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# A white paper exploring barcode outsourcing in sample management

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# Overview

**This white paper offers an overview of the current challenges and opportunities facing compound and sample management, and explores crucial themes in outsourcing the preparation processes associated with labware procurement, barcoding, and container taring.**

# Emerging trends and their challenges

### Mergers, acquisitions, and partnerships

Pharmaceutical, biotech organizations, and academic institutions – and their sample libraries – are collaborating all over the world, on a seemingly daily basis. The result of an increased sample base available to researchers is a valuable business asset, just so long as the libraries, processes, and tracking systems can be successfully integrated and relied upon. This is a challenge for facilities that partner with other research institutions to share libraries, in addition to those who merge internal collections.

### Sharing compounds

Usually, libraries predominantly hold compounds specific to their individual disease strategies. Organizations that strategize to merge or share can therefore pool their sample availability, and hence increase their capacity to successfully discover novel drugs and treatments.

Such a powerful opportunity deserves the most robust sample identification system, to support the high throughput screening that can identify potentially beneficial treatments and discoveries from the newly expanded sample library.

### Biologics

Increasingly, many compound libraries are now also becoming home to biologics. This inevitably means distinctive processes, additional samples, demanding storage environments, different workflows, and a host of new considerations in terms of identifying and tracking samples.

It is important as ever, to realize the full potential of the sample assets an organization holds, tracking and identification must be as reliable and consistent as technically possible.

Utilizing labware that has already been procured, marked, tared, and packed according to usage guidelines is a growing industry trend; a solution that is specifically aligned with the demands of ever-changing and more complex compound library and sample management.

## HOW LABWARE PREPPING ACTIVITIES IMPACT QUALITY

### Standard Components of Quality Process:

| AUTOMATION PERFORMANCE | STORAGE CONDITIONS | QUALITY OF GLOBAL DATA | PROCESS RELIABILITY |
|---|---|---|---|
| Ensure your supplier understands the importance of the position of 2D codes and linear barcodes on the containers. 'This, along with crystal-clear codes, will ensure automation functionality is optimal & uninterrupted. | Ensure storage conditions are included in your SOP & discussed with your label/labware suppliers so the identity of samples can be guaranteed throughout their lifecycle. | If possible, funnel labware prepping activities for all global locations through one supplier so barcode sequences can be managed and all product is consistent. | Ensure the reliability of your process by starting with the basics and working upward from there. Where will we get our containers? How will they be identified? How will they be stored and in what quantities? From there you can document processes for consistency & reliability. |

# The in-house challenges associated with sample tracking activities

For organizations and labs relying on compounds and samples for research every day, correctly identifying and tracking each plate, tube or vial can be both exacting and laborious.

### Skilled staff in low-skill roles

To ensure accurate chain of custody and maintain in-house control, activities such as tare weighing and sample labeling often fall on the shoulders of skilled scientific staff. Essential as these tasks are, they reduce the capacity of a team to carry out its core, most productive scientific activities. In addition, when a collection has been merged or shared, relabeling projects can consume days if not weeks of premium time. The costs incurred through under-utilizing scarce resources must be compared to the research that isn't getting performed when skilled staff's time is spent on administrative, non-science activities.

### Throughput speeds are limited

In facilities where any degree of manual processing takes place, throughput speeds are compromised. As mentioned earlier in regards to under-utilizing skilled staff, the same trade-off holds true when discussing throughput. Throughput speeds are only as fast and consistent as the processes and workflows that are in place. The hurdles that tend to slow these automatic processes can more often than not be attributed to how well the chosen systems and samples integrate and work with each other. For example, a misplaced barcode on the bottom of a tube that hence cannot be scanned can bring even the most seemingly flawless automatic process to a complete halt. Merging and partnering to utilize additional samples often comes with the challenge of ensuring each container and its unique ID will in fact integrate with existing systems and processes.

Similarly, if unsuitable labels are used, degradation of the adhesive over time will affect the container's weight, causing process disruption and volume uncertainty. Utilizing an incorrect label or identifier can also lead to unscannable/unreadable codes at a later point in the time, which in turn equates to unusable samples and/or wasted research.

**5%** of a typical sample collection is un-useable due to labeling errors. Outsourcing to utilize a service such as READY Labware is shown to reduce the percentage to less than 1%.

### Data and audit trail could be stronger

Another significant limitation associated with the manual processing of any kind in relation to samples is that of data integrity and chain of custody. When merging a sample base and manually identifying samples, the possibilities for enhancing data integrity and maintaining a strong chain of custody are more challenging.

Particularly with regard to hazardous, therapeutic, or controlled substances, there are legal imperatives driving the need for a clear audit trail that directly correlates to the unique information stored on each sample's barcode identifier. Equally, the high value/ cost of certain compounds or samples means organizations can ill-afford to employ a less-than-robust tracking and barcoding system.

### Errors await

As long as human intervention is part of a process, errors can and will be made. Given the safety and security considerations relating to many compounds, blood products, controlled substances, or volatile materials, reducing or eliminating human error potential is a constant challenge.

## An outsourcing checklist

When organizations pool their compounds or samples – whether internally, or through a partnership – or a biologics library is added, there are some factors and issues which are likely to arise. In regards to tracking and traceability of samples, the following is a checklist which can be useful to consider;

1. Ask yourself: Do my current suppliers have the technology and quality systems in place to accommodate our expansion? Are there other services we could outsource or products we could obtain from them?

2. Analyze current processes and workflows in search of opportunity for improvement/ streamlining. This step can drastically reduce non-scientific labor costs. Some factors to consider:

    - Automation performance
    - Quality of global data
    - Process reliability
    - Costs

3. Ask yourself: What needs to be added to our SOP/quality checklist as a result of these changes?

4. Ask yourself: Do our suppliers have backup plans in case of a natural disaster? Is there a risk management plan in place? If so, does this need to be altered due to our recent expansion plans? This should be weighed in terms of risk vs. cost.

5. What are the future technologies and how can they integrate into our current systems and workflows?

6. In terms of labware/label suppliers specifically, can your suppliers and partners address your needs relating to:

    - Sample storage conditions
    - Sample contents (biologics/compounds)
    - Length of sample storage
    - Chemical exposures (DMSO, methanol, xylene, water, etc.)
    - Compliance to barcode specifications for automation/ guaranteed consistent barcode placement tolerance Automation functionality & integration/scannability

**30%** of total label costs can typically be saved by companies adopting pre-prepped labware outsourcing such as READY Labware.

- Mix of containers
- Yield
- Use of 2D codes/ linear codes/ human readable information within placement tolerance requirements
- Project timelines
- Share your goals & strategy associated with your expansion with your suppliers. Partnering with the right service provider should result in the following benefits
- Increased efficiency
- Expanded research opportunities
- Cost savings

## Outsourcing: an ideal

**Helpful Hint:** Labeling needs should be considered during a transition rather than when the implementation is complete.

Considering whether or not to outsource in its simplest terms is a matter of finding a balance which is acceptable to the organization. On the one side are reduced labor costs, more efficient use of resources and released capital. On the other, the organization is handing over a certain amount of control – and by implication, part of its reputation -to an external party.

This is particularly true in the case of outsourcing the procurement and pre-marking/ taring of labware. The benefits of doing so can only be realized if the provider's technical solution, scope, and corporate culture are fully capable of the task.

Therefore a successful outsourcing partner must provide the following competencies:

- Have the capacity to handle the scale of the outsourcer's workload in addition to its existing commitments
- Offer the technology and resources to fulfil its promises in practice
- Consistently provide a solution that performs with and enhances existing automation systems
- Have the innate flexibility to create and deliver a custom solution
- Exhibit the culture and structure to deliver true partnership based on transparency and effective communication
- Provide the service and savings originally specified, on a consistent basis

## Outsourcing: maximizing the benefits

A comprehensive solution to maximize the sample tracking and traceability benefits associated with merging or sharing samples can include labware sourcing, marking, tare weighing, and packing, with labware delivered to the customer's facility immediately ready for use. Even if your organization isn't considering affiliating its sample base with other organizations or internal groups, outsourcing the processes associated with sample tracking and identification can provide a host of new benefits.

### Freeing staff for more productive work

Through outsourcing the need to procure, label, and pre-tare labware, scientific staff can focus their time on the productive, skilled work their experience and education has

equipped them for. Productivity and job satisfaction are enhanced as a result, and staff are also freed from the risk of developing repetitive strain injuries.

Over time, this updated SOP will not only improve consistency in sample tracking, but the quality of research itself will continue to be realized through better utilization of researcher's time and tighter controls of basic quality processes. In cases where sample libraries have been merged or shared, both parties can rest assured that, since entrusted to a single supplier, any relabeling or re-classification will result in samples that are accurately tracked and traced throughout the research and utilization process.

**1/3** of big pharma companies realize the conveniences associated with receiving pre-barcoded and pre-tared labware, as provided by the READY Labware Service Program from Computype.

It has been noted that up to 49% of time spent on tasks related to information processing in the lab can be attributed to non-value added activities. One could reasonably argue that tasks associated to labware labelng, taring, and sorting could fall within this classification of non-value added work. Through outsourcing such tasks to a trusted partner, the in-house benefits of time savings and reallocation of resources will be realized in terms of value added research and a more reliable library of samples.

### Throughput speeds increased

As discussed previously, even the most sophisticated automated storage and picking systems can come to a screeching halt due to an illegible barcode or unscannable sample. Stories of researchers walking into their lab in the morning with the expectation of their samples having been processed automatically overnight, only to find an unfinished process at a complete standstill due to scannability issues are not uncommon. When something as seemingly simple as a 2D barcode can have this effect on strict process and project timelines, it is critical to ensure your foundational quality process includes labware and labeling solutions that seamlessly integrate with your workflows so as to maximize throughput and reduce downtime.

Choosing to outsource the marking and barcoding of labware removes the risk of illegible/unscannable barcodes and ensures that each code be:

a. Scannable so as not to disrupt processes, and
b. Precisely placed in the correct location on the labware to ensure proper integration and functionality with automated workflows

### Data integrity optimized

With expertly printed and applied barcodes and sequential order management, the potential for human error can be virtually eliminated. Further, advanced marking technologies and barcodes engineered specifically to withstand demanding lab processes allow samples to remain consistent and legible over time. Waste caused by unidentifiable samples and manual re-labeling tasks are also eradicated.

When the decision is made to outsource the container marking process, data integrity associated to each sample is drastically improved. Sequence management can now be assumed through your chosen outsourcing partner to eliminate the possibility of duplicate codes in addition to issuing order releases based on specified barcode ranges. This can be especially beneficial for libraries with compounds in multiple sites, or for libraries that have merged or share compounds for expanded research. In addition to barcode data integrity, outsourcing the pre-taring of containers also provides increased data control as an output file can be provided to cross reference each code with its associated tare weight. Importing/merging this data with your Laboratory Information Management System (LIMS) will ensure a strong and consistent foundation prior to involving intangible compound or irreplaceable biologics

### Resources released

Outsourcing the labware procurement and barcoding steps negates the requirement to maintain an in-house inventory of containers and labeling materials. For facilities

processing thousands of samples, eliminating this inventory can release a significant amount of resource in capital, and scarce physical space on site. As lean manufacturing processes and 5S events become more and more popular in lab settings, the elimination of unnecessarily stocked supplies and increased lab space can assist in reaching more strategic organizational goals related to quality and throughput.

## Increasing quality, reducing waste

A labware and label outsourcing program can deliver significant quality and lean advantages.

| WASTES | DESCRIPTION | ALLEVIATION THROUGH THE UTILIZATION OF OUTSOURCING |
|---|---|---|
| Defects | Mismanaged samples &/ or inaccurate/ inconsistent data; time spent doing something wrong and later having to fix it | Pre-barcoded labware ensures defects and waste is minimized as each container has been inspected for quality and is guaranteed to have a unique identifier that will withstand the specified storage conditions and environmental hazards. Following a strict quality approach at this pre-processing stage ensures that corresponding steps in the workflow aren't compromised due to illegible traceability of a compound or biologic. |
| Over-Production | Redundant &/or unnecessary production of too much product too soon for proper utilization | Tighter controls over data and sample identity can only lead to improved production usage and greater efficiency as a whole. Foundation-up strategies that employ barcoding and labeling methodologies with the end result in mind are not surprisingly the same strategies that have the best production usage rates. |
| Transportation | Excessive movements of product or samples between departments, &/or site locations | When receiving labware that's ready to use, several processes can be removed entirely from your lab, from tare weighing to kitting and sorting. Through utilizing a service for these activities, internal transportation related to labeling processes are often reduced by up to 75%. Furthermore, pre-labeled and tared labware can be batched and shipped to the site of intended usage based on demand schedules to even further reduce processing and handling. |
| Waiting | Downtime/ idle time between shipments of samples, data, use of instruments, &/or supplies | Receiving labware that's already labeled and tared equates to fewer steps in the prepping process, and hence, fewer opportunities for wasted downtime. Additionally, when barcode sequence management services and tare weigh output files are provided, there is less time needed to process data associated with the identity/ start weight of a container. |
| Inventory | Space, data, and process components dedicated to supplies &/or yet-to-be processed samples, obsolete/expired/damaged inventory tying up cash | Also offered as a component to outsourcing services can be that of inventory management programs. Through utilizing such services, you'll only have the labware on hand that you deem necessary for immediate/ near future use, thus reducing space needed to house unneeded inventory. Furthermore, inventory related to labels, media, and labware is virtually eliminated, hence freeing up space for improved organization. |

continued...

| WASTES | DESCRIPTION | ALLEVIATION THROUGH THE UTILIZATION OF OUTSOURCING |
|---|---|---|
| Motion | Poor ergonomics on instruments, unnecessary/ inefficient movements or steps in a workflow | Hand in hand with the wastes associated to that of transportation, unnecessary steps related to moving boxes of supplies and labware within the lab, department, etc. lead to inefficient use of staff time. In addition the risk of repetitive strain injuries pose a threat especially in cases where manually applying labels or repetitively weighing containers for extended periods of time. These risks and wastes are greatly reduced through the utilization of outsourcing, as the steps involved and number of overall movements needed are minimized. |
| Over-Processing | Unnecessary steps in current SOP resulting in more work than is needed to complete tasks | Procurement of labware, pre-barcoding, pre-taring, and custom packing of labware can eliminate the entire step in your SOP dedicated to labeling, hence reducing the prep time associated with starting a project. Outsourcing these tasks not only saves skilled time, inventory, and administrative costs, but drastically improves consistency, accuracy, and precision. |

## Outsourcing: all or nothing, or somewhere in between?

Outsourcing the labeling process associated with sample management is ultimately an option which may appeal to different organizations in differing ways. Widespread outsourcing can be a good fit for some; others may find such changes more challenging to adopt. Outsourcing the steps involved in labware procurement, barcoding, and taring is definitely not a 'one size fits all' solution.

There is a complex equation to consider: the cost savings, release of resources, and productivity gains outsourcing can deliver must be weighed against passing control to an outside provider, and the actual value the provider can deliver moving forward. These considerations will naturally vary in their details according to the scale, culture, and modes of operation of each facility and their strategic goals.

Outsourcing of labware procurement, barcoding, and tare weighing, as discussed in this whitepaper, can provide a practical, logical solution for one step of the overall sample management quality process. It can enhance productivity, optimize use of skilled labor, and reduce both errors and waste. The fact that these gains can be achieved without making radical changes to process structures or existing workflows can make this a beneficial transition that is relatively easy to action.

For more information or advice on outsourcing the barcoding steps associated with sample management, please **contact us** or visit **www.computype.com/ready**