



IDT Biologika broadens capacities and competencies by new sites in the USA and Canada

Leading-edge vaccine technologies more and more globally recognized



Madrid, October 12, 2015. **IDT Biologika, underlines at the CPhI 2015 in Madrid its prime position as a globally recognized contract manufacturer of innovative vaccines and biopharmaceutical parenterals. Over the last few months, IDT Biologika has successfully implemented the next steps in its expansion and globalization strategy. The partnership with key vaccine players in the international marketplace is based now on a broadened presence around the globe.**

Today, with production facilities in the USA and Canada, the German biologics company offers its customers services from vaccine development to vaccine manufacturing for clinical trials through to high-volume vaccine production. International established awards – such as the Facility of the Year Award (FOYA) for facility integration and the CMO Leadership Award for quality, reliability, productivity and innovation, both granted in the last [x] months – underline the industry's recognition of IDT Biologika as a prime partner.

IDT Biologika Corporation in Rockville, Maryland (USA): A highly experienced CMO-partner for phase 1 and 2 projects

Recently IDT Biologika announced the dedication of its first U.S. vaccine manufacturing facility in Rockville, Maryland. IDT's vaccines business is global, addressing potential customers with challenging vaccine production technology needs and/or high volume orders with a broad range of competencies and capabilities.



“As a new site within the IDT organization, IDT Rockville offers an enhancement of capacities within the leading state-of-the-art manufacturing competencies of our company. The Rockville production facility gives IDT more flexibility for customers with projects in clinical phases 1 and 2. IDT Rockville is a highly capable and experienced CMO-partner,” said IDT Biologika CEO Dr. Ralf Pfirmann. “For customers desiring to begin their activities in the United States with the expectation of their projects going beyond phase 2, they can stay now with IDT until industrial production, undergoing seamless efficient transfer within one development, supply and quality partnership. For customers desiring to begin their activities in the United States and to clarify their perspective, IDT’s expertise is now available in this country.”

Embedded in IDT’s global network, quality approach and capabilities, the state-of-the-art facility provides the translational bridge between pre-clinical development and phase 2 clinical trials with end-to-end capabilities, including process development, cell banking, cGMP manufacturing, purification and formulation, and fill and finish.

Autogenous viral and bacterial vaccines for Canada

At the end of August, IDT Biologika announced the acquisition of Gallant Custom Laboratories, based in Ontario, Canada. Gallant Custom Laboratories is the only Canadian company authorized by the Canadian Food Inspection Agency (CFIA) to manufacture autogenous viral and bacterial vaccines.

“With its strong scientific focus, in-house research and development and production of autogenous vaccines for the Canadian market, Gallant is an outstanding complement to IDT Biologika’s other global offerings,” said CEO Dr. Ralf Pfirmann. “With this second acquisition in North America within just a few months, we are highlighting our



expanding commitment to meeting the vaccine manufacturing needs in key North American markets.”

Gallant serves customers throughout Canada, particularly those who provide vaccines to the Canadian livestock and poultry industry. The company relies on modern in-house diagnostic laboratory facilities to identify viral and bacterial diseases in pigs, sheep, goats, cattle and poultry, and to subsequently manufacture and supply the appropriate autogenous vaccines corresponding to specific pathogens out of its Cambridge-based manufacturing facilities in Ontario. Gallant will continue to do business as “Gallant Customs Laboratories, an IDT Biologika company.

IDT Biologika receives ISPE's 2015 FOYA Award

IDT Biologika has received the International Society for Pharmaceutical Engineering (ISPE) 2015 Facility of the Year Award (FOYA) for facility integration. The award spotlights companies that set the standard in pharmaceutical facility design, integration and operational excellence.

Completing a major expansion of its biologics and vaccines production facility in Germany late last year, IDT Biologika established highly automated filling and freeze-drying operations, providing the basis for large-scale commercial manufacturing and increased quality of aseptic operations.

“With the new facility in [where?], the company now accommodates production of an ever-more diverse range of biotechnologies with extraordinary precision, safety and integrity,” said Dr. Andreas Neubert, head of IDT’s vaccines business unit. “Designed to be modular, fast and expandable, the IDT Biologika facility is now one of the most flexible biologics operations in the world certified to biosafety levels (BSL) 1 and 2 for live vaccines.”



CMO Leadership Award for quality, reliability, productivity and innovation

IDT Biologika accepted the CMO Leadership Award for quality, reliability, productivity and innovation in March 2015. Recognized for leadership in 4 of 5 key areas, IDT Biologika was among the highest rated biotech companies.

"As IDT Biologika expands to serve an ever-larger customer base, more industry partners have come to recognize the depth of our capabilities," said Dr. Pfirmann. "Being recognized for quality, reliability, productivity and innovation is a testament to IDT's on-going investment in technical talent, infrastructure and automated product management systems. Just as importantly, it is a testament to our owner, the Klocke Group, who recognizes the extra value that comes with a long-term commitment."

About IDT Biologika

IDT Biologika is an innovative, privately-held life science company with more than 94 years history and expertise in research, development and manufacturing of biologics for the global protection of human and animal health. Headquartered in Dessau-Rosslau, Germany, the company holds an additional animal health vaccine dedicated R&D and manufacturing location in Greifswald – district Riems. In Denmark, the Netherlands, France, Spain and Canada, IDT's Animal Health Business Unit operates through its own subsidiaries.

In its recently acquired U.S. manufacturing facility in Rockville, Maryland, IDT Biologika Corporation, a subsidiary of IDT Biologika GmbH, primarily provides vaccine development for clinical phase I and II projects and provides early development capabilities for the human vaccine market.



In Canada, IDT Biologika recently acquired Gallant Custom Laboratories, based in Cambridge, Ontario. Specialized in manufacturing and supplying of autogenous vaccines the company now does business as "Gallant Customs Laboratories, an IDT Biologika company.

In the 2014 financial year, IDT Biologika achieved sales of approximately €172 million with its animal health, vaccines, and parenterals, biologics and final drug products packaging business segments, an approximately 14 percent increase in business compared to the previous year. IDT Biologika currently has some 1,500 employees.

IDT Biologika is a company of the Klocke Holding Group. The Klocke Holding Group companies specialize in contract manufacturing and packaging of pharmaceuticals, vaccines, and cosmetic products. With more than 2,100 employees and producing at eight locations in Europe and North America, the family-owned Klocke Group offers comprehensive services for production and packaging of pharmaceutical products.

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