

Pharma Serialisation Buyer's Guide 2026



How to Select the Right Serialisation Solution for Your Pharmaceutical Packaging Operations

Introduction

Pharmaceutical serialisation is no longer just a regulatory requirement—it has become a strategic investment in product security, supply chain visibility, and operational efficiency.

Whether you are implementing serialisation for the first time, replacing an aging system, or expanding to additional production lines, selecting the right solution can significantly impact compliance, productivity, and long-term costs.

This guide helps pharmaceutical manufacturers and CMOs evaluate serialisation solutions and avoid common implementation pitfalls.

1. Why Serialisation Matters

Serialisation creates a unique identity for every saleable unit produced. Combined with aggregation and Track & Trace capabilities, serialisation enables:

- Protection against counterfeit medicines
- Compliance with global regulations
- Supply chain transparency
- Faster recalls and investigations
- Improved product security
- Better inventory visibility

For many pharmaceutical companies, serialization has evolved from a compliance initiative into a key component of digital manufacturing and Industry 4.0 programs.

2. Key Questions Before Starting a Serialisation Project

Before speaking with suppliers, answer the following questions:

Production Environment

- How many packaging lines require serialization?
- What are the line speeds?
- What packaging formats must be supported?
- Which printers are currently installed?

IT Environment

- ERP system?
- MES system?
- Existing serialization software?

Business Requirements

- Future aggregation requirements?
- Multi-site deployment plans?
- Contract manufacturing operations?
- Regulatory regions served?

3. The Five Layers of Serialisation

Many buyers focus only on printers and cameras. Successful projects consider the entire architecture.



4. Upgrade vs Build

Option	Best When	Advantages	Challenges
Upgrade Existing Lines	• Packaging equipment is relatively new • Space is limited • Budget is constrained • Downtime must be minimized	• Lower investment Faster deployment • Reduced disruption	• Legacy system integration • Mechanical limitations • Multiple suppliers
Dedicated Serialisation Station	• Existing lines lack space • Volumes are lower • Multiple products run on one station	• Rapid implementation • Lower complexity • Flexible operation	• Additional product handling • Potential throughput limitations
New Serialised Packaging Line	• New production facilities are planned • Significant capacity increases are required • Long-term scalability is critical	• Optimized performance • Future-proof architecture • Simplified validation	• Higher initial investment

5. Essential Features Every Serialization Solution Should Include

Software Features

- Secure code management
- Audit trails
- User permissions
- Electronic signatures
- Reporting tools
- ERP integration
- Aggregation support
- Multi-line capability
- Multi-site capability
- Quality inspections

Hardware Features

- High-speed code verification
- OCR / OCV functionality
- DataMatrix verification
- Barcode verification
- Easy format changes
- Compact footprint
- Remote diagnostic

6. Validation Considerations

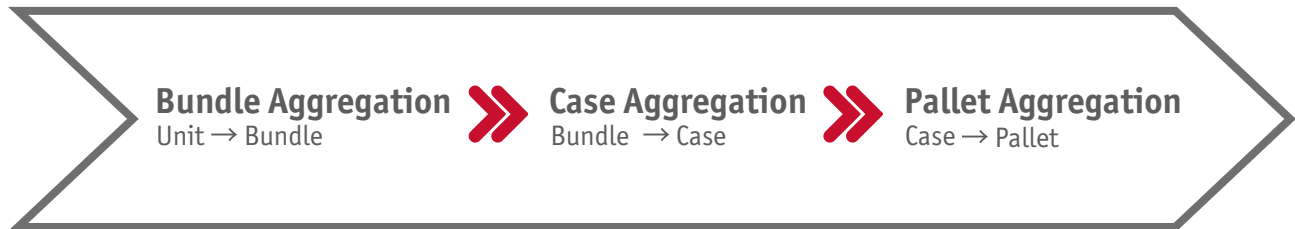
Validation frequently becomes the largest hidden cost in serialisation projects.

Questions to ask vendors:

- Is validation documentation included?
- Is FAT support available?
- Is SAT support available?
- Do templates reduce qualification effort?
- Is 21 CFR Part 11 support available? Are GAMP principles followed?

7. Aggregation: Think Beyond Serialisation

Many companies initially implement serialisation only and then later discover aggregation requirements. Modern solutions should enable:



Benefits:

- Faster warehouse operations
- Improved traceability
- Reduced shipping errors
- Supply chain visibility

8. Common Mistakes to Avoid



Focusing Only on Compliance

The lowest-cost compliant solution may become the most expensive system to maintain.



Ignoring Aggregation

Many projects require expensive upgrades later because aggregation was not considered during initial planning.



Underestimating Validation

Validation and documentation can represent a significant portion of project effort.



Choosing Multiple Suppliers

Separate hardware and software suppliers often increase integration risk and project complexity.



Looking Only at Today's Requirements

Serialization solutions typically remain in operation for the long-term.

9. Checklist: Questions Every Pharma Buyer Should Ask

Technology

- ☐ Can the solution integrate with our existing line equipment?
- ☐ How are software updates managed?
- ☐ What databases are supported?

Support

- ☐ Is 24/7 support available?
- ☐ What response times are guaranteed?
- ☐ Is remote support included?
- ☐ Do I need a service contract?

Implementation

- ☐ What is the typical project structure?
- ☐ Who performs installation?
- ☐ What validation support is included?
- ☐ What training is provided?

Scalability

- ☐ Can we add new lines easily?
- ☐ Can multiple sites be connected?
- ☐ Can the system support future regulations?

Notes

Conclusion

The right serialization partner should deliver more than regulatory compliance. They should provide a scalable platform that supports production efficiency, supply chain visibility, and future business growth.

Contact the expert team at Laetus for an in-depth conversation about how our serialisation solutions would fit your packaging environment.