FOCUS ON Content Uniformity via Flow Control Systems

Norwich development and pilot scale facilities are located within nearly 13,000 square feet of DEA approved, potent compound capable space that also contains two laboratories dedicated to support R&D and GMP development projects.

These facilities are strategically designed and equipped to provide solid dose manufacturing technologies in both GMP and non-GMP environments. The facilities, equipment and technology mirror Norwich commercial capabilities, allowing direct transfer from analytical to quality control, and enabling a fast track to trade production.

With a focus on improving outcomes for patients, Norwich discovered a content uniformity issue during the technical transfer of a low dose product and then provided a novel solution to ensure reliable product supply. Through physical testing, it was determined that the formulation consisting of blended powders was highly sensitive to segregation via the fluidization mechanism. Essentially, any free vertical drop led to segregation and content uniformity issues.

Norwich identified two solutions to minimize fluidization during the manufacturing process in order to resolve the content uniformity challenge. The first solution was to replace the use of a v-blender with a bin blender to reduce material handling. Norwich changed the blender within the Scale-Up and Post-Approval Changes class to reduce regulatory impact, thus removing an unnecessary discharge step – the discharge step caused the blend to become fluidized, resulting in segregation.

The second solution involved the implementation of a powder flow control system that minimized blend fluidization during the discharge of the bin to the tablet press. The system evacuates air from within the transfer tube using an internal bladder system. The transfer tube connects the bin and the tablet press. This prevents the free fall of powder associated with opening the discharge valve on the bin and minimizes fluidization of the blend. The powder flow within the transfer tube will approximate plug flow motion.

Norwich's expertise in engineering the mechanical, electrical and control functionalities inherent in the above mentioned flow system resulted in two solutions that provided the customer with supply assurance and a successful transfer. Through partnership with the customer, Norwich delivered a solution with the highest level of quality and reliability.