

RESOURCES

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Checklist: Estimating Your Total Cost of Ownership



Total cost of ownership (TCO) is a financial estimate of the direct and indirect costs to help companies calculate their total investment over the life of a product or system. If you are in the midst of solution selection now, it's important to ask questions to avoid the risk of having your long-term serialization costs soar. As you conduct your research, use this checklist of questions to guide your TCO analysis.

Address your global compliance needs.

- Will you need a solution that satisfies multiple market requirements?
- What will it cost to upgrade software when responding to changes in regulatory or trade requirements?
- What will it cost to retrofit those changes into your customized instance of the solution?

Determine your overall budget.

- How will serialization impact your processes across your organization?
- What's your annual and estimated revenue and budget?
- How many serial numbers and events do you estimate annually?

Calculate your licensing, subscription, and variable fees.

 How much will you pay for all associated license, subscription, or variable fees upfront and/or annually?



- How much will you pay for database and application server fees?
- How much will you pay for serial number or variable event-processing fees?
- Are there multi-year discounts?
- Is there tiered pricing based on the size and revenue of your company?

Identify your software and hardware expenditures.

- What's the cost to upgrade system architecture to support serialization database and transaction demands?
- For standards and reporting, how many updates and how many days of work are required for each update?
- How many annual releases are there?
- What do you anticipate for IQ/OQ/PQ/UAT creation and execution?
- What will it cost to support ongoing customization, testing, and validation for your solution?

Estimate your trade partner integrations.

- How many CMOS, 3PLs, and brand owners are in your ecosystem?
- How long will each take to integrate?
- What's the average daily rate you will be charged by a provider to perform these (point-to-point vs. integrate once)?
- What's the average annual cost to perform required partner upgrades?
- Will there be any outsourcing or consultant fees?
- If you operate as a CMO, how many customers do you have?
- What percentage of those customers will integrate?

Identify expenses for line and warehouse systems.

- Given the launch dates of the products you produce on each internal or external line, what will it cost for each line to be integrated with your serialization solution so it can start producing serialized product?
- What will it cost to integrate your warehouse and other systems?



Evaluate downtime considerations and production impacts.

 How will your retrofitting requirements impact the cost of supply capacity, given line downtime?

Determine training and support fees.

- How much will you pay for product training?
- Are there fees for 24/7 technical support?
- Does your solution provide trade partner training so they understand what they need to do to support your serialization efforts?

With the first DSCSA serialization deadline just 15 months away, your ability to serialize product at scale will be in serious jeopardy if you and your solution partner can't answer these questions now. Companies that can't see beyond the initial purchase price will start to see their serialization costs soar.

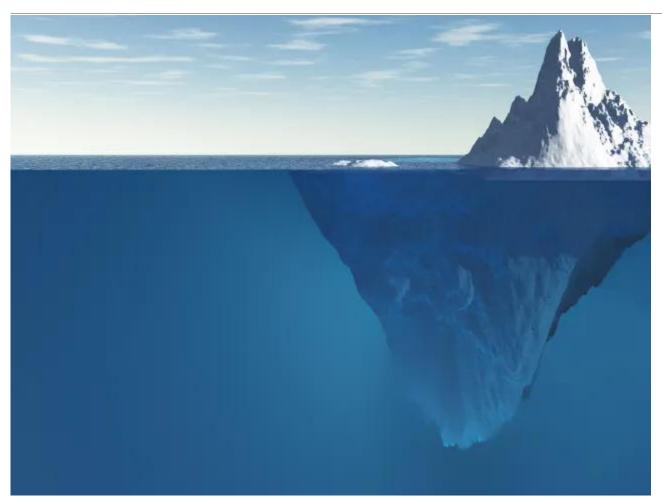
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Hidden Costs of Serialization

Are you prepared to navigate the entire serialization iceberg? View a breakdown of all costs you will incur.





How Much Will Serialization Really Cost?

Get insights into how much serialization will really cost your company. Proven serialization solution providers can help identify additional costs.





Serialized Operations: Challenges and Opportunities

How do your serialized operations compare with more 100+ pharmaceutical companies? Get the results of TraceLink's serialization program assessment.





Case Study: IBSA | Using Serialization to Ensure Product Integrity

Learn how IBSA used serialization to protect their product from counterfeiting.





Case Study: Ferrer | Building a Master Data Strategy for EU FMD

Learn how Ferrer worked with TraceLink to manage its master data for EU FMD compliance. **View More**





CMO Line Upgrades: Who Will Pay?

Pharma companies and CMOs must work together closely to be ready for serialization, yet there is no established commercial model. Learn about the dynamics.