Pharma&Biotech

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Lonza

News Release

Serialization Capabilities Now Operational at Lonza Edinburgh Facility for Liquid-Filled Hard Capsules

- Counterfeit and diverted medicines are a growing threat to patients
- Investment in former Capsugel site improves anti-counterfeiting security for Lonza's global supply chain
- Lonza customers are already benefiting from increased protection for their patients, well ahead of U.S. and EU legislation implementation

Basel, Switzerland, 14 December 2017 – Lonza announced today that its integrated development and manufacturing site for biopharmaceutical liquid-filled hard capsules in Edinburgh (UK) has new anti-counterfeiting security capabilities in place and is in full compliance with EU and U.S. regulatory requirements for serialization. Lonza's customers will benefit from this investment to secure the integrity of sales packs now and in the future.

With increasing threats to patient safety from counterfeited and diverted pharmaceuticals, regulatory mandates for serialization in more than 40 countries are being implemented to secure the world's pharmaceutical supply chain. Serialization – also known as track-and-trace – refers to country- or region-specific systems used to track the passage of pharmaceuticals through the supply chain and into the marketplace.

According to the World Health Organization, an estimated 7-15 percent of all medicines sold in developed countries are falsified – either contaminated or containing the wrong active or the right active in the wrong dose – and up to 40 percent of medicines in developing countries are counterfeit.

The EU Falsified Medicines Directive (FMD) Safety Features Delegated Regulation dictates that all licensed drug products must be serialized from early 2019. Similarly, serialization will be officially required in the United States from November 2018 in line with the U.S. Drug Supply Chain Security Act (DSCSA).

"It's important for our customers to know that our Lonza Edinburgh facility is ahead of the curve and already fully compliant with the new regulatory requirements in the United States and EU to combat anti-counterfeiting," said Jane Fraser, PhD, Site Head at Lonza's Edinburgh facility. "Our new serialization line and quality system – fully commissioned and qualified this year – are now being used to serialize our customers' sales packs, well in advance of the serialization deadlines."

The requirements of serialization and product tracking (SPT) mandates vary by country or legislative region. However, every region is implementing compliance reporting systems that oblige pharmaceutical companies to provide the regulators a mix of master data, packaging and serialization information or supply chain transaction events, among others.

The implementation of these anti-counterfeit technologies is the most extensive preventive measure used by government authorities to help guarantee a secure supply chain worldwide.

"Lonza is committed to providing exceptional quality and service to our customers," said Gordon Bates, Head of Chemical Division, Lonza. "Our investment in serialization and product-tracking capability, which is now online, reflects Lonza's ongoing commitment to respond to the needs of our customers and to protect patients."

Lonza's Serialization Processes
Lonza's new serialization line will serialize and tamper-proof liquid-filled hard-capsule (LFHC) sales packs (cartons) and will aggregate cartons to shippers and shippers to pallets. The system utilizes ©Optel Group Ltd. technology and has been designed to meet the varied requirements across all key countries and regions. The system also serves to complement the site's capabilities in supplying commercial market-ready packaging (blisters, leaflets, cartons, shippers) for its customers.

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Specifically, these five new processes are in place to combat counterfeiting schemes and protect the security of supply of Lonza's LFHC products:

1. **Sales Pack (Carton) Printing and Inspection**
   Cartons will be printed by thermal inkjet with fully traceable unique identifier serialization coding and human readable text. All cartons are 100 percent inspected for quality of print, and all packs that are below the required standard are 100 percent rejected
2. **Shipper to pallet aggregation**
   The system will aggregate the sales pack to the shipper and associate the shippers to the pallet
3. **Post Batch Rework**
   Serialization data provides allowance for damaged and sampled drug product within a serialized batch
4. **Receiving Serialization Codes**
   The system is capable of receiving serialization codes from customers' systems via a secure server
5. **Data Storage and Communications**
   The system will securely store serialization and aggregation data and communicate this information back to the customer's server, for communication with the central hub

About Lonza
Following the closing of the Capsugel acquisition, Lonza further strengthened its position as one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. Lonza harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life.

An integrated solutions provider serving the healthcare continuum, Lonza offers products and services from the custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries. In addition to drinking water sanitizers, nutraceuticals, antidandruff agents and other personal care ingredients, the company provides agricultural products, advanced coatings and composites and microbial control solutions that combat dangerous viruses, bacteria and other pathogens.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 50 major manufacturing and R&D facilities and nearly 14,000 full-time employees worldwide. Further information can be found at www.lonza.com.

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