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ASIA EDITION

Vetter’s new clinical manufacturing site now fully integrated

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A growing number of pharmaceutical and biotech companies are seeking clinical manufacturing partners that provide strategic support and comprehensive resources?for their development process of new, promising injectable drug products.

- Expansion of clinical capacity to address growing market demand
- Site status now ‘ready for media fill’
- Next milestone – approval of Austrian authority

Vetter, a leading global Contract Development and Manufacturing?Organization?(CDMO) has further?invested in additional?capacity to meet this growing global demand.

Only one year after the purchase of the clinical manufacturing location in Rankweil, Austria, the site has been modified to the high Vetter quality standards in aseptic fill and finish for drug-delivery systems. “With this additional?facility?we will further expand?our?capability?for early clinical development for?phase I and phase II drug candidates,” says?Vetter Managing Director Peter Soelkner. “The dedicated manufacturing site will focus on supporting our customers on quality, timeliness and technical expertise.”

The production site?currently offers 100,000 square feet of offices, laboratory space, areas for material preparation as well as room temperature, cool and frozen storage and one automated vial filling line for liquid and lyophilized?products. ”Through various measures and modifications, all systems and manufacturing processes have been successfully integrated into our business operations and the site is now ready for operations,“ explains Vetter Managing Director Thomas Otto. “The site also offers opportunities for possible future expansion.”

In the coming months, media fills for different vial formats will be performed onsite that simulate the actual drug manufacturing process and represent an important step in preparing for future customers projects. “When establishing the new location, Vetter’s general expertise in aseptic manufacturing processes was, of course, very valuable,” outlines Dr. Claus Feussner, Senior Vice President Vetter Development Service. However, another major contributing factor was the know-how and experience we gained over the last ten years at our successfully established US Development Service facility in Chicago. These learnings will be incorporated into the customer business and future production for in-human

trials in Rankweil.”

The next milestone for the new clinical site will be the official GMP inspection for obtaining the manufacturing license in the beginning of the fourth quarter 2021. The authority responsible for this site is the Austrian BASG/AGES (Federal Office for Safety in Health Care/Agency for Health and Food Safety).