УДК 615:661.12]:339.14

THE IMPACT OF WMS SETTINGS TO ENSURE QUALITY REQUIREMENTS OF PHARMACEUTICAL PRODUCTS

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Quality requirements for pharmaceutical products in distribution practice and with regard to the accepted range and variety of options cannot be ensured without using the specialized software, such as warehouse management software (WMS). In the pharmaceutical distribution business, the role and functionality of the specialized software must be expanded to create conditions for trade flows, pharmaceutical product options and mutable laws requirements.

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GDP (Good distribution practice) has been developed for pharmacy and aims at ensuring product quality. Process quality is a key component in pharmaceutical distribution. We may talk about process quality, provided such processes are formalized and undergo regular validation. The contents of process quality are so extensional in the distribution practice, that responsible managers or organizations require software support. A software product of WMS type is an IT tool to solve this task. Correct algorithms of this software are a key component of quality assurance, in terms of distribution process quality.

These are built upon a product that has its physical and pharmaceutical handling specifics. Assurance of these specifics and requirements are the very basics of rules put into this software. For this purpose, specifics and requirements mean the following: pharmaceutical groups, storage temperature ranges, humidity, expiration, series and batches (lots). These determine receiving, storage and shipment processes of medications in a distribution center.

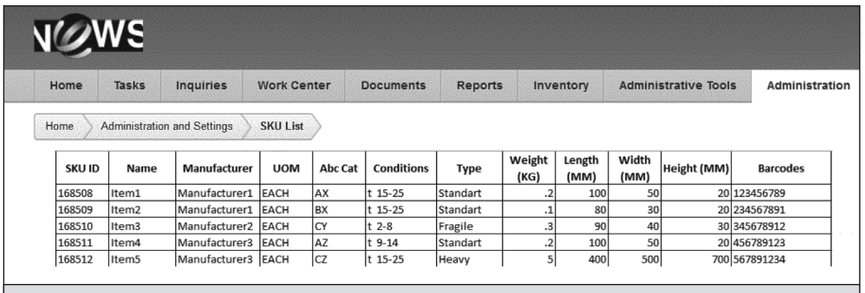
One may come across 5 to 200 thousands of available medications (depends on the market), and a great number of combinations is possible, with view to specifics of such medications. Therefore, one may conclude that quality assurance of a variety of medication groups is no longer possible without any software support.

Considering storage and automation systems, level of solutions is even higher, due to coordination between the equipment and product specifics.

What is WMS? Software of **WMS** (**W**arehouse **M**anagement **S**ystem) type is a tool for formalizing goods flows inside a distribution center. Along with formalization of the processes themselves, the software of medications distribution centers must cover the above pharmaceutical specifics and, obviously, logistics parameters, like dimensions, weight and ABC classification.

All these specifics must be incorporated into algorithms which provide the ability to automatically conduct processes of optimal goods placement in storage areas, and shipment of medications from a warehouse in the controlled sequence.

Consider a case that is typical for everyday operation



SKU ID	Name	Manufacturer	UOM	Abc Cat	Conditions	Type	Weight (KG)	Length (MM)	Width (MM)	Height (MM)	Barcodes
168508	Item1	Manufacturer1	EACH	AX	t 15-25	Standart	.2	100	50	20	123456789
168509	Item2	Manufacturer1	EACH	BX	t 15-25	Standart	.1	80	30	20	234567891
168510	Item3	Manufacturer2	EACH	CY	t 2-8	Fragile	.3	90	40	30	345678912
168511	Item4	Manufacturer3	EACH	AZ	t 9-14	Standart	.2	100	50	20	456789123
168512	Item5	Manufacturer3	EACH	CZ	t 15-25	Heavy	5	400	500	700	567891234

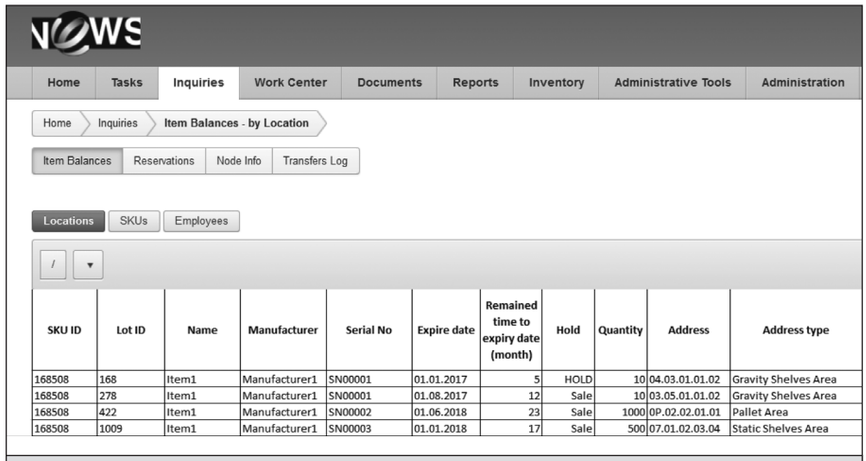
Screen shot 1. WMS interface – catalog of pharmaceutical and logistical specifics of medications

Photo 1. A gravity flow racks structure at a pharmaceutical warehouse

of pharmaceutical warehouses. A new goods batch was delivered to a warehouse and it contains medications that expire earlier than those being shipped at the moment. With view to the GDP requirements, one must strictly adhere to the **FEFO** (**F**irst **E**xpire, **F**irst **O**ut) principle. What is the algorithm for the WMS, if the picking area of the warehouse is equipped with a structure of gravity flow racks where one picking channel corresponds to one SKU and extraction of that SKU will lead to significant labor efforts?

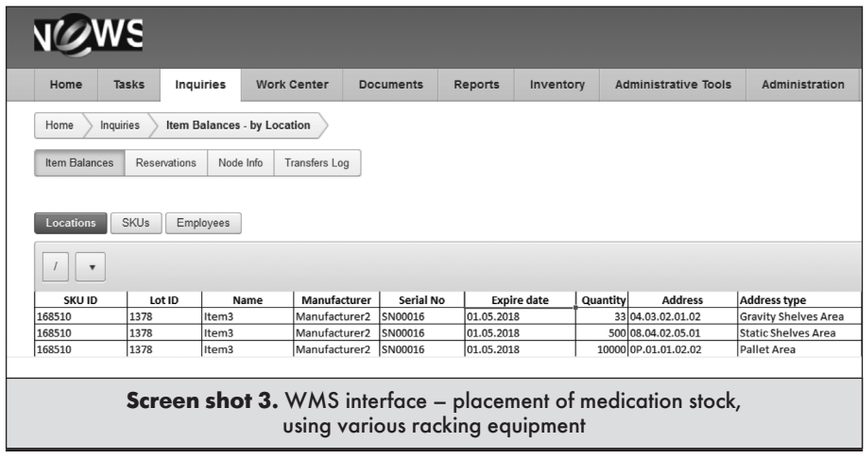
For such cases back-up channels of racking equipment have to be envisaged in quantity which is approximately equal to 10% of total SKU quantity in stock while planning warehouse equipment and processes. Thus and so, WMS will easily lock the channel containing the medication with later expiry date from picking and place the medication with earlier expiry date into an empty channel, enabling it for packing. It will also automatically enable picking of the medication with later expiry date, after the warehouse runs out of the medication with earlier expiry date. Thus and so, the software ensures FEFO and minimizes any extra labor efforts at this point automatically.

Pharm logistics specialists face the dilemma of satisfying GDP requirements and logistic operation efficiency every day. Consider a graphic example – there is a need to ship 2,222 pieces of a medication. For the purpose of labor optimization, areas of single pieces picking, picking by multipacks and box storage area are arranged at warehouses. Looking exclusively from the point of minimization of internal logistics costs, it is obvious that 22 pieces of the medication should be picked from the single pieces picking area, 200 pieces from the area of picking by multipacks, and 2,000 from the box storage area. But what about the FEFO, if the required number of the medication pieces with different series and, accordingly, different expiry dates is placed in all of these areas? Each



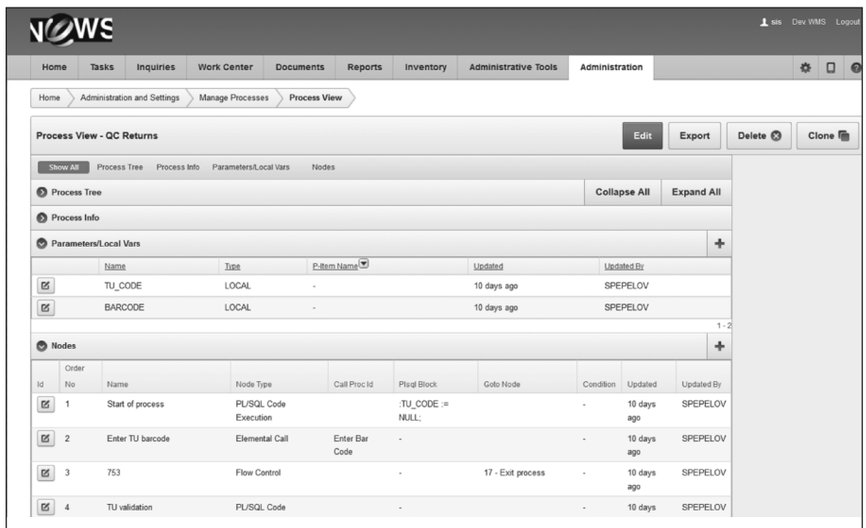
SKU ID	Lot ID	Name	Manufacturer	Serial No	Expire date	Remained time to expiry date (month)	Hold	Quantity	Address	Address type
168508	168	Item1	Manufacturer1	SN00001	01.01.2017	5	HOLD	10	04.03.01.01.02	Gravity Shelves Area
168508	278	Item1	Manufacturer1	SN00001	01.08.2017	12	Sale	10	03.05.01.01.02	Gravity Shelves Area
168508	422	Item1	Manufacturer1	SN00002	01.06.2018	23	Sale	1000	0P.02.02.01.01	Pallet Area
168508	1009	Item1	Manufacturer1	SN00003	01.01.2018	17	Sale	500	07.01.02.03.04	Static Shelves Area

Screen shot 2. WMS interface - the medication held out in a picking channel



SKU ID	Lot ID	Name	Manufacturer	Serial No	Expire date	Quantity	Address	Address type
168510	1378	Item3	Manufacturer2	SN00016	01.05.2018	33	04.03.02.01.02	Gravity Shelves Area
168510	1378	Item3	Manufacturer2	SN00016	01.05.2018	500	08.04.02.05.01	Static Shelves Area
168510	1378	Item3	Manufacturer2	SN00016	01.05.2018	10000	0P.01.01.02.02	Pallet Area

Screen shot 3. WMS interface – placement of medication stock, using various racking equipment



Screen shot 4. WMS interface - process designer as a scenario tool

pharmaceutical company sets up its own scenarios for such situations in the software, while striving to satisfy the GDP as far as possible and minimize labor efforts at the same time. For example, picking of the series with the earliest expiration date located in different places, which does not ensure strict adherence to the FEFO principle, however, optimizes arising labor efforts, on the other hand.

The WMS must resolve such challenges automatically, obviating the need for decision-making by the personnel. On the other hand, responsible managers should be able to regulate and control software settings, hence to have access to such settings for the purpose of process validation and quality assurance.

Thus and so, transparency of process settings that ensure quality is a requirement that must be taken into account in the choice of any WMS software, allowing responsible managers to validate and adjust such processes, if any discrepancies, new laws or circumstances come into play.

ВЛИЯНИЕ НАСТРОЕК СУС НА ОБЕСПЕЧЕНИЕ ТРЕБОВАНИЙ КАЧЕСТВА ФАРМАЦЕВТИЧЕСКИХ ПРОДУКТОВ

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РЕЗЮМЕ

Обеспечить требования к качеству фармацевтической продукции в дистрибьюторской практике и с учетом принятого диапазона и разнообразия вариантов невозможно без использования специализированного программного обеспечения, в частности системы управления складом (СУС). В фармацевтическом дистрибьюторском бизнесе роль и функциональные возможности специализированного программного обеспечения должны быть расширены, чтобы создать условия для реализации торговых потоков, вариантов фармацевтического продукта и удовлетворения изменяемых требований законодательства.

УДК 615.456.014:615.12].07

ОРГАНИЗАЦИОННО-ПРАВОВЫЕ РЕЗЕРВЫ МОДЕРНИЗАЦИИ ПРОЦЕССА ОБЕСПЕЧЕНИЯ КАЧЕСТВА ИЗГОТОВЛЕННЫХ В АПТЕКАХ ПАРЕНТЕРАЛЬНЫХ ЛЕКАРСТВЕННЫХ ФОРМ

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Введение. *Несмотря на риск развития нежелательных реакций, многие страны сохранили за аптекой традиционные функции индивидуального подхода к лекарственному обеспечению населения экстемпоральными лекарственными формами. В РФ изменения в сфере обращения лекарственных средств (ЛС) привели к резкому сокращению объемов аптечного изготовления за счет закрытия производственных отделов и производственных аптек, вследствие чего возможно разрушение системы аптечного изготовления ЛС и снижение доступности лекарственного обеспечения.*

Цель исследования *– ситуационный анализ состояния проблемы внутриаптечного изготовления парентеральных лекарственных форм и выявить резервы повышения качества изготовленных инъекционных и инфузионных лекарственных форм.*

Материал и методы. *Объектами исследования служили законодательная и отраслевая нормативно-правовые базы РФ в сфере обращения ЛС, рецептура производственных аптек при медицинских организациях. Использовались ретроспективный, ситуационный, графический методы анализа и контент-анализ.*

Результаты. *Сформирован перечень парентеральных (инъекционных и инфузионных) лекарственных форм, изготавливаемых в аптечных условиях. Структурированы наиболее распространенные нарушения лицензионных требований и условий в аптеках.*

Заключение. *Выявлены резервы модернизации процесса обеспечения качества изготовленных в аптечных условиях парентеральных лекарственных форм и определены приоритетные проблемы в исследуемой области.*

Ключевые слова: *аптечное изготовление парентеральных лекарственных форм, инъекционные лекарственные формы, качество лекарственных средств, нарушения лицензионных требований и условий в аптеках.*