Hamburg, Germany
January 27th, 2017

CMC Pharma GmbH and AmpTec GmbH close consulting agreement for API-mRNA production according to GMP FDA 21 CFR Part 210, 211, ICH Q7 for IND/CTA use in early phase clinical studies

CMC Pharma GmbH is a GMP service provider for pharmaceutical and life science companies as well as their suppliers. CMC Pharma offers FDA registration services (US agent with permanent address in the USA) for companies producing pharmaceutical drugs or preparations (small molecules, biotech, APIs), medical devices, foodstuffs or food additives. In addition to core competencies, CMC pharma offers also services such as translation of specialist texts, interpreting services, e.g. for FDA inspections. CMC Pharma ´s US Agent maintains close contacts to FDA officials. The team offers "Mock audits" by former FDA investigators, as well as support in the preparation, execution and follow-up. CMC offers these services for all above mentioned areas from pharma to food.

AmpTec GmbH is an ISO 13485:2007 certified provider of synthetic nucleic acids for worldwide leading companies in the field of molecular diagnostics and biotechnology and has already in 2012 implemented cGMP-compliant production of synthetic RNAs for **diagnostic applications (GMP FDA 21 CFR Part 820)**.
In order to expand the scope for **therapeutic applications (GMP FDA 21 CFR Part 210, 211, ICH Q7)** AmpTec has established a cooperation with CMC Pharma to use their great consulting expertise in this field. CMC Pharma has completed training courses and an onsite GMP assessment.

Peter Scheinert, CEO of AmpTec, says: "We are very pleased about the productive cooperation with CMC Pharma and their impressive training experience."

Stefan Schmitz, CEO of CMC Pharma, says: "Today, November 23, 2016 the announced first review of AmpTec´s compliance review with cGMP (21 CFR 210, 211) was performed. It can be stated that AmpTec is compliant with the requirements of 21 CFR 210 and ICH Q7 (section 19: APIs for use in clinical trials) which is adequate at this phase of the project for early clinical studies."

„At a later stage, with the beginning of clinical phase 3, it is expected by the authorities to be also in compliance with 21 CFR 211 and fully in compliance with ICH Q7 (GMP for API manufacturers). Before full GMP compliance for API manufacturers is achieved by AmpTec, a few more things need to be reviewed and adjusted. Follow-up reviews will be implemented to monitor the step-by-step progress towards full GMP compliance."

„The commitment of management and staff to drive the company in the direction of full GMP compliance for API manufacturers is highly appreciated and will lead to a successful transition from preclinical to clinical and market supplies."

For further information please contact:

CMC Pharma GmbH

Dr. Stefan Schmitz
M5, 11
68161 Mannheim, Germany
Phone +49 (0) 621 400 68 795
Fax +49 (0) 621 400 68 797
Cell +49 (0) 172 69 66 028
http://www.cmc-pharma.de

AmpTec GmbH

Dr. Guido Krupp
Dr. Peter Scheinert
Email: info@amp-tec.com
Phone: +49 40 636747-22
http://www.amp-tec.com