LO1 Tracker

Process control, work-in-process inventory, and manufacturing control at your fingertips, 24/7, anywhere and anytime you have Intranet or Internet access.

LIFE
SCIENCE
SERVICES
INTERNATIONAL

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Information collected by LO1 Tracker allows you to:

* Control costs, improve yields, and ensure schedules and quotas are met

* Track which raw material lot was used to produce each final product

* Know the value of WIP inventory at any point in time

* Easily reconcile raw material in versus finished products out

* When appropriate, locate where scrap resulted, identify how much was able to be reused or reworked, and its value

* Validate and improve processes and ensure Regulatory Compliance

LO1 Tracker
An Immediate Solution

* LO1 Tracker is scalable for small to large clients to divisions of major corporations

* Readily adapted and configured to your environment – pharmas, biotechs, medical devices

* Includes a multi-language capability for international applications

* Easy to validate – requires no special workstation software
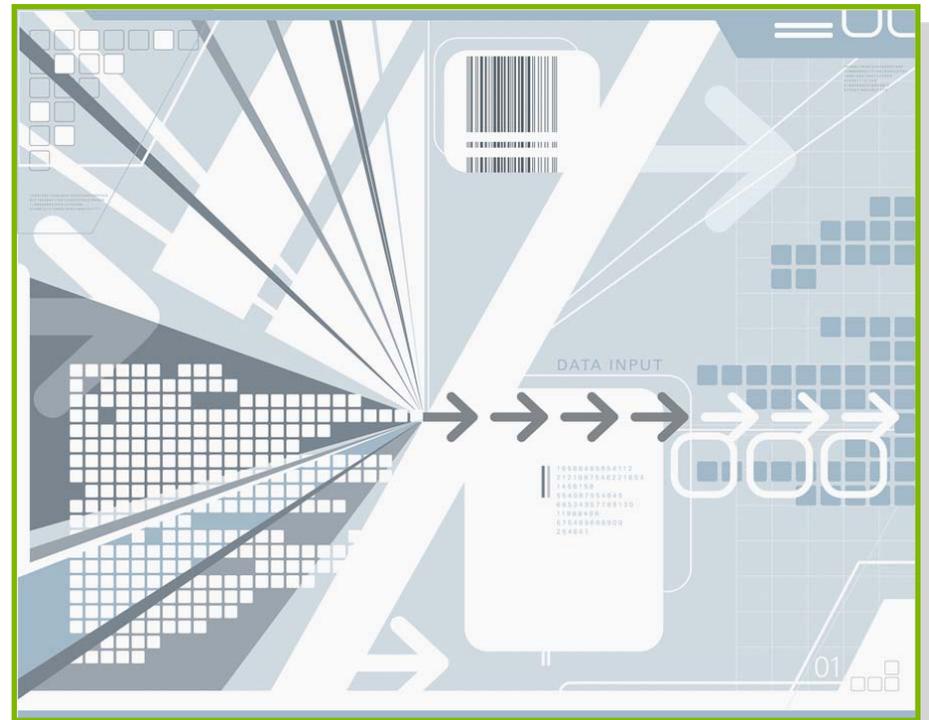
LO1 Tracker
Improve Performance and Results

* LO1 Tracker uses Automatic Identification Data Capture (AIDC), incorporating standard barcode technology and/or RFID, to transform data into critical information you need to **significantly improve performance and results.**

LO1 Tracker
Improve Performance and Results

* With LO1 Tracker, you will gain improved performance and results through:

    * Streamlined Processes

    * Process Surveillance and Control

    * Quality Assurance

    * Regulatory Compliance

LO1 Tracker
Process Insight

* Data is collected throughout a predefined process and managed within a unique centralized information system, LO1 Tracker.

LO1 Tracker
Process Insight

✴ LO1 Tracker knows exactly where each item should be within your process. It knows when an item has missed a step and if an item has deviated to a location where it should not be: helping you to avoid costly mistakes and assure consistent quality.

LO1 Tracker Process Insight

- ✳ Obtain feedback on performance improvement initiatives

- ✳ Determine whether schedules are being met

- ✳ Gain insight to determine what to make, how much, and when

LO1 Tracker
Real-Time Linkages

* Linkages within the LO1 Tracker database provide for raw materials, processing steps, and finished products to be tracked and traced to provide a complete story of the product throughout the process and its life cycle

* Can exchange data with SAP, JDE, and other ERP systems
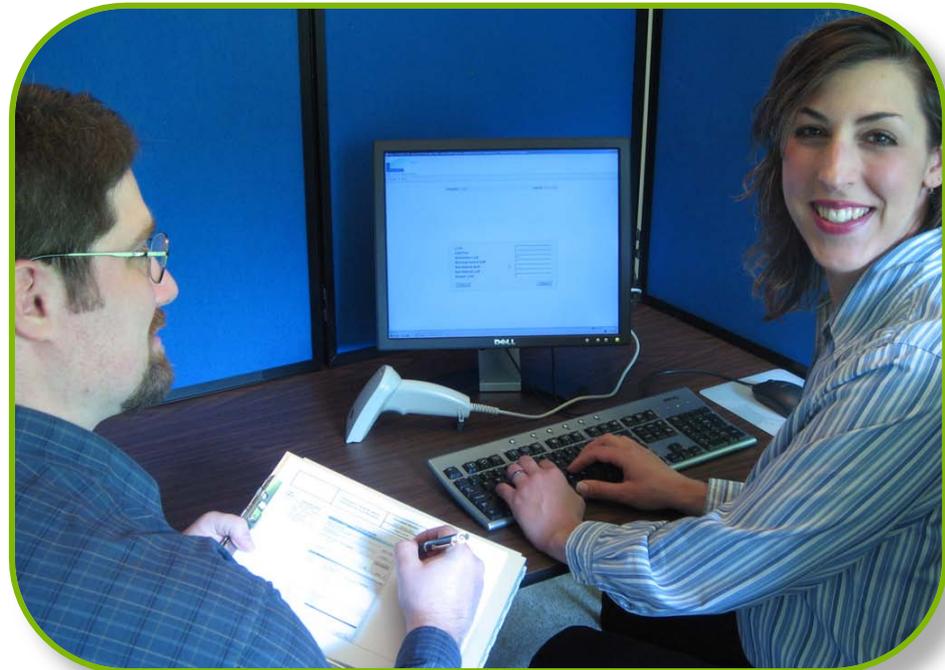
LO1 Tracker
Innovative Scrap Control & Reconciliation

* Unique and innovative scrap control system identifies non-conforming items

* Provides data to identify how a particular scrap item may be reused within the process

* Provides data for material reconciliation

* Enables corrective actions to be made to prevent future quality issues

LO1 Tracker
Regulatory Compliant

* LO1 Tracker meets all security and audit trail requirements.

* Provides for complete traceability (FDA, ISO, and European Commission regulations)
    * 21 CFR Part 820 (QSR)
    * Part 210 & 211 (cGMPs)
    * ISO 13485
    * Part 11 (ER/ES)
    * EC Annex 11
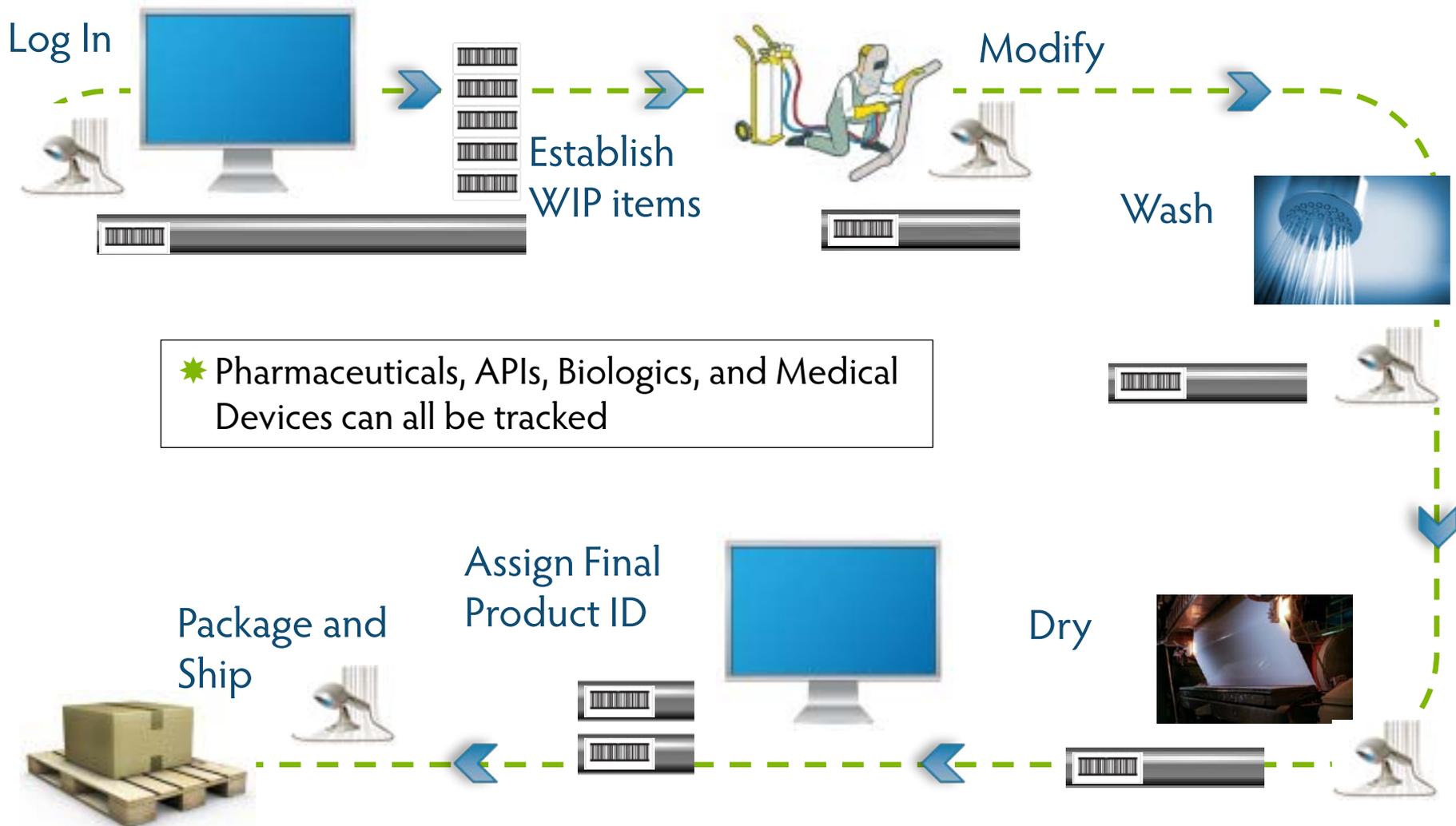   * ISPE GAMP 5

LO1 Tracker
Regulatory Compliant

- Within a regulated environment, LO1 Tracker can track all raw materials to the finished product and ultimately to the customer.

- Validation documentation templates are available for LO1 Tracker.

- Meets pharmaceutical, medical device and biotech U.S., E.U., CHM, and JMHLW requirements

LO1 Tracker Process Control Capabilities

The following walkthrough will illustrate how easy it is to track processes and WIP inventory using LO1 Tracker.

Log In

Establish WIP items

Modify

Wash

* Pharmaceuticals, APIs, Biologics, and Medical Devices can all be tracked

Assign Final Product ID

Package and Ship

Dry

The following illustrates how easy it is to track a pharmaceutical process using LO1 Tracker.

Receiving Warehouse

Dispensing & Mixing

Sieving

Granulation & Milling

Add Excipients

Blending

Final Packaging, Warehousing & Shipping

Packing

Coating

Compression
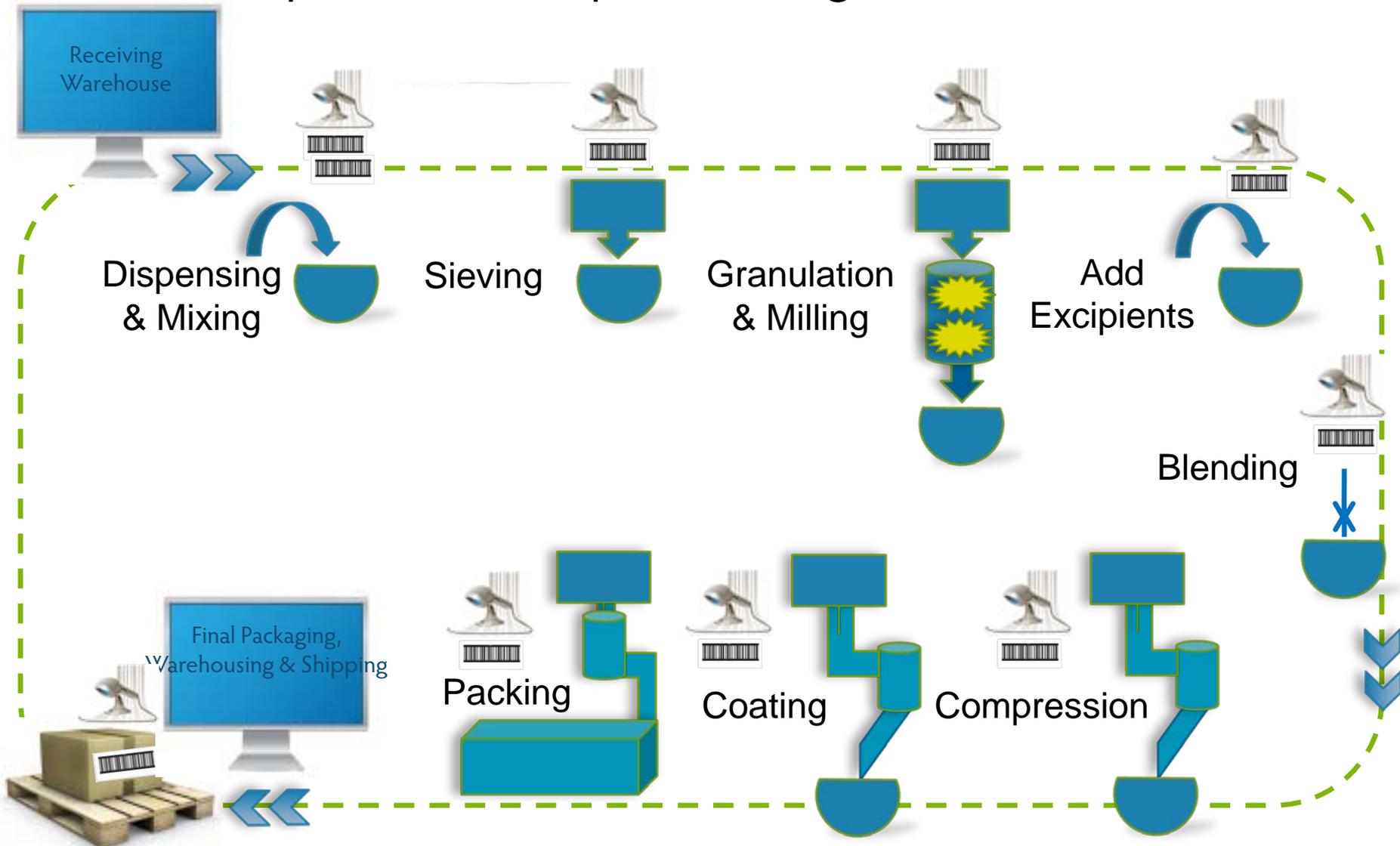
Each workstation has a unique ID and each user has a unique ID.

Log In

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Start	
Userid	UserDemo
Password	••••••••••••
	Login

LO1 version 2.0.2   © 2007 All Rights Reserved   LSSI

The user creates a barcode tag for each work-in-process (WIP) item, lot, and/or step.   In this example, LO1 Tracker assigns the WIP items to a sterilization lot and records the raw material lot information for each item launched into the process.

Scan Raw Material
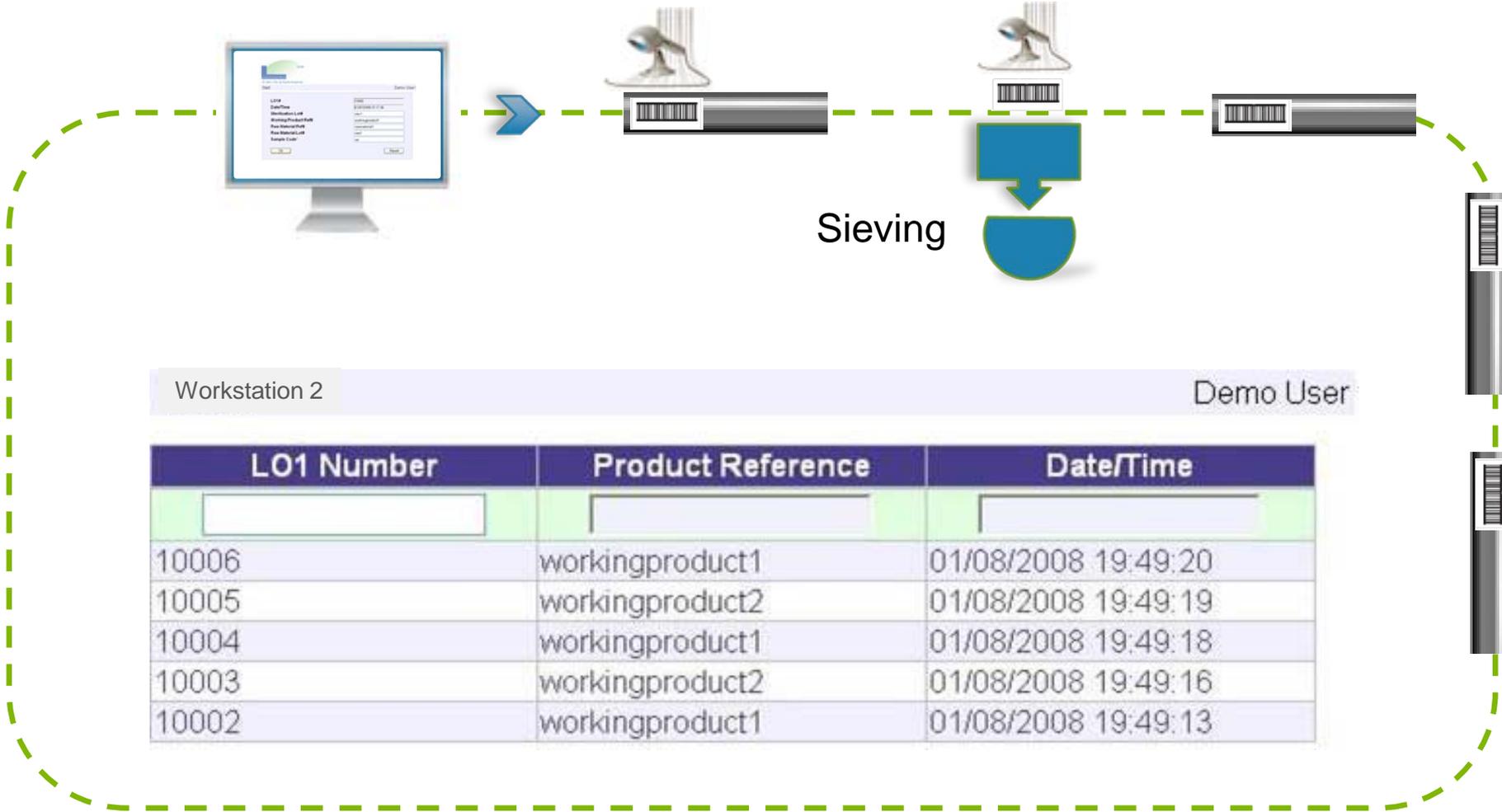
* The WIP items are entered into a predefined process to achieve the desired Final Product.

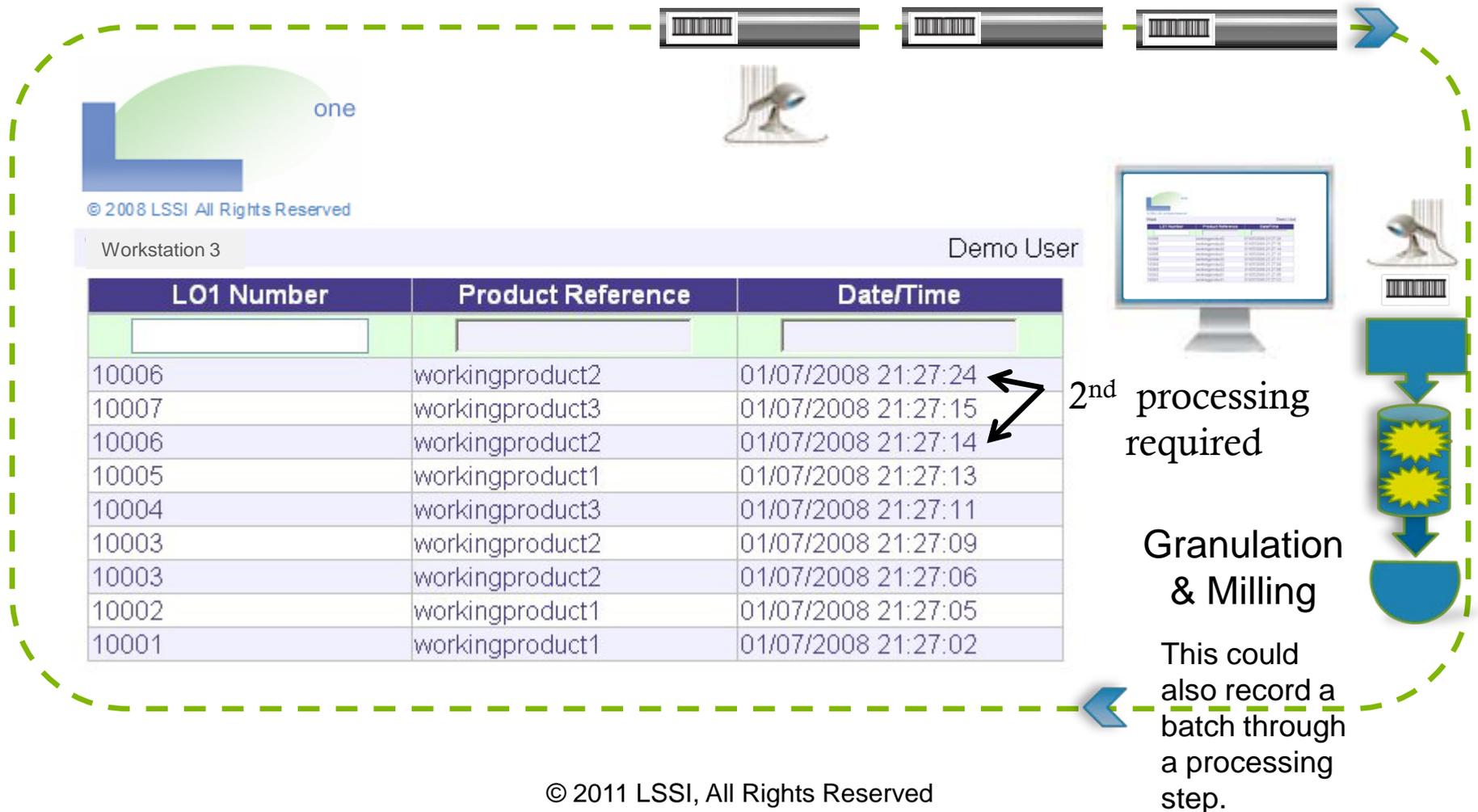| Workstation 1	Demo User
LO1#	10002
Date/Time	01/07/2008 21:17:36
Sterilization Lot#	ster1
Working Product Ref#	workingproduct1
Raw Material Ref#	rawmaterial1
Raw Material Lot#	raw1
Sample Code*	qa

Ok   Reset

Each item entered into the process has a unique barcode that will be captured at each workstation.

Sieving

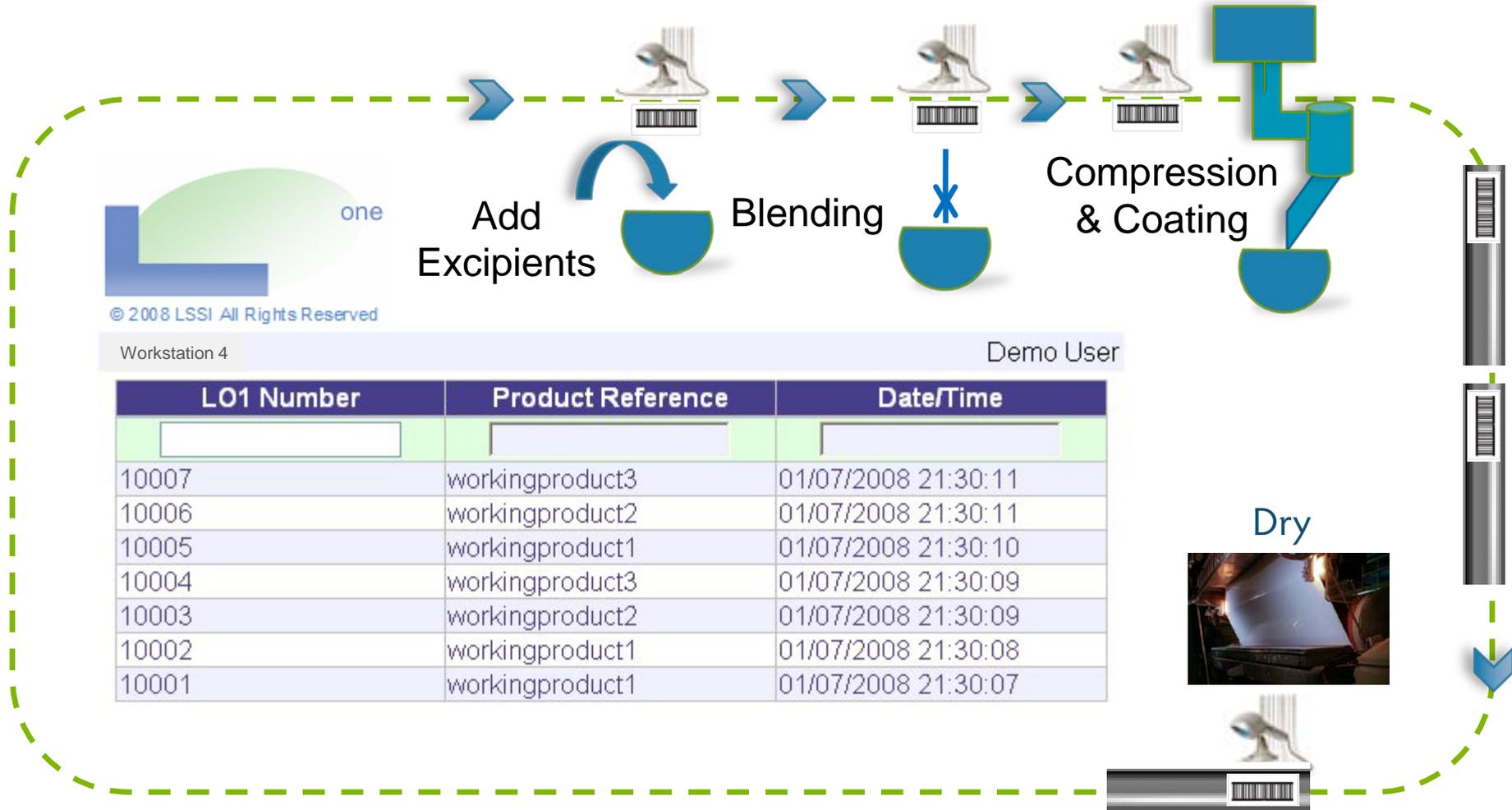| Workstation 2		Demo User
LO1 Number	**Product Reference**	**Date/Time**
10006	workingproduct1	01/08/2008 19:49:20
10005	workingproduct2	01/08/2008 19:49:19
10004	workingproduct1	01/08/2008 19:49:18
10003	workingproduct2	01/08/2008 19:49:16
10002	workingproduct1	01/08/2008 19:49:13

In this example, items are scanned to record that they were processed through a workstation. If a second processing is required, the item is rescanned and then entered back into the process.

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Workstation 3 — Demo User

LO1 Number	Product Reference	Date/Time
10006	workingproduct2	01/07/2008 21:27:24
10007	workingproduct3	01/07/2008 21:27:15
10006	workingproduct2	01/07/2008 21:27:14
10005	workingproduct1	01/07/2008 21:27:13
10004	workingproduct3	01/07/2008 21:27:11
10003	workingproduct2	01/07/2008 21:27:09
10003	workingproduct2	01/07/2008 21:27:06
10002	workingproduct1	01/07/2008 21:27:05
10001	workingproduct1	01/07/2008 21:27:02

2nd processing required

Granulation & Milling

This could also record a batch through a processing step.

… and then on through the next process step.

We configure each process step to meet the client's requirements.

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Add Excipients

Blending

Compression & Coating

Dry

LO1 Number	Product Reference	Date/Time
10007	workingproduct3	01/07/2008 21:30:11
10006	workingproduct2	01/07/2008 21:30:11
10005	workingproduct1	01/07/2008 21:30:10
10004	workingproduct3	01/07/2008 21:30:09
10003	workingproduct2	01/07/2008 21:30:09
10002	workingproduct1	01/07/2008 21:30:08
10001	workingproduct1	01/07/2008 21:30:07

Workstation 4 — Demo User

After a WIP item is scanned at the final quality control checkpoint, the types of Final Products that can be made from that WIP item will be displayed. The Final Product(s) quantity created are entered and any scrap quantity is automatically calculated.

This also works well for pharma processes and assists with reconciliation.

Assign Final Product ID

Finally, the products are ready to be packed and shipped.

Pack		Demo User
LO1 Number	**Product Reference**	**Date/Time**
10015	finalproduct03	01/07/2008 21:44:32
10014	finalproduct03	01/07/2008 21:44:30
10013	finalproduct03	01/07/2008 21:44:28
10012	finalproduct05	01/07/2008 21:44:27
10011	finalproduct03	01/07/2008 21:44:25
10010	finalproduct02	01/07/2008 21:44:23
10017	finalproduct05	01/07/2008 21:44:11
10008	finalproduct01	01/07/2008 21:43:57

Final Packaging,
Storage & Shipping

Packing

How do you measure success?
LO1 Tracker!

✸ Call Life Science Services International to discuss your requirements and how we can provide a solid, proven solution at a price you can afford.

**Life Science Services International
6077 Far Hills Ave #123
Dayton, Ohio 45459-1923
(937) 433-2220 (Dayton Office)
www.lssi-us.com**

Life Science Services International (LSSI)

✳ Incorporated in 1992, LSSI has the experience and proven methodology to provide a wide range of vital services from feasibility studies and requirements analysis to design, development, validation and system deployment to assist our clients in meeting their objectives and assuring regulatory compliance.