LOGFILE Feature 26/2020 – Hygienic design of pharmaceutical manufacturing processes - example: tablet press

5-6 Minuten

When designing facilities there are numerous aspects to consider. These include not only the regulatory and normative requirements but also the functionality and cost effectiveness as well as the principles of hygienic design. Hygienic design refers to the easy-to-clean design of parts, components and production machinery. Hygienic design results in machines with a closed design that have little dead space and are easy to clean.

For a tablet press, hygienic design is important in two respects: In addition to the surfaces that actually come into contact with the product, the tablet press also has indirect and non-product-contacting surfaces that are critical for the product to be manufactured. Of all the component surfaces, those in contact with the product make up the smallest proportion, while those without direct product contact make up the largest proportion. Since these surfaces also come into contact with the pharmaceutical product during the manufacturing process, they are also important for the hygienic design considerations. This is especially true for tablet presses used to manufacture different products (multi-purpose equipment). Here, cleanability plays an important role in preventing cross-contamination.

In order to implement the hygienic design of a tablet press, the first thing to consider is the manufacturing process of the tablet in the press. The process-critical areas, i.e. those that come into contact with the product, include the solids feeding system and the components required to manufacture the tablet. These are the

rotor, the punches and the segments or dies. The product outlet for the discharge of the finished tablets should also be included in the consideration.

Once the process-critical areas have been defined, it is necessary to consider how the following design requirements can be implemented:

- Ease of removal
- Ease of access
- Dead space-free design without undercuts
- Reduction of screw connections
- Minimized number of internals in the press compartment

The surfaces and components surrounding the process-critical and product-contact areas are also important in the consideration. These areas also come into contact with pharmaceutical products and should be easy to clean when changing products. Although these surfaces are not product-contact surfaces, they can lead to possible cross-contamination between the different products if the hygienic design and cleanability is insufficient.

Figure 4.C-58 High-containment design tablet press: de-duster (left), and press compartment (right) (courtesy of Fette Compacting GmbH)

For hygienic design, shaft feedthroughs should be designed so that the seals to the base plate are not on the base plate level, but on a raised section incorporated into the plate. As shown in the detail drawing in Figure 4.C-59, with the liquid drain, the base plate is manufactured in one piece and the feedthroughs are milled into the base plate as raised sections. This significantly reduces deposits in the seals. The base plate is also milled at an angle to a lowest point so that the cleaning medium can drain off. All seals are flush with the surrounding surfaces and therefore do not allow product deposits to form. Another feature of good hygienic design is the avoidance of recesses in screw heads and other elements where product residues can accumulate. This can be achieved by consistently avoiding recesses and, as in the example, using custom screw designs.

In the tablet press filling unit hygienic design was also implemented systematically:

- There are no mounted components within the product flow space which could hinder cleaning.
- All external components are easy to dismantle and arranged so that the external surfaces are easily accessed and cleaned.

Figure 4.C-59 High-containment design tablet press: detail of filling unit (left), and fluids discharge (right) (courtesy of Fette Compacting GmbH)

This text is an excerpt from Chapter 4.3 Hygienic Design of the GMP Compliance Adviser.

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