Press release

Vetter Development Service Chicago Completes Recent On-Site Expansion Activities
Continued demand and increased customer product transfers are generating a positive business outlook for the company's early-stage development facility

Skokie, USA, and Ravensburg, Germany: June 10, 2015 – Vetter, a leading contract development and manufacturing organization (CDMO) that specializes in aseptic filling, has announced today that a number of activities undertaken at its Skokie facility to satisfy existing and ever-increasing future customer demands have been completed. The initiatives include an additional staff shift for daily clinical manufacturing operations, as well as the doubling of capacities for performing visual inspection and In-Process Control (IPC). The facility also expanded its on-site offerings by giving customers the option to obtain secondary packaging services for small batches of frozen drug products such as vial labeling, cartoning, and carton labeling. Furthermore, the long-term collaboration with *Sentry BioPharma Services*, a provider of cGMP clinical packaging solutions and supply chain management, supports a streamlined path from filling to clinic.

Satisfied customer demand creates a positive business outlook

"We are extremely pleased with our past years performance at the Skokie facility, as well as our overall success to date," said Vetter Managing Director Peter Soelkner. The site, located at the Illinois Science + Technology Park in suburban Chicago has successfully passed audits and qualifications by as many as 30 companies, including 9 of the top 20 leading (bio-)pharmaceutical companies. This performance has resulted in a wide-ranging customer base that includes not only those in the US, but also European companies based for example in the UK and Denmark, as well as Asian headquartered companies such as in South Korea.

"Many of our customers have already returned for development work for a second, third, or even fourth molecule," added Dr. Susanne Resatz, President of Vetter Development Services USA, Inc. who is responsible for heading up the operation. "Furthermore, our outlook for future performance is very positive as demonstrated by a pipeline filled with high quality customer projects for biologics." Drugs under development by Vetter's customers include treatments for blood cancer, muscular dystrophy, wound healing, and dwarfism.

Company-wide consistency in filling lines, processes, and quality systems

As a CDMO, Vetter offers manufacturing resources starting from early drug development through to market launch and commercial supply. If desired, customers can not only get a 'modular service' offering, but also a seamless transfer approach for their drug product from Vetter's US early-stage facility to one of its European development and commercial manufacturing facilities. The sites on both continents use similar equipment and processes whenever possible, including product contact materials such as excipients and primary packaging materials. This flexible approach results in less overall risk of unforeseen manufacturing issues, and creates a consistency between clinical and commercial drug product handling.

In addition, the core of the aseptic manufacturing process i.e., the filling lines themselves are designed in the same manner at Vetter's clinical and commercial sites. The Chicago facility, designed specifically for high yield and flexible use, employs scaled-down versions of the company's commercial filling lines. This aligned facilities approach reduces time and means less development work will be necessary to realize the transfer and scale-up process of the individual customer drug product.

Furthermore, all Vetter sites in US and Europe are part of the same company-wide Quality System, offering a consistent quality approach over a project lifetime and avoiding non-productive time to adapt to new systems. The interaction of Vetter teams from both the US and Europe allows customers to access global expertise as necessary, an attribute that is especially valuable for projects with a very high level of complexity.

To date, four customer products in development have already been successfully transferred from Vetter's US clinical manufacturing facility to the company's European sites for manufacturing of late-stage clinical supply and for subsequent commercial production. The company plans for additional product transfers from the US to Europe in the near future.

Vetter's facility at the Illinois Science + Technology Park in Skokie.

Lyophilized vial capping at Vetter's Skokie facility.

About Vetter
Vetter is a premier contract development and manufacturing organization (CDMO) and a global leader in the fill and finish of aseptically prefilled syringe systems, cartridges and vials. Headquartered in Ravensburg, Germany, with facilities in Germany and the United States, the company provides state-of-the-art manufacturing, from early clinical development through commercial filling and packaging of parenteral drugs. The CDMO's extensive experience covers a broad range of complex compounds, including monoclonal antibodies, peptides and interferons. Vetter supports its customers every step of the way, guiding their products through development, regulatory approval, launch and lifecycle management. Known for quality, the company offers a foundation of experience spanning more than 35 years, including dozens of product approvals for novel bio/ pharmaceutical compounds. Since 2014, Vetter operates a representative office in Singapore, increasing the presence of the company and the awareness of its service portfolio in the Asian healthcare market. Visit www.vetter-pharma.com

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