Professionals discuss future manufacturing strategies

“How can one be best prepared for mega trends like digitalization, demographic and political change while traditional healthcare models continue to evolve and new drug and device types are being developed to meet individual patient needs?” This is a difficult question to answer and why industry experts recently convened to discuss not only these issues, but also emerging future opportunities. What is clear from their discussion is that achieving success in the development and manufacturing of new drug products requires top-notch knowledge and strong partnerships between a CDMO and its stakeholders.

On June 15, Vetter hosted the Manufacturing Professionals Day in Ravensburg, Germany. Together, an esteemed group of healthcare experts, consultants, and manufacturing professionals from across Europe discussed industry insights, shared information about regulatory changes, and exchanged knowledge about topics ranging from the impact of connectivity in device development, to the technical, communicative and logistical challenges for a drug product slated for global commercialization. Moderated by Johannes Clemens, Director Business Development Europe, attendees also heard directly from Vetter customers who presented ‘real-life’ case studies, and had a first-hand opportunity to learn of the benefits of working with Vetter via a tour of the company’s manufacturing and development facilities.

Injectables on the rise

Good knowledge about the industry is essential. To help provide this context, Dr Sybille Esser, Vice President Market Intelligence and Strategic Alliances at Vetter, presented insights on the global market. Highlights include:

- The US pharmaceutical market continues to expand at a faster rate than the global market while China’s growth will slow to 5-8%. The markets of India and Russia are expected to grow much faster.
- With VC funding accelerating in 2017, smaller biotech companies are in good financial shape, allowing them to maintain their paces of outsourcing spend.
- The injectable share of all therapeutic NDA/BLA approvals has increased in recent years with further increases expected until 2024.
- The orphan drug sector will double in size by 2024 with VC funding taking aim at oncology, rare diseases and high prevalent chronic diseases such as pain.
- CDMO usage is at a high level looking at small biotech/pharma

Meanwhile, Vetter invests in state-of-the-art technology, infrastructure and innovation in order to continue as a best-in-class CDMO. Joerg Zimmermann, Vice President Vetter Development Service at Vetter reviewed the company’s capabilities and investments. His presentation highlighted the advantages for customers receiving services along the value chain as a one-stop-shop solution, including secondary packaging and labelling to secure global supply. Vetter advantages include investments in cleanroom expansion, Vetter CleanRoom Technology® , and Ravensburg West which was recently given the Facility of the Year Award (FOYA) in the *Facility of the Future* category for its new Center for Visual Inspection and Logistics.
Dr. Markus Neumeier, Technology and Process Transfer specialist at Vetter highlighted the company’s quality and knowledge leadership in a presentation that included different scenarios and challenges that can occur during a technology transfer. Dr. Neumeier emphasized that it is crucial to conduct a gap analysis at the beginning of a project to identify potential project risks that can cause a product launch delay in the global market. By use of expert knowledge, pitfalls can be avoided and products can be made available upon regulatory approval.

Future approaches influenced by globalization and digitalization

Managing Director Dr. Hiltrud Horn of the German-based HORN Pharmaceutical Consulting provided insights on how Brexit impacts regulatory bodies that are repositioning and reorganizing themselves with major consequences for healthcare businesses in Europe. She further presented recent major regulatory changes and GMP-challenges, highlighting data integrity and serialization as most critical for biopharmaceutical companies to be prepared. In addition she presented the impact of the new clinical trials regulation on industry as well as important aspects of ICH Q12 on life-cycle management.

Laurent Foetisch, owner of the Switzerland-based Supply Chain Operations SA highlighted speed to market, responsiveness and flexibility as further challenges on the path to successful commercialization. While there are many secondary packaging and labeling strategies that ensure global market supply, Laurent presented the 'postponement approach'. This approach should be considered, for example, when vastly different country requirements or demand overheads determine the possibility for packaging at a later stage.

The PA Consulting Group, represented by Simon Hall provided insights on the influence of digitalization to the entire health sector. Digitalization is more than adding connectivity, it's to improve design, capture clinical study outcome data, improve our understanding of disease and drive behavior change. There is growing investment in wearable smart devices in today's market. Investment is being driven by increased patient demand for enhanced user experience and usability as well as an increased focus on symptoms. There is opportunity for smart wearable devices, integrated with connected drug devices to improve capture and management of outcomes across therapeutic areas, particularly in orphan and chronic diseases.

Strong Client-CDMO Relationship

Based on their close working relationship, two of Vetter's customers presented their experience and success with the company. In the first case study, the close linking of strong planning and forecasts, along with highly experienced teams on both sides helped to launch a global ready-for-market drug. In the second case, strategic project milestone planning, effective milestone communication, seamless cooperation and market excellence in technology transfer demonstrated the advantages of working with Vetter.

Following the presentations, attendees were offered tours by Vetter's Frank Lehle, Director pharmaceutical production, and Frank Böttger, Director Manufacturing Science & Process Development, of Vetter cleanrooms and one of the facility's state-of-the-art laboratories.

Perhaps the event was best summarized by the remark an attendee: "Thank you for a very insightful and stimulating event. I am glad that I had the chance to meet with such an interesting professional panel and enjoyed the program. I have been impressed by the visit of your facilities and the openness and expertise of your teams."

Contact:
Vetter Pharma International
Johannes Clemens, Director Business Development Europe
Phone: +49-7 51-37 00 -1782
Email : Johannes.clemens@vetter-pharma.com