

INSIGHTS**Serialization Ready***Optimizing the Repack Process*

Picture this: You are at the beginning of your company's serialization effort. As you began, the focus was on the packaging line. This huge step in the process connects your plant's packaging line(s) to your corporate serial number repository to record serialization numbers. You have moved your serialized product from the packaging line to the warehouse. Now, on the next step of the journey, you need to respond to your business colleagues' requests for additional QA samples from inventory. In order to obtain a sample of the serialized product, you have to open pallets, cases, and perhaps even inner packs. Once those unit product samples are removed, you would now need to reassemble into a new complete inner packs and cases. And thus, you are facing REWORK.

For our definition, rework is: the process of breaking down and reassembling serialized materials from unit cartons, inner packs, cases, and/or pallets, and then, reassembling them into new complete inner packs or cases. While doing rework, you will not be making new sellable serialized units, but you will disassemble and reassemble everything else. Rework may also be called repacking.

Situations that may cause you to rework your serialized materials are: damage in material handling, reassembly to new case or pallet configurations, the need to provide additional QA samples or retention samples, or the change of a packaging component. Rework can extend the functionality in the packaging production line operations or be used in warehouse operations.

“ For our definition, rework is: the process of breaking down and reassembling serialized materials from unit cartons, inner packs, cases, and/or pallets, and then, reassembling them into new complete inner packs or cases. ”



While reworking, you may need to update or create new inner packs, new cases, partial cases, and partial pallets. So, to do this process of rework or repacking, you will have to control and manage any changing parent serial number IDs, grandparent serial number IDs, and great-grandparent serial number IDs.

Because the serial number structure is complex, there are risks of potential errors – and frustration. Rework requires formal, documented business processes and system-assisted controls to record and organize the serial number changes. Therefore, you ask...

Do we have a rework solution?

Your serialization operation may need to use rework to repack cases due to accidental damage in material handling or for additional samples.

The need to rework a serialized product requires information updates for several situations:

- 1 The supply chain needs to know how the serialized products are repacked. This information updates the packaging relationship between serial numbers, namely children to their new parent serial numbers.
- 2 Any removed product serial numbers must be decommissioned since they are no longer available to the market.
- 3 Full cases or intermediary packaging may now be in a partial state; thus, these containers are no longer standard full quantity packaging and must be relabeled as partial containers.

Rework/repacking scenarios occur after the original serialization packaging run, when there is a need to disassemble or reassemble serialized packaging. To provide an illustrated example, let's consider a breakage scenario where we need to replace two unit cartons from one case of serialized materials, resulting in one full case and one partial case. Each case will be properly labeled. This is illustrated in Figures 1 and 2, below.



Figure 1: **BEFORE** - Serialization product from the packaging line



Figure 2: **AFTER** - After rework, child serial numbers have been moved, resulting in one full case and one partial case.

In instances where a packaging operation previously had no other solution than to rerun the entire batch, a rework packaging solution offers a lower cost and lower impact solution to packaging issues.

The ability to keep track of changes to product packaging serial number relationships is the key to efforts at the repack or rework station. Organizing the several EPCIS events into a consistent, reliable interface is critical. The historical tracking and reporting of serial number changes – including unpacking, packing, commissioning, decommissioning – are needed in proper sequence to correctly process the transformation of the serial number hierarchy. The physical changes and business information must be coordinated and synchronized while the operator is working at the repack station.

Fortunately, properly designed systems can guarantee that serialized products are reassembled correctly, and that the application's embedded algorithms keep business information in the appropriate sequence. This means that you don't have to dread pulling samples or changing packaging components. Now, with confidence, you can provide your customers with complete, fully packed cases of serialized material. The business will now be able to pull up reports for a given pallet or unit carton and see the full traceability which occurred on the given serial number.

At Clarkston Consulting, we've worked with our clients to develop this technology. As a practical example, we have implemented a working model to communicate information from the rework (or repack) station to the global serial number repository.

The rework solution integrates the Global Corporate EPCIS Serial Number Repository with the packaging line supplied by Optel Vision's Tracksafe Linemaster. Tracksafe manages the repacking station and packaging operations. The advantage to this design is to provide the rework operator with the same interface as the packaging line and as all printing and packaging devices. The repack station interacts with the corporate repository to seamlessly communicate the existing serial number

hierarchy, and then allows for breakdown and repacking changes, as needed. Once complete, the revised serial number hierarchy is placed back in the Global Corporate Serial Number Repository for future activities...like shipping.

With this solution, rework sounds simple, even with complicated serialization hierarchies to manage. When examining a rework solution for your company, we suggest the following characteristics:

- **Easy:** Uses a set of rules or guiding principles to help the operator disassemble and reassemble correctly. The operator uses the same user interaction as the original packaging operations.
- **Continuity:** Transforms the serial numbers from original state to new state. These changes are reflected, in proper order, to the Corporate Serial Number Repository.
- **Historical:** Provides proper history of changes through valid EPCIS reporting.
- **Integrity:** The system provides housekeeping rules for full serial number accountability.
- **Compliant:** Meets GS1 compliant rules, including labeling with 1D and 2D barcodes.
- **Integrated:** The packaging rework station and corporate repository operate as a single unit, making sure that multiple events process together.

With serialized products, there will be a need for logistical and aggregation changes after packaging and before shipment. The rework station gives your operation an automated solution that will keep serialized products moving to customers and patients in a safe and efficient method.

So, are you ready for serialization rework? We are.



About the Authors

David Treadaway is a senior manager with Clarkston Consulting. He has over 25 years of information systems experience in the consumer products, pharmaceutical, medical device, and high tech industries. For the last three years, Mr. Treadaway has managed a Serialization and Track & Trace project involving pharmaceutical anti-counterfeiting efforts and regulatory compliance for the US and EU. Mr. Treadaway is also working with several clients to design and develop their serialization strategies and prepare them for meeting worldwide serialization regulations. He and his team also developed a serialization training course for Clarkston's clients.



Seth Andrews is a consultant with Clarkston Consulting. He is a solution architect for Serialization and Track & Trace solutions for life sciences companies to meet global regulatory requirements and supply chain needs. His deep functional and technical understanding of the industry trends and services has provided companies robust solutions to meet industry challenges and evolving regulations.

For more information about Clarkston's Serialization Solution, please contact David Treadaway at dtreadaway@clarkstonconsulting.com



Headquarters
2655 Meridian Parkway
Durham, NC 27713
Phone: 800.652.4274
Fax: 919.484.4450

www.clarkstonconsulting.com

0941_0514

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rating of 97%.

For more information, email us at info@clarkstonconsulting.com