PRESS RELEASE

Aenova publishes white paper on the "Safe and efficient handling of high potent drug products"

Starnberg, 04 October 2022 - The market for HPAPI (High Potent Active Pharmaceutical Ingredients) will continue to grow in the coming years and decades. HPAPIs are used, among other indications, for the treatment of oncological diseases, immunosuppression and hormone therapy or endocrine therapy. Highly potent pharmacological agents are frequently used to treat diseases for which patients have a particularly high medical need. Therefore, the development and production of these mostly life-sustaining or life-saving HPAPI products already play a particularly important role for Aenova as one of the world's leading CDMOs (Contract Development and Manufacturing Organization).

Since many molecules in the aforementioned indication areas are in the preclinical or clinical trial phase, safety in production is a particular challenge for commercial production due to potential toxicity. The development and manufacturing of drugs with highly potent active ingredients is very complex and often has to be done under great time pressure, as many of these new molecular entities (NMEs) are approved as "breakthrough therapy" in a fast-track process to quickly address a high unmet medical need. For such scenarios, pharmaceutical companies need reliable and experienced CDMOs as partners at their side.

At Aenova, experts in the field of HPAPI production have therefore developed and implemented a holistic concept for the safe and efficient handling of HPAPI. This concept - from the basics to practical implementation - has now been published in the **white paper "Safe and Efficient Handling of High Potent Drug Products".**

The handling of highly potent active pharmaceutical ingredients is internationally regulated in OEB or OEL classes (Occupational Exposure Banding or Occupational Exposure Limits) in order to ensure both the quality of the product and the health of the processing personnel. In the risk assessment developed by Aenova, the potency of the active ingredient, the physio-chemical properties, the quantity and the duration are set in relation to each other in order to achieve the best possible risk minimization in development and production (see Fig. 1).

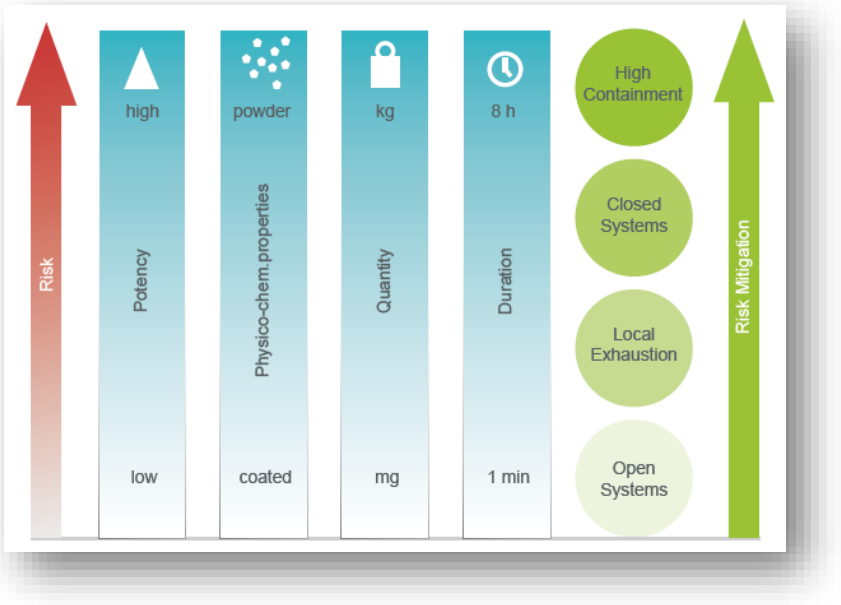


Fig. 1: Risk assessment depending on the different procedural processes (Graphic: Aenova).

For the safe and efficient development and production of highly potent active ingredients, the structural measures, the production facilities themselves, the processes, and the training and "mindset" of the employees follow a sophisticated, holistic production concept (see Fig.2).

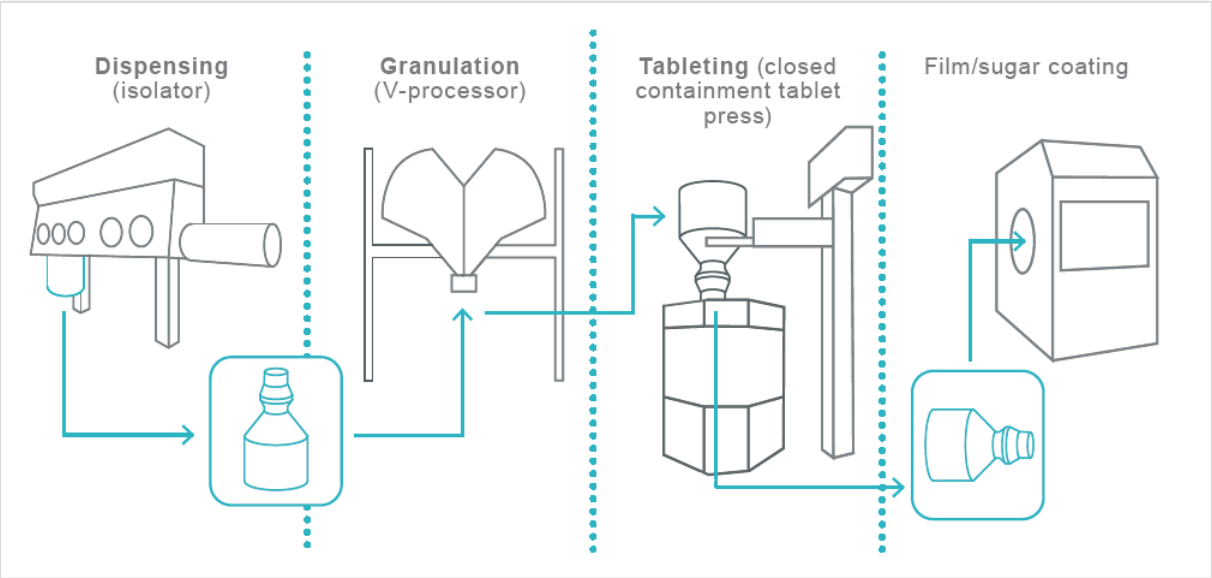
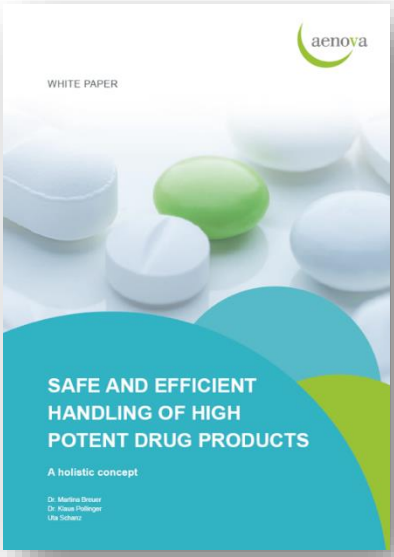


Fig. 2: Schematic structure of the closed containment production concept for tablets with high potent APIs (Graphic Aenova)

Request your free personal copy of the white paper "Safe and Efficient Handling of High Potent Drug Products" now. Send a short e-mail with your name and organization to: contact-sales@aenova-group.com .



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