

AUGUST 2018 Vol. 4 No. 2

# JOURNAL OF PROPERTY AND ASSET MANAGEMENT

Medical Warehousing: Property Management Process Control Kelly Marchese, Barbara Rosenbaum, and Yvan Caceres Deloitte Consulting LLP

Medical Warehousing: Property Management, Inventory Management, and Material Handling Kelly Marchese, Barbara Rosenbaum, and Yvan Caceres

Deloitte Consulting LLP

A Model of the Property Management Specialist (PMS) in a Multipurpose Company in Russia Julia Sharygina, CPPS

Separation of Duties
Kelly Marchese, Barbara Rosenbaum, and Yvan Caceres
Deloitte Consulting LLP

A Publication of the NPMA, Inc.

# THE NPMA

# JOURNAL OF PROPERTY AND ASSET MANAGEMENT Volume 4, Number 2, August 2018

# **CONTENTS**

INDEXi
National Property Management Association's Executive Boardiii
National Property Management Association's Editorial Review Boardv
Editor's Columnix
ARTICLES:
Medical Warehousing: Property Management Process Control
Medical Warehousing: Property Management, Inventory Management, and Material Handling16
Kelly Marchese, Barbara Rosenbaum, and Yvan Caceres Deloitte Consulting LLP
A Model of the Property Management Specialist (PMS) in a Multipurpose Company in Russia38
Julia Sharygina, CPPS
Separation of Duties46  Kelly Marchese, Barbara Rosenbaum, and Yvan Caceres  Deloitte Consulting LLP

# **National Executive Board**

### **National President** Cinda Brockman, CPPM, CF

**Executive Vice President** Brandon Kriner, CPPM, CF

Sunflower Systems

**Immediate Past President** Marcia Whitson, CPPM, CF

Retired

Vice President of Administration

Kimberly A. Saeger, CPPS Raytheon Missile Systems

Vice President of Certification

Iris Thompson, CPPM, CF Elbit Systems of America

Vice President of Communications &

Marketing

Jessica Dzara, CPPM, CF Sunflower Systems

Vice President of Finance

Gary Quinn, CPPM

UT Southwestern Medical Center

Vice President of Membership

Ivonne Bachar, CPPM, CF **Stanford University** 

Vice President of Parliamentary Procedures

Dr. Douglas Goetz, CPPM, CF

**GP** Consultants LLC

Vice President of Professional Development

Tara Miller, CPPM, CF Witchita Tribal Enterprises

Vice President - Central Region

Ken Black, CPPM, CF

Texas Department of Transportation

Vice President - Eastern Region

Bill Franklin, CPPM

Noblis Inc

Vice President - Western Region

Robert Kaehler, CPPS Sunflower Systems

# Property Professional Editorial Staff

National Editor Billie Jo Perchla, CPPM CF

Managing Editor Meg Lombardo, CPPS

Central Region Editor Ann Foster, CPPA

Eastern Region Editor Toby Bell, CPPM

Western Region Editor Keith Record, CPPM

Editor Emeritus Dr. Douglas N. Goetz, CPPM, CF

### © 2018 NPMA Inc.

National Property Management Association (NPMA) 3525 Piedmont Road Building 5, Suite 300 Atlanta, GA 30305

P: 404-477-5811 F: 404-240-0998



# Editor's Column

### Ladies and Gentlemen:

Welcome to this edition of the NPMA Journal of Property and Asset Management, which I would like to refer to as the JPAM. Since acronyms run rampant in our profession – it sounded like a good idea!

This issue of the JPAM presents to our profession four wonderful articles. The authors in this edition are:

Kelly Marchese

Barbara Rosenbaum and

Yvan Caceres who have submitted THREE collaboratively authored articles. And, Julia Sharygina, CPPS – and this is a first -- Julia is one of our members in Russia!!!

This is the second set of contributions by three authors of our NPMA family -- Kelly Marchese, Barbara Rosenbaum and Yvan Caceres. Their focus – the Medical Warehousing environment. Once again, a new topic for many of us, but they have provided some very rich and detailed information regarding their chosen field. Their articles deal with:

Medical Warehousing: Property Management Process Control

Medical Warehousing: Property Management, Inventory Management, and Material Handling And

Separation of Duties.

These are detailed articles, well referenced and heavy with citations – everything a Journal could ask for!

Julia Sharygina provides us a comparative analysis of the organization of property and asset management related work in Russia versus our more common application – work here in the United States. And it is an eye-opening presentation as to the major similarities and a few key differences between her property environment in Russia and ours in the United States. And again -- well referenced and heavy with citations – everything a Journal could ask for!

My congratulations to the authors and to the NPMA as the JPAM continues to grow in depth and breadth. BRAVO to all! Ladies and Gentlemen, you have in front of you Volume 4, Issue 2 of the Journal of Property and Asset Management. I encourage you to read deeply!

Dr. Douglas N. Goetz, CPPM, CF

Editor, The Journal of Property and Asset Management (JPAM)

# Medical Warehousing: Property Management Process Control

Kelly Marchese Barbara Rosenbaum Yvan Caceres Deloitte Consulting LLP

# Introduction

Across the warehousing and distribution industry, process control policies seek to effectively incorporate standard operating procedures and supply chain leading practices. These policies drive adherence to quality standards and safe practices for personnel and assets. Appropriate application of procedure and practice lies in the consistency in implementation of key process control components, a focal point of performance in medical warehousing. This publication will examine these practices, including procedural regulatory compliance, continuous assessment of standard operating procedures, goods issues and receipts, internal goods movement, separation of duties, roles and responsibilities, process oversight, property management, inventory management, and material handling.

# **Property Management**

### **Process Control Overview**

Process control is a methodology for maintaining the uniformity of an output each time the process is repeated. It is especially important to have established process control in a medical warehouse so that critical medical supplies and equipment are appropriately received, secured, managed, moved, and issued accurately and in a timeframe appropriate for that supply.

Process control is applied continuously in parallel with process management. It starts with defining the process and setting standards against which the output will be measured. Documents such as standard operating procedures, process maps, measurement techniques, etc. must be developed to provide users with a step by step approach to successfully complete a process. Once the user follows the defined logical sequence of steps and executes the process, performance of the process is measured and controlled by comparing actual output against the pre-set standards. If a deviation from the standard is detected, then a corrective action must take place to identify the root cause and rectify the issue. Regardless of the outcome of performance measurement, a process should continually be improved to eliminate any potential problems before they are realized.

### **Define Standards for Process Control**

Standards for process control are the baseline objectives that set the criteria for measuring performance. For medical warehouse processes, standards can be adapted from widely accepted industry norms such as International Organization for Standardization (ISO) standards, government regulations or specific measures identified by organizations for their applications. Once the criteria for acceptable performance is identified, medical warehouse managers can monitor processes against standards and identify potential problems early in the process. Potential problems such as inventory inaccuracy, physical security of controlled substances, poor facility layout, and expired medical supplies can be identified using process control methodologies such as statistical process control, control charts, check sheets and automated technologies such as warehouse management systems, barcoding and radio frequency identification devices (RFID) scanning systems.

### **Control of Records and Documents**

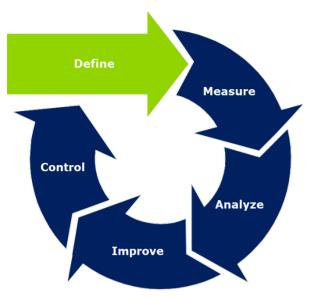
Medical warehouse processes such as goods receipt, internal movement, goods issue need to be documented to provide a logical sequence of steps for warehouse staff to follow and deliver a uniform repeatable output. Process control documents include policies, standard operating procedures, process flow diagrams and process records such as log books, measurements, training records, etc. In addition, organizations must establish document and record control processes to help users follow the most current standards, information is frequently reviewed and updated, changes to documents are controlled and access is provided to all appropriate personnel.

### Monitor/Measure/Audit

Performance measurement involves taking actual sets of data at certain control points of a process and comparing them to predetermined criterion. The measurement units must be clear, well-defined, and easily identifiable to remove any subjective interpretation from the analysis. Once actual data is compared to pre-set standards, any deviations and their causes must be determined. It is also important to frequently audit processes to help ensure defined procedures are followed and processes are effective. Such audits can help identify process weaknesses and areas for improvement. Key measures for medical warehouses include, but are not limited to: inventory accuracy rate, percentage of expired medical supplies, number of security and safety incidents, order processing time, adequate shelf life, stock-out rates, and warehouse accident rate.

### **Continual Improvement/ Corrective Action**

If a process produces outputs outside its set boundaries or non-conformities are detected, then corrective actions should be taken to fix the current problem and eliminate the root cause of the issue to prevent reoccurrence. In addition, preventive actions, which proactively identify potential issues and help to ensure that they don't materialize, should be employed during medical warehouse processes. Such actions help continually improve the processes and achieve more efficient, effective process flows which can deliver uniform outputs.



An example of process control techniques is applying the Lean Six Sigma (LSS) methodology, which emphasizes the creation of reliable processes that meet quality standards. LSS combines a focus on process simplicity and product improvement to identify root causes of issues and develop solutions. Implementing LSS at a medical warehouse requires focus on customer needs, proactive thinking, data driven decision making and continuous monitoring of process performance. LSS utilizes an improvement cycle called the DMAIC methodology (Define, Measure, Analyze, Improve and Control), which is illustrated in

Figure 1

Figure 1 for reference and is further described below. DMAIC is a structured, disciplined, rigorous, five-phased approach for improving existing business processes and is inspired by Edwards Deming's Plan-Do-Check-Act (PDCA) Cycle.

### **Define**

In the Define phase, the goal of the process or project is identified, the scope is determined, a project charter is created and key activities are documented. In addition, stakeholder identification and interviews are conducted to gather data and determine key focus areas. Some of the tools and techniques used in this phase include: Supplier-Input-Process-Output-Customers (SIPOC), Voice of Customer (VOC), Critical to Quality (CTQ), Tree Diagrams, Arrow Diagrams, and Stakeholder Analysis.

### Measure

In this phase current performance of the process is measured through data collection, high-level process maps, value stream mapping and Value Add/Non Value Add (VA/NVA) analysis. Customer needs and requirements are also identified during the Measure phase. Hypotheses are built and tested using various statistical analysis tools determined by experts. During this phase, processes could be measured with Deloitte Consulting's proprietary Value Stream Analysis tool, which analyzes actual process performance and illuminates where Non Value Added work occurs.

### **Analyze**

Each key finding from the Measure phase is analyzed using root-cause analysis methods such as "5 Why's" and affinity mapping diagrams. Brainstorming sessions with stakeholders during this phase help develop improvement ideas and solutions. The main purpose of the analyze phase is

to identify the root cause of a problem within a medical warehouse so the corrective actions employed will prevent reoccurrence.

### **Improve**

Solutions to eliminate root causes identified in Analyze phase are further developed, piloted and implemented during the Improve phase. High level business cases and conceptual plans are produced to prioritize improvement initiatives. After prioritization, selected solutions are further refined with detailed implementation roadmaps as well as change and communication plans. In some cases, solutions might be piloted to test and refine processes on a smaller scale before full implementation takes place. These solutions could be as simple as implementing a manual solution like a check sheet or as sophisticated as employing a warehouse management system or a RFID scanning system to increase inventory accuracy, picking accuracy, or to reduce order processing time or the number of expired medical supplies within a medical warehouse.

### **Control**

In this phase, solution is fully implemented and process performance is monitored using a variety of tools such as statistical process control (SPC), control charts, check sheets, key performance indicators (KPI) management tool, etc. For instance, SPC methodology has been applied to control performance of warehouse processes such as service delivery time at a study conducted by City of Houston, TX (Lightfoot et al, 2003). Monitoring process performance allows the medical warehouse to evaluate the benefits realized from the solutions and maintain a consistent process and output quality at a level acceptable to the customer. It is critical to employ change management techniques and training to help transition to the new process.

### **Regulations and Standards**

As mentioned earlier, medical warehouses must comply with laws and regulations that come from all levels of government: federal, state and local. To achieve regulatory compliance and produce consistent, reliable and high quality outputs, medical warehouses should also implement process control methodologies that satisfy industry standards such as ISO. These standards not only help ensure uniform outputs but also allow warehouse management to reduce cost, improve productivity and increase competitiveness in the market place. Based on warehouse specifications, medical supplies stored, physical locations and other factors, different regulations and requirements might apply to a specific medical warehouse. Examples of the governing bodies and widely accepted industry standards are provided below.

Regulatory bodies and regulation examples:

- Food and Drug Administration (FDA)
- World Health Organization (WHO)
- United States Agency for International Development (USAID)
- Health and Human Services (HHS)
- General Services Administration (GSA)

- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA)
- State and Local Government Regulations
- Control Substances Act

Industry-standards and certification examples:

- ISO 9001 Quality Management Systems: This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits<sup>i</sup>.
- ISO 55000 Asset Management Systems: This standard provides an overview of asset management and asset management systems. It enables an organization to achieve its objectives through the effective and efficient management of its assets. The application of an asset management system provides assurance that those objectives can be achieved consistently and sustainably over time.<sup>ii</sup>
- APICS Certifications: An evaluation against a predetermined set of industry standards for knowledge, skills or competencies for production and inventory control, supply chain management and logistics, transportation and distribution management.<sup>iii</sup> Medical warehouses would benefit from personnel who are trained professionally and knowledgeable about industry standards and regulations.

The Process Control framework has been summarized in Figure 2 below, including quality planning, assurance and control phases as well as continuous surveillance, feedback and improvements throughout the process control lifecycle.

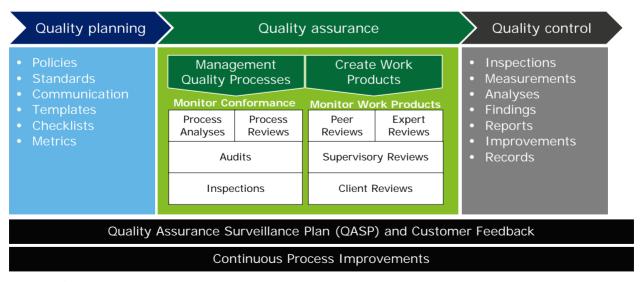


Figure 2<sup>iv</sup>

# **Goods Issue and Receipt**

Process control within operations of a medical warehouse would begin at the point of goods receipt. A process of issuing purchase orders, receiving goods and verifying conformance should be documented and controlled by a receiving plan. The medical warehouse manager should help ensure the supplier brings products to the warehouse in the most appropriate way for the buyer to minimize touches in the warehouse. Medical warehouse management should work with the supplier to agree upon all aspects of the deliveries including packaging, items per carton, cartons per pallet, cases per layer, layers per pallet, labeling requirements, and modes of transportation. Identifying and resolving these issues prior to receipt of goods can minimize complications in the warehouse and during the put-away process. Inspection of goods is critical upon receipt to verify the medical equipment and materials are in acceptable condition per specifications, indicate an expected life and are ready to store. If there are large quantities of items, performing a sample inspection of the lot could indicate the quality of the shipment.

### **Receiving**

### **Inspection Processes**

Ideally goods can be moved directly from the dock to the storage or dispatch areas. Unfortunately, the goods expected are not always what is actually delivered by the supplier—the implementation of an inspection process helps catch these errors before the shipment is accepted and sent to the buyer. The type, quantity, content, proper packaging and storage, expiration date, and damage are all useful attributes to review during the check process at a medical warehouse.

A key inspection process often times requires an onsite laboratory to test the quality of material received. For example, pharmaceuticals and synthetic products must be tested by a laboratory. Typically, samples are taken and tested, the shipment is put in a "quarantine" status until the testing is completed. This adds time to the product cycle; however, it is an important step that it is at times required by legislation. This time may be increased when the laboratory is located offsite and samples have to be sent to be tested.

Typically, spot checks are conducted using either a delivery note count or a blind count. In a delivery note count, an operator uses the delivery notes of expected quantities to check if the proper products and quantities have been received. A blind count is when operators are not made aware of quantities expected until after the count has been completed. The counted quantity is then cross checked against the paperwork to determine if the whole load was received. Blind checks tend to take longer, but usually result in more accurate counts of batch numbers and recording of expiration dates for comparison against delivery paperwork.

The frequency of checks should depend upon the warehouse manager's certainty that suppliers are 100% accurate in their deliveries. For new suppliers or suppliers with historically poor performance, it may be best to conduct whole consignment checks until the supplier establishes a reputation or shows sustained performance improvement. Afterwards, the frequency and thoroughness can be determined at the manager's discretion based on the supplier's continued performance. Measuring supplier performance may assist a manager in scheduling inbound product checks—the rate of checking can be directly linked to supplier's accuracy rates. Random

checks of certain product lines may be more efficient than checking every order from a supplier with solid performance.

### **Goods Pre-receipt**

Good Faith Receiving is another potential practice in which products are accepted into the warehouse without on arrival check. Random checks are undertaken and if discrepancies are found, the supplier is charged on a pro rata basis. This potentially minimizes time drivers spend waiting to continue with deliveries and puts the onus on the supplier to increase shipment accuracy. Generally, following up with a full load inspection in instances when a spot checked shipment contains discrepancies is a leading practice. Regardless of inspection methodology used, all checks should be conducted as quickly and efficiently as possible to prevent dock congestion. When establishing warehouse layout, a clearly marked, dedicated area on the warehouse dock should be reserved for inspection processes. This space should be clearly fenced off or isolated by some effective means to ensure product is not picked and put away before the planned QA review is complete. It is worth noting that less than full inspection on receipt can increase the risk of stock outs when picking for delivery, and of incorrect stock being stored in boxes.

### **Security/Safety Steps**

Access to both the dock and the QA area should be restricted only to authorized staff to help secure goods and deter theft. Depending upon the products received, further subdivision of this space may be required to temporarily house hazardous materials requiring quarantine. Clear signage distinguishing the quarantine area will help prevent co-mingling. An on-site lab/testing facility may accelerate the QA process, depending upon product types received. Some of the leading practices include the following:

- Employ the use of closed-circuit television at strategic points throughout the warehouse.
- Unannounced inspections and walkabouts provide another effective, cheaper option.
- IT/Data Security: Develop and maintain proper security measures for all IT systems used to streamline warehousing process (i.e. WMS, ERP, EDI).
- Backup data daily to offsite storage.
- Protect servers, computers and laptops to prevent data from being stolen or copied by securing hardware with a lock or electronic access code.
- Appropriate record keeping for all products w/ accurate audit trails.
- Ensure authorization is provided for all dispatches.
- Stock checks<sup>vi</sup>

### **Pick and Pack**

### Record Keeping, Scanning and Warehouse Management Systems

Thorough record keeping is essential to medical warehouse management as it enables each individual product to be tracked from its time of entry to its departure from the facility. This detailed information about each item provides accountability for defects, assists in resolving issues and informs intelligent decision making about warehouse processes.

Traditionally, record keeping starts with goods receipt. Upon product drop off the supplier should be required to provide necessary paperwork (i.e. Bill of Lading) along with the product.

Included in this paperwork should be specifics around agreed upon quantity, packaging, etc. which can be compared to and validated against an operator's expectations prior to accepting the goods. For medical products, included in this information should be details such as special temperature storage requirements or hazard warnings.

While traditionally record keeping has been a paper-based process, taking advantage of technology and storage equipment can help improve warehouse identification and management of internal goods movement. These tools work together to track and trace the movement of materials throughout the warehouse. For example, rather than providing a bill of lading, a supplier can be asked to provide an Advanced Shipping Notice (ASN) via an Electronic Data Interchange (EDI). This ASN streamlines warehouse processes by providing more accurate information around truck arrivals, their contents, and other required paperwork. These ASNs can be linked into a Warehouse Management System (WMS) to help accurately and efficiently track, put away, store and pick a warehouse's entire stock.

Barcodes and RFIDs provide a unique identifier that when scanned, pinpoints activity which can be used to indicate each movement location of inventory, equipment, and any relevant commodity. A WMS can allocate product locations in advance and inform operators where to place goods. This requires reliable access to information such as size, weight and height, whether a First-Expiration-First-Out (FEFO) or First-In-First-Out (FIFO) process is used, goods combinations, size of warehouse, weight capacity or racking, etc. Without a system, the manager should identify the best location for goods by assigning fixed positions.

### **RFID and Barcode Scanning**

Barcode scanning can be used to speed up this process significantly and improve accuracy. Bar code scanners allow actual and expected details to be compared in real time to determine discrepancies. This allows for goods to be quickly entered into the warehousing system. Barcoding introduces a complication in that there is no conformity between companies and countries in bar code creation and tracking, making it difficult to transfer products between them. Currently there is debate in pharma industry between 2D barcoding technology and RFID. vii

Handheld barcode scanning can also increase productivity by helping to ensure operators do not need to return to the office for additional instructions after each task—subsequent steps are included on the screen. Drawbacks may include difficulty in performing tasks while holding reader. When scanners are put down or holstered, they can miscount items. Scanners are easily damaged and can pose a safety risk. Recent advances include hands-free, wearable scanners which allow users to handle items with two hands. Potential benefits of these hands-free scanners is that they are easy to integrate while requiring little re-training and no software modifications. They can increase productivity and accuracy by removing the drawbacks of the handheld scanner.

Stationary scanners will read a barcode as it passes a point, but it requires easily visible, intact and in a uniform position on the item. One of the largest drawbacks to barcodes is their potential to be damaged, resulting in difficulty or inaccurate reading. New technologies are incorporating scanners with warehouse maps to show operators where in the warehouse to place an item.

Creators of these items claim they can reduce the put away and picking processes by up to 30 seconds per item.

RFID scanning allows simultaneous reading of multiple items, making it substantially faster than barcodes which must be read one by one. RFIDs can also further reduce inspection time. Products with RFID tags can be immediately identified and counted on entry into the warehouse. It is also possible to pass this information to a WMS in real time. RFIDs are used by 70% of the best-in-class companies over paper documentation. VIII

Currently, it is costly to use RFIDs for individual item level tracking—however RFIDs are used cost effectively for unit-load identification. RFIDs are commonly used to tracking of roll cages, pallets and returnable packaging, simplifying the tracking process and making it more cost effective. One major downside is their high cost compared to bar codes. However, as RFIDs are more widely adopted it is anticipated their costs will decrease dramatically. Other disadvantages include reading issues when in close proximity to liquids and metal, dead areas in warehouses, damage caused by liquids and electric surges, and intermittent data capture. ix

### **Picking and Storage**

Internal goods movement procedures are governed by a clear and recognizable structure to warehouse flow and assignment of spaces. Particularly when considering the control of goods once they are issued, the organizational approach to warehouse identification ties directly to the quality of properly dispensing and controlling inventory. Figure 3 below demonstrates the improvements stemming from standardized and organized picking procedures. For consumables, storing materials in a safe, and efficient manner will help protect the integrity of the goods from receipt to distribution. Proper storage equipment also plays a part in helping warehousing materials maintain their quality and integrity while stored in the warehouse.

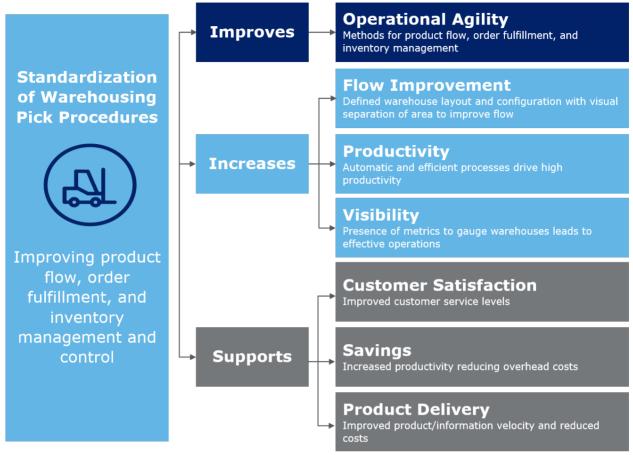


Figure 3

### Floor Space

*Benefits and Uses*: Faster moving product, product that is heavier and requires lifts to store, products that require quick access or frequent evaluation, fire hazardous material.

Warehousing floors space is a constraint to manage when considering how product will be stored and moved on a daily bases. Many times, floor space comes at a premium when considering warehouse flow. Utilizing vertical storage capability is a good practice to maintain open floor space and efficient movement.

Storing materials on racking is one method that can help with maximizing vertical storage opportunity. Another option is building a mezzanine for materials that may not need to be issued with other medical equipment, such as maintenance parts or other nonmedical commodities.

### **Shelving and Racking**

Benefits and Uses: Volume with variable turn over designated by shelf space

Quarantine space and special accommodations for high value goods must be considered in the storing process. Fastest moving items should be placed in the middle row of shelving so the picker does not need to bend or reach. Slower moving items occupy high and low shelves. Group items by similarity so items often on the same pick list are located side by side.

### Mezzanine

Benefits and Uses: Slow moving product, lighter weight products, products that require segregation from other products, products requiring access restriction

### More efficient use of storage space

Keeping a clean and orderly warehouse also helps to ensure health and safety of workers by removing any clutter or debris that might pose a hazards when moving through the plant. Lean warehouses in both layout and process, can help improve efficiency and minimize cost by reducing labor cost, leveraging asset turnover, and reducing non-value added cycle time. Other lean practices such as Value Stream Mapping help identify value added activities through building detailed process flows of the warehousing operation. This close look identifies opportunity to decrease cost and improve efficiency. Containerizing and palletizing materials in conjunction with leveraging warehousing equipment protects the packaging and standardizes the storage space used in the warehouse both on the floor and with racking. Using standardized containerization and palletizing also improves the ability to transport materials from floors, to racks, to issue.

### **Pallets and Storage Equipment**

The optimal type of storage equipment depends on volume requirements. As a rule of thumb, the more densely pallets need to be stored, the less access and more time it will take to deposit or retrieve pallets. Common racking configurations include: wide aisle adjustable pallet racking, double deep pallet racking, narrow aisle racking, very narrow aisle racking.

### **Racking**

- Mobile racking—upright frames with horizontal beams to provide pallet storage levels
- Cantilever racking—racking is mounted on rails which are movable and can be power or manually operated
- Live storage racking—stationary racking with rear load/front pick which if loaded correctly ensures first in first out picking of material
- Push-back system—stationary racking that allows front load/front pick of materials where
  each new material is loaded in front of the older material and pushed back on racks; this
  ensures last in first out picking of material<sup>x</sup>

Other common warehouse storage equipment

• Mobile conveyors, roller conveyors, platform trucks, scissor lifts, caging

### **Palletizing**

Palletizing products helps protect packages from loss or damage during the handling and transport process, and can reduce the number of resources required to load/unload containers. Loading/unloading is sped up and less space is required on the dock. The downsides of pallets is the reduction of space utilization because the pallets themselves will take up a portion of the truck. This is further exacerbated if the pallets cannot be stacked. It is possible to reduce this space utilization impact by using slip sheets in place of pallets. Slip sheets do, however, require a special forklift attachment. Increasing legislation around wooden pallets are making slip sheets a more attractive option. Compared to pallets, they increase available load space, reduce unloading

time and are easier to clean. Regardless of pallet type used, costs will increase by 15%-33%. xi If expecting multiple product lines, the warehouse should work with the supplier to determine how the various product lines will be configured within the container. This can help speed up the unloading process.

Loose loaded products should be palletized prior to put away in racking. Product should be palletized so there is no overhang and no potential for damaging the product while still maximizing the use of the cubic feet of the pallet space. COTS software can be used to assist in load building where cartons are oddly shaped. This helps keep pallets clean and reduces potential damage to products. XIII

### **Safety and Training**

Managing and operating a medical warehouse requires skilled personnel from goods receipt to issue. The processes for training and assessing personnel, as well as assuring awareness and practice of standard operating procedures will help to maintain control of processes. Special Training is required for any persons designated to operate warehouse equipment, and specific training may be needed for safety and operational familiarization of lift truck equipment (pickers, truck lifts, elevating operators, forklifts, hand trucks, etc.). XIIII

Designate areas for material flow and pedestrians walking through the warehouse to help ensure pedestrian/vehicle segregation. Load/unload areas are not generally safe for high pedestrian activity. Restrict and identify areas where pedestrian movement is permitted and those employees who should or should not move throughout the warehouse floor. Take a look at the type of facility and determine whether it is more efficient to have manual trucks to pick and move volume based on aisle width, product movement frequency and dimensions or weight characteristics needed to pick. Make sure any vehicles that move throughout the facility can pass through the lanes and can turn or pass another vehicle.

Producing signage with clear directions of where warehousing material should go is necessary to help direct the warehousing equipment drivers during operation. It is also important to include signs that indicate when anyone traveling (vehicle/pedestrian) should stop, which directions turns are permitted, and which locations are restricted. Reducing the need to reverse is also safest; provide a warehouse design with one way traffic flow to prevent the need to reverse. Overhead mirrors can improve flow and help to provide a line of sight that is not directly visible of oncoming warehouse traffic. xiv

Lift trucks should not be used in locations where flammables are present to prevent any flammable material from being fed into the engine air intake and potentially catching fire. Common types include:

- Pickers
- Truck lifts
- Elevating Operators
- Forklifts

In addition to creating a safe work environment, effective training increases productivity of an operation by reducing bottlenecks and engaging and growing warehouse personnel within their

oles. With pharma and medical products, OSHA role-specific training will also be required on vork-place hazard. xv

# **Points of Contact**

Kelly Marchese
DC Principal
Deloitte Consulting LLP
Federal Supply Chain Service Line Lead

kmarchese@deloitte.com

Kelly is a principal with Deloitte Consulting LLP and leader of the Federal Supply Chain practice. She has over 20 years of experience leading projects in highly engineered manufacturing industry sectors, specifically Aerospace and Defense. Kelly also leads the Global Supply Chain Risk service offering and is a thought leader in Product Development and Engineering Effectiveness through Manufacturing Operations Excellence. She had helped clients navigate through complex transformations, including helping a federal agency develop a multibillion dollar global business case to streamline their aviation supply and maintenance processes and advising a life sciences company through a full lifecycle of divestiture, acquisitions and IPO.

### Barbara Rosenbaum

Consulting Managing Director Logistics and Distribution Offering Lead Deloitte Consulting LLP brosenbaum@deloitte.com

Barbara is a managing director in the Deloitte Federal Strategy and Operations Practice focused on Supply Chain. She leads the Logistics and Distribution service offering within the Federal Supply Chain service line, building upon over 30 years of experience leading federal and commercial projects across all areas of the supply chain. She currently works across federal clients with a particular focus in National Security and has market eminence as a thought leader in supply chain transformation, planning and inventory optimization.

### **Yvan Caceres**

DC Specialist Leader Logistics and Distribution Subject Matter Expert Deloitte Consulting LLP ycaceres@deloitte.com

Yvan is a Specialist Leader with Deloitte's Public Services Organization with over 20 years of xviexperience in the areas of Transportation, Logistics, Distribution Network Planning, 3PL Operations, and advanced planning functions. He has extensive experience in systems integration, requirements development, systems architecture, and implementation lifecycle, having managed Supply Chain implementations in the consumer packaged goods, industrial and automotive, high technology, retail industries as well as major programs in the DoD. Yvan has extensive knowledge of commercial supply chain technologies such as APS, Inventory Management, Supply Planning, Transportation, and Simulation Modeling.

# $\frac{https://deloitte.et.deloitte.com/PC/PracticeComm/Industries/HSG/Federal/Capture/Pages/Buildingblocks.aspx$

- vv Richards, Gwynne. 2014. Warehouse Management: A Complete Guide to Improving Efficiency and Minimizing Costs in the Modern Warehouse, 2nd edition.
  vi Ibid
- vii Richards, Gwynne. 2014. Warehouse Management: A Complete Guide to Improving Efficiency and Minimizing Costs in the Modern Warehouse, 2nd edition.
- viii Richards, Gwynne. 2014. Warehouse Management: A Complete Guide to Improving Efficiency and Minimizing Costs in the Modern Warehouse, 2nd edition. ix Ibid.
- <sup>x</sup> Health and Safety Executive. 2007. Warehousing and Storage, a guide to health and safety. UK: Crown.
- xi Richards, Gwynne. 2014. Warehouse Management: A Complete Guide to Improving Efficiency and Minimizing Costs in the Modern Warehouse, 2nd edition.
- xii Richards, Gwynne. 2014. Warehouse Management: A Complete Guide to Improving Efficiency and Minimizing Costs in the Modern Warehouse, 2nd edition.
- xiii Health and Safety Executive. 2007. Warehousing and Storage, a guide to health and safety. UK: Crown.

xiv Ibid.

xv Ibid.

XV

<sup>&</sup>lt;sup>1</sup> http://www.iso.org/iso/home/standards/management-standards/iso\_9000.htm

ii https://www.iso.org/obp/ui/#iso:std:iso:55000:ed-1:v2:en

iii http://www.apics.org/careers-education-professional-development/certification/certification

# Medical Warehousing: Property Management, Inventory Management, and Material Handling

Kelly Marchese Barbara Rosenbaum Yvan Caceres Deloitte Consulting LLP

## Introduction

In recent years, the demand for medical devices and supplies, as well as pharmaceutical products, has risen dramatically. In the United States alone, the population of senior-aged citizens, those 65+ years old, has increased by 29% since the year 2000; in comparison, the overall population has only grown by 12%. As this portion of the population increases which is a primary consumer of medical supplies, so too does the need for readily-available medical inventories. Looking at pharmaceuticals, recent studies estimate the use of prescription drugs among adult-age Americans has reached a staggering 60%, with 15% of those surveyed using five or more maintenance medications concurrently. Such widespread use of pharmaceuticals and aging populations not only drives significant medical-product demand, but has many implications across the public and private sectors, influencing everything from government regulation, to supply chain and manufacturing methods, to internal pharmacy operations. By considering key impact areas when selecting warehousing locations and designing distribution networks, medical logistics providers can make great strides in assuring consistent, high quality, and cost-effective business delivery models.

# **Property Management**

When selecting a site and standing up a new location, medical logistics providers face formidable challenges, in the form of an extremely competitive commercial real estate market and increasing regulatory oversight. To better position themselves for future success, certain considerations must be incorporated into the location, infrastructure, and systems design processes.

### **Regulations & Real Estate**

Unlike many other consumer-based industries, the potential threat posed to the public by inconsistent medical and pharmaceutical manufacturing, distribution, and delivery can be fatal. As a result, the medical logistics industry continues to be impacted by increasingly stringent, state and federal regulatory guidance—and in particular the pharmaceutical sector. As providers look to optimize their distribution networks and consider new warehouse locations, they should carefully consider the requirements outlined in these guidelines. The facility design, upkeep, and the operational resources required to meet regulatory standards can all significantly impact

overall logistics costs. Through the careful consideration of both regulatory policies and commercial real estate trends, manufacturers and distributors can greatly improve their strategic outlook.

Federal efforts to regulate and secure the pharmaceutical supply chain began in the 1930s, with the Food, Drug, and Cosmetic Act (FDCA)—focusing on approval and production of medications. In the late 1980s further regulation surrounding the distribution and handling of prescription medications began to take shape—aimed at guiding modern medical logistics practices. However, as a result of legal challenges the enactment of these policies did not occur until after 2000. This delay in federal action led to many states enacting their own regulatory requirements. In particular, California enacted strict regulations regarding traceability of prescription medications (both production and distribution). In many cases, this state-level regulation is now being overruled by federal policy, the most notable of these policies is the Drug Quality and Safety Act (DQSA), which went into effect in 2013.

As a result of certain provisions contained in the DQSA, specifically within Title II, medical logistics providers are required to provide or possess the following abilities within ten years of enactment (descriptions quoted directly from FDA publication):

- **Product identification**: Manufacturers and re-packagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing**: Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification**: Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response**: Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification**: Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- Wholesaler licensing: Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- Third-party logistics provider licensing: Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

Provisions were included in the DQSA with specific timeframes for implementation, after which point providers should be prepared for regulatory audit and potential punishment for non-

compliance. See Figure 1 for a detailed look at this timeline. Certain deadlines have already passed and other requirements are on the verge of going into effect.

	DQSA—Implementation Timeline		
January 1, 2015	Manufacturers, wholesalers, and repackagers required to provide and/or receive pedigree for each transaction		
4 Years Post Enactment	Manufacturers required to include a product identifier number on each package and homogenous case of prescription drug products		
6 Years Post Enactment	Wholesalers required to accept or distribute only prescription drug products that include a product identifier		
7 Years Post Enactment	Dispensers required to accept or distribute only prescription drug products that include a product identifier		
10 Years Post Enactment	Mandates the full implementation of an interoperable electronic system		

Figure 1—DQSA Implementation Timeline iii

In addition to regulatory compliance, medical logistics providers must also consider recent warehouse and commercial real estate trends seen across the US. Thanks in part to the recent explosion of eCommerce and the subsequent surge in demand for distribution capacity, warehouse vacancy rates in the US have been noted as being as low as 6.2% through the first quarter (Q1) of fiscal year (FY) 2016. Warkets such as Los Angeles have even seen vacancy rates as low as 1%, while cities such as Memphis, Chicago, and Charlotte are all hovering near 10%. Given the extremely low vacancy rates in certain regions of the US, medical logistics providers will likely face fierce competition for space, which in turn could drive lease and rent prices up. Even with robust investment in new construction over the past five years, these levels of vacancy are expected to continue through 2016 and beyond, making markets with 10%+ vacancy rates much more attractive due to lower facilities and land costs, particularly for buildings with security and climate features required for medical logistics and distribution.

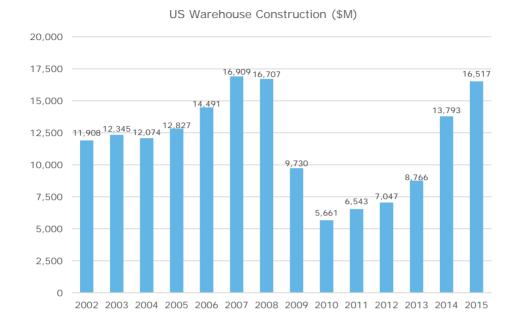


Figure 2—U.S. Warehouse Construction (\$M USD)<sup>v</sup>

Similar to traditional (non-medical) warehousing, considerations such as the weight and dimensions of products, proximity to transit hubs, and local infrastructure can all play key roles in location-related decisions. Generally speaking, prescription medications possess size and weight characteristics ideal for air shipments, a key service in meeting customer and supplier lead-time demands. By locating warehouse and distribution centers in close proximity to major airports or air-cargo hubs, providers can maximize 'fit', while minimizing use of truck/train routes—lowering the opportunity for spoilage (due to minimizing increased handling and inconsistent climate control that comes with truck/train modes of transport). Unless a facility is located in a particularly challenging or high-risk climate (e.g., coastal, tropical, etc.), no unique infrastructure requirements are required as standard material handling and climate-control features will prevent the damage or spoiling of cargo. These topics are expanded upon in later sections.

### Facilities, Infrastructure, and Systems Enablement

When considering the requirements of medical logistics facilities, two primary categories of building features should be explored: 1) those related to people and product safety, and 2) those needed for systems and IT enablement—both of which support site regulatory compliance.

As with any facility, the safety of all employees and visitors is paramount. Although building size and warehouse square footage will vary based upon a provider's product mix and volume, certain safety features should be standard. Such features include, but are not limited to: vi

• Exterior access controls: Truck-yard fencing, driver check-in locations, badge or ID requirements for site-entry, high-value product cages/restricted zones, and the surveillance of entry/exit points, and dock areas are all often recommended or required.

- Shipping & receiving dock door locks and safety systems: Particularly important when loading/unloading hazardous materials. This assumes that semi-trailers are primary delivery vehicle, and dock-height will align accordingly.
- **Flooring**: Must possess the required strength, durability, and surface-texture to handle daily equipment traffic.
- **Lighting methods**: Must provide proper visibility while not increasing the risk of spoilage. Examples of these risks include excessive UV-ray emission and heat production.
- **Climate control**: Depending on the local climate, air conditioning may be required throughout the facility—with refrigerated and freezer spaces being available for certain medications.
- **Specialty storage**: Many medical products require cold storage, secure storage, or flammable storage locations. All of these areas must be supported by reliable energy, emergency response (fire suppression) and entry systems.
- **Hazardous materials & first-aid readiness**: All materials required for safe and sufficient spill, accident, fire, etc. response should be maintained in easily-accessible locations. Common categories are fire suppression, personal protective equipment, and first aid stations (including eye and body rinse stations).

Recently enacted regulatory policy requires medical logistics providers to maintain substantial reporting and traceability capabilities at all times, resulting in modern warehouses with an extremely high level of connectivity and security. Warehouse management systems (WMS), radio frequency identification (RFID), and secure access points are all ways in which providers cannot only position themselves for regulatory compliance but also remain on the leading-edge of industry best-practices. Facility features which enable these capabilities include, but are not limited to:

- **Automated access-points**: Must be linked to personnel databases, effectively regulating access to trusted employees/visitors.
- Wi-Fi signal strength in all areas of the warehouse: WMS, RFID, and other systems/technologies all rely on warehouse equipment & devices being able to report transactional data via wireless connectivity. Prior to go-live, robust testing of all equipment and systems connectivity should be complete throughout the warehouse, with additional routers being added where needed. Racking, conveyor lines, and stored-product can all prove as barriers to signal and should be considered when testing.
- **Redundant power supply**: Secondary (and potential tertiary) power supply sources should be maintained at all times, not only for IT systems but for climate control, safety systems, and access-points.
- **Data backup**: WMS or other IT systems' data should be stored and saved in a secure location(s), this can include off-site server space, cloud-storage, or controlled server space on-site (highest risk). Frequent data-backup will not only assist with regulatory compliance, but greatly reduce risks associated with disaster recovery procedures.

# **Inventory Management**

### IT & Warehouse Management Systems

Inventory management is an essential component of an effective medical warehousing system. To assist with warehousing activities, the inventory must be updated continuously to provide an accurate view into the status of medical equipment, pharmaceuticals, and inventories of supportive assets within the warehouse. Update points include initial data collection; as information is updated, such as when pharmaceutical goods are delivered, or when new equipment arrives or is retired; and during annual inventory audits. Medical warehousing includes the inventory of pharmaceuticals, medical equipment, and the inventory of additional supportive assets, such as spare parts and testing and safety tools and equipment. Inclusion of equipment in an inventory is decided through a risk-based analysis to help ensure appropriate time and resource allocation, and to potentially eliminate unnecessary work. Personnel within a medical warehouse decide on the level of detail to be included in its inventory that satisfies its own requirements and according to its own capabilities. Inventory management can be conducted using a paper-based or computer-based systems, as determined by the resources available.

Once established, the inventory serves as the foundation for moving forward within the medical warehousing management system and facilitating safe and effective medical supplies. Examples of how inventory may be used include, but are not limited to:

- Developing budgets for future purchases
- Facilitating hiring and training of technical support
- Establishing service contracts
- Supporting an effective medical equipment management program
- Stocking spare parts and consumables
- Recording the purchase, receipt, and discard of pharmaceuticals and equipment
- Facilitating site risk analysis and mitigation and emergency and disaster planning vii

Figure 3 lists data that is often included in inventory records:

Item	Description	Type of inventory
Product Identification Number	Unique identifier for each piece of equipment	All
Type of product	Identifies what the product is	All
Product description	Brief description of the product	All
Manufacturer information	Name, serial number, model/part number	All

Item	Description	Type of inventory
Inventory date	Date the product entered inventory and day it was last modified	All
Purchase supplier	Contact for resupplying product	All
Purchase cost and date	Cost and date of purchase	All
Batch number	Number given to the batch location of a product	All
Expected product lifetime	Length of time a product is expected to last	All
Expiry date	Date the product expires	Medical Inventory
Safety/risk assessment classification	Risk assessment of the product	Medical Inventory
Preventive maintenance schedule and procedures	Lists necessary maintenance steps to ensure viability of product	Medical Inventory
Special storing instructions	Storing restrictions for products	Medical Inventory
Safety hazards	Warning and handling instructions of products	Medical Inventory

Figure 3—Example of Inventory Record<sup>viii</sup>

### **Inventory Management Systems**

Inventory management systems (IMS) are a critical and necessary part of medical warehousing. An IMS determines when to order products, how much to order, and how to maintain an appropriate stock level for all products, avoiding shortages and oversupply. In general, there are two ways to manage inventory in a warehouse: manually or with an automated system (such as an IMS).

Type of system	Characteristics	Description	Considerations
Manual	Bin Card, Inventory Control Card, Warehouse Ledger	Hand-written inventory management organized according to date and transaction reference	<ul> <li>Pros</li> <li>Low cost</li> <li>Less expensive at start-up</li> <li>Cons</li> <li>Difficult to keep track of high volumes of products</li> </ul>
Automatic	Bar Codes	Computerized warehouse management system based on the use of bar	<ul> <li>Pros</li> <li>Less expensive than RFID</li> <li>Reduces human errors</li> <li>Immediate feedback</li> <li>Increased inventory accuracy</li> </ul>

<b>Type of system</b>	Characteristics	Description	Considerations
		code stickers attached to each product	<ul> <li>Cons</li> <li>Cost associated with changing and integrating the system</li> <li>More expensive than a manual system</li> </ul>
Automatic	Radio Frequency Identification (RFID)	Computerized warehouse management system based on the use of RFID tags that can determine the exact location of a product at every step of the inventory management process	<ul> <li>Pros</li> <li>Able to store large amounts of data</li> <li>Durable to harsher conditions than barcodes</li> <li>Some tags can be recycled</li> <li>Reduces human errors</li> <li>Immediate feedback</li> <li>Increased inventory accuracy</li> <li>Real time, product location</li> <li>Cons</li> <li>Cost associated with changing and integrating the system</li> <li>Expensive</li> </ul>

Figure 4—WMS Comparison

### **Manual Inventory Management Systems**

Manual inventory systems involve hand-written stock-keeping, such as ledgers, stock cards, and bin cards. While there are varying approaches to manual inventorying, all manual systems are organized according to date and transaction reference, which is the unique number of the corresponding transaction record for a receipt or issue, and/or the name of the facility from which products are received and issued. They record receipts; issues, losses, and adjustments; balance on hand; and, sometimes, batch or lot numbers and expiry dates. They also record the date and results of physical inventories; i.e., when items are counted to verify the quantity in storage. Manual inventory management methods are a low-cost, effective way to manage inventory for a limited number of stock keeping units.

In all manual inventory systems, there are three primary elements: a bin card, an inventory control card, and a warehouse ledger. A **Bin Card**<sup>ix</sup> is an individual stock-keeping record that contains information about a single product, by lot or batch number. Every item in that lot has the same expiration date. For example, one bin card could have information about a single lot of paracetamol at a storage facility. The card should note the stock on hand for that lot only, as well as any losses and adjustments for that lot. Bin cards are usually displayed on or at the bins—or at the shelf or pallet position where the lot is located.

An **Inventory Control Card**<sup>x</sup> is an individual stock-keeping record that holds information about all lots of a single product. Keep one inventory control card for each product. The inventory

control card can summarize many bin cards for a particular product. For example, one inventory control card could hold information about all the paracetamol in a storage facility. It should note the total stock on hand of paracetamol in the warehouse, as well as the record of losses and adjustments, without regard to lot number or where the product is located in the warehouse. To help ensure each lot is managed correctly, in larger warehouses, it is advised to maintain both inventory control cards and bin cards. In smaller store-rooms, a single stock-keeping record, such as a stock card or inventory control card, would be sufficient.

A Warehouse Ledger<sup>xi</sup> is a stock-keeping record that contains the same information as the inventory control card. However, unlike inventory control cards, a stores ledger is bound like a book. In some countries, government policy requires the use of stores ledgers. Managers may believe that ledgers increase accountability, because missing pages are obvious. However, the ledger format is less desirable than individual cards, because it is easy to run out of space for an individual product and it is also difficult to add new products. Individual inventory control cards can be alphabetically organized as new cards are added. In many countries, the Ministry of Finance determines the format of stock-keeping records; all government units use the same format because commodities are considered assets of the government and must be accounted for carefully. In addition to regulating the format of such records, many medications are categorized by regulatory bodies. In general, controlled (e.g., narcotics) medications are labeled as Schedule I—V substances, based upon their likelihood to be abused or diverted (I being high-risk, V being low-risk) and are handled accordingly within warehouses and by pharmacists, often being placed in vaults or restricted areas and being subject to strict ledger or audit controls and procedures.

### **Automatic Inventory Management Systems**

As the quantity and volume of products increase—either stored in or moved through a warehouse—more and more warehouse managers are turning to computerized warehouse management systems (WMS) to keep track of inventory. These systems can be a stand-alone software product, or a module within an Enterprise Resource Planning (ERP) system. Warehouse Management Systems support inventory management and other tasks routinely performed within a warehouse, such as receiving, put-away, replenishment, storing, picking/packing, shipping products, report management, and cycle counting. In considering a WMS, warehouses often consider the number of stock-keeping units handled—the more units, the more likely a warehouse will employ a WMS. Furthermore, a WMS allows warehouses to more effectively adhere to First-Expiry-First-Out and First-In-First-Out (FEFO/FIFO) requirements, as well as maintain substantial reporting and traceability capabilities. Both areas have become increasingly regulated in the medical warehouse industry. Some of the many benefits of a WMS are illustrated in *Figure 5*:

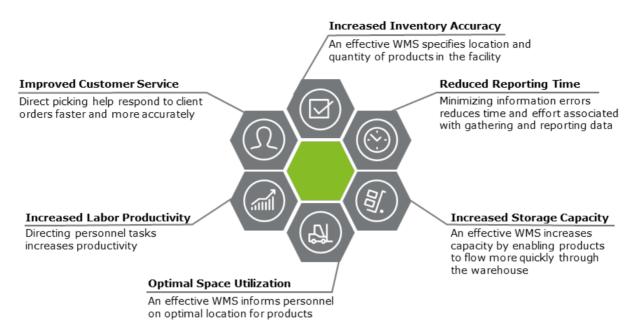


Figure 5—Advantages of Automatic WMS

Within a WMS, there are three main components: WMS software, barcoding technology, and radio frequency communication equipment. The software component is the only essential piece of the WMS. The other two components—barcoding technology and radio frequency communication equipment—are optional. Many WMSs can be implemented without barcoding or radio frequency, but these additions can eliminate information lead times and make inventory data almost 100 percent accurate. A WMS can be a standalone software product or housed within an Enterprise Resource Planning (ERP) system.

Bar codes are different combinations of bars and spaces that represent different characteristics in a numeric and alphanumeric code. When scanned by a scanning device, the optical signals are converted to electronic signals that convey characteristics that the bar code represents. Bar codes can be created for just about any characteristic of a product, such as stock-keeping unit or part number, quantity, supplier identification, serial number, expiry date, or manufacturing date.

When considering bar code technologies, there are several potential benefits to consider:

- Barcoding systems can reduce the number of human errors
- The scanners are easy to use
- The data captured is uniform and standardized
- The feedback is usually faster, leading to increased productivity and efficiency
- Barcoding systems can potentially save money in the long term.

Furthermore, barcodes can be put on the product themselves, the bins that contain the products, and even the cargo holds allowing for further information to be gathered through every step of the process. However, barcoding also has its challenges—the two greatest being the cost of

hardware, and significantly, the cost of integrating the technology within the warehouse, including any existing WMS. The cost of changing systems, training staff, and maintaining/servicing barcode printers and scanners must be carefully considered.

Radio Frequency Identifiers (RFID) are devices with imbedded computer chips attached to an object that transmits data to an RFID receiver. RFID technology is beneficial as it has the potential to store large amounts of data on a receiver device. Another advantage is that an RFID tag can be read through other materials and can be read quickly. Theoretically, an RFID reader could read all of the tags of a mix of products on a palletized load without physically moving any of the materials or opening any cases. In addition, the more expensive read/write tags can change or add data as they pass through different operations, adding information to the tags at each step of the supply chain. RFIDs can be scanned at each step in ingoing and outgoing supply chain process allowing for personnel to track the product to its exact location in the warehouse. RFID tags also are more durable against harsh conditions than most barcodes. As this technology decreases in size and cost, it will become increasingly attractive.

However, RFIDs have some drawbacks. Currently, the most significant drawback is the cost of both the technology and the tags. While a barcode sticker is relatively inexpensive, the least expensive RFID tag is many times that of barcodes, creating a prohibitive cost burden for individual products, or even for individual shipments. More expensive rewritable tags can be recycled for multiple shipments, but the cost may still be prohibitive. In addition, the tags may hold more information than what is needed for most warehouses and distribution centers.

#### **Key Performance Indicators & Best Practices**

Key performance indicators (KPIs) are established to measure and report performance over a range of supply chain activities. It is important to track these indicators regularly to maintain knowledge of performance at a specific point in time and to understand how performance is trending over periods of time. Clearly structured and delineated performance measures increase operational visibility and help to review and adjust how management time is allocated. For example, real-time visibility into available inventory is a key driver of the overall customer experience. In this manner, KPIs can be used to identify weak areas in the supply chain and can initiate the development of a performance improvement process.

While many warehousing and logistics providers determine their own KPIs based upon their product offerings and corporate strategies, others may have their primary performance measures defined within service level agreements (SLA). SLAs are entered into by key customers or partners and establish contractual performance requirements that, if not met, will result in financial or sales penalties. When SLAs are put in place, warehousing and logistics providers typically establish similar performance standards or agreements with their own supply base—effectively driving KPI compliance across the supply chain. Whether SLAs are present or not, certain types of KPIs and areas of focus are found throughout the warehousing and distribution industry.

Cost KPIs focus on managing warehouse inventory in a cost-efficient manner. Warehouse costs include direct receive, put-away, and pick and pack, and back-offices expenses relating to operations administration. Process driven errors frequently lead to imbalances in stock and

customer service dissatisfaction. *Cost of returns per period* is one example of a cost KPI. The more efficient the product return procedure, the lower the cost of returns per period. Thus, cost KPIs help to measure the effectiveness of the overall system while specifically driving down associated costs of the process.

Reliability KPIs measure accuracy. The more accurate the inventory management system, the less strain is placed on warehouse staff and systems which increases overall operational efficiency. Measuring *Inventory Accuracy* is one way to assess the reliability of an inventory management system. *Inventory Accuracy* calculates the number of inventory counts where actual stock level matched book level and is reported as a percentage of the total number of counts completed in a calendar month period. The higher the Inventory Accuracy, the more reliable the stock levels and consequently the more efficient the inventory management system.

A third type of KPI relates to the agility of the system. These KPIs measure the time-efficiency of specific processes. For example, *Return Cycle Time* calculates the total time it takes to process a returned product. Typically the quicker a returned product is processed, the lower the associated cost because staff and systems can process more returns or focus on other processes. However, this is contingent on the continued reliability of the inventory system. If the return cycle time is low, but the process is executed haphazardly, then errors may be committed resulting in a lower inventory accuracy and higher costs. In this way, different types of KPIs work together to help drive efficiency and lower costs, while highlighting different components of the overall inventory management process.

There are many different examples of KPIs that can measure various aspects of inventory management. The table below outlines some common KPIs.

Process	KPI type	KPI	
Inventory Planning	Asset Management	Inventory days of supply	
	Cost	Inventory carrying cost	
	Reliability	Percent of obsolete inventory	
		Percent of damaged goods	
		Defect rate	
		Inventory accuracy	
Warehouse Management	Responsiveness	Pick to ship cycle	
		Dock to stock tie	
	Reliability	Order shipping accuracy	
_		Picking accuracy	
Receive Returns	Agility	Total receiving time	
	Cost	Costs of returns per period	
		Cost to receive returned products	
Process Returns	ocess Returns Responsiveness Return cycle time		

	Cost	Costs of returns per period	
Distribute Returns	Reliability	Distribution accuracy rate	
		Percent of returns process without issues/errors	

Figure 6—Example KPIs<sup>xiii</sup>

The above KPI examples are generally applicable to all warehouses and distribution centers. There are, however, specific topics especially relevant for medical warehouses. The below table lays out an abbreviated version of a self-assessment survey designed specifically for medical warehouses. Each section targets a different aspect of medical warehousing and is meant to help identify weak areas of the warehouse management. The survey questions drive the generic KPI results which can be used to show how adjustments to low scoring sections in the survey have produced tangible performance improvements as expressed by KPIs.

Section D: Special Storage Requirements		Score (Y=1, N=0)	Maximum Score
D1.	Does the location store cold chain required product and does it have designated cold chain facilities?		1
D2.	Is there sufficient capacity for cold chain product?		1
D3.	Are all fridges and cold rooms operational?		
D4.	Are temperatures monitored for each discreet storage unit?		1
D5.	Do the refrigerators run on solar power?		1
D6.	If the cold chain facilities run on electricity, is there a back-up source of power? (ie. Generator)		1
D7.	Is there funding for the back-up source of power?		1
D8.	Is there a designated area for flammable/hazardous items?		1
D9.	Are flammable/hazardous items kept in a separate area away from the main building?		1
D10.	Are high-value commodities kept in a locked or caged area?		1
Total			/10
Score for this section			%

Figure 7—Medical Warehouse Self-Assessmentxiv

Leading practices can be observed, developed, and applied to improve performance to specific KPIs. The graphic below outlines a few example leading practices and their impact on overall processes.<sup>xv</sup>

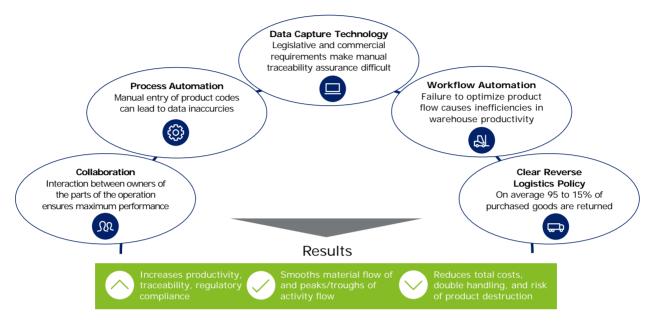


Figure 8—Inventory Management Best Practices

#### **Reverse Logistics**

It is important to maintain an effective reverse logistics system to efficiently deal with recalls, returns, and counterfeit products. There are four broad stages of the reverse logistics process: preparation, communication, execution, and disposal. These stages are discussed below as they relate to recalls, returns, and counterfeit products. xvi

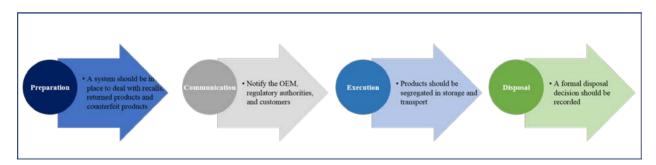


Figure 9—Reverse Logistics Process

#### **Step 1: Preparation**

Creating and maintaining a system will ensure quick and effective response to recalled, returned/damaged, and counterfeit products. Typically reverse logistics systems are outlined in a written procedure and have a designated person(s) responsible for managing and executing the process. Assigning this responsibility to a specific person(s) creates accountability and consequently increases the likelihood of prompt corrective action. The procedure is most reliable when it is regularly checked and periodically updated to evaluate its effectiveness at a set

interval. In the case of a remarkable event, for example a regulatory change or technological advance, the procedure can be altered outside of the set interval.

#### **Step 2: Communication**

The communication phase of reverse logistics is initiated once a product is recalled, returned, or suspected of being counterfeit. It is common to contact all relevant parties when the reverse logistics process is engaged. In the case of a recalled product, it is important to notify the original manufacturer, ideally prior to the actual implementation of the recall process. In addition, all customers and authorities of the countries to which the recalled product has been distributed should be notified in most cases. The appropriate authorities to contact depend on the specific situation, but often include national and international regulatory bodies. Product records can be accessed to identify which customers the product has been distributed to. These records are most useful if readily available and include all relevant details including export information. A designated person(s) can be tasked with handling these records to ensure familiarity and accountability for this phase of the reverse logistics process. Typically a final report details the reconciliation between delivered and recovered quantities of the product.

#### **Step 3: Execution**

Whether the product is a recall, damaged, or counterfeit, it is common to immediately segregate it from other products in a secure area. The product can then be clearly labeled to prevent distribution or sale before a final decision is made regarding its disposal. When in transit, the product remains segregated. If segregation is not possible in transit, then it is securely packaged, clearly labeled, and appropriate documentation is recorded. The necessary storage conditions for the product should continue to be maintained until a final decision is made regarding its disposal.

Every organization should have a quarantine program whose purpose is to segregate discrepant material (the organization must clearly define what a discrepant material is in their circumstances). The procedure typically outlines the responsibilities of each department and the quarantine coordinator, who is responsible for material tracking and input/removal from quarantine.

The quarantine program is most effective when it begins with open communication between the quarantine department and organization as a whole. The department that identifies the discrepancy is responsible for notifying the quarantine coordinator, who then distributes a quarantine notification (e.g. internal memo, discrepancy tracking system, phone call and inperson follow-up, etc.). Quarantine records are then prepared which detail the material, batch number, weight/quantity, and the reason for quarantine. A sequential log number is assigned to the record and substantiating documents should also be attached to the record.

Quarantine material is then segregated in a specific location while accounting for the necessary storage conditions. Access to the segregated area should not be permitted without the presence of the quarantine coordinator. Following segregation, the material should be properly labeled. Finally, the quarantine coordinator will release the quarantined material based on the manager's written request or the approval of a discrepancy investigation. If disposed, the accompanying documentation is attached to the quarantine record. Once the quarantine record is closed, it will be filed based on log number in an area separate from the outstanding quarantine records. \*\*xvii\*\*

A quarantine database can be maintained to track quarantine material and provide data inputs and reports associated with discrepant material. It is the quarantine coordinator's responsibility to update and manage the database. The database often includes: material description, batch number, quantity and unit of measurement, date of quarantine, reason for quarantine, and log number. xviii

#### Step 4: Disposal

A designated person(s) assesses the product and makes a decision regarding the disposition of the products in question. This decision should be recorded. Factors considered during the assessment include, but are not limited to:

- Nature of product
- Special storage conditions required
- Condition and history of product
- Time elapsed since product was issued

A product is not to be considered suitable for reuse or resale if there is any question regarding its quality. Safe transport should be arranged for rejected products and they should be destroyed in accordance with international, national, and local requirements. Accurate and detailed records should be kept for all product disposal decisions and results.

# **Material Handling & Storage**

Just as site-selection criteria and inventory management systems greatly impact the ability of medical logistics providers to meet regulatory standards, and maintain safe, quality, and reliable business performance, so too do material handling and storage methods. In general, distributors of medical or pharmaceutical products should maintain robust product-profiles or databases, including detailed storage guidelines provided by manufacturers. For distributors dealing with pharmaceuticals, these manufacturer guidelines, along with general warehousing leading practices, can greatly impact the way goods are handled and stored.

#### **Arrival & Receipt**

The unloading, receipt, and movement of products into inventory can often be an overlooked, and underutilized, part of the distribution process. Depending on the type of shipping, packaging, supplier-provided paperwork, and other factors, there may be unique requirements that must be addressed prior to bringing the items into inventory. However, the activities outlined below should always be considered—particularly when dealing with pharmaceuticals and medical devices:

Inspection of the shipping container/trailer, packaging, and paperwork should be performed
to protect against counterfeiting and the receipt of damaged goods. Items arriving from
international locations and supplier will likely require additional customs and shipping
documentation prior to receipt.

- Receipt of products and materials should only take place once their quantities, part numbers/SKUs, order numbers, and any other verifiable information have been reviewed and confirmed as being accurate.
- Record, either electronically or manually (if needed), the batch number, individual serial number, or other unique product identifiers within the inventory management system—key to regulatory compliance and recall-readiness.
- Label and organize all inbound products and materials for immediate placement into stocking locations—staging large quantities of product for extended periods of time can increase the risk of product mixing and pilferage.
- Confirm, either electronically or manually, that the inventory has been placed in the
  appropriate location or area within the warehouse. Bar-code scans or other precise
  verification methods should be used upon put-away, as well as during all cycle-counting or
  inventory control processes.

#### **Handling & Storage**

After incoming stock has been checked and approved, it is formally released from the receiving area and moved to the warehouse to be stored in the appropriate zone. New stock may be stored on floor pallets, pallet racks, or shelves depending on the packaging and safety characteristics. Stock requiring cold storage or special handling procedures should be separated or flagged to ensure they are not mixed with standard goods—they may also require expedited handling to avoid spoilage. The following topics should all be considered when designing the material handling and storage procedures within a medical warehouse:

#### First-In-First-Out (FIFO), First-Expiry-First-Out (FEFO)

To avoid accumulation of expired and obsolete stock, a stock control system should be used to record the expiry date and the date of receipt. Stock must be stored so that earliest expiring or first delivered batches can be picked and issued first. This control system should be closely integrated with the batch, serialization, and other product data-points gathered during the receipt process.

#### **Cold Storage**

Maintaining proper temperatures for medical inventories, most commonly pharmaceuticals, is an essential part of the distribution process. The Centers for Disease Control and Prevention (CDC) has estimated that \$300 million in vaccines alone are destroyed or spoil annually, due to improper climate controls during the distribution process. \*\*Medical logistics providers simply cannot risk the distribution or sale of compromised inventory. See below for various cold-storage considerations:

• **Divide** or partition cold-storage locations within the warehouse. Wherever possible, use demand/volume-based forecasting to determine exactly how much refrigerated or freezer space is needed. Beyond capacity requirements, product information should be used to segment this further into specific temperature ranges or zones—this will allow for minimal energy consumption and costs (e.g., Room A is kept at—10°F, Room B at 28°F, and Room C at 55°F based on product manufacturer guidelines).

- **Reduce** the number of touch-points for cold-storage product. Every time a package is momentarily removed from refrigeration, opened, or otherwise tampered with, its odds of spoilage can greatly increase. A prime example of the importance of this strategy can be found in the food industry, where it is estimated that for every two degrees (F) a shipping container/trailer's temperature rises, the contained produce's shelf-life can be reduced by up to 50%. XX While food often gives outward indications of spoiling, medications and drugs can often become unsafe without providing any obvious signs to material handlers or end-users—temperatures must be controlled at all times.
- **Install** redundant power sources/supplies to ensure temperatures remain at or below acceptable levels in the event of a power-outage.
- **Integrate** inventory management systems and any warehouse-automation technologies with temperature-sensing systems and product-profiles (containing storage requirements). This integration can provide early-detection of spoilage risks, prevent the mixing of inventories during handling, and also increases traceability/reporting capabilities within the warehouse.
- **Utilize** refrigerated trailers and containers, insulated packaging materials, thermal blankets, dry ice, etc. when moving or transporting products that require cold-storage.

#### **Secure Storage**

Distributors should establish secure storage procedures as well as designate secure zones within the warehouse. These procedures and areas should be utilized for high dollar or high-attrition (risk of theft) products such as narcotics. Caging, user-assigned keys, or electronic badge screening can be used to limit employee access. These items and areas should also be frequently audited and counted. Depending on the location within the warehouse and the site's labor schedules, 24/7 surveillance at all entry and exit points (at a minimum) is strongly recommended.

#### **Physical Quality Assurance**

Beyond spoilage, material and cosmetic quality assurance is a primary concern of any distributor or warehousing provider, particularly when dealing with high-value or high-visibility products. Any medical products or materials shipped or sold directly to end-customers should be handled and transported in protected packaging, commonly referred to as over-pack. These totes, boxes, or other packaging materials protect the product from cosmetic or material damage during the handling process. For example, prior to shipping, a product will be picked or placed into a tote or over-pack carton where it will then remain throughout all internal transportation and handling (riding on a conveyor, order-picker, etc.). When shipping to a high-volume, long-term, or otherwise trusted customer/location, these cartons and totes can be used as recyclable shipping containers—being returned to the shipper via transportation partners.

#### **Product & Operational Safety**

Medical logistics and warehousing providers are responsible for the safe, reliable, and efficient flow of products and supplies from source to user—these responsibilities should always maintain this order. The following sections cover basic safety and inventory control methods to enable providers to operate in an acceptable manner.

#### **Hazardous & Flammable Product Storage**

When it comes to product safety and storage methods, flammables and hazardous items most obviously differ from their cold storage counterparts in one key way—they can not only harm end-users if handled incorrectly, but can pose a significant risk to all employees, other inventory, and local environments throughout the distribution process. Hazardous, toxic, or extremely flammable materials or containers such as alcohol and ether, must be stored in special buildings or rooms to reduce the risk of fire or explosion. While a separate building is ideal, due to its ability to prevent a fire potentially spreading to other buildings, its cost presents a significant barrier to most medical logistics providers. Therefore, designated rooms or areas are commonplace for flammable storage. These areas must be well ventilated, constructed from fire-resistant materials, possess fire suppression systems, and should have sufficient fire-prevention and spill-cleanup equipment stored nearby. Any personnel who work in these areas should undergo specialized fire and chemical-spill response training—often done in conjunction with local first responders (who should be notified of the contents of such areas).

#### **Operational Safety**

Beyond categorical safety procedures (by product type), such as those mentioned above, each material handling process needs not only definition from a systems standpoint but also from a safety perspective. Some products will require physical handling by the warehouse employee, so a maximum product weight needs to be defined at both the piece level and the line-item level. For illustrative purposes, one can assume the maximum piece weight of a handheld product is 50lbs. If 18, 40lb pieces are received, that is 720lbs worth of repetitive motion for deconsolidating or putting-away of the product(s). Even though the individual piece weight is under the maximum amount of 50lbs, the physical stress of repetitive motion associated with the movement of 18 pieces can be of concern from a safety perspective. The maximum weight of line-items should thus be determined as well as the piece level. If the line-item weight breeches that maximum, coworker or machine assistance may be needed. This is visually depicted in Figure 10, below.

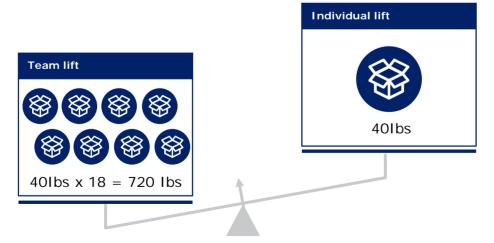


Figure 10—Operational Safety Example

For products over the maximum piece-weight threshold, the use of a machine or material handling equipment will be necessary. For any personnel operating this machinery, certification

and associated safety training should be required prior to operation. This training material and certification standard can be attained from the equipment manufacturer, or through the facility Safety Manager. These materials may also assist in the defining of safety response standards. If any safety incidents occur (e.g., damaged rack, damaged product, damaged machine, etc.), a time-sensitive incident review and progressive discipline recommendation should be completed by the management staff. The details of such safety procedures and policies should be set upon site stand-up and thoroughly communicated to all employees and staff.

### **Points of Contact**

**Kelly Marchese** 

DC Principal
Federal Supply Chain Service Line Lead
Deloitte Consulting LLP
kmarchese@deloitte.com

Kelly is a principal with Deloitte Consulting LLP and leader of the Federal Supply Chain practice. She has over 20 years of experience leading projects in highly engineered manufacturing industry sectors, specifically Aerospace and Defense. Kelly also leads the Global Supply Chain Risk service offering and is a thought leader in Product Development and Engineering Effectivness through Manufacting Operations Excellencee. She had helped clients navigate through complex transformations, including helping a federal agency develop a multibillion dollar global business case to streamline their aviation supply and maintenance processes and advising a life sciences company through a full lifecycle of divestiture, acquisitions and IPO.

#### Barbara Rosenbaum

Consulting Managing Director Logistics and Distribution Offering Lead Deloitte Consulting LLP brosenbaum@deloitte.com

Barbara is a managing director in the Deloitte Federal Strategy and Operations Practice focused on Supply Chain. She leads the Logistics and Distribution service offering within the Federal Supply Chain service line, building upon over 30 years of experience leading federal and commercial projects across all areas of the supply chain. She currently works across federal clinets with a particular focus in National Security and has market eminence as a thought leader in supply chain transformation, planning and inventory optimization.

#### **Yvan Caceres**

DC Specialist Leader Logistics and Distribution Subject Matter Expert Deloitte Consulting LLP yeaceres@deloitte.com

Yvan is a Specialist Leader with Deloitte's Public Services Organization with over 20 years of experience in the areas of Transportation, Logistics, Distribution Network Planning, 3PL Operations, and advanced planning functions. He has extensive experience in systems integration, requirements development, systems architecture, and implementation lifecycle, having managed Supply Chain implementations in the consumer packaged goods, industrial and automotive, high technology, retail industries as well as major programs in the DoD. Yvan has extensive knowledge of commercial supply chain technologies such as APS, Inventory Management, Supply Planning, Transportation, and Simulation Modeling.

- $^{\rm iv}$  http://www.us.jll.com/united-states/en-us/Research/US-Industrial-Stats-Q1-2016-JLL.pdf?0e2934dd-027e-4c5d-8c5f-e0413a2eeb24
- <sup>v</sup> http://www.statista.com/statistics/184484/new-private-sector-warehouse-construction-in-the-us-from-2002/
- <sup>vi</sup> USAID | DELIVER PROJECT, Task Order 4. 2014. Guidelines for Warehousing Health Commodities. Arlington, Va.
- vii http://apps.who.int/medicinedocs/documents/s21565en/s21565en.pdf
- viii http://apps.who.int/medicinedocs/documents/s21565en/s21565en.pdf
- ix http://deliver.jsi.com/dlvr\_content/resources/allpubs/guidelines/GuidWareHealComm.pdf
- <sup>x</sup> http://deliver.jsi.com/dlvr\_content/resources/allpubs/guidelines/GuidWareHealComm.pdf
- xi http://deliver.jsi.com/dlvr\_content/resources/allpubs/guidelines/GuidWareHealComm.pdf
- xii http://apps.who.int/medicinedocs/documents/s16875e/s16875e.pdf
- xiii Deloitte Integrated Supply Chain (DISC) Toolkit
- xiv http://deliver.jsi.com/dlvr\_content/resources/allpubs/guidelines/GuidWareHealComm.pdf
- xv Deloitte White Paper: Warehouse Optimization POV
- xvi World Health Organization, Good Distribution Practices
- xvii http://www.pharmtech.com/quarantine-
- glance?id=&sk=&date=&%0A%09%09%09&pageID=2
- xviii http://pharmaceuticalcommerce.com/special-report/improving-efficiency-effectiveness-of-drug-recalls/
- xix http://blog.fisherbioservices.com/bid/326748/Cold-Chain-Qualification-5-Questions-You-Must-Ask-When-Shipping-Biologics
- xx Maintain the Cold Chain: Six Supply Chain Best Practices for Temperature Sensitive Freight, C.H. Robinson

<sup>&</sup>lt;sup>i</sup> http://www.forbes.com/sites/joelkotkin/2014/10/30/aging-america-the-u-s-cities-going-gray-the-fastest/#45f0ba7ddd82

ii http://www.newsweek.com/prescription-drugs-rise-new-estimates-suggest-60-americans-take-least-one-390354

iii Rachel Morgan, Oversight of the U.S. Drug Supply: H.R. 3204, the Drug Quality and Security Act, 2014

# A Model of the Property Management Specialist (PMS) in a Multipurpose Company in Russia Julia Sharygina, CPPS,

# Johnson Space Center Chapter

Economic development and production becomes more and more dependent on management's use of the knowledge bases of their employees. The value of human resources (HR) increases when knowledge is used effectively. Following this line of thinking, it is necessary for an organization to monitor factors of external and internal environments (demographic factors, technical progress, labor markets, conditions of property systems within the organization, property relationship) when designing a PMS model.

In comparison with other countries, such as the United States or those countries in the European Union where human resources are more evenly distributed, Russia's human resources are primarily located in large cities such as Moscow and St. Petersburg.

Human resource distribution in Russia forces two different strategies regarding the PMS model. First, that companies in cities with high concentrations of talent develop means and tactics to attract qualified and possibly already trained personnel from another company; and second, that companies outside the large cities grow their own property specialists from within the company.

Features of the modern labor market, not only in Russia, consist of different expectations of different generations. Ignoring this fact leads to a reduction in the potential labor capability of a company regarding the inherent abilities of a competent specialist.

One of the main challenges today is that the labor market is continuously changing. Secondly, there is the problem when there is a shortage of qualified property specialists. A third challenge is having specific competencies/skills for a number of workers. These problems continue to be present in multipurpose companies in all countries despite technological development and improvements in those countries.

A PMS model creation strategy, recognizing today's environments and needs, is mandatory as organizations address asset accountability. The model of the specialist will continue to promote HR function implementation and business development goals.

#### These are the tasks required to achieve this goal:

- Available company personnel and planning for the use of those resources how many, what specialties, and where will these people come from during implementation. Is it an external search or an internal search such as promotion of employees or the movement of people between divisions;
- Effective employee motivational systems;
- Analysis of labor efficiency; and,
- Ensuring organization efficiency during model implementation.

Market changes involve updates both a company's HR-strategy and the PMS model t account for the fluid increase and/or decrease of personnel. The main part of this policy is the training of young specialists. As each new PMS enters the workforce and start working, they notice the difference between what they learned in their formal education and the real work. A university teaches the student to think utilizing available resources, but on the job, the graduate receives the necessary competencies and application skills of the knowledge gained in the university in order to be a valuable contributor to the organization's success.

Today, employers' requirements are also changing. Previously, required tasks were assigned – tasks were completed. Now employees are not just required to complete tasks, but to do so timely and efficiently. Minimum expectations are higher resulting in twice as much work than that of a few years ago: if the person was working on repairing equipment he may now be required to provide a minimum trouble-free operation time, the accountability personnel may now be required to provide an amount of paid penalties or number of detained accounts. Requirements to personal qualities become tougher for average personnel as new and higher expectations are levied: resistance to stress and responsibility are important.

Now the ability to do risk assessments, to optimize the use of resources, accurately estimate efficiency from results acquired, and to see the task creation of general values and purposes are added to the obligatory list. Similar qualities lie on the surface, however there was an unusual situation in Russia: many companies noted shortages of administrative abilities while recognizing in many cases availability of deep technical competencies of heads of production or industrial locations.

**Specialist model** – criteria of qualities and professional competencies, knowledge, and skills in a certain sphere.

Scientists studied various models of experts and applied variable options of the model and developed images of the future expert:

- A strong foundation of personal qualities/ethics and professional knowledge; i ii
- Vocational training, personal qualities, physical, mental, moral health;
- Professional competences for required tasks which each worker must possess; iii iv
- Mandatory requirements of future experts coming from outside the employer; vi vii
- Competence-based modeling of the expert where structural elements are professional, personal, and social competencies; viii
- Expert model for concrete specialty supported by the purposes, functions, competencies, qualities, knowledge, decisive rules, and criteria achievement of goals. ix

There is no specific profession of property management specialist in Russia. All questions that include property are typically addressed by the accounting and legal departments of an organization. They watch for personal property to be registered, all responsible persons to be informed of their obligations, and all documents to be processed according to Russian law. Looking at the international experience in this sphere, Russia should consider a change in its property management system architecture.

Reviewing the research of expert's models<sup>x xi xii</sup> allows us to accumulate knowledge from the scientists and to make use of their experience in development of the PMS model.

#### Design of the PMS model is based on the following conceptual provisions:

- expansion of fields of professional activity;
- the advancing development of technologies of logistics and production;
- anticipation of social and economic changes in society;
- ensuring strategic development of the potential of the PMS; and,
- forecasting the main tendencies of development of fundamental and applied science, and productions.

#### Fields of professional activity of the PMS are:

- development and realization of technologies for life cycle management of reutilized property;
- quality management of a control system of a risky enterprise (management of property, production);
- marketing;
- development of methods of management for life cycle of property as objects of scientific and technical activity.

Property management specialists have to be able to resolve the problems occurring in the modern day company. They must quickly master the latest equipment and production technologies, analyze the myriad situations with property management, make data based decisions, learn and understand modern technologies, and to improve one's own professional activity and competence.

#### The offered generalized PMS model consists of four components:

- I. Developmental objects in the course of vocational training:
  - Values and valuable orientations of the future property management specialist (relationship to the tasks, methods of achievement of results, and relations during work).
- Thinking type of cogitative actions and operations research, converting and informative character, directed to a solution.
- Knowledge know the facts and laws in various professional areas that allow making optimal administrative solutions.
- Styles of behavior receptions, skills, communicative skills.
- Experience in the solution of problems of professional and universal character.

#### II. Personal quality requirements for the PMS:

- Social and psychological stress resistance, intuition development, observation, open to problems, interpersonal competence, active perception of reality.
- Intellectual a high level of knowledge/education, creative thinking, ability for creativity, learning ability, concentration, non-standard thinking, efficiency of reaction, analytical ability, ingenuity.
- Communicative sociability, tendency to leadership, vital optimism, independence, collaboration with colleagues.
- Behavioral enterprise, distributed leadership, initiative, ability to make contacts, assessment of events, adaptability, commitment, organization, ability to work in team, objectivity.
- Ethical existence of moral and professional principles in life and work, maintaining confidentiality.

#### III. Professional qualities of the PMS:

- 1. General professional qualities:
  - high qualification;
  - professional mobility;
  - readiness for continuous increase in skill level;
  - creativity (innovations);
  - high organizational culture; and,
  - intellectual potential.

#### 2. Knowledge and skills of a technical component:

- skills for design of technological and logistic processes in property management;
- knowledge of IT, availability to work with computer programs;
- knowledge of international standards;
- ability to understand various technical questions, technical terminology and documentation;
- ability of carrying out the tests and quality control of the equipment and production;
- ability to understand production requirements to repair the equipment;
- work in rigid standardization conditions; and,
- knowledge of the floor spaces of the organization, the location of available equipment, to have an idea of problems and opportunities for their use, storage, utilization and control measures.

#### 3. Knowledge and skills in economics, production and social management:

- knowledge of organizational and technical interrelations between company divisions;
- knowledge of organization and assignment of work, observance of safety measures;
- knowledge of management theory and methods;
- possession with skills of resolving of standard production tasks and acceptance of operational decisions;
- ability to plan, organize, control operation in all directions of the organization's activities:
- ability to analyze the current situation, to realize search of optimum way solutions;
- ability to develop the local normative documents concerning organization processes, planning, monitoring and motivation of production activity;
- ability to stimulate employees to high-quality work, to increase in level of qualification, to create conditions for career development of subordinate;
- knowledge of normative documentation, the rights and duties, to possess legal knowledge in the sphere of the professional activity of PMS;
- to have organizing qualities, to distribute duties; and,
- to have economic knowledge, in order to understand an economic objective of processes and events.

#### IV. Types of professional activity:

[It is possible to carry production and technological, organizational and administrative, design, research types of activity to basic and invariant types of professional activity of PMS.]

#### 1. Production and technological type:

- a continuous research of property management production processes for the purpose of identification of productive actions and losses;
- designation of necessary improvements and development of new, more effective remedies of quality control and storage of property;
- technological bases of formation of quality and labor productivity; metrological support of design, production, operation of the equipment, technical products and systems;
- development of methods and means increases in safety and environmental friendliness of technological processes;
- implementation certifications of control systems of property quality and controlling complex;
- calibration of measuring instruments of technological processes and equipment.

#### 2. Organizational and administrative:

- the organization of operation of collective property management subdividing in the organization;
- the organization of effective internal interaction at different stages of the life cycle of the equipment;
- planning, organization, and monitoring of production operations;
- assessment of economic efficiency of use of the property management function of the organization;
- safety of the staff;
- organization of management accounting and practical use of indices of variable and constant costs of support of direct uses of the equipment;
- control of the material and information flows of property management in organizations.

#### 3. Research and development:

- planning and the organization application-oriented scientific researches when using property;
- analysis, synthesis and process optimization supports of quality of tests, certifications of the used equipment using job oriented methods;
- analysis of a status and indications of indices of development of systems controls of a property complex in the organization.

#### 4. Experimental and research:

- acceptance tests on new equipment with different figures of merit;
- involvement in development of specifications and programs of carrying out experiments;
- involvement in laboratory, stand and field tests of the equipment with use of information technologies.

#### 5. Operational and technical:

- the organization of installation, adjustment, operation, repair, hardware upgrade, and means of mechanization and industrial automation of equipment;
- development of technological processes of use of the equipment, compilation specifications on design of the industrial equipment;
- development and implementation programs for modernization of the enterprise.

#### 6. Information and projecting activities:

• use information technologies in design

• employ administrative and financial activities in property management system.

#### 7. Scientific and pedagogical:

- the assessment of efficiency of administrative decisions in the organization and educational programs for property management specialists;
- implementation of pedagogical activity during the organization of studies, seminars, conferences;
- mentoring in process work of young specialists.

Thus, PMS has to have formal training and economic knowledge of the development of new types of property management operations in the organization, carry out business planning, and carry out internal audits in functional divisions of the organization.

It is possible to create organizations supporting and developing the specialists for help in creation of the model of the specialist in property management. These organizations can provide various support structures of the PMS: legal advice, training and certifications for employees; and meetings for exchange of experience and providing information about innovations in this sphere. There is the National Property Management Association (NPMA) in the USA, for example, which carries out programs of certification of specialists and offers three progressive levels of certifications:

- the Certified Professional Property Specialist (CPPS);
- the Certified Professional Property Administrator (CPPA); and,
- the Certified Professional Property Manager (CPPM).

This system of certification has multistage structure and each stage of certification has unique requirements.

Each course of certification performs a functional check of the level of knowledge and abilities in the management of property. This is in conjunction with the developed property rules and regulations of the specialized organization or branch.

The author's model must have a competence-based essence approach (includes not only cognitive and operational and technological components, but also motivation, social parts), xiii continuity and multi-levelness, integration of the scientific educational environment, production, and business. Defined criteria of basic competencies in professional transition during creation of PMS professional model are mandatory.

Key provisions and conclusions of this article provide the grounds to assume that the conducted research does not exhaust all aspects of the considered problems. It can form a conceptual and theoretical basis for further scientific research in the development of a system of PMS formation and improvement. The developed PMS model for the organization or production, defining and justifying that there should be a property specialist based on the employer needs, will be the basis for a property management specialist's professional competence. This will also allow the elimination of the existing contradiction between the process of training the specialists and their professional activity.

Progressive approach to an employee's assessment allows the employer to form teams with high competencies, larger responsibilities, gradually expanding employees' participation in the workings of the organization. Similar tactics can lead to transition from models of management with strict hierarchy and rigid control to a self-regulatory organization. This then leads to the formation of administrative models where the result is uniform purpose and everyone is capable

to affect the final product. xiv Parallel work is important here for optimization and formation of a new model of the mobile property specialist who will join in a new corporate culture with upgraded equipment and integrated interindustry communications.

The specialist becomes not just an ally in the course of changes in the company, but one from their mentors. Key tools at the same time are design groups modeling the future of the company and business, and designing creative laboratories and hubs in the company. They rely on key competitive advantages of business, strategic thinking, and needs of clients and tools of HR analytics.

The model of the specialist is a description of required level of performance of functions, and what qualities they must possess. Models allow for distinguishing one expert from another, including levels (qualities) of training for specialists of the same type. The model acts as a backbone factor for contents selection education and forms of his realization in the educational process. xv

Undoubtedly, the model - the tool of an expert assessment and a basis for recruiting characteristics for the necessary expert, is equally valuable for career development of the expert. Career development in a section of the model of the specialist includes such aspects of activity of an individual as intensely conscious work processes. The second important point is the desire to immerse oneself in business perspective to develop above functional competence. In addition, the third factor that is seriously influencing success - is a readiness to move, to change locations, and not to live tied to one place. These "three whales" can give serious a break in competencies and be a motivator in a profession<sup>xvi</sup> for achievement of results.

Thus, the huge sphere of formation of personnel resources is divided between various departments of organizations in Russia, and the model of the specialist will be able to help organize this sphere to look at personnel from a different angle. It is necessary to build work based on deep understanding of technological changes and related risks to the companies in Russia. Expertness in a specific industry, flexibility of thinking, and the ability to integrate breakthrough decisions into already operating structures, and conditions for constant improvement are important.

#### References

- Shadrikov V. D. New model of the expert: innovative preparation and competence-based approach//the Higher education today. 2004. No. 8. Page 26-31
- "Zeer E. F. Key qualifications and competences of personal focused professional education//Science and education. No. 3. 2000. Page 90-102.
- <sup>III</sup> Akhmetzyanova G. N. Competence-based model of the worker of an automobile cross-section in system continuous formation//Prospect of science. 2011. No. 17. Page 12-15.
- iv What Are Workplace Competencies? by Shelagh Dillon
- http://smallbusiness.chron.com/workplace-competencies-46820.html (date of the address 03.12.2016.)
- <sup>v</sup> Zhuravleva T. B. model of an assessment of compliance of level of training of the expert to requirements the employer to vacancy//News of higher educational institutions. North Caucasus region. / Social sciences. 2003. No. 2. Page 22-31.

- vii Seleznyov B. I., Telina I. S. Model of the organization of training of specialists in the field of high technologies//University steering: practice and analysis. 2003. Page 5-6, Page 89-94. vii Jeff Nowak. Can an Employer Require That an Employee Submit. FMLA Certification from a Specialist to Support the Need for FMLA Leave? on FMLA Insights Guidance & amp; Solutions for Employers November 4, 2016 Posted in Medical Certification <a href="http://www.fmlainsights.com/can-an-employer-require-that-an-employee-submit-fmla-certification-from-a-specialist-to-support-the-need-for-fmla-leave/">http://www.fmlainsights.com/can-an-employer-require-that-an-employee-submit-fmla-certification-from-a-specialist-to-support-the-need-for-fmla-leave/</a> (date of the address: 02.05.2017).
- Mustafina D. A., Rakhmankulova G. A., Korotkova N. N. Model of competitiveness future software engineer//Current high technologies. 2010. No. 8. URL: <a href="http://cyberleninka.ru/article/n/model-konkurentosposobnosti-buduschego-inzhenera-programmista">http://cyberleninka.ru/article/n/model-konkurentosposobnosti-buduschego-inzhenera-programmista</a> (date addresses: 18.05.2016).
- <sup>ix</sup> Andryukhina T.N. Competence-based model of training of the specialist in operation and to service of motor transportation and technological machines and equipment//Messenger Samara state technical university. 2007. No. 2(8). With 4-8.
- \* Asaul A. N. Training of engineers managers on steering of innovations pledge successful development of the company//Economic revival of Russia. 2009. No. 1. Page 3-7.
- <sup>xi</sup> Kovalyov A. P. Steering of property at the enterprise: the textbook//– M. Finance and statistics. 2009.
- <sup>xii</sup> Kovtun E. N. Formation level assessment modes competences / Report at a seminar "Improvement of competence-based approach in NIU SGU", St. Petersburg Pushkin. Training center of training of heads, on June 10-11, 2014
- wiii Windeatt, S., 2011. The Internet Resource Books for Teachers. Oxford University Press, pp. 136.
- xiv Crisis, business, shots as changes a situation in the Russian companies <a href="http://www.hr-portal.ru/blog/krizis-biznes-kadry-kak-menyaetsya-obstanovka-v-rossiyskih-kompaniyah">http://www.hr-portal.ru/blog/krizis-biznes-kadry-kak-menyaetsya-obstanovka-v-rossiyskih-kompaniyah</a> (date of the address 03.04.2017.)
- <sup>xv</sup> Tatur Yu. G. Competence of structure of model of quality of training of the expert//the Highest education today. 2004. No. 3. Page 20 26.
- xvi Jobs in Motivation & amp; Training by Julie Davoren, <a href="http://work.chron.com/jobs-motivation-train">http://work.chron.com/jobs-motivation-train</a>

#### BIO:

Julia Sharygina, a Moscow based employee of U.S company TechTrans International, is a property and inventory specialist supporting a contract with NASA for the International Space Station Program. She is a graduate of Plekhanov Russian University of Economics and has experience in the logistics arena having worked with transportation companies in Moscow. Recently she obtained her certification from the Johnson Space Center in Houston, Texas for Certified Professional Property Specialist (CPPS).

# **Separation of Duties**

Kelly Marchese Barbara Rosenbaum Yvan Caceres Deloitte Consulting LLP

## Introduction

Personnel are a critical part of warehouse operations, as they are directly responsible for the execution of operations to meet supply and demand requirements. The complexity of material handling in pharmaceuticals and medical equipment, along with the risk of potential theft, make a case for the implementation of safeguards in the organization. A key industry leading practice is to employ the concept of Separation of Duties, which is having more than one person required to complete a task and serves as an internal control to prevent fraud or error. This concept must be applied through a structure in place for personnel operations and management supported by guidance that implements overarching regulatory requirements and enforces industry leading practices, specifically around the following three focus areas:

- Organization Structure: Aligns end-to-end processes across various departments to promote more than one employee oversight in operations
- Roles and Responsibilities: Provides guidance for staff that clearly defines the expectations and limitations of their assigned position
- Management Oversight: Promotes management control and visibility into warehouse operation to monitor production and promote early identification of challenges

These three focus areas are the foundation for effective employment and management of warehouse personnel, which directly leads to operational efficiency. Leading practices for each focus area are expanded upon below. The International Organization for Standardization (ISO) lays out a comprehensive risk framework in ISO 31000 which has been accepted across industries worldwide. To apply this framework, it is important to consider the specific context of the operations and facility being evaluated. After establishing context, the risk framework moves into the assessment phase, consisting of risk identification, analysis and evaluation. The subsequent step is risk response. Responses typically include mitigation strategies to underwrite the dangers or concerns involved. Throughout each step of the framework, risks and strategies should be monitored, reviewed, communicated to all those involved and continuously improved.

# **Organization Structure**

#### **Division of Personnel**

In order to help ensure the proper checks and balances in operations, it is essential to design a staffing model that implements the separation of duties of warehouse operations across more than one department and person. This leading practice is implemented to dissuade against any wrongdoing in operations, whether intentional or accidental. It is imperative that all warehouses design and publish a clearly define organization structure and chart that promotes the separation of duties through division of roles and responsibilities of the end-to-end process. A sample organization structure that promotes the separation of duties is shown below.

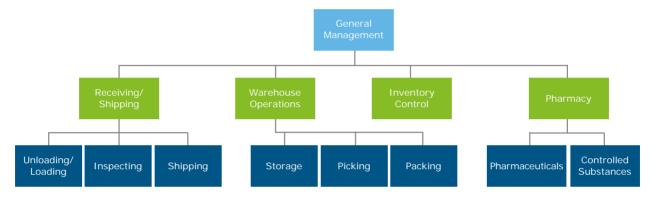


Figure 1: Leading Medical Warehouse Organization Structure<sup>i</sup>

To facilitate operations across departments, it is common to have a designated person appointed at each acceptance, transfer, or distribution point to increase operational efficiency. Also, proper checks and balances require a minimum separation of duties between the purchaser, or the one who places the order; the receiver, or the one who physically receives and inspects the order; and the payer, who actually issues payment to vendor. Regulations require that those who are accountable for the products cannot be responsible for performing inventory counts, and therefore the General Management is responsible for designing and delegating inventory control operations to other warehouse personnel.

#### **Leading Practices**

To further promote the separation of duties, warehouses can implement visible measures that differentiate the various staffing departments, and their respective operational roles. Examples of visible differentiation measures are:

- Staggering the start time of various departments by either 30 minutes to 1 hour
- Issue different colored uniforms for each of the departments
- Designate different locations for facilities/locker rooms for each department

## Roles and Responsibilities

#### Guidance

The organization structure and separation of duties is implemented and enforced through the development of standardized guidance for personnel. This guidance should align to overarching regulations and clearly define the responsibility, authority, and interrelationships of all personnel. A standardized operating procedure is developed to foster a common understanding of the end-to-end warehouse operations, and includes high-level processes and key touch points among personnel. A single, standardized version of this document is implemented across all warehouse departments in order to align operations with policies and guidance, reduce process variation, and help ensure resources are used properly. It is important that there are no gaps or unexplained overlaps in oversight or roles and responsibilities, which could lead to operational challenges or a lack in checks and balances.

It is a common practice to have work instructions or desktop procedures that outline detailed, step-by-step processes for each major activity within each warehouse department. This helps to standardize all operations and clearly identifies resource responsibilities for all aspects of operations. By defining all activities in detail it can prevent any mishandling or theft through providing process visibility and setting expectations of task and activities across warehouse resources and departments. When defining resource responsibilities, it is important to consider that workload and responsibilities must be reasonable to one position and enable proper time, attention, and dedication to tasks. If workload is not properly aligned, it could create risk to product or process quality, or lead to errors or inefficiencies.

#### **Knowledge and Resources**

The personnel assigned to each warehouse department and position must have the appropriate skill set and experience qualifications to perform the duties as outlined in the position description and desktop procedures. It is important to understand any certifications or background checks that are required for positions of a sensitive nature. For example, key personnel in the distribution of pharmaceuticals must have the appropriate experience and certifications for handling and dispensing pharmaceuticals.

Paring with knowledge and training, all managerial and technical warehouse personnel must have authority and access to the necessary resources to perform tasks in their area of responsibility. This could include, but not limited to, warehouse management system access, warehouse access, and equipment keys.

## Management Oversight

#### **Policies**

Proper warehouse management requires knowledge and understanding in all aspects of warehouse operations to oversee activities and identify any potential issues before they arise. They are required to know the processes and rely on performance guidance to identify and correct deviations in processes and operations. To support the performance guidance and mitigate against any fraud or theft, management must implement codes of practice and disciplinary procedures to prevent and address situations of suspected or confirmed misappropriation or theft.

Additionally, management must incorporate preventative measures so that personnel are not subject to commercial, political, financial or other pressures or conflict from other personnel or operational influences. This includes implementing resources for personnel to contact in regards to policy, compliance, or reporting of suspicious or corrupt behavior. Certain warehouse departments and activities that are more attractive to theft, such as controlled substances and medical equipment, may require special attention or amplified oversight.

#### **Performance Measurement**

Performance metrics are important to monitor and manage the health and effectiveness of warehouse operations. Proper performance metrics are aligned to direct operations and are actionable for early identification of any challenges. Effective metrics are required on operations performance and process adherence, reporting on business performance, projections vs. plans, and workload performance. To drive achievement of metrics targets, it is important to understand what delivers value for the operations and personnel, which is essential in driving desired behaviors and performance outcomes to achieve targets. Effective performance metrics are:

- Linked to member value and drive improvement and action
- Balanced across operations (e.g., process, learning and development, customer, etc.)
- Aligned to the goals and strategy of warehouse operations

Performance metrics should be tracked on a continuous basis in a dashboard format to easily identify any metrics that are not meeting expected targets to quickly diagnose and resolve issues.

## Points of Contact

#### **Kelly Marchese**

DC Principal
Deloitte Consulting LLP
Federal Supply Chain Service Line Lead
kmarchese@deloitte.com

Kelly is a principal with Deloitte Consulting LLP and leader of the Federal Supply Chain practice. She has over 20 years of experience leading projects in highly engineered manufacturing industry sectors, specifically Aerospace and Defense. Kelly also leads the Global Supply Chain Risk service offering and is a thought leader in Product Development and Engineering Effectivness through Manufacting Operations Excellencee. She had helped clients navigate through complex transformations, including helping a federal agency develop a multibillion dollar global business case to streamline their aviation supply and maintenance processes and advising a life sciences company through a full lifecycle of divestiture, acquisitions and IPO.

#### Barbara Rosenbaum

Consulting Managing Director Logistics and Distribution Offering Lead Deloitte Consulting LLP brosenbaum@deloitte.com

Barbara is a managing director in the Deloitte Federal Strategy and Operations Practice focused on Supply Chain. She leads the Logistics and Distribution service offering within the Federal Supply Chain service line, building upon over 30 years of experience leading federal and commercial projects across all areas of the supply chain. She currently works across federal clinets with a particular focus in National Security and has market eminence as a thought leader in supply chain transformation, planning and inventory optimization.

#### **Yvan Caceres**

DC Specialist Leader Logistics and Distribution Subject Matter Expert Deloitte Consulting LLP yeaceres@deloitte.com

Yvan is a Specialist Leader with Deloitte's Public Services Organization with over 20 years of experience in the areas of Transportation, Logistics, Distribution Network Planning, 3PL Operations, and advanced planning functions. He has extensive experience in systems integration, requirements development, systems architecture, and implementation lifecycle, having managed Supply Chain implementations in the consumer packaged goods, industrial and automotive, high technology, retail industries as well as major programs in the DoD. Yvan has extensive knowledge of commercial supply chain technologies such as APS, Inventory Management, Supply Planning, Transportation, and Simulation Modeling.

<sup>&</sup>lt;sup>i</sup> USAID Guidelines for Warehousing Health Commodities, http://apps.who.int/medicinedocs/documents/s16875e/s16875e.pdf



3525 Piedmont Road Building 5, Suite 300 Atlanta, GA 30305

P: 404-477-5811

Email: hq@npma.org