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## Press release

### **Vetter's state-of-the-art Chicago facility is fully operational**

First site to use Bosch's new fully automated vial filler, designed for early clinical-stage compounds

**Ravensburg, Germany & Skokie, Illinois, USA: October 5, 2011 – Vetter, a leading contract development and manufacturing organization that specializes in aseptic filling, today announced that its first U.S. facility is now fully operational. Located at the Illinois Science + Technology Park in suburban Chicago, the 24,000-square-foot site includes microbiology and chemical analysis labs, material preparation and compounding functions, three cleanrooms for aseptic filling, and visual inspection. The first to use Bosch's new MHI 2020 B fully automated vial filler, Vetter's Chicago facility offers state-of-the-art technology and processes to support preclinical through Phase II compounds.**

### **Advanced technology lowers costs and decreases risk**

Designed specifically for early clinical-stage, high-value biopharmaceuticals, Vetter's new automated vial filler can run up to 10,000 liquid or 6,000 lyophilized vials per batch.

- Minimum tubing lengths help reduce API loss and increase product yield.
- The system's use of Restricted Access Barrier System (RABS) and its high degree of automation – including both filling and capping – mitigate risk of contamination by minimizing human intervention.
- The unit is capable of running a range of fill volumes, from 0.1 to 23 ml, providing ample flexibility.

Intended for liquid fills, a second cleanroom houses a flexible semi-automated filler. The system can fill a variety of packaging materials – syringes, cartridges and vials – with a capacity of up to 500 units per batch.

Both automated and semi-automated units provide a 100 percent in-line check-weigh system, which helps ensure accurate fill volume – critical in small, early-stage fills. Because no sampling is required to verify fill volume, the system increases API yield.

### **Use of disposables saves time to clinic**

The facility uses exclusively disposable components in material preparation, compounding and filtration areas, which eliminates the need for cleaning validation – and thus saves valuable time and cost.

A third cleanroom will expand current operations and provide filling of pre-sterilized syringes.

### **Focused customer service, global business strategy**

Said Vetter Managing Director Peter Soelkner, "Our Chicago facility provides customers with a top-of-the-line clinical manufacturing site located in the heart of the United States. Because Vetter consistently strives to stay at the forefront of innovation, securing Bosch's new fully automated vial filler was a natural for us. Here in Chicago, our state-of-the-art systems and infrastructure, coupled with our professional expertise, offer customers the quality they expect from Vetter."

Vetter's Chicago facility is an expansion of Vetter Development Service, which employs more than 100 personnel in Europe and the United States. Strategic to Vetter's plan for worldwide growth,



the launch of Chicago operations highlights Vetter's dedication to serving the North American market, where nearly half of Vetter's client base resides.

Further demonstrating Vetter's U.S. commitment is the company's preferred partnership agreement with Midwest-based Sentry BioPharma Services, signed last year. From its site in Indianapolis, Indiana, Sentry is able to label, package and ship clinical supplies filled by Vetter, upon customer request. The collaboration will help streamline the path of study drugs from filling suite to clinic while safeguarding product integrity.

As with all Vetter facilities, the Chicago site and its processes meet stringent FDA and EMA quality requirements. Adjunct services include regulatory counsel and product lifecycle management. Experienced project managers steer all product development projects, so that projects can stay on track, quality standards can be maintained, and deliverables can be met on time and on budget. The Chicago facility provides seamless product transfer to Vetter's large-scale manufacturing facilities in Europe for Phase III and commercial manufacturing.



Picture caption: Vetter's Chicago facility at the Illinois Science + Technology Park.



Picture caption: Fully automated vial filler at Vetter's Chicago facility: Lyophilized vials are prepared for capping.



Picture caption: Semi-automated filler at Vetter's Chicago facility: Vial filling.

**About Vetter:**

Vetter is an international contract development and manufacturing organization (CDMO) specializing in the aseptic filling of syringes, cartridges and vials. The company has extensive experience with a broad array of compounds, including monoclonal antibodies, peptides, interferons and vaccines. An independent firm headquartered in Ravensburg, Germany, Vetter provides support for pharmaceutical and biotech clients from preclinical development through regulatory approval and global market supply. Vetter's new Chicago facility, an expansion of Vetter Development Service, supports early-stage products. The CDMO works with the world's top 10 pharmaceutical/biotech firms and emerging companies alike, and employs approximately 2,400 staff across Europe and the United States. The innovator of the Vetter Lyo-Ject<sup>®</sup> dual-chamber syringe and V-LK<sup>®</sup> cartridge, the company holds nearly 140 patents and is a leader in the use of RABS technology in cleanrooms. Approved as a foreign manufacturer by the government of Japan, Vetter's global regulatory experience includes numerous customer product approvals by the FDA, EMA and other authorities. Over its more than 25-year history in aseptic filling, Vetter has won many awards for its facilities and operations, including Frost & Sullivan's 2011 European Prefilled Injection Systems Customer Service Leadership Award.

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