

# Fit for the Global Market

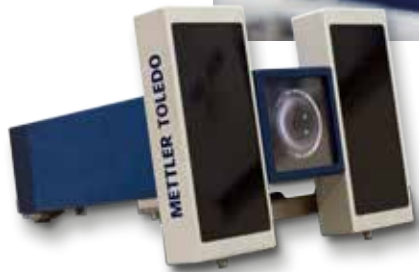
## Aggregation Solution for R-Pharm in Illertissen



**Compliant medicinal products for the global market: R-Pharm Germany GmbH in Illertissen operates as a contract manufacturing organization (CMO), producing and packaging pharmaceuticals for customers which are then distributed in more than 150 countries. In order to supply pharmaceuticals to markets that demand serialization or aggregation, the company uses tools such as the Case Aggregation Kit from METTLER TOLEDO PCE on a semi-automatic case packer from Christ Packing Systems.**

### Serialization from as early as 2017

Protection against falsified medicines has become the leading issue for the pharmaceutical industry in recent years. According to EU Regulation 2016/161, all pharmaceutical packaging must be serialized and fitted with an anti-tampering device from February 2019. The USA has



High-resolution camera

**R-Pharm Germany GmbH**  
Serialization & Aggregation



Secure, ergonomic, and flexible technical solutions for aggregation

also set a similar law in motion, the Drug Supply Chain Security Act (DSCSA), which requires serialization to begin as early as 2017. Other major markets are already calling for measures to protect against product piracy. Those wishing to export goods to China, Korea, or Saudi Arabia, for example, are already required to aggregate their pharmaceuticals. "If we are to serve these strategically important and high-volume markets, we need secure and flexible technical solutions for aggregating packaging," explains Michael Unbehaun, Manager of Engineering Projects at R-Pharm. "Over the years, we have built up a firm partnership with METTLER TOLEDO PCE in the field of pharmaceutical serialization and aggregation. Together we have been able to successfully implement a number

of technological developments that focus on the production process. The first of ten serialization and aggregation lines was launched back in 2009 – this is why we recently opted for another semi-automatic aggregation solution from METTLER TOLEDO PCE."

#### **Customizing for Perfect Processes**

R-Pharm Germany GmbH has rounded out its service portfolio with the Case Aggregation Kit – the new aggregation solution from METTLER TOLEDO PCE – in combination with a compatible case packer platform from Christ Packing Systems. This means that the company can now execute manual, semi-manual and fully automatic serialization and aggregation for folding boxes, bottles, and wallets. The result is a needs-based service with a highly flexible structure,

which enables the customer's production requirements to be implemented cost-efficiently at all levels of aggregation. It was with this end goal in mind that the company joined forces with METTLER TOLEDO PCE and case packer manufacturer Christ Packing Systems in 2014 to devise a new packing line that could aggregate ready-packed, serialized, and sealed individual packages in a centralized manner. The investment decision followed an external benchmarking process, in which technology from various providers, concept designs, and the potential outlay were analyzed and compared.

A semi-automatic case packer from Christ's CaseTeq 100 product range forms the basis of the packing line. The Case Aggregation Kit from METTLER TOLEDO PCE – which consists of the software, cameras, control monitor, and cabinet – sits on top of this. In order to ensure that this solution would work efficiently in three-shift operation, the individual components of the apparatus first had to be precisely coordinated with one another. "The challenge lay in ensuring that the case packer and the aggregation software could communicate with each other without any problems," explains Achim Gombert, a sales engineer at METTLER TOLEDO PCE. "To make this possible, we used our PCE Line Manager software and adapted the workflow to fit the case packer." Michael Meyer, Product Manager at Christ Packing Systems, is happy with the results: "Thanks to our close and constructive collaboration with METTLER TOLEDO PCE, we were able to rapidly develop a solution that is perfectly tailored to the specific needs of R-Pharm Germany GmbH."



Visual inspection functionality with high-resolution cameras

### Aggregation via Camera

For open orders, the employees at R-Pharm manually place the bundled pharmaceuticals on a conveyor belt. The semi-automatic case packer from Christ transports the bundle past a camera, which in this case identifies preprinted serial numbers on the individual packs layer by layer and forwards the data to the PCE Line Manager software. The system then places the bundle into a box in such a way that the serial numbers are visible on the top. Once the box is completely filled, an employee applies a self-adhesive shipping label that contains the aggregation code including the serial number and other variable data. Once the code has been verified using a handheld scanner, the software is notified that this box is full and has been labeled. This prompts the software to assign to the box all the serial numbers recorded in it. The boxes are then transported to the sealing station, where they are closed up for transport. This enables R-Pharm to ensure that the compounds and serial numbers within a specific box can be determined at any time within the supply chain. "Aggregation of boxes is not just stipulated by regulations – it also lays the foundations for a high degree of transparency and thus for the potential to improve

the logistics process for our customers. This guarantees that our digitization solutions are viable in the long term and creates benefits for patients and companies," says Michael Unbehaun.

### Statistics & Line Reporting

During the ramp-up phase for this system solution, R-Pharm made use of the log and debug files in the Line Manager software from METTLER TOLEDO PCE to carry out statistical evaluation, enabling the company to identify and eliminate weaknesses within the packaging process. Audit trails also allow pharmaceutical manufacturers and packers to verify that the serialization process has complied with the regulations at every single stage and has not been manipulated.

Finally, once the packaging process is complete, the Site Manager software from METTLER TOLEDO PCE forwards the serial numbers processed for a specific order to external platforms run by the customer or markets via specially configured connectors and interfaces.

The combination of the semi-automatic case packer and the Case Aggregation Kit from METTLER TOLEDO PCE supports R-Pharm in the efficient production

of its orders. In bundle mode, 250 to 300 pharmaceutical packs per minute can be packaged and aggregated. The system is highly flexible and a single person can implement a format change in under one hour. This solution is perfectly attuned to the operational excellence concept of R-Pharm Germany GmbH. "In the context of serialization and aggregation, our understanding of 'right first time' is being able to offer our customers an attractively priced solution that boasts optimum product and data security along with efficient processes," says Michael Unbehaun.



Case Aggregation Kit combined with a suitable case packer platform



Christ CaseTeq 100 case packer platform



Manual aggregation



R-Pharm Germany GmbH, Illertissen

### R-Pharm at a Glance

- 370 employees at the Illertissen site
- 4000 orders per year
- 1500 different packaging formats
- Compliant packaging for more than 150 markets
- Aggregation line with throughput of 250 to 300 packs per minute
- Connected to TraceLink

► [www.mt.com/pce](http://www.mt.com/pce)



#### Mettler-Toledo GmbH

8606 Greifensee  
Switzerland

E-mail: [product.inspection@mt.com](mailto:product.inspection@mt.com)  
Website: [www.mt.com/contact](http://www.mt.com/contact)

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