



## **Pharmaceutical Solutions**

to comply with all regulations and fulfill Quality Inspection and Traceability demands of your production



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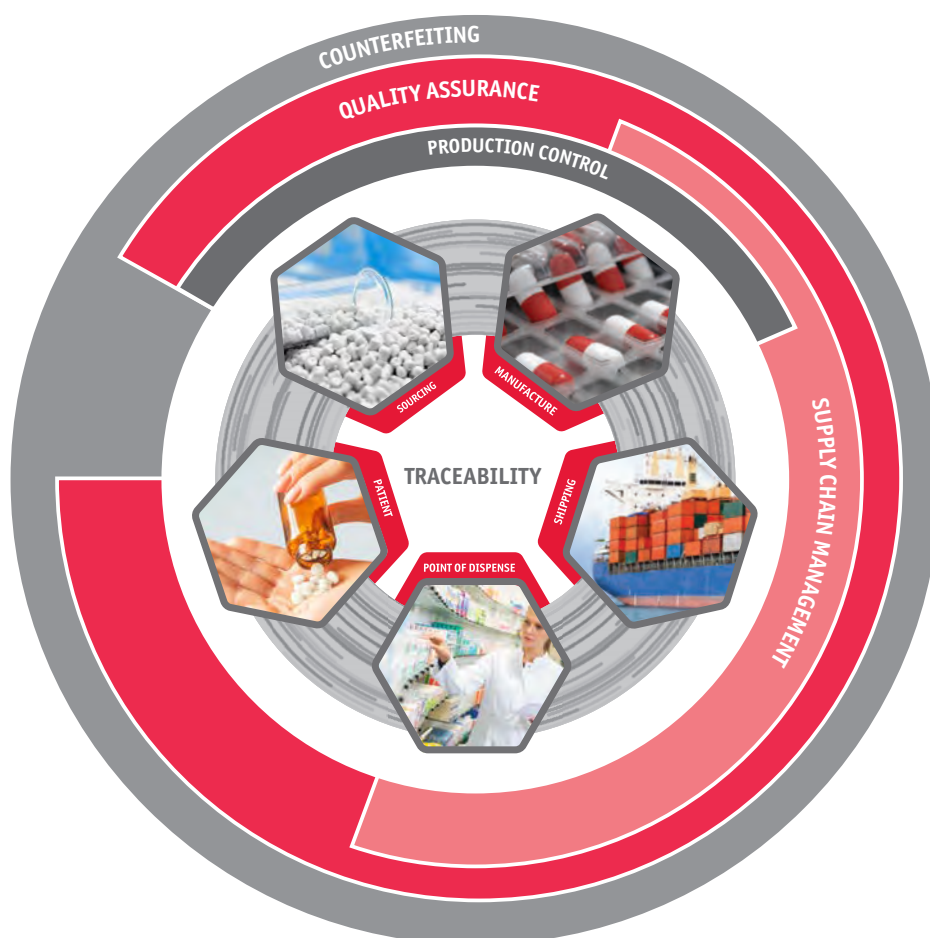
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# 1. Lifetime Traceability of your Product with Track & Trace Solutions from Laetus

Traceability enables companies in the pharmaceutical industry to minimize the risk of counterfeiting and thereby increase both the safety of their products and the level of trust among consumers. The use of reliable track and trace solutions from specialists such as Laetus makes it possible to monitor the entire supply chain, from the manufacturer's packaging line all the way through to the pharmacy.

In recent years, many countries throughout the world have issued comprehensive rules and regulations on the serialization and aggregation of pharmaceutical products for human use. The objective is to effectively prevent counterfeit, illegally imported or stolen medications from entering the legal supply chain. They also aim to eliminate the possibility of fraud via the drawback systems.

As one of the world's leading suppliers of track and trace solutions, we are well placed to support you with a large selection of turnkey systems for the serialization and aggregation of pharmaceutical products as well as the corresponding home-made software solutions.



## Your advantages at a glance:

### Sophisticated and customized track and trace portfolio

Laetus has been a specialist in quality inspection and track and trace solutions for more than 45 years and helps ensure maximum product safety in the pharmaceutical industry as well as the consumer and industrial goods sector. Thanks to their modular structure, our systems can be easily adapted to the specific needs of your production environment. The scalability also ensures an optimum price-performance ratio.

As your professional partner, we are ready to support you if it comes to developing individual solutions for your production environment.

### Flexible adaptation to legal framework conditions

Satisfy all new or currently applicable legal specifications with the flexible systems from Laetus. These include the Drug Supply Chain Security Act (DSCSA) in the USA and the European directive on the prevention of falsified medicinal products (2011/62/EU) as well as the regulations of the Agência Nacional de Vigilância Sanitária (ANVISA) in Brazil. Laetus has also prepared customer systems for the crypto-code (Markirovka-Project) that has been introduced in Russia. As of 1st July 2020, this prescribes the marking of secondary and tertiary packaging of all medications and numerous other product groups that have been manufactured locally or imported. For China, the National Drug Administration (CNDA) released the first draft on drug traceability in 2016.

The new proposal on the new Drug Traceability Code (DTC) should consist of letters, numbers and symbols and contain information such as the name of the manufacturer, dosage form, date of manufacture and expiry date.

Protection against counterfeit drugs brings more patient safety, brand protection and transparent processes. Global pharmaceutical supply is faced with complex regulations governing the identity of pharmaceutical products, the traceability of their circulation and changes in ownership throughout the supply chain. The Laetus Track & Trace solutions are prepared for all requirements and are easy to implement and customize: from checking individual packaging units to multi-level aggregation over the entire line to order picking.



For the latest version of this map visit the Laetus website: [laetus.com](http://laetus.com)



## 2. Added Value along the entire Product Lifecycle

### Everything starts with a code

With the serialization of your product you will open the door to a wide range of possibilities and advantages. It is the base for different applications that enable you to get more value from your product:

#### 2.1 Quality Assurance

"From January 2013 to October 2018, almost 8,000 medications were recalled by pharmaceutical companies across the United States and abroad."<sup>1</sup>



##### Pain

- Recalls
- Industry standards
- Multiple regulations

##### Gain

- Preventive maintenance
- Quality check
- Compliance with regulations

In Pharmaceuticals, quality inspection involves a complete assessment and testing of medicinal products to ensure that they meet the required standards. The needs of the customer are a major concern in pharmaceuticals. Therefore, errors and defects should be detected and minimized during production and defective products should be rejected in time.

"Specific control requirements can be implemented on various different packaging machines to suit your requirements. Regardless of whether it is for packaging lines for boxes, folded boxes, or blister lines, defined quality criteria can be inspected just as they are on pouch packaging machines or labeling machines."

### Quality inspection for a wide range of products



## 1 Carton control

Folding cartons carry a large number of possible codes and variable data that need to be read. Carton Control is ideally equipped for this task. From Pharmacode to graphic elements and variable data, everything gets checked quickly and reliably.



## 2 Label control

Whether bottles, cartons or other products with labels - our Label Control checks all content according to your specifications. Label inspection can take place before, during or after the application.



## 3 Blister control

Colored tablets, capsules of various consistencies and contents (solid, loose or liquid), smooth or dull surfaces: our system detects various defects such as color, shape, size, contamination, damage, foreign object, positional errors, presence, overfilling, height (3D) and contour (2D).



## 4 Leaflet control

Does a box contain the correct package insert destined for it? Controlling the presence of various components of the product, such as the presence of the package inserts, are essential quality characteristics.



## 5 Color coding identification

Colored rings provide clear identification of glass ampoules.



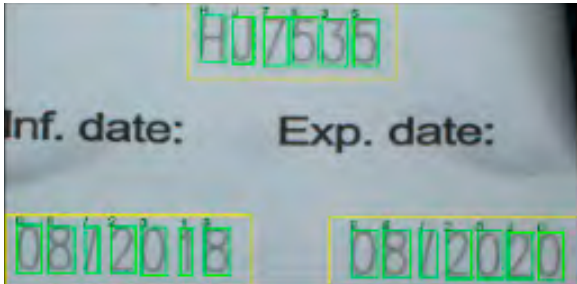
## 6 Distance measure control

Checks an object by measuring distances towards the edge. In the example, the distance between the upper edge of the lid and the fill level is measured in order to check the fill level. Background illumination is used to find the edges.



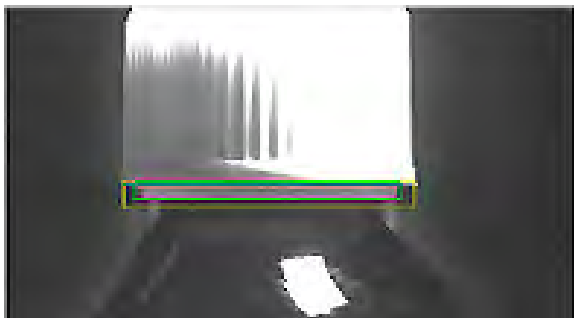
### 7 Print inspection of plain text

In addition to codes, packaging also includes numerous additional information in plain text, such as product or company information or logos, pictograms, and other symbols. Print inspection of this information is carried out using OCR/OCV reading.



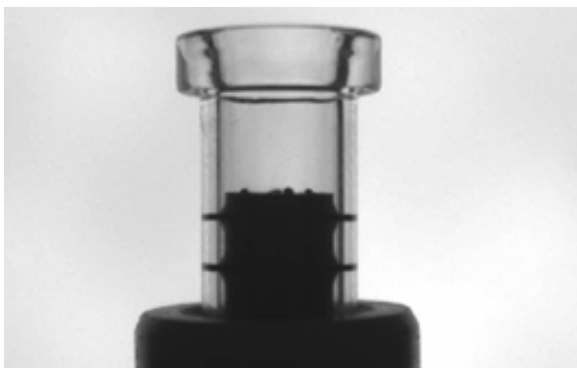
### 8 Presence monitoring – Sealing ring

Is the sealing ring present and in the right position in the search window?



### 9 Presence monitoring - Glass flask

Presence of glass flask, the existence of the insert, the intactness of the insert, pattern matching, the integrity of the printing screen.



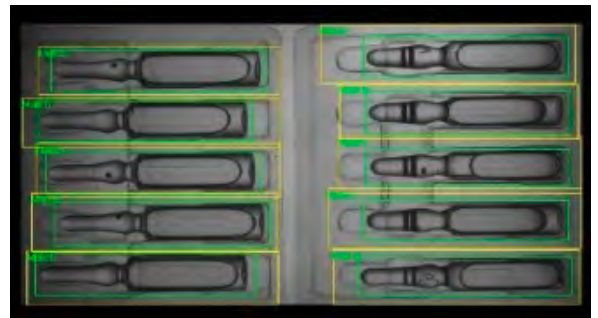
### 10 Presence monitoring – Information leaflet

For successful treatment, it is vital that the information belonging to the drug has been enclosed in the form of patient brochures or leaflets. This is guaranteed using presence monitoring.



### 11 Presence monitoring – Ampoules in tray

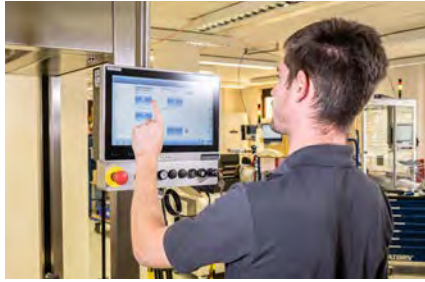
Check if the tray is completely filled with the correct, unbroken ampoules and if they are facing the right direction.





## 2.2 Production Control

"Manufacturing companies typically operate around 60 - 65% OEE. World-class OEE is at 85% or better."<sup>2</sup>



Our track and trace solutions can be integrated into all commercially available systems and connected to the PLC. This means that you can monitor, evaluate and optimize each and every one of your processes accurately. Any deficiencies that may occur during the packaging process such as incorrectly marked boxes are reliably detected by code and printing controls and the affected goods are taken out of circulation. The result is maximum safety and Overall Equipment Effectiveness (OEE) within your production environment. To increase your OEE, we also recommend preventative maintenance (scheduled updates of respective lines) which will prevent break-downs before they happen, ensure a continuous production and the safety of your data.

### Pain

- Downtimes
- Data transfer
- Complexity

### Gain

- Uptime
- Quick changeover
- Parallel processing

"Obviously, the most direct impact of downtime is a loss of production capacity. If you typically produce 600 units per hour with an average profit per unit of \$50, a single hour of downtime costs your company \$30,000 in lost revenue. Account for a few hours of downtime per month and the costs really add up."



## 2.3 Supply Chain Management

"Goal is a supply chain that can withstand unforeseen disruptions. However, 72% of companies see risks to their supply chain increasing."<sup>3</sup>



Serialization plays a significant role in your supply chain, improving your business processes by providing better data. A basic process that will be improved is recall management. Serialized data will help to more quickly identify where a specific recalled product is in the supply chain and efficiently remove it before it reaches patients. Patients' safety will be improved. Better data access can also help streamline processing accuracy of orders and returns because data about delivered shipments can be verified.

### Pain

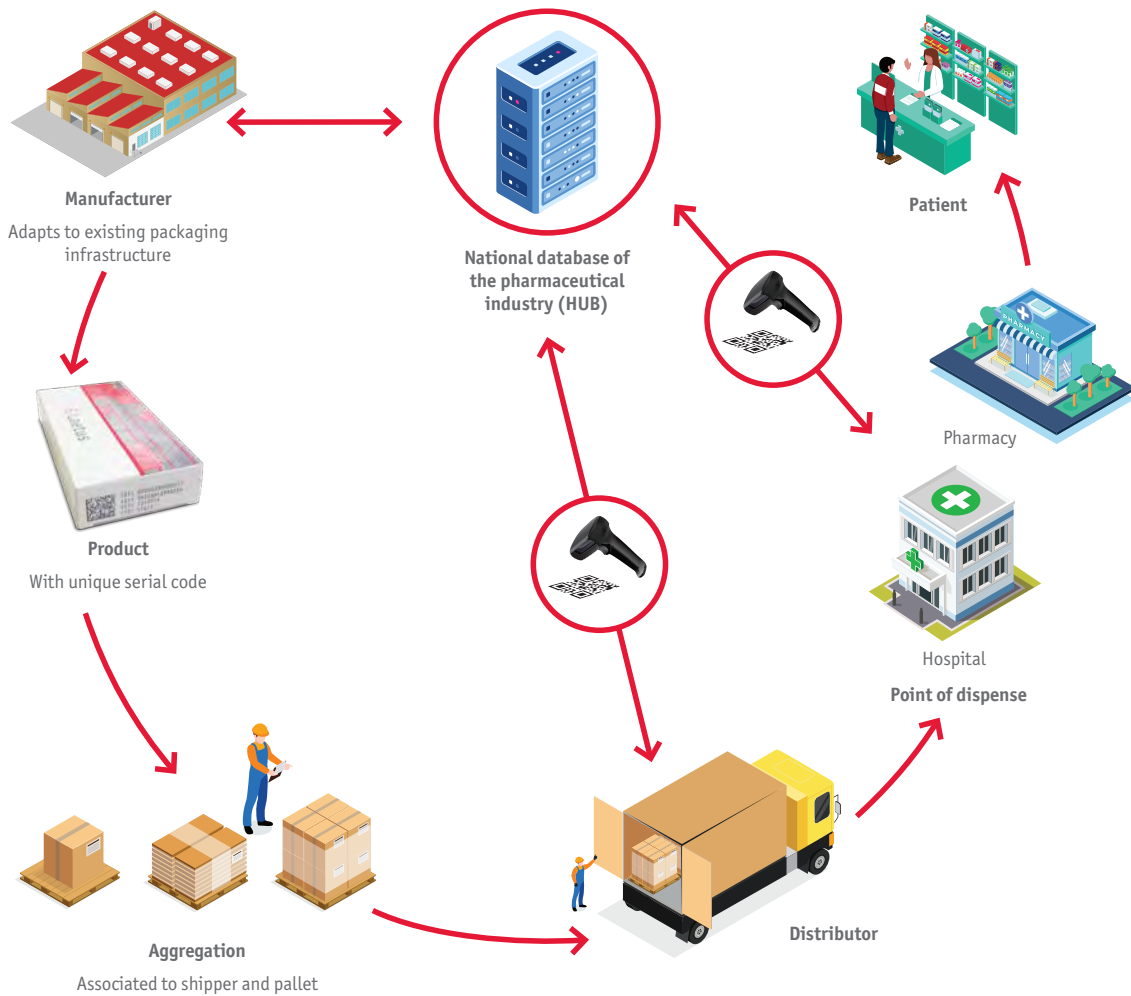
- Product variation
- Short product life cycle
- Lack of data/ visibility/ product information

### Gain

- Clearly defined processes
- Data transparency strategy
- Real time information

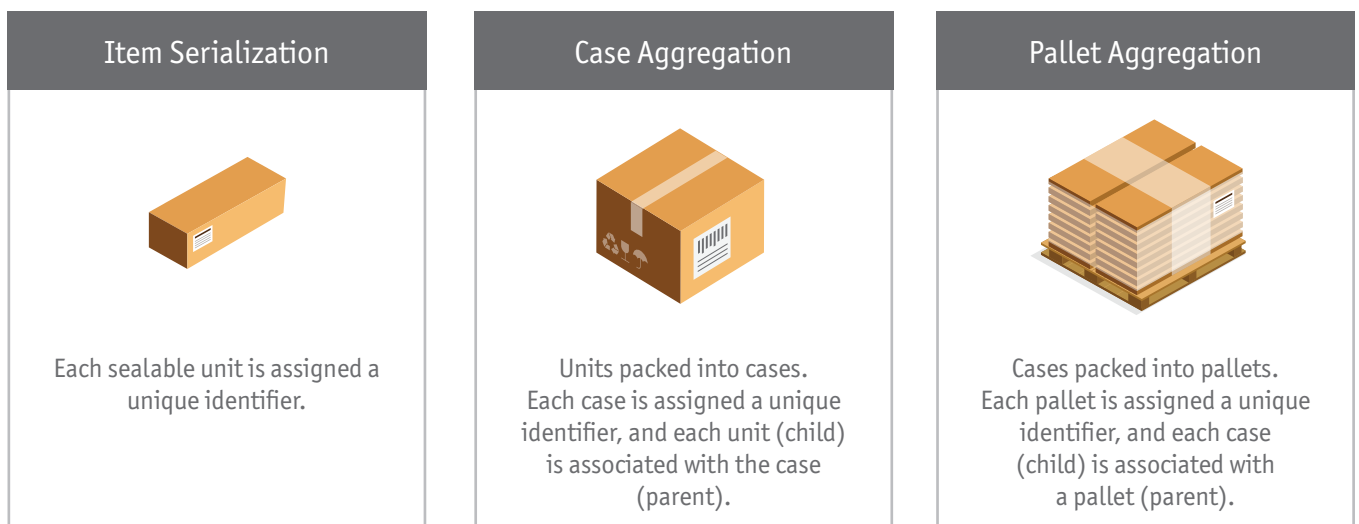
"Forecasting, also known as demand variability, tops the list of biggest challenges for the supply chain. Other top business challenges include inventory management/optimization, cost containment and reduction."





Aggregation takes place after serialization: The individual packages are combined into larger units and parent-child relationships are created between the individual packaging units. During aggregation, an individual package is assigned to a carton and later on, to a pallet, making it possible to find any package at any time and at any point in the supply chain. Thus, returned goods can be handled relatively easily with an existing aggregation hierarchy.

Aggregation should definitely be planned early in the production process. It is almost impossible to consider aggregation separately from serialization.



## 2.4 Counterfeit Protection

"The World Health Organization has estimated that the value of the global counterfeit drug market is over \$200 Billion annually. Shockingly, up to 30% of all medicines sold in developing markets are said to be fake."<sup>4</sup>



### Pain

- Fakes
- Trademark abuse

### Gain

- Compliant to regulation
- Guarantee control

**Warning: Health risk!** In addition to the negative impact, a counterfeit product can have on the profit of affected companies, it can also have severe consequences on consumers' health. This especially applies to the food and pharmaceutical industries, as well as the airline and automotive industries. These areas affect all of us and demand immediate action.

"Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malaria medication might be responsible for an additional 116 000 deaths (WHO, 2017c)."

1. Source (September 17, 2019): <https://www.uspharmacist.com/article/overview-of-the-fdas-drugrecall-process>
2. Source: <https://www.oee.com/world-class-oee.html> and <https://www.leanproduction.com/oee.html>
3. Source (March 2019): <https://www.mckinsey.com/business-functions/operations/our-insights/a-practical-approach-to-supply-chain-risk-management>
4. FarmaTrust (December 11, 2017): <https://medium.com/@farmatrust/fake-drugs-real-problem-8682cea967eb>

### 3. Software Platform: Laetus UP (Unified Platform)



#### One platform for all demands:

#### Modular - create your own solution!

Laetus UP is designed to meet all requirements of the packaging and distribution process as a whole and in all its variations. This ranges from simple serialization to multi-level aggregation, de-aggregation and re-aggregation steps in warehousing and supply chain, to manual rework at wholesale.

Laetus UP is a cross-application, unified platform, which prepares these vast quantities of data, further processes them and as a result considerably simplifies data handling. The Laetus UP Suite supports your production process with a large selection of standardized modules. Here, tailored solutions can be supplemented by further modules as soon as additional requirements arise or the demand changes.

Due to its modularity, they can be adapted quickly and flexibly to country specific regulations and process requirements, ensuring a high level of overall equipment effectiveness (OEE)! UP can be integrated into any existing infrastructure irrespective of brand and model. Solutions can easily be built into packaging machines such as cartoners, bundlers and case packers. System modules are ideal for integration into packaging lines or for use as standalone units.



Create **YOUR Solution** as you would create your meal

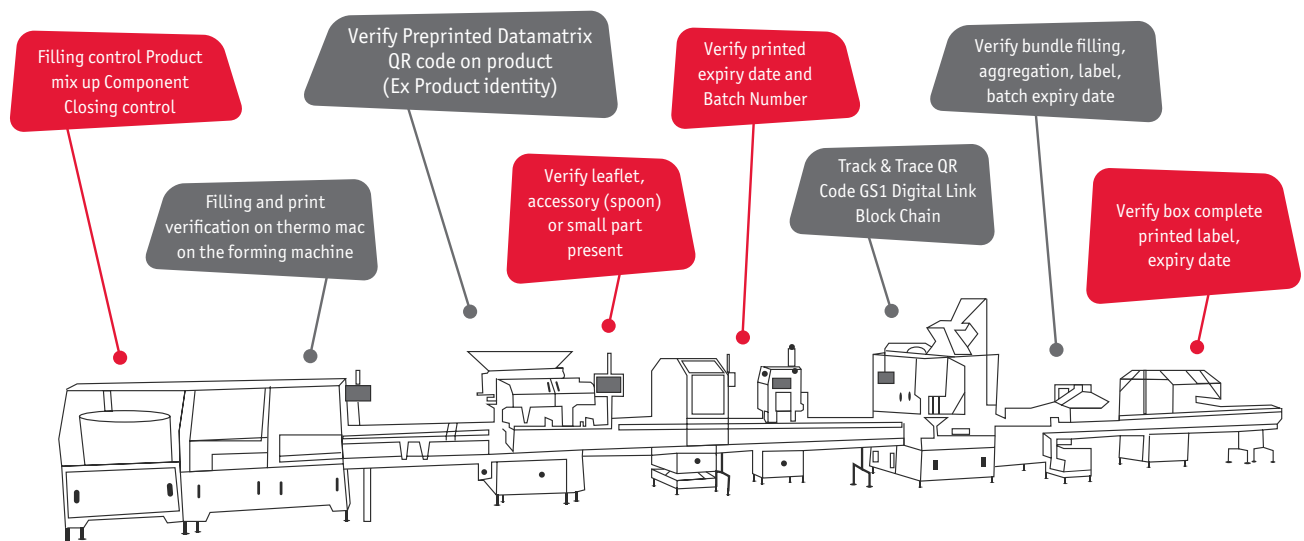
			Quality Assurance	Production Control	Supply Chain Management	Counterfeiting/ Brand Protection
	<ul style="list-style-type: none"> <li>User Management</li> <li>PO Management</li> <li>Central LOG file</li> <li>Master Data Management</li> </ul>	With the UP CORE you get all the basic tools to set up and manage your production.	✓	✓	✓	✓
	<ul style="list-style-type: none"> <li>Vision Inspection</li> <li>Quality Control</li> </ul>	This module allows you to implement all kinds of quality control applications into your production line.				✓
	<ul style="list-style-type: none"> <li>Printing and verifying of batch constant data</li> </ul>	The UP BATCH module enables you to define, print and verify batch constant productions.		✓	✓	(✓)
	<ul style="list-style-type: none"> <li>Code-Pool Handling</li> <li>Data integrity</li> <li>Unique identification</li> <li>Item Tracking</li> </ul>	Allows you to generate a unique and safe serial number for each of your products.	(✓)		(✓)	✓
	<ul style="list-style-type: none"> <li>Aggregate Plus</li> <li>Repacking Operations</li> <li>Multi-Level Aggregation</li> </ul>	Used to build a serialized relationship between unique packs assigned to packaging containers.			(✓)	(✓)
	<ul style="list-style-type: none"> <li>Data Exchange ERP/ SAP</li> <li>Data Exchange MES</li> <li>Data Exchange SCADA</li> </ul>	With this module you can exchange any production data into any IT system to ensure seamless interoperability.		(✓)	✓	✓
	<ul style="list-style-type: none"> <li>Hotline 24/7</li> <li>Remote support</li> <li>Update support</li> </ul>	Provides an all-round safety package. We ensure that your production lines are safe and downtimes are reduced.	✓	✓		



# 4. Hardware Equipment - Engineered for your Success

In addition to our highly flexible platform Laetus UP, we offer suitable hardware solutions for any unique demand or regulation requirement. Efficiency and flexibility are two demands that are a standard for all of our products.

With our hardware solutions, we attach great importance to the right mix of performance, adaptability and easy integration into existing processes. We have the right traceability solution for you.



## 4.1 Integration Solutions

Simple OEM integration. Our solutions can be easily connected to proprietary systems such as MES, ERP or company repositories as well as to the databases of the responsible authorities. The management of data records and process flows can be flexibly adapted to the requirements of brand manufacturers and commissioned CMOs.

Laetus offers all the components required for successful track and trace from a single source. The modules and systems can be completely integrated into both existing and new systems. Our developments and the service we offer are built on many years of successful partnerships with a large number of established OEMs.

- Adaptable to current equipment and modules
- Reliability and efficiency to accomplish mass production
- 100% compliance for serialization/batch-constant requirements
- Fully integrated in L3 and L4 levels

## 4.2 Standalone Solutions

Our latest standalone solutions (**Series 1000 Compact & Series 1000 Modular**) represent a new generation of serialization systems and is synonymous with increasing efficiency and flexibility in your packaging line. Fully automated and therefore reproducible format changes in less than one minute provide fast refitting times and increase ease of use. Operator errors during format changes are a thing of the past. This saves time and increases the effectiveness of the entire system. Moreover, it impresses users with their unique flexibility in regards to the packaging sizes that are getting processed at consistently high production rates. The modular structure forms the basis for swift responses to changing market demands.

- Large format range with quick, automatic format adjustment
- Constant Product Quality
- Automatic Tamper Evident application on two sides
- Electric Eject - no mechanical pusher or compressed air necessary
- High automation density on the most compact footprint
- Maximum OEE
- Made in Germany



Series 1000 Modular



Series 1000 Compact

Our well-known standalone solutions are compact and ensure minimal downtime for integration, making it effortless to add them into any existing production line. The **MV-50** is our **smallest fully compliant Track & Trace serialization solution**. With its dimensions it fits into any production environment and can be integrated into any line. The **MV-70** is the ideal solution for the most demanding requirements for secure marking of folding boxes in the packaging line.

- Fully independent run - can be added into any existing production line
- Minimized downtime of lines due to machine integration
- Flexible and versatile solution
- Speedy machine set-ups
- Production runs of many small batches as well as big batches
- No impact on existing equipment
- 100% compliance for serialization/ batch-constant requirements
- Possibility to be integrated in L3 and L4 levels
- Can be used as a test-zone - reduces time spent on validation in line



MV - 50



MV - 70

	Series 1000 Compact	Series 1000 Modular	MV-50	MV-70
Throughput	Up to 400 pcs / min	Up to 400 pcs / min	Up to 400 pcs / min	Up to 400 pcs / min
Carton size (min)	30 x 15 x 60 mm	30 x 15 x 60 mm	35 x 15 x 50 mm	35 x 15 x 70 mm
Carton size (max)	120 x 100 x 200 mm	120 x 100 x 200 mm	120 x 100 x 180 mm	120 x 140 x 240 mm
Belt speed	60m / min	60m / min	Up to 70 m / min	Up to 60 m / min
Printer	Up to 2 printers	Up to 2 printers	1 printer	1 printer
Tamper Evident Labels	Included	Optional	N/A	Optional

### 4.3 Aggregation

Our mobile packing stations are the ideal solutions for location-independent manual rework and quality checking of individual folding boxes. Depending on the equipment, the stations can be integrated into the packaging line as a manual aggregation module or – with hand scanners and printer systems – used as a line-independent standalone solution.

Laetus aggregation solutions are also valuable for all aggregation and manual picking requirements in the warehouse and can be easily connected to our track & trace software.

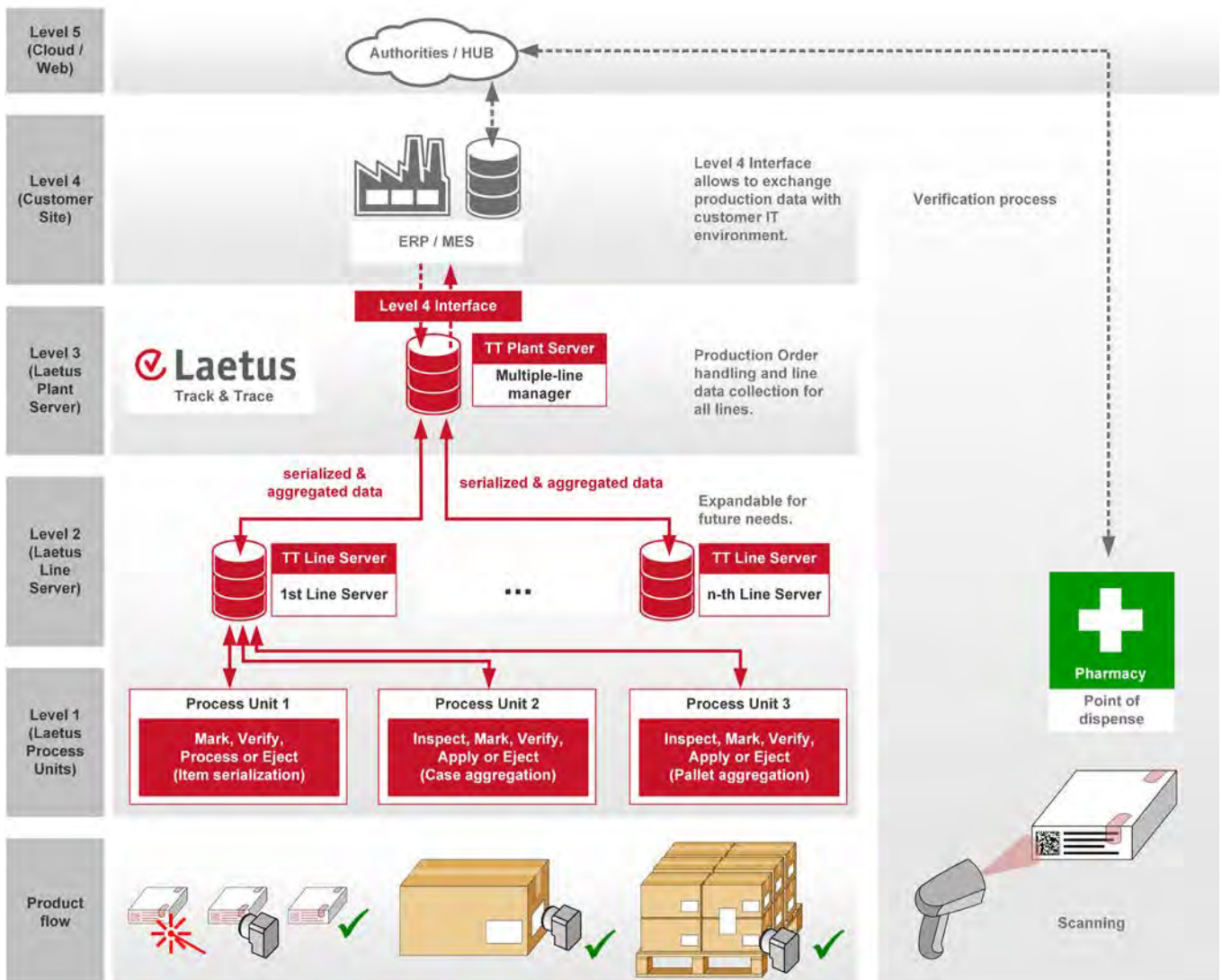
- Solution combines flexible manual and reliable automatic operations
- Applicable to different levels of aggregation: bundles, cases, and pallets
- Price competitive workstations to be compliant with legal regulations and other track & trace requirements



CS-115 with top scan

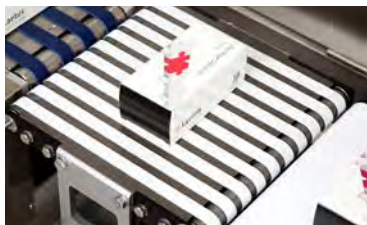


CS-60



## 5. Add-Ons

You need more? For any other production demands, we offer the right add-on:



### Checkweighing

- Check the product weight to ensure the completeness of your product (Quality!)
- High speeds
- Combination with serialization and packaging requirements



### Marking & Verification (MV)

- Print human readable (alphanumeric), and machine readable (barcode and data matrix) codes
- Verification of codes and their quality on up to 3 sides



### Labelling

- Vignette labeler application compliance
- Integrated vision system for integrity and position control



### Tamper Evident

- In-line label applicators at high production speeds
- Automatic verification of correct application



### Market Regulations (such as Crypto Code, DSCSA, EUFMD)

- Fully compliant with Russian pharma regulation and regulations for other industries (Medical Device, Animal food, etc.)



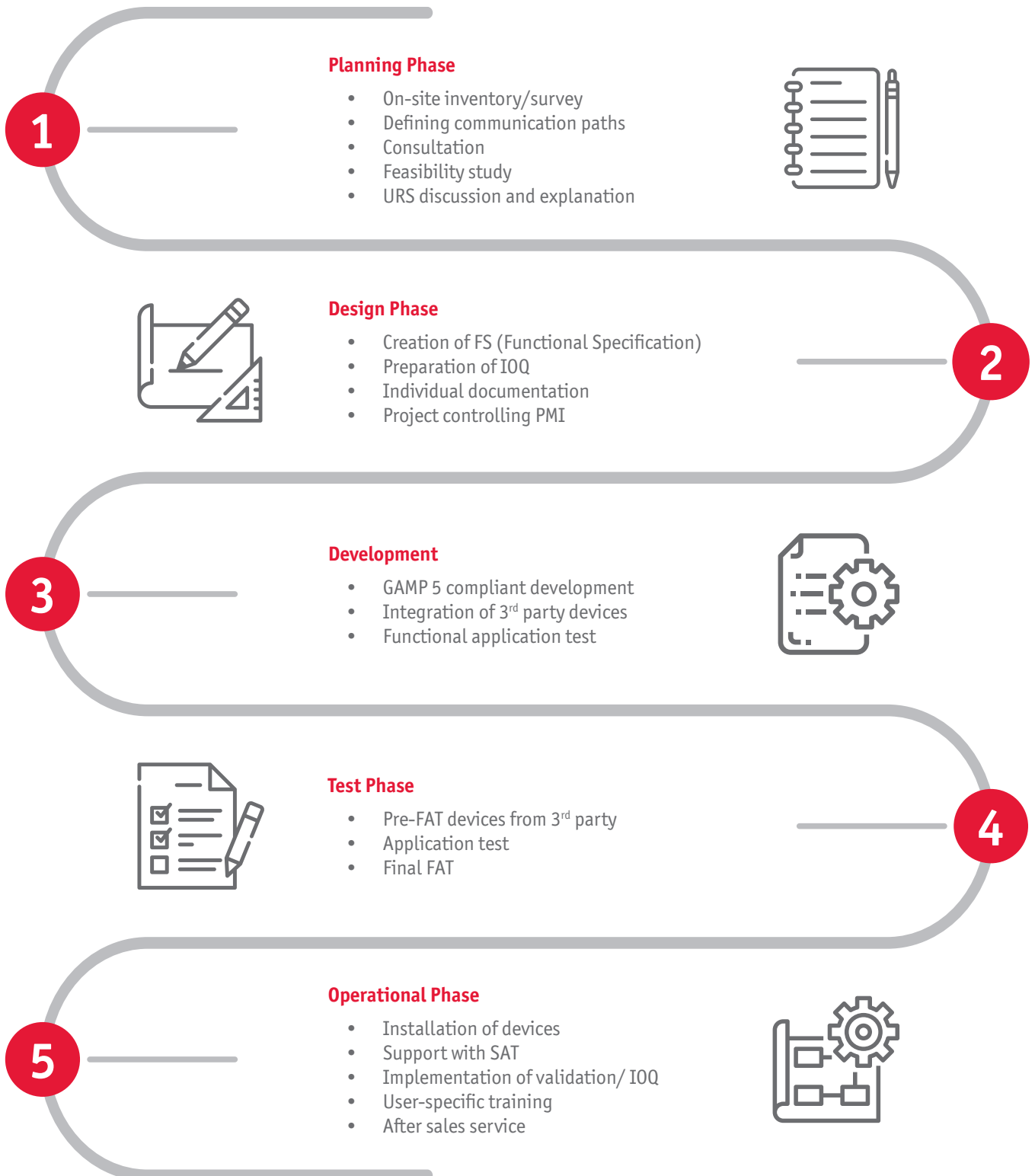
### Aggregation

- Manually, semi-automatic, integrated solutions available
- Can be implemented in every 3<sup>rd</sup> party serialization



# 6. Project Competence

With our know-how and long-lasting experience, we analyze your processes together and support you in the definition of your special requirements for a Track & Trace solution. As a result, we can ensure a competent project management for the implementation of Laetus UP in your company. Whether in individual project phases or throughout the entire project – we take full responsibility for the project.



# 7. World Wide Service Network

With our comprehensive after-sales service, we can provide fast and flexible support for the maintenance (SLAs, preventative maintenance for database and machines), regular repair and optimization of your systems at any place in the world. Our experts also share their unique expertise through courses at the Laetus Track & Trace Academy. (Remote or face-to-face)



## Project Management

- Guide from first consultation to project completion
- Function as general contractor



## Service Level Agreement

- Standardized global SLAs
- SLAs for Track & Trace or Quality Inspection



## Training

- Open enrollment training
- Tailored training on- and off-site



## Preventative Maintenance

- Regular maintenance of database and/or machines
- Prevent breakdowns from happening



## Spare Parts

- Maintain spare parts inventory
- Ensure continuous production capability



## Hotline

- Available 24/7 for immediate technical support

## WHY LAETUS?

**We partner with you**

**– from initial contact and implementation to continuous support.**

- 50 years of experience in vision inspection and quality control
- Expertise in track & trace solutions for pharma, food, beverage, cosmetics and other industries
- Flexibility in integrating solutions due to brand agnostic and modular approach
- Project management from consultation to implementation
- Training academy with individual offers
- Worldwide technical support with 24/7 hotline



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