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Sources of Contamination: Rooms and Facilities

by Thomas Peither

Ensuring a clean production environment – sounds simple enough. However, in the pharmaceutical context, cleanliness and contamination are clearly defined, delineated and, of course, regulated, particularly in the manufacture of active ingredients and medicinal products. Meeting the requirements often involves a complex web of measures, work instructions and documentation. Problem areas are often invisible.

In this LOGFILE, we focus on production rooms and facilities as potential sources of contamination.

Rooms and Facilities

Dimensions matter. The requirement for "sufficiently large" rooms has a simple reason from a production hygiene perspective. Cleaning staff can move around easily and can reach all the areas to be cleaned.

However, rooms that are too large also pose risks. For example, manual cleaning can lead to individual variations in results or as we also know from our own homes if space is available, unneeded materials or machines are often stored there.

Small rooms, on the other hand, are usually designed in such a way that the space is utilised as efficiently as possible. This is not ideal for cleaning. For example, machine parts that are close to the wall are difficult to reach.

Don't worry, you don't necessarily have to reduce or increase the size of your production rooms. If you specify or check the cleaning and disinfection processes in as much detail as possible with detailed instructions, you can easily compensate for non-ideal dimensions.

Arrangement/Layout

Carried over product residues pose a risk to other products and can promote the growth of germs, but can also be effective in the wrong product. Therefore, personnel and material routes should be designed to prevent mix-ups or cross-contamination.

Particular care must be taken when transferring materials from one cleanliness class to another. Appropriate measures to reduce germs or particles, such as the introduction through an H_2O_2 airlock or removal of double-bagged packaging, are essential.

Design

In addition to the general hygienic design of the rooms, machinery and equipment, attention should be paid to smooth and durable surfaces. Glass or stainless steel walls, for example, are easy to clean and make it easier to visually check the cleaning results. The general principle also applies to the choice of materials: surfaces must not interact with

or absorb cleaning agents and disinfectants.

Surfaces, walls, floors and ceilings that come into contact with the product should be inspected regularly and repaired as soon as possible if necessary. This naturally also applies to parts that do not come into contact with the product, such as machine bodies or covers. Transitions between walls and floors or walls and ceilings, and between individual components must be properly sealed. Condensation points should also be avoided wherever possible. Lighting in the rooms and at work surfaces must be adequate to allow visual inspection of the cleaning process.

Feed lines in systems and rinse lines should be blowable in order to prevent water residue after rinsing. Exceptions to this are feed lines carrying high viscosity, self-preserving syrups. These are not emptied during short downtimes, but a multiple of the line volume is discharged during start-up.

Equipment such as pallets, stainless steel trays, hoses and plastic boxes must also be checked periodically and replaced if necessary.

Waste water disposal is particularly critical. For example, drains are not allowed in Grade A/B rooms. Production areas for non-sterile products, on the other hand, require a sufficient number and size of drains to allow them to be cleaned with water. They must be regularly disinfected and equipped with non-return valves to prevent the risk of stagnant, contaminated water entering them.

Sanitary facilities also pose a high hygiene risk. There is a certain dilemma here. Although the Workplace Ordinance stipulates that toilets must be in the immediate vicinity of the workplace, this is not acceptable in the production area for hygiene reasons. Toilets within the production area should only be accessible via an airlock or at least have an antechamber that allows for cleaning and disinfecting of hands and the removal of pharmaceutical clothing.

Almost identical requirements also apply to break rooms in order to prevent contamination of clothing and the inhalation or ingestion of product dust with food.

Practical tip:
Good planning pays off. Unfavourable room and system designs usually have to be compensated for by increased cleaning effort.

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