lines represent a large investment. How best to maximise the Return-On-Investment (ROI) is the most important factor!

- Remember - Good GMP never conflicts with line efficiency, so minimising line clearance time and overall changeover time must go hand-in-hand with minimising risk!

- Correct machine design means easy to change over, easy to clear and therefore easier to return to production status.

Overview

- Correct selection of the auxiliary components like the security and printing equipment will also maximise the ROI for the same reasons and optimise line clearance and overall changeover time.

- Considering the application in terms of long or short production runs, this will help select the correct type of equipment for the application and can optimise line clearance time.
  - § Example: clinical trials and small blister machines

Overview

- Falling batch sizes are increasingly presenting the pharmaceutical packaging industry with a challenge. The ratio of set-up time to running time is constantly worsening, with the result that in many cases line efficiency is below 30%.
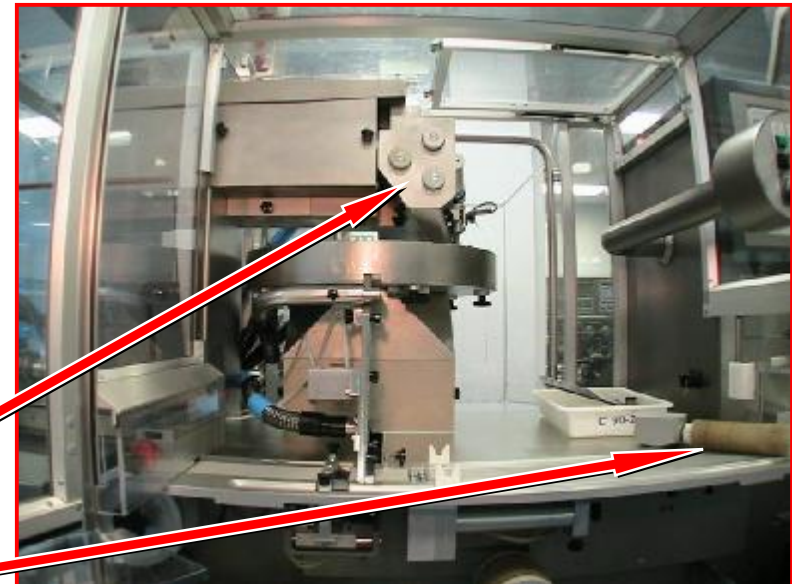
Ideas to Improve Line Clearance

- Consider the flow of materials and personnel with time, avoiding the risk of re-contamination after clearance. Cleaning and clearance are separate processes.

- Segregate materials from the old batch. Have clear identification of the next product to be packed and all other packaging components to be used - aids clearance.

- Consider methods of reconciliation of components on the line. The largest source of contamination is leftovers from a previous batch - John Sharp 2000.

Ideas to Improve Line Clearance

- Have physical separation between adjacent lines – aids clearance.

- Good housekeeping – aids clearance, we cannot clean where there is mess!

- Advertise the status of the line clearly both pre and post clearance and into production – line mounted information sheets help everyone understand the line status.

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Primary Packaging

- Improving the visibility within the machine - additional lighting and clear guards, add mirrors for difficult to see spaces where small components like a tablets can lodge.

- Make difficult to clean parts of the machine dedicated to a product.

Dedicated de-duster

Dedicated settling brush

Primary and Secondary Packaging

- Methodology of line clearance for efficiency, identify 'hot-spots' on the machine and give consideration to improving them.

- Designated areas of machine receiving different cleaning protocols.

- Having to clear, clean and change-over only from the operator side speeds up the line clearance.

- Avoiding flat surfaces where packaging components can collect, this philosophy can extend across the entire packaging area, not just the machine and aids line clearance.
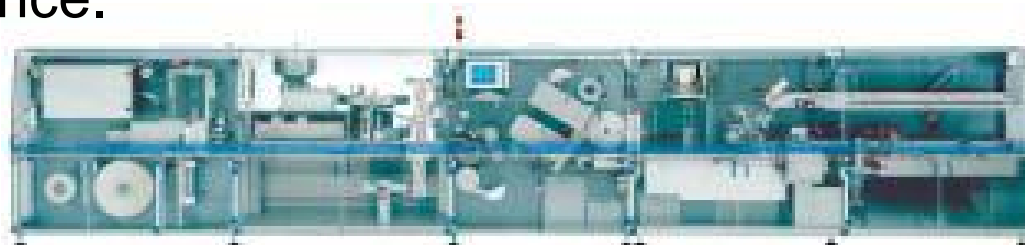
Secondary Packaging

- Balcony construction machine improves line clearance efficiency by removing traps

- Example:
  - § A leaflet on the bottom of the machine could not get into the finished product and therefore can be considered to be low risk
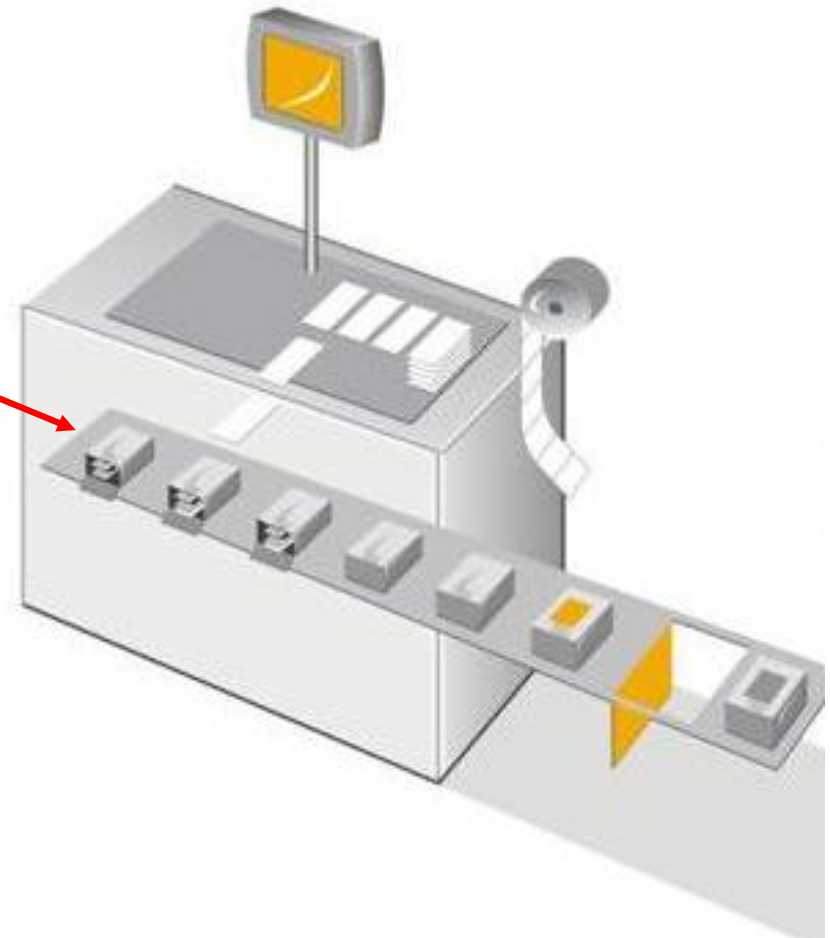
Human Machine Interfaces (HMI's)

Mechanical Requirements

- Touch screen

- Easy to clean

- No traps like keyboards, mice or heatsinks with small fins

- No exposed components – smooth external surfaces

Human Machine Interfaces (HMI's)
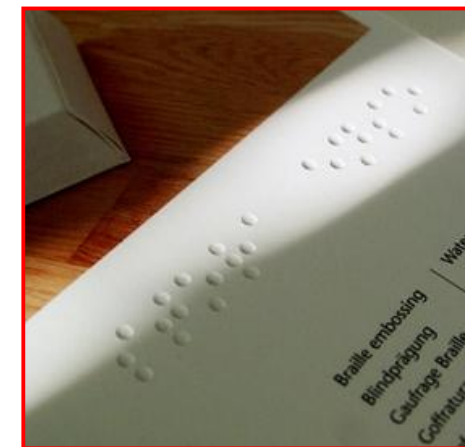
Operational Requirements

- Easy to visualise and program

- Ergonomic for speed and efficiency

- Product oriented download

Human Machine Interfaces
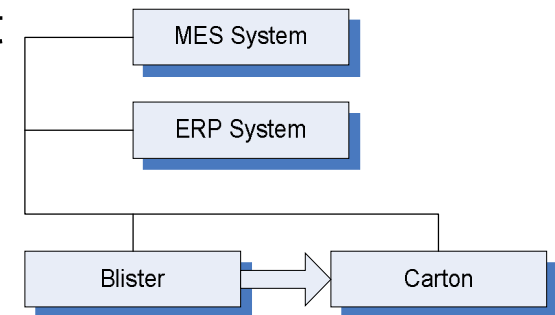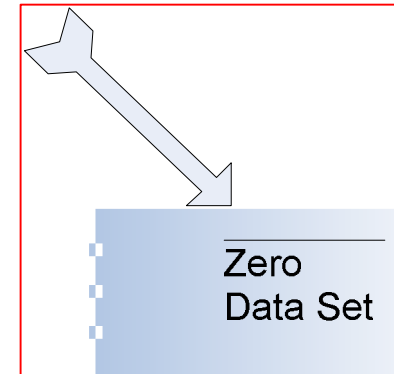
Security and Printers

- Single point data entry for bar codes, variable text cameras and programmable printers

- Moving away from embossing except for Braille

Human Machine Interfaces
Security and Printers

- Some customers already require that they be able to load 'zero data sets' in between batches – the electronic equivalent of line clearance prior to new product data being brought to the line

Zero Data Set

- Final integration step - Production security data can be integrated directly with the manufacturing systems ERP, MES for direct download of product specific security information

MES System

ERP System

Blister → Carton

MES = Manufacturing Enterprise System
ERP = Enterprise Resource Planning

Human Machine Interfaces

Security and Printers

- On-demand in line printing for foils – bring less product specific material to and from the line – lowers the risk and aids clearance

- Ultimate goal – The white lines packaging concept – packaging materials printed in line, on demand and just in time

- This can be just a data change when full digital printing is done

Human Machine Interfaces
Printing and Late Stage Customisation (LSC)

- LSC allows suppliers to produce a standard, generic, core pack (Blister, Carton) in bulk volumes, with only a single bar code identification on it.

- Then have this blister or pack customised with local language either in-house, or at an outsourcing facility.

- This is a genuine new development in the industry and brings with it new considerations for line clearance activities.

Pack Rationalisation & Brand Imaging

- Standardised Pack and blister formats imaging reduces machine changeover time

- Brand imaging seek to make all packs identical

- But these factors can have negative effect on line clearance, as visible differentiation becomes more difficult for the operators

- Of course the security devices will detect incorrect packaging elements

Packaging Lines - Control and Validation

Thank you for your attention

Find us and your

documentation at:

www.pptech.eu