

The DSCSA Guideline: Background and Practical Tips

Everything you need to know to ensure compliance with legal requirements



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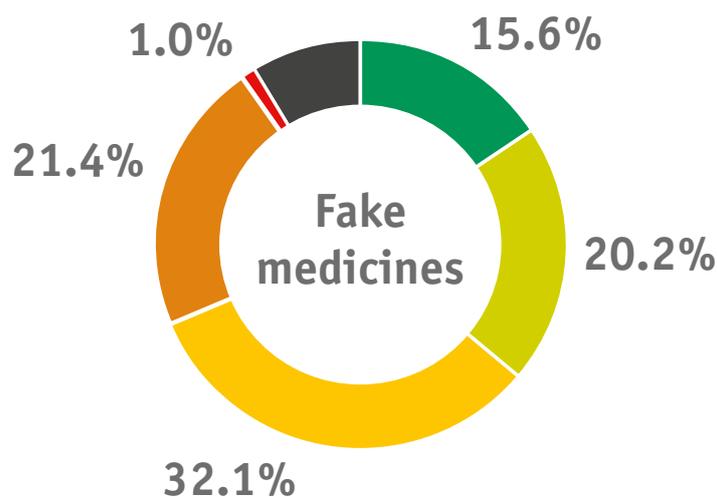
Counterfeit Medicines – A Growing Problem

Types, Extent, Dangers

Counterfeiting is a global problem, and it no longer affects just the consumer goods industry. Organized crime networks have long ago discovered how lucrative the counterfeit drug business is, with margins that surpass those of drug trafficking and carry relatively low risk. According to the German Federal Criminal Police Office (BKA), one kilogram of the lifestyle product Viagra is likely to yield between \$105,000 – \$117,000 on the black market. For cocaine profits are only \$76,000 and for heroin even less with “only” \$58,000. The purchase price for one kilogram of Viagra’s active ingredient sildenafil is estimated at \$70, while the raw material for cocaine and heroin is between \$1,700 and \$8,400¹. Nearly all countries are affected, whether it is the country of production, the transit or the target country. The World Health Organization (WHO) estimates that up to one percent of drugs available in developed countries are counterfeits. while in regions such as of Asia, Africa and Latin America, the proportion of counterfeiting can be up to 30 percent. Consequently, the average for global counterfeits rises to 10 percent.

What are Fakes?

Fake medicines are divided into five categories:



	Counterfeits containing the same active substance in the same amount as their packaging (15.6%)	They are a nearly perfect imitation of the formula and the packaging. From a medical perspective, the risk to the patient in this category is lowest, provided the quality is right. However, as no quality standards are considered during production, impurities often occur.
	Counterfeits containing an active substance in different amounts (20.2%)	Falsifications in this category are distributed in packaging that is identical to the branded product. As a rule, these products contain the active ingredient of the branded product, but often in a lower quantity and quality. This can lead to limited efficacy of the drug and eventually contribute to the development of resistant pathogens in antibiotics.
	Counterfeits containing no active substance (32.1%)	Counterfeits that look the same as the original but do not contain any active ingredients and therefore have no medical benefit.
	Counterfeits containing wrong, harmful substances (21.4%)	Counterfeits in this category contain harmful or toxic substances.
	Counterfeits that are exact copies of the original product (1%)	

¹ Arzneimittelkriminalität: ein Wachstumsmarkt, Forschungsergebnisse, Bundeskriminalamt (BKA), 2017

USA – Number of Identified Counterfeits is Rising



According to the Pharmaceutical Security Institute (PSI), the number of drug counterfeit cases reported in the US alone in 2017 increased to 1,677 (from 1,579 in 2016). (Each incident is qualified when it is possible to identify illegal drugs whose origin, destination, place of confiscation or transit was in the United States of America). The number of incidents gives no indication of the total amount or how many different drugs are affected. These range from the smallest quantities of a product to hundreds of thousands of counterfeit medicines in various categories. In total, 3,509 such events were registered worldwide. This means that approximately half of the world's counterfeit medicines affect the US market². According to PSI, the US leads the market for identified counterfeits, followed by Asia. The figures do not automatically argue for a significantly higher number of counterfeit offenses in the affected countries. On the contrary, it can also mean that controls and prosecution measures are more effective here and thus, an above-average number of counterfeit cases were identified.

Counterfeiters' Favorites

Counterfeiters focus on pharmaceuticals that promise high profits. These include both generic and branded products. The range varies from lifestyle products to potency increase, weight loss to high-priced medicines in HIV and cancer therapy. The most common counterfeit medicines include antibiotics and anti-malaria drugs.

² Pharmaceutical Security Institute, Counterfeit Situation, Geographical Distribution, <http://www.psi-inc.org/geographicDistributions.cfm>

Much of the counterfeiting concerns are also found within the following therapeutic fields:

- Diseases of the urogenital tract
- Anti-infective agents (antibiotics)
- Central nervous system disorders
- Hormones
- Cytostatics (e.g., the treatment of cancer and autoimmune diseases)

Securing People's Lives



While counterfeit medicines from these therapeutic areas guarantee a high profit margin for the counterfeiters, the impact on affected patients can be traumatic and even life-threatening. Incorrectly dosed or missing active ingredients, toxic additives and impurities prevent successful treatments and directly endanger human life. In addition, low doses of antibiotics used over the long-term form resistances and indirectly can endanger the lives of patients. In the end, all this leads to a loss of patient confidence in medical treatments, healthcare, and the pharmaceutical industry.

Combating Counterfeit Medicines

Other Countries – Other Rules

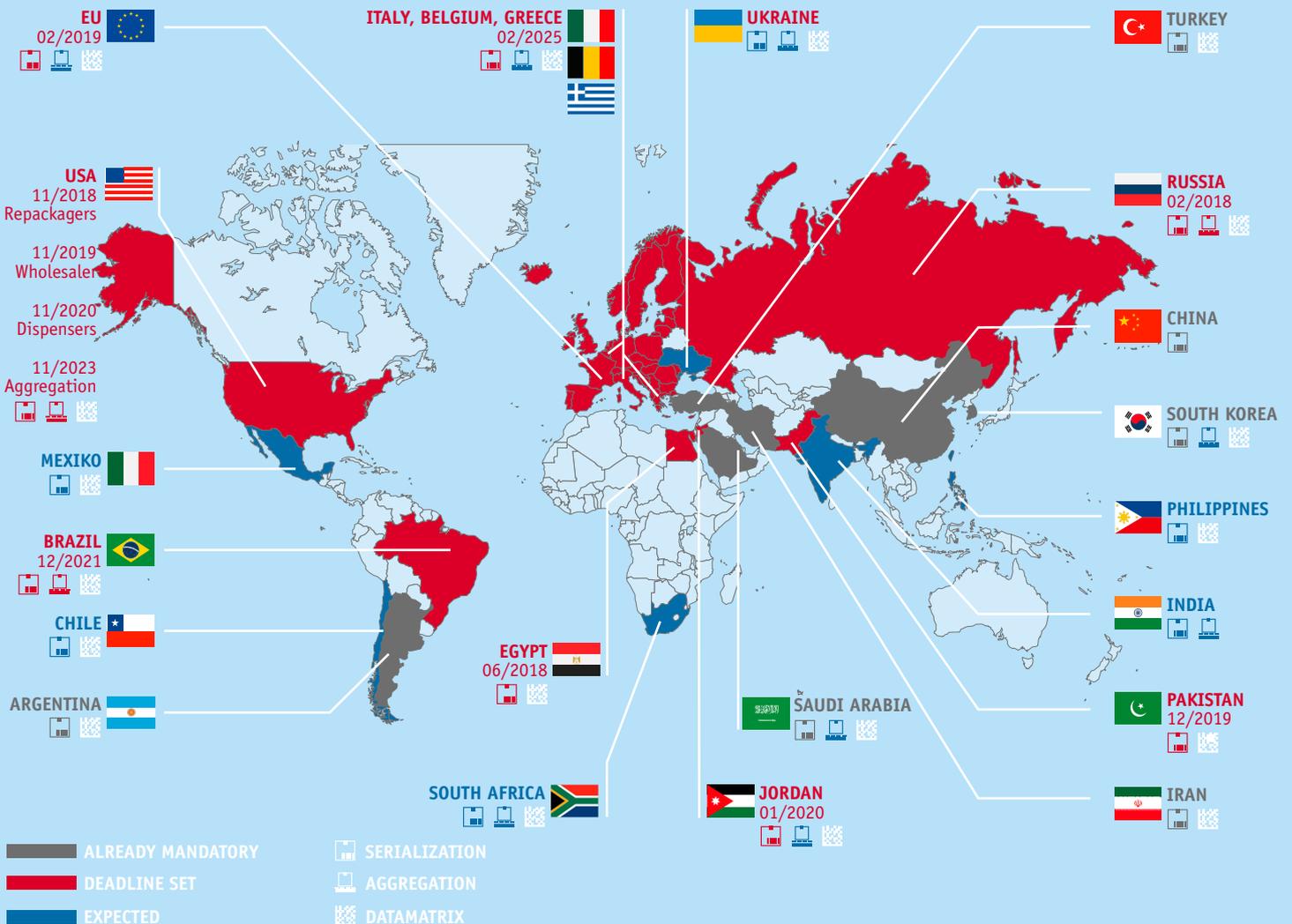
As counterfeit pharmaceutical products continues to increase, legal regulations have been created and are being introduced in numerous countries to prevent these dangers. For example, there are such efforts in Argentina, Brazil, Europe, Russia, the Middle East, the United States, and some countries in the Asian and Pacific regions. While some of these are already enforced, others are being implemented.

Regulations differ among countries by:

- affected drug categories
- packaging levels need to be serialized
- type of volume
- type of labeling
- additionally required data and information
- place of identification / verification (end-to-end or e-pedigree)

Their common goal is to make the legal distribution channels of pharmaceutical products safer and by preventing counterfeit pharmaceuticals. This is done by identifying the smallest sales units with unique serial numbers that make each product unique and traceable.

Global Serialization Landscape



DSCA / DSCSA Overview and Fulfillment

The State of California took the first steps in 2004 to make prescription drugs safer for patients. This was done by serializing the individual sales packaging and providing an electronic proof of origin that would track the path of each individual package through the supply chain. As a result, forgeries could be detected more reliably, and recalls could be carried out more efficiently.

This method proved its worth, and it became a pioneer in a new federal law: U.S. Pat. The Drug Quality and Security Act (DQSA) came into effect on November 27, 2013. Under Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA) outlines key steps toward building an electronic, interoperable system for the identification and traceability of prescription medicines sold in the United States. With the final implementation by November 27, 2023, the new law replaces all existing national regulations.

The DSCSA will be implemented gradually:

Milestones of the DSCSA Timeline

1st step: Transaction data

January 1, 2015 is the first milestone of the implementation phase. Until that date, manufacturers, wholesalers and repackagers needed to be able to provide lot-level and / or batch-level transaction data to their supply chain partners on every change of ownership. For hospital and retail pharmacies, July 1, 2015 was the deadline.

Transaction data are the so-called 3T's:

1. Transaction Information (TI)

- National Drug Code (NDC)
- Product name
- Dosage
- Dosage Form
- Container size
- Number of containers
- Lot
- Transaction Date
- Shipping date (if more than 24 hours after the transaction)
- Transfer from party (name, address)
- Transfer to party (name, address)
- Contact details of the wholesaler

2. Transaction History (TH)

Starting with the manufacturer, this is a single document that contains all the information of each transaction. For the direct purchase in wholesale, special versions of the transaction history are possible. Initially allowed in paper form; an electronic format has been required since 2017.

3. Transaction Statements (TS)

Declaration confirming that the party transferring the property:

- is authorized and registered
- received the product from an authorized and registered party
- acknowledged the transaction information and statement transferred from the previous owner
- knowingly did not ship any suspicious or ineligible products
- did not knowingly change the transaction history

All suspicious and illegitimate products must be reported. The reporting deadline for illegitimate products must not exceed 24 hours. All transaction data must be transferable to authorized trading partners within 48 hours.

2nd step: Clear Product Identification (Serialization)

Deadline	Who's effected	Requirements
November 2017	Manufacturers	serialize product, verify SNI and transmit T3 Electronically
November 2018	Repackagers	serialize and associate & verify SNI
November 2019	Wholesalers	receive and ship serialized product, verify SNI for returns
November 2020	Dispensers	ship and receive serialized products and verify SNI

- Smallest saleable unit requires packaging with a 2D data matrix and associated human readable text including GTIN, SNI, Lot, Expiration Date.
- Shipping cases to include SNI via SSCC.

Scenario	Identifier on Lowest Saleable Unit	Identifier on case	Identifier on pallet
Full homogeneous case where there is a GTIN for that case configuration, and the case is packed onto a pallet with other cases	SGTIN (based on the item-level GTIN)	SGTIN (based on the case-level GTIN)	SSCC
Partial/incomplete homogeneous case, and the case is packed onto a pallet with other cases	SGTIN (based on the item-level GTIN)	SSCC	SSCC (different than the case-level SSCC)
Mixed case, and the case is packed onto a pallet with other cases	SGTIN (based on various item-level GTINs)	SSCC	SSCC (different than the case-level SSCC)
Full homogeneous case where there is a GTIN for that case configuration, and the case is shipped by itself as a logistic unit	SGTIN (based on the item-level GTIN)	SGTIN (based on the case-level GTIN) and SSCC	n/a
Partial/incomplete homogeneous case, and the case is shipped by itself as a logistic unit	SGTIN (based on the item-level GTIN)	SSCC	n/a
Mixed case, and the case is shipped by itself as a logistic unit		SSCC	n/a

Must have ability to check product identity within 24 hours.

The associated data must be kept available for 6 years.

3rd step: Traceability through Article-level Serialization (Aggregation)

By November 2023, all stakeholders should be able to provide information to their respective partners in the supply chain that will allow them to accurately track the path to the manufacturer or repackager. For this they need:

- interoperable system for tracing
- secure, interoperable way to quickly exchange Transaction Information and Transaction Statements and process them for salable returns
- Systems and processes to inspect products at the item level
- Systems and processes to reliably collect the transaction history
- A way to respond to information requests within 24 hours

Code Requirements

Data elements

Based on the code requirements of the 2009 FDA directive, the code consists of a Standardized Numeric Identifier (SNI). This includes the National Drug Code (NDC) and a serial number of up to 20 characters. This combination is also known as Serialized National Drug Code (SNDC). Although not clearly stated in the DSCSA, the FDA provides for the use of GS1 standards, i.e. the use of a Global Trade Item Number (GTIN).

The following data elements must be included:

- Application Identifier (AI) 01: GTIN
- Application Identifier (AI) 21: serial number
- Application Identifier (AI) 17: expiration date
- Application Identifier (AI) 10: batch / lot number

Use Case	Typical Barcode Type	Data Element	AI	Characters following the AI
Serialized drug (trade item)	GS1 DataMatrix	GTIN	01	14 digits
		Expiration Date	17	6 digits
		Batch/Lot Number	10	1-20 alphanumeric characters (*)
		Serial Number	21	1-20 alphanumeric characters (*)
Logistic unit (mixed case, pallet, etc.)	GS1-128	SSCC	00	16 digits
Location tag in a warehouse	GS1-128 GS1 DataMatrix	GLN	414	13 digits
		GLN Extension	254	1-20 alphanumeric characters (*)

Prosecution Postponed

On June 30, 2017, the US Food and Drug Administration (FDA) issued a draft guideline on DSCSA product identification requirements. It notes that the FDA does not intend to take action against manufacturers who do not apply for a product identifier on each individual pack or box of similar products to be placed on the market before 26 November 2018. It is important to note that this only means that the punishment for non-compliance is initially suspended, but the original deadlines and implementation steps remain valid.

The fact that the FDA has suspended the punishment but still maintains the deadline is a clear sign that the law and the planned implementation steps remain untouched. It is very likely that the FDA will crack down at the end of the suspension period as manufacturers and Contract Manufacturing Organizations (CMOs), who have not meet the requirements, are de facto in violation of applicable law for one year.

At the Nexus 17 in June 2017 in Barcelona, 200 participants from over 120 companies were asked about their assessment of the current state of implementation. Nearly a quarter of respondents still need to serialize at least half of their inventory. In addition, 68% of companies believe that the CMOs are not well prepared for the regulations. This means that there is still a lot to do to meet the requirements³.

Note: This is just a summary of the current state of DSCSA and its implementation phases. For detailed information, please refer to the current legislation.

³ Serialisierung – Momentaufnahme: Der aktuelle Bereitschaftsstatus, Umfrage von NEXUS 17, Juni 2017, Barcelona

Checklist for the Implementation of DSCSA:

Start early with a comprehensive analysis of requirements to realistically estimate the necessary time and budget:

Needs analysis

- How many Rx products do you distribute or pack?
.....
- How many Rx packaging sizes do you distribute or pack?
.....
Do you pack cartons or bottles?
- For CMOs: will you generate serial numbers or will you get serial numbers from your customers?
.....
- Does your company mandate CMOs?
If so, how many and which products do they pack?
.....
- Which other markets / countries are currently relevant for you?
.....
- Which other markets / countries are relevant for you in the future?
.....
- Do you have dedicated space on your packaging for serialized information?
- Do you have an IT info structure to handle the serialized data requirements?
- Will you produce an RFP outlining your requirements?

Stakeholders

- Which departments are affected?
 - Shipping
 - Production
 - Quality assurance
 - Logistics
 - IT
- Do you have a project team with representatives from all departments involved?
- Which external partners need to be involved?
 - packaging suppliers?
 - printers?
 - wholesale?

Production lines

- How many production lines do you have producing Rx products?
.....
- How many Production locations need to be converted?
.....
- Do you have space concerns with regard to implementing new equipment?
- At what speeds are you running (cartons, bottles, cases, pallets)?
.....
- Do you have compressed air available?
- Do you have ethernet drops available?

- Do you have power drops available (110/220)?
- Are there any special IP rating requirements?
- What are the space requirements for your environment?
.....
- Will you include aggregation from the beginning or serialization only?
.....

Printing / Coding

- How fast do you need to print?
.....
- Does your packaging materials have real estate for serialized information?
- What type of printing technology will be required?
.....
- What will your print layout look like?
.....

IT infrastructure

- Which software is currently in use in the packaging process?
.....
- Which ERP systems are used?
.....
- Which database system is in use?
.....
- Which interfaces must exist?
.....
- How will you generate serial numbers?
.....
- Which system will you use as your data repository?
.....
- How will you push data into the supply chain?
.....

Training

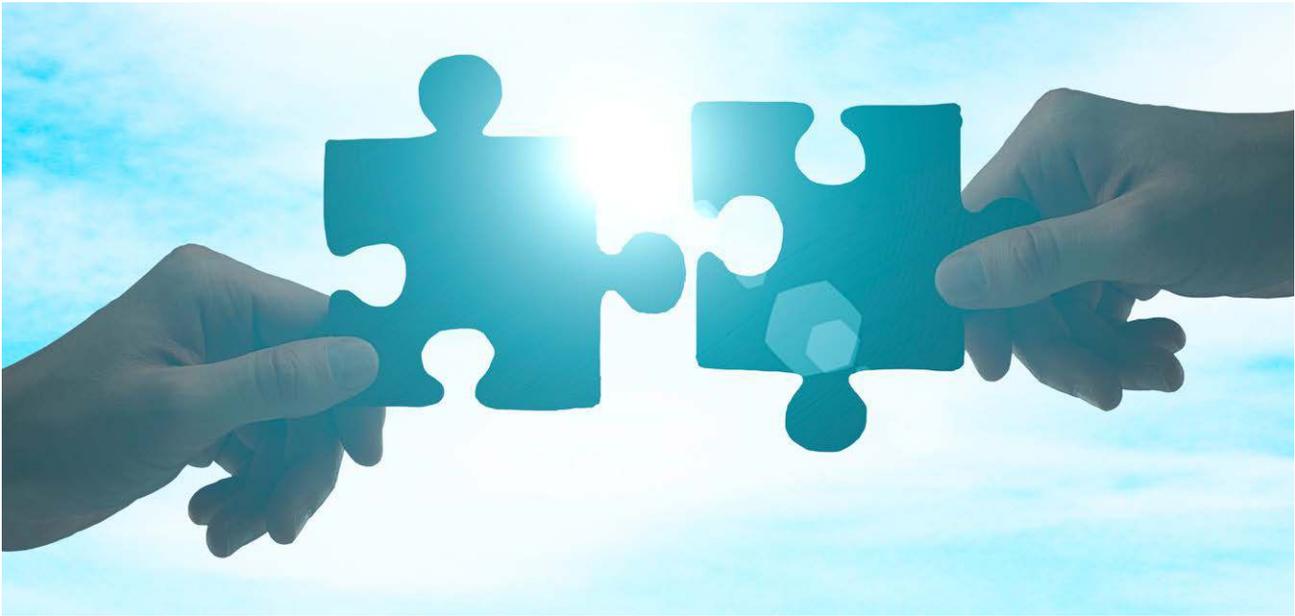
- Which stakeholders need to be trained?
.....
- Which line employees should take part in trainings?
.....
- When should the training begin so that all employees are ready to go live?
.....

Test phase

- How much time is needed to test the systems before real production?
.....
- Is a pilot project possible or the establishment of a test line useful?
.....

For a quick analysis of your results please contact us [@Laetus US Sales](#)

Strong Partner for Reliable Compliance



The complexity of such serialization projects is high, and its influence on existing processes should not be underestimated.

On the one hand, the challenge lies with the implementing companies. It is important to analyze and possibly standardize processes, to provide sufficient financial and human resources and to find the right provider. For the serialization system and software vendor, the task is to know in detail the customer's production/packaging processes, their product and production-specific control requirements. With this information gathered, the right solution can be implemented with the required data accurately secured.

Suppliers, therefore, need not only comprehensive software knowledge, but also detailed know-how in sensor technology and actuators. To be successful in carrying out complex serialization projects, it requires a comprehensive knowledge of packaging and understanding mechanical integration of machines and modules in the packaging line.

It makes sense to look for a partner who has extensive industry experience and detailed process knowledge: The German company Laetus, based in the Darmstadt Rhein Main Rhein Neckar engineering region, near Frankfurt, offers value-added quality control systems and track & trace serialization solutions for the Pharmaceutical Industry, Cosmetics, Food and FMCG industry and has more than 40 years' experience in inline quality control. Since 2015, Laetus has been part of the Danaher Group and operates with more than 250 employees and offices in the US, Mexico, Brazil, China, UK, Italy, Spain, Poland and France as a stand-alone company within the product identification platform. In addition, around 50 agents and distributors represent the company worldwide. As a result, the provider of optical inspection and track & trace solutions is well positioned to successfully implement even complex, global projects.

In addition to the development and implementation of a reliable serialization solution, we also support you:

- in the needs analysis
- when creating a User Requirement Specification (URS)
- in project management (if necessary, we also assume the overall responsibility)
- at Factory Acceptance Test (FAT)
- with Site Acceptance Test (SAT)
- in the validation including documentation
- through on-site trainings and/or trainings in the Track & Trace Academy
- through comprehensive services (worldwide on-site service, repair and spare parts service)
- and extensive support also online or via remote assistance

The Road to Securing DSCSA Compliance



One thing is certain, despite the postponement of punitive measures until 2018: the next implementation steps of the DSCSA will come. Companies that are not compliant, must act now!

Laetus supports you on your way to secure DSCSA compliance.
Contact us today: 1 630 694 2832 or Sales_US@laetus.com

[Click here to request our UPM Case Study on Serialization.](#)

Legal

This white paper has been prepared to the best of my knowledge and belief. However, we assume no legal guarantee for the completeness and accuracy of the content.

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Why Laetus

- Over 40 years of experience in optical quality control ensures reliable solutions
- Track & Trace expert supporting small, medium and global companies
- Flexibility in integrating solutions due to a modular approach
- 24/7 hotline
- Worldwide technical service
- Project management from initial consultation to final implementation
- Quality management through validation
- Training academy with a multitude of individual training courses



Solution Partner
Laetus GmbH