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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 (Warehouse Management System) 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.

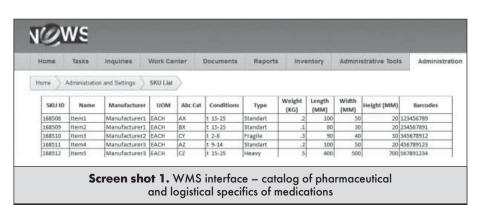
All these specifics must be incorporated into algorithms which provide the ability to automatically conduct processes

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



A gravity flow racks structure at a pharmaceutical warehouse



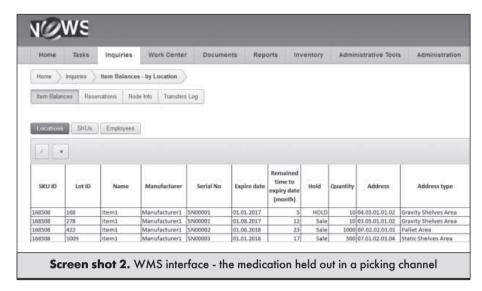
of pharmaceutical warehouses. A new goods batch was delivered to a warehouse and it contains medications that expire earlier than those being shipped at the

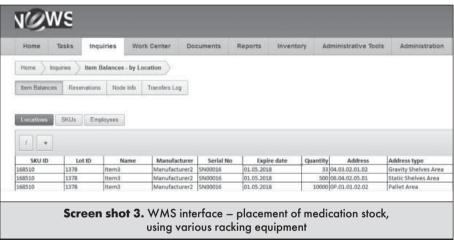
moment. With view to the GDP requirements, one must strictly adhere to the FEFO (First Expire, First Out) principle. What is the algorithm for the WMS, if the picking area of the warehouse is equipped with a structure of gravity flow racks where one picking channel corresponds to one SKU and extraction of that SKU will lead to significant labor efforts?

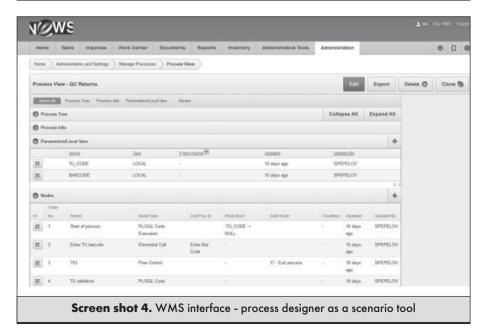
For such cases back-up channels of racking equipment have to be envisaged in quantity which is approximately equal to 10% of total SKU quantity in stock while planning warehouse equipment and processes. Thus and so. WMS will easily lock channel containing the medication with later expiry date from picking 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







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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.