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Serialization during folding-box production - an efficient, reliable alternative to the inline solution

Serialization of drugs is confronting pharmaceutical companies all over the world with challenges, especially in relation to data handling and the integration of additional equipment and functions into existing packaging lines. Offline solutions, where secondary packaging is serialized directly by the folding-box manufacturer, combined with sophisticated data flow architectures, are a reliable, flexible and immediately available alternative to inline serialization.

By means of Delegated Regulation (EU) 2016/161, the European Union has drawn up a mandatory standard to prevent the penetration of falsified medicines into the legal supply chain and to increase patient protection. According to this Regulation, all prescription medicines – with the exception of those on the "White List" – as well as those medicines for self-medication cited on the "Black List" must be provided with an individual distinguishing feature (serialization) and with protection from manipulation (Tamper Evidence).

In addition to improved patient safety, pharmaceutical manufacturers hope, through serialization of their drugs, to contain the substantial world-wide increase in economic damage due to product piracy and theft. Apart from economic damage, manufacturers are also afraid that their brand image will be seriously damaged.

From an economic viewpoint, pharmaceutical companies can benefit from other aspects of serialization. For example, recognizability in the event of returns and clear identifiability in the event of recalls, which can be carried out in a more targeted fashion, therefore affecting a smaller quantity of products, reduce costs substantially in some cases. Also, the grey

marketing of drugs, i.e. the selling of original products outside designated commercial channels, can be better controlled in this way.

Pharmaceutical companies therefore have an interest in promoting serialization of their products. However, above all they must comply with national standards in order to be allowed to continue to supply after the respective introductory periods. Its introduction confronts pharmaceutical companies with major challenges, in particular with regard to the assignment of data to packaging lines and to the integration of serialization equipment into existing packaging lines. In the case of retroactive integration, the pharmaceutical contractor is the general contractor, who, however, frequently does not have available the necessary technical personnel with the qualification required for this.

Serialization places demands on pharmaceutical companies at both systems level and production level.

Apart from the EU, a large number of governments throughout the world are tackling serialization of medicines and are in the process establishing standards which differ greatly from each other. Manufacturers who wish to sell their drugs world-wide must, permanently and at short notice, get to grips with and react to new requirements, some of which may change suddenly.



Application of the codes on the individual medicine pack requires secure management within the company of the serial numbers of each individual product and, if necessary, of each individual destination country. During printing using digital print technology there is a requirement for a system at the production machine which prevents duplications, particularly in fault situations and exceptional situations, and which can reliably record the successfully printed codes despite interference factors. Because of the use of Asian fonts, the need to apply specific information to medicine packaging which people can read leads to a large quantity of characters to be processed and to exponentially demanding requirements in terms of data processing.

The alternative to inline serialization on the packaging line – offline serialization by the folding-box manufacturer – means that the pharmaceutical company is spared the integration of printing technology, cameras and ejection equipment in each individual packaging line, as well as the training of employees in the use of print technology. The lost production time for the integration and validation period can likewise be saved.

In the case of inline solutions, print heads for applying the codes in the required print quality and permanence, as well as cameras to check them and software for central control of the new modules, must be integrated into existing installations. In addition, for some countries aggregation with balancing must be installed. The latter is also necessary for the offline variant, where serialization is handled by the folding-box manufacturer. However, any further investment or delicate interventions in systems is not necessary, so their efficiency remains to a large extent unaffected. The basis for offline serialization is reliable data exchange with the folding-box manufacturer.

For EU coding and for most other countries (except China) coding of the expiry date and batch information is required. Depending on the medicine, this data makes the coding process subject to time pressure. If serialization takes place at the folding-box manufacturer, then the latter must have a database system and a quality assurance system which have been proven in practice so that fast, error free deliveries are guaranteed.

Whether inline or offline, serialization demands the perfect interaction of hardware, software and reliable, qualifiable processes. Different IT systems at the equipment level (line server), at production level (plant server) and as part of enterprise resource planning (ERP) must be combined.

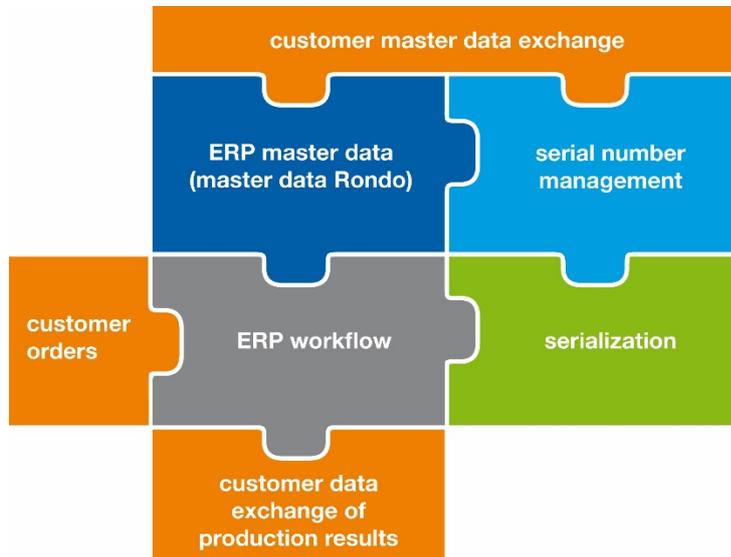
Serialization by the folding-box manufacturer - ultramodern printing techniques are combine with reliable data flow architectures and processes which comply with pharma requirements

The offline variant is an attractive option in particular for medium-sized pharma companies, in terms of avoiding additional investment for each individual packaging line and maintaining the efficiency of existing equipment - especially if the time for converting all lines is tight. In addition to solutions for tamper evidence and the application of special security features, Rondo also offers its customers this service. The Swiss company has invested in an Atlantic Zeiser DIGILINE Single Pharma 450, which covers all the requirements for reliable offline serialization. All current codes are applied using OMEGA Drop-on-Demand inkjet technology in high-quality, high-contrast print and codes, using UV-hardening ink, and are therefore resistant to abrasion, water, alcohol and other solvents. The legibility of bundles which are packed in shrink foil is significantly improved as a result, and this reduces finishing costs to a minimum. Almost all typical materials can be printed on with a print quality of at least 1.5 according to ISO/IEC 15415:2011 (Grading C).



With its extensive format range of 80 x 100 mm to 450 x 500 mm, the system handles all common sheet and cardboard sizes in the pharmaceutical industry. Up to 240 folding boxes per minute can be printed on in consistent high quality and provided with serial numbers. In this way Rondo is providing its customers with solutions which can also handle fairly large orders at short notice.

All modules of the coding machine, such as the mix-up and inspection cameras, are controlled via central production software. The seamlessly integrated Unique Code Software enables as many sets of numbers as required to be managed and ensures consistent serialization results. For example, in the event of interruptions in production, whether they are intended or not, no duplicate serial numbers are assigned. If desired, the list of successfully printed serial numbers can also be made available to the customer. Integration into Rondo's existing ERP system makes duplicated inputs impossible and guarantees error-free, secure data exchange. The software has been specially adapted for Rondo, in order to enable secure management of print orders and their assignment and distribution across one or more machines for parallel production.



In addition to the software, the data flow architecture has also been adapted to the specific requirements of the pharmaceutical industry. Importing of data from the customer is also automated, as is data export of the result files. Assignment of serial numbers to the production order is performed using unique naming with automatically generated file names. For production, the data is provided automatically via an enhanced master data management system.

For quality assurance, a second camera which checks the correctness and quality of the codes is installed in the equipment. The production results report and the balance file can be generated in different data formats according to the customer's wishes and sent to the customer via electronic data exchange.

Innovative folding-box manufacturers offer secure offline solutions for efficient and reliable serialization of medicines

Outsourcing the serialization of their medicines to a folding-box manufacturer such as Rondo offers pharmaceutical manufacturers a number of benefits. They access the very latest print technologies with high-contrast print images for optimum verifiability and secure software solutions without having to invest several times in production equipment or impair their

efficiency. In addition, outsourcing serialization does not increase the cost of line clearance during the packaging process.

With Rondo, pharma companies can rely on secure data handling and reliable balancing. Data management runs in the background and cannot be influenced by users in any of the individual process steps. Input errors are therefore prevented.

Furthermore, pharmaceutical manufacturers can access the expertise of folding-box manufacturers in terms of print, materials and solutions. For instance, in addition to serialization of flat cardboard blanks, Rondo also offers its customers reliable, high-quality printing of glued folding boxes, significantly reducing the quantity of serial numbers required by the process. Integration of additional security features and tamper evidence are also possible. This means that Rondo can provide its customers with both standardized and customized solutions for secure packaging which meet all international standards.

Images:



Figure caption: More and more governments throughout the world require the application of an individual distinguishing feature (in this case: China Code) and protection from manipulation (tamper evidence) on all prescription drugs.



Figure caption: The DIGILINE Single Pharma 450 from Atlantic Zeiser enables application of all data which varies according to the market, language and product on a flat or glued folding box, with simultaneous serialization

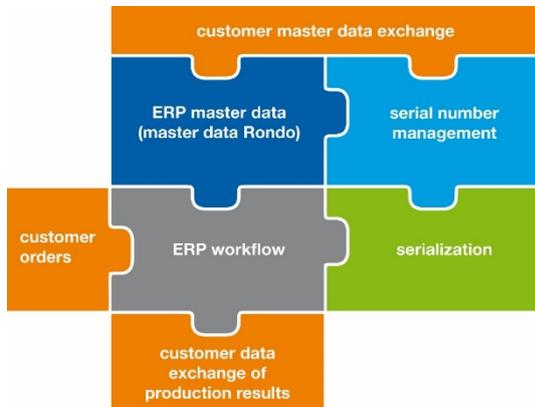


Figure caption: At Rondo, all processes and systems required for generation, provision and exchange of data are fully integrated.

Company information:

Rondo AG in Allschwil, Switzerland offers production facilities in Czech Republic, in USA and in Puerto Rico. Rondo is specialized in the development and production of high-quality cardboard packaging solutions for the pharmaceutical industry.

Rondo is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group. Körber unites around 11,500 professionals in industry-leading companies, achieving annual earnings of 2.3 billion Euros. As a Medipak Systems company Rondo offers beside high volume standard folding cartons and customized packaging solutions for all types of applications also services like assembling of top-loading folding boxes.

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