Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Inspection of cross contamination controls in shared facilities

Graeme McKilligan, UK, MHRA.

Key steps expected after HBEL determined

Sites need to consider the content of an HBEL assessment and/or if using a ‘traditional approach’ understand the hazard, context and extent of the HBEL

Sites should use a practical common sense approach - what the exposure limit would equate to in terms of contamination left in equipment at batch and unit dose contact points or transferred via air borne or other contact. Consider the significance of this and how easily such a quantity could be missed or transferred, particularly should errors occur.

Sites should have initiated a risk assessment using the relative hazards/risks identified from HBEL to determine the level of detail required – matrix approach may be relevant to negate the need for separate RAs for each product.

Based on the hazard and risk, justification should be recorded for the extent and content of the risk assessment.

The process train, current or proposed controls should be documented in appropriate detail in the risk assessment. Opportunities for failure in controls should be recorded and further controls identified as necessary. The assessment should consider the effectiveness of controls and not assume they are effective.

Where inherent controls such as the pharmaceutical form are considered to be mitigating factors to the hazard then this should be recorded and justified.

Clear, concise risk assessment expected with robust evidence based justification for suitability of controls. Controls in place should be clearly recorded along with justification for suitability. ‘We have a procedure and have done it this way for years’ not regarded as suitable justification without supporting evidence.

Identify clearly where specific separation or dedicated parts, equipment or area is required based on an unreasonable risk of failure or difficulty to control otherwise.

Specific processes expected with greater detail and control where hazards are greater and /or remaining risk subject to error/failure:

- Cross contamination control assessment
- Setting cleaning and control limits
- Risk management/development of organisational and technical control measures
- How to develop cleaning methods (expecting to include use of drawings of equipment with additional physical examination)
- Cleaning validation
- Training
- Ongoing verification options
- Quality system management, data gathering and periodic review.
- Clear evidence of ongoing control
- New product introduction controls

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