

PACKED WITH LABELING EXPERTISE

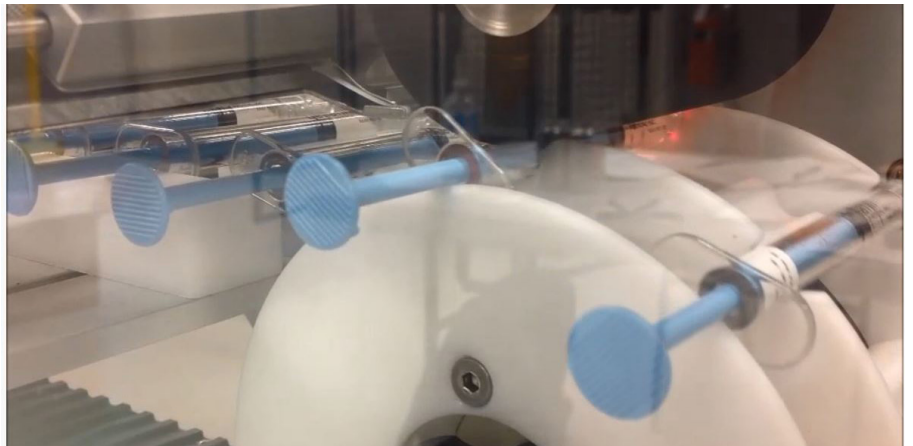


A Comprehensive
Guide for
Pharmaceutical
Product
Manufacturers

Calculating Total Cost of Ownership (TCO) for Labeling Machinery

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INTRODUCTION

Cost calculation is an important early step to determining potential return on investment (ROI). When investing in labeling equipment however, calculating the initial purchase price alone is not enough. To properly inform your investment decisions, it's important to understand the total cost of ownership (TCO).

Accraply has created a comprehensive guide to help pharmaceutical product manufacturers and co-packers calculate TCO for labeling equipment. This guide includes a list of cost factors to consider, advice for keeping costs low, tips from industry professionals, and links to additional cost calculation tools and resources.

What is TCO and why does it matter?

Total cost of ownership (TCO) refers to the long-term costs associated with owning and maintaining a labeling line or machine throughout its entire lifecycle. In addition to your initial capital investment, you will incur costs associated with the purchasing process, plant operations, validation, machine maintenance, technical support, and more.

By accounting for all these costs, you can accurately calculate the total cost of owning the equipment and, subsequently, better predict your ROI. For co-packers especially, calculating TCO is helpful because it accounts for important business imperatives including equipment flexibility, production efficiency, changeover rates and more.

Identifying common labeling equipment cost factors

When you're launching a new product labeling line, there are several project-specific factors to consider. Maybe you're releasing a new product and you need to double your labeling output. Or maybe you've expanded your product offerings and you need need a different style of label altogether. Whatever the case may be, it's important to consider these factors up front. Doing so will allow you to gain early alignment in the development of your project and ensure effective cost management, not just during the purchasing process, but throughout the life of the equipment.

While every project comes with its own unique cost factors, there are several factors that are common with most packaging equipment purchases. These costs can be simplified into three categories – capital costs, operational costs, and maintenance costs. In the following pages, you will find a breakdown of the top cost factors to consider in all three categories. This information was collected from experts across the Accraply's organization and by following [PMMI's industry standard guide for defining TCO](#).



CAPITAL COSTS

Capital costs are the initial expenses that you will incur up front with the purchase of your labeling equipment. These costs are typically one-time expenses that can be calculated by considering factors such as equipment design, commissioning, certifications, acceptance testing, installation, and equipment validation.



COST FACTORS

Equipment Design

Initially, your equipment design is largely dependent on your required production rate, product sizes, printing requirements, and packaging formats. These factors – along with your controls, inspections, data collection, and automation requirements – will give you an idea of the machine standards required as well as the speed and capability of those machines.

Additionally, you'll want to carefully consider your health, safety, and environmental requirements. Failure to address these requirements can result in major fines down the road, so it's critical that you discuss them with your labeling equipment supplier during the design phase or sooner.

Commissioning, Certifications, and Acceptance Testing

Continuing through the equipment acquisition process, validation and documentation can be a significant cost 10-15% of the total cost of the line. Initial user requirements, design documentation, and testing qualifications impact every area of the machine. Ensuring

your equipment suppliers are ready to provide you the information you need to create FDA inspectable validation documentation will reduce your validation department's time and expense.

During factory acceptance testing (FAT), it's important to consider the costs of the materials and products you'll need to properly test the solution. Remember, you may need a sizable quantity of sample products for each type of product you plan to run on your new equipment. Additionally, you should factor in the setup time and travel costs that your supplier will charge for their services. Similarly, account for all costs associated with confirming FAT results, along with any punchlist items, final acceptance testing of the equipment, and acquiring the documentation from the labeling equipment supplier.

Shipping and Installation

The shipping and installation stages of your project encompass quite a few tasks. For shipping, you should consider the price of freight and whether you'll be shipping the equipment by air, truck, or another method. For installation, common tasks include unloading and uncrating of equipment, assembly and initial setup, technician installation services, and start-up time to get the system running in your facility.

You should consider both the cost of these tasks and the amount of risk that you're willing to incur by taking on any of those tasks in-house. We'll circle back to this later.

Equipment Commissioning

Commissioning encompasses the final tasks that are required for the OEM to hand off the new equipment to you. Expenses might include travel time and the costs associated with your team members visiting a location to view equipment in action, or to approve finished equipment prior to shipment. During this stage, you should be working to ensure that the installed equipment meets the quality and throughput requirements that the OEM committed to deliver at the beginning of the project. This is an opportunity for you to verify that your operators can operate the equipment in the actual production environment and any peripheral solutions have integrated with your label applicator as intended.

2 WAYS TO LOWER CAPITAL COSTS

Take a consultative approach during contract negotiations

When negotiating a contract with your integrator, it's best to take a consultative approach. Imposing too many strict demands (ex: tight time constraints, total control over OEM selection, asking the integrator to commit to "liquidated damages") will drive up the purchase price. On the other hand, taking on responsibility in-house for tasks you're not set up to handle can also put the project at risk.

The best way to navigate this conundrum is finding the ideal balance between cost and risk. This requires looking inward at the depth and strengths of your in-house resources and asking yourself a series of questions. Who should be responsible for each task? What risks are associated with owning those tasks in-house? What assurances are granted by contracting the integrator to do them? These questions will help you make cost-effective decisions during contract negotiations.

Maximize SKU variability with flexible labeling and packaging solutions

Sometimes, considering equipment speed and capability alone is not enough. It's also important to evaluate the need to interchange between each of these factors, especially if you are a co-packer. Investing in a flexible solution that is easily configurable and designed for quick changeovers will allow you to produce multiple SKUs as quickly as possible on the same machine. By evaluating the need for flexibility during the equipment design phase, you can reduce your need for future capital investments.



AVOID BUYERS REMOURE BY CONSIDERING OEE EARLY

As a pharmaceutical product manufacturer, you should consider OEE before requesting equipment quotes. In recent years, these markets have seen increased demands for labeling machines capable of handling shorter runs, frequent changeovers, and higher production speeds. If you purchase a labeler that wasn't designed for these functions, your actual production time could be far lower than your planned production time.

For help identifying a list of machine requirements that will support OEE for your product line, we recommend consulting with one of our Accraply labeling experts. Our experts have a vast knowledge of both labeling equipment and the pharmaceutical product markets, allowing us to recommend equipment that maximizes machine availability, labeling performance, and quality.

OPERATIONAL COSTS

Operational costs are the ongoing expenses that you will incur to run your labeling equipment. These costs recur throughout the life of the equipment and are calculated by considering factors including staff training, labor requirements, automation, utilities, and more.

COST FACTORS

Staff Training

To calculate training costs, you need to account for the time and resources required to train operators and maintenance personnel on several tasks including setup, changeovers, cleaning, troubleshooting, and more. The time factor is driven by the training setting (i.e., classroom or hands-on) and the complexity of the tasks being taught. Your supplier should also provide you with a user manual or other documentation to ensure that your staff is sufficiently prepared for operation and troubleshooting long after training is complete. Some suppliers now offer human machine interface (HMI) screens that can assist with these types of training items.

Automation & Labor

While labor and automation are really two separate cost factors, they're closely related and should be considered one and the same. Labor refers to the number of operators and

maintenance personnel needed to keep your equipment running. It also refers to the skillsets required of those staff members. If your new equipment requires additional staff or skillsets beyond what can be taught during training, you might need to budget for additional labor costs and the costs associated with advanced training, recruiting, and hiring.

Automating changeovers, case-packing, palletizing, and other operations can reduce your labor requirements and optimize production time. In recent years, many manufacturers have found it preferable to keep fewer operators, whether because of health and safety precautions, turnover and training strains, or other reasons. But automation also changes the skillsets you'll need to operate, maintain, and troubleshoot the equipment. Automation comes with costs for software, integration, and any upgrades that are required to integrate with the rest of your plant to make it cohesive.

Utilities

To calculate utility costs, you should determine the desired production rates and then look at each utility that is required for the machinery. These might include air, electrical, gas, water (potable, purified, WFI as required), wastewater treatment, and more. While labeling equipment itself does not typically have a significant utility demand, depending on the process equipment that feeds the line upstream, you could be looking at significant utility usage.



3 WAYS TO LOWER OPERATIONAL COSTS

Keep best in class training and troubleshooting resources on hand

At a minimum, your labeling equipment supplier should provide you with an operator manual and step-by-step training documents for future employee onboarding. This will mitigate some of the recurring costs of training. Additionally, many of today's top packaging OEMs include operator training resources via the HMI. These HMIs provide greater insight into your labeling operations and provide tips to operators that help increase the overall productivity of your plant.

Create efficient changeovers with packaging automation

Whether you're a private label manufacturer or a co-packer, maximizing your production time is a priority. As you evaluate machines for your packaging line, look for options that will automate processes that would otherwise require a hefty investment in manual changeovers. Toolless changeovers are very popular because they're easy and cost efficient. Once the operator programs the recipe in the HMI, they can quickly and efficiently process a changeover, eliminating unnecessary tools, and reducing the opportunity for errors to occur.

Streamline material movement

Whether it be labels, packaging, or other material movement, your goal should be to lower operational costs by mitigating complex distribution from the warehouse or controlled storage to point of use on the line. One strategy



SIMPLIFY OPERATIONAL EFFICIENCY WITH A SMART HMI

To continuously improve OEE even after a purchase, operational leaders must address several key challenges. These include streamlining operator training, establishing reliable access to support technicians, and developing procedures to quickly resolve unplanned downtime.

As a solution, we recommend Accraply's SmartLink HMIs for labeling machines. With support from Barry-Wehmler's Intelligent Systems Team, our engineers develop HMIs that include video tutorials and on-demand training guides to make setup and operations simple. They also include remote OEM support functionality and analytics dashboards that provide critical information regarding the machine's availability, performance, and condition.



for aiding in operational efficiency is to centralize material supply locations. This helps optimize fork and hand truck movement and minimizes empty trips (i.e., trips where the fork truck has nothing on it). You can also utilize visual, audible, and other cues to suggest when a machine center may be running low on a necessary material. The combination of these efforts creates an efficient supply of materials to keep the line supplied and running.

MAINTENANCE & SUPPORT COSTS

Maintenance and support costs are the ongoing expenses associated with keeping machinery in working order, troubleshooting and resolving unexpected disruptions. These costs can be trickier to manage than capital and operational costs because it's not always clear when maintenance and support will be required. However, you can mitigate unexpected costs through careful consideration of maintenance schedules, documentation, spare and wear parts, and other factors that are more predictable.

COST FACTORS

Documentation

The manuals and documentation your OEM provides for operators should also include guidance on proactive (or preventative) machine maintenance tasks. These resources will help you proactively schedule maintenance to be a planned event instead of unscheduled downtime. The documentation should define the optimal process and schedule for maintenance tasks like cleaning, lubricating, and making other adjustments to the machine. Some premium labeling equipment suppliers now offer HMI screens that can assist with preventative maintenance reminders and alerts.

Parts Lists (Spare and Wear)

When it comes to spare and wear parts, there are two factors to consider that greatly impact TCO: access and availability. It's important to determine how available and accessible parts will be under the contract you sign with a labeling partner. Part of this is preventative; you want to keep enough wear parts on hand so you can replace parts quickly and continue operating with limited downtime. Sometimes, OEMs provide onboarding consumable parts ordering directly from the HMI to ensure speed of availability. The other question to consider is how quickly you can get technical support and parts from the OEM. The longer it takes to get the parts you need, the more production time you'll lose.

Aftermarket Support

Aftermarket support refers to the costs associated with any services that are required after the initial sale, start-up, and commissioning and validation of your labeling machinery. This can include a broad range of services including spare parts, technical audits, additional training, field service, remote troubleshooting support, machine upgrades, and more.

It may be valuable to talk with your supplier about the location of their service team. This can help estimate travel costs and determine availability of a service tech in your area.



4 WAYS TO LOWER MAINTENANCE COSTS

Stick to the maintenance schedule

Abiding by the supplier-recommended maintenance schedule is the easiest (but most important) way to keep your maintenance costs low. Completing tasks such as cleaning, lubricating, and replacing worn out parts within the recommended time frame results in fewer breakdowns, less downtime and lower emergency maintenance costs, as well as increased safety for your machine operators. When possible, set preventative maintenance reminders from your machine's HMI to ensure maintenance is being completed regularly.

Include a parts and service agreement in your contract

Parts and service agreements can reduce your maintenance costs by giving you fast access to wear parts and ensuring OEM availability when you need emergency technical support. By working with your supplier to create a package that supports your long-term maintenance needs and your overall investment and production strategy, you can better plan for the costs ahead and mitigate any unplanned expenses.

For example, Accraply offers lifecycle support to their customers, which means they will provide you with the parts and services you will need throughout the life of the equipment. This includes maintaining spare parts lists, pre-scheduled audits, and so on.

Choose maintenance-friendly equipment designs

Individual equipment designs should account for the frequency of specific maintenance tasks and provide efficient access for maintenance personnel. This will limit the time and duration required to perform frequent maintenance tasks. For example, you want to make lubrication and frequent wear part exchange easy to access. If you're required to remove major machine components for regular maintenance, you are lowering your entire line's production efficiency.

The trend today is to reduce the items and areas of the machinery that need to be maintained and

add features that operators can maintain without getting maintenance people involved. An example of this would be toolless changeovers that can be completed by an operator, rather than bringing in a maintenance person who is usually more skilled than is necessary to change a machine over.

Ask about remote support services

As labeling equipment becomes more technologically advanced, the skillsets required to maintain that equipment have changed. Co-packer facilities are often located in rural areas where it's harder to attract maintenance personnel with these new skillsets, as a result many organizations rely on the OEM for technical support. Troubleshooting with a support technician remotely via your machine's HMI or a supplier's mobile app can eliminate the downtime and costs associated with needing to fly a technician out to your site. With remote support, you can have a technician dial in and solve the issue quickly. Almost 90% of the issues we see from our customers can be solved this way.



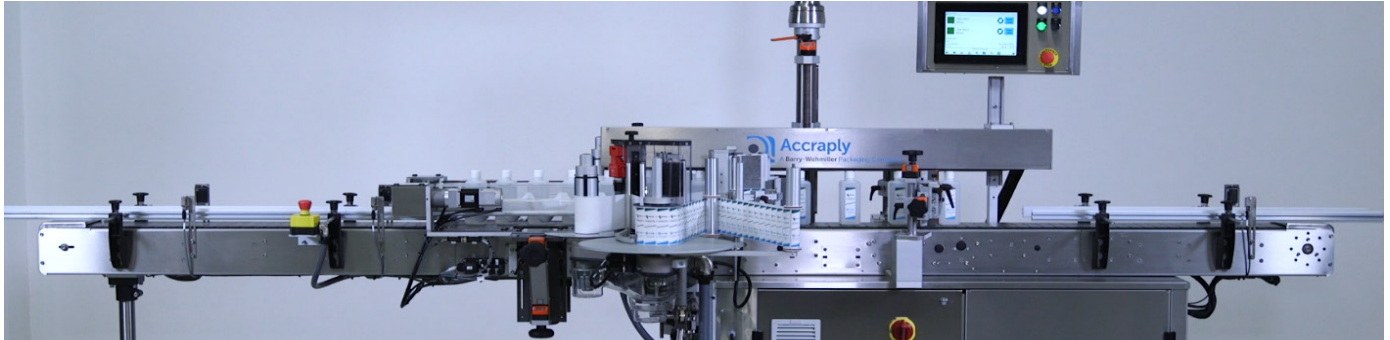
SERVICE IS KEY

When a machine goes down and you can't get access to a maintenance or service technician quickly, you'll start to feel the pressure of lost production. Every minute of downtime is lost revenue. Because we understand this, Accraply promises excellent support. Aftermarket service isn't an afterthought. We service all of our equipment for the life of the machine. Our service team provides consultative audits, technical assistance, spare and replacement parts, change parts, upgrades, field service and pre-owned equipment with exceptional commitment to customer satisfaction.

We provide global expertise, delivered locally, allowing us to be a focused and responsive partner that supports all your labeling needs.

PROVEN LABELING SOLUTIONS

At Accraply, we take a consultative approach to solving your labeling problems. By collaborating with you, we can better understand your challenges and deliver a custom-engineered solution that is unique to your requirements, while providing the lowest TCO possible. Accraply's pharmaceutical product labeling solutions are best-in-class in terms of quality and robustness. Our solutions are designed to specific, rugged specifications. This allows for 24/7 operation and frequent changeovers. Here are some examples of our pharmaceutical product labeling solutions:



PILL BOTTLES

- Pressure-sensitive wraparound, front, and back labeling machines for elliptical or rectangular bottles
- Shrink sleeve tunnels and applicators for full-body product labeling
- Full booklet labeling application available



VIALS

- Low to High-speed pressure-sensitive labeling machines at speeds of 600 products per minute
- Serialization integration support is available



SYRINGES

- Pressure-sensitive labeling that offers flexibility and precision for this unique shape
- Serialization integration support is available



AMPOULES, SINGLE-USE SWABS

- Pressure-sensitive labeling focuses on flexibility, accuracy and easy integration ideal for ampoules or single-use swab products that require sophisticated product handling
- Serialization integration support is available



DROPPER BOTTLES

- Pressure-sensitive wraparound labeling perfect for this small size
- Shrink sleeve tunnels and applicators for full-body decoration and tamper-evident labels
- Serialization integration support is available
- Full booklet labeling application available



TAMPER-EVIDENT OPTIONS

- Shrink sleeve tunnels and applicators for stand-alone applicators and complete sleeving systems to protect your vials to pill bottles
- Pressure-sensitive, tamper-evident security labels also available for erected cartons, track-and-trace serialization capabilities available

ADDITIONAL RESOURCES



Did you find this guide useful? If so, you may be interested in some of our other resources. Click on the links below for expert advice on related topics:

- How to Maximize the Productivity of Your Labeling Process
- 8 Must-Have HMI Features for Your Labeling Machinery
- Benefits of Accraply's Service

BW Packaging Systems

Accraply is one of several Barry-Wehmiller companies represented in BW Packaging Systems, which brings together the labeling and packaging capabilities of Accraply, BW Flexible Systems, BW Integrated Systems, Pneumatic Scale Angelus and Synerlink. Through their collective experience, BW Packaging Systems' companies provide deep, vast knowledge of packaging machinery to identify the best solutions for your pharmaceutical product packaging needs. Learn about our other companies:



End-of-line packaging equipment solutions and systems integration. Learn More: bwintegratedsystems.com

Brands Include: Ambec, Fleetwood, Goldco, Nigrelli, SWF, Tisma



Flexible packaging solutions that include bag filling and palletizing, vertical form-fill-seal, and horizontal flow wrapping. Learn More: bwflexiblesystems.com

Brands Include: Hayssen, Rose Forgrove, Sandiacre, Schib, Simionato, Slidell, Streamfeeder, SYMACH, Thiele



Packaging machinery for wet and dry filling, capping, can seaming, labeling, and centrifugation applications. Learn More: psangelus.com

Brands Include: Angelus, Burt, Carr Centritech, Consolidated, Continental/Closetech, Mateer, Multi-Tech Systems, onTrack, Pneumatic Scale, Zepf Solutions



Cup filling, bottle filling, and FFS rigid packaging solutions. Learn More: synerlink.com

Brands Include: Arcil, DairyPack, Dinieper, Ermi, Hema

Ready to start exploring pharmaceutical labeling solutions? Contact our labeling experts at accraply.com/contact-us