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Pioneering in Track & Trace Technology, Serialization in Pharmaceutical Production

Illertissen, February 2018 – In twelve months from now – in February 2019 – serialization of pharmaceuticals will become mandatory in the European Union. To protect patients against forgery, medicines must be serialized during packaging and fitted with an anti-tampering device. One of the pioneers in this field is R-Pharm Germany – formerly part of the Pfizer production network. Already back in 2009, the experienced CDMO (Contract and Development Manufacturing Organization) developed systems for serialization and aggregation and went live with several packaging lines in its facility in Illertissen, Germany.

Today, R-Pharm supports manufacturers, which are not ready for the upcoming requirements, by providing packaging capabilities including serialization as a standard service. In addition, the company shares the relevant organizational and technical expertise in a so-called “Track & Trace User Academy”, a collaboration with Mettler Toledo PCE founded in 2017. The support by R-pharm is reducing the customers ramp-up phase to a minimum.

If a customer is not able to establish the necessary equipment and procedures in its own facilities in time, R-Pharm can bridge the gap guaranteeing to meet the deadline.

To avoid the investment in the regulatory-compliant serialization and aggregation systems, customers may also decide to source out the packaging to R-Pharm completely. The CDMO has many years of experience and is certified in over 150 markets worldwide. Among them are all markets,

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where regulations about serialization of pharmaceutical products are already effective, like Korea, China, USA, EU and Saudi Arabia. The integration in R-Pharm's systems including the necessary IT solutions is smart and very convenient for new customers.

“Twelve months is an extremely short time to set-up a proper system and the needed site organization for a serialized and aggregated production”, says Michael Unbehaun, Manager Engineering Site Projects: “If a manufacturer hasn't started yet with a solid implementation project, it definitely is about time.” To commission a CDMO with serialization and aggregation is a possible solution, but even then, it is now time to take action, as capacities might be short soon.

About R-Pharm Germany GmbH

R-Pharm Germany operates one of the most modern production plants worldwide for manufacturing and packaging of pharmaceutical products and nutritional supplements. The contract manufacturer offers various services and solutions for formulations, product development, and cost-effective manufacturing and packaging, scalable over different batch sizes.

More information about the full service contract manufacturer:

www.r-pharm.de.

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