

“Logistics of pharmaceuticals in hospitals”



EAHP Academy Seminar 14-16 May, 2010, Riga Latvia
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Saturday, 15 May 2010:

Supply Chain and economic Indicators

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“Logistics of Pharmaceuticals in Hospitals”



Disclosure of Relevant Financial Relationships

The following content contains information about healthcare product or services.

Regarding the healthcare products or services that will be discussed in the content, I have had no financial relationship in any amount in the last 12 months with the manufacturers of the products or providers of the services.

signed: Klaus-Michael Fortmann

Supply Chain and Economic Indicators - Overview -

Saturday, 15 May 2010

09.00 – 10.30	Fundamentals Logistic tools
10.30 – 11.00	Coffee Break: hotel lobby
11.00 – 12.30	Logistic tools
12.30 – 14.00	Lunch
14.00 – 15.30	Storage systems on wards Storage condition monitoring
15.30 - 16.00	Coffee Break: hotel lobby
16.00 - 18.00	Storage models Results and discussion
19.15	Academy Dinner & Social Activity (meet in hotel lobby at 19.00 for departure)

Supply Chain and Economic Indicators

- *Fundamentals*
- *Logistic tools*

Supply Chain and Economic Indicators - Fundamentals -

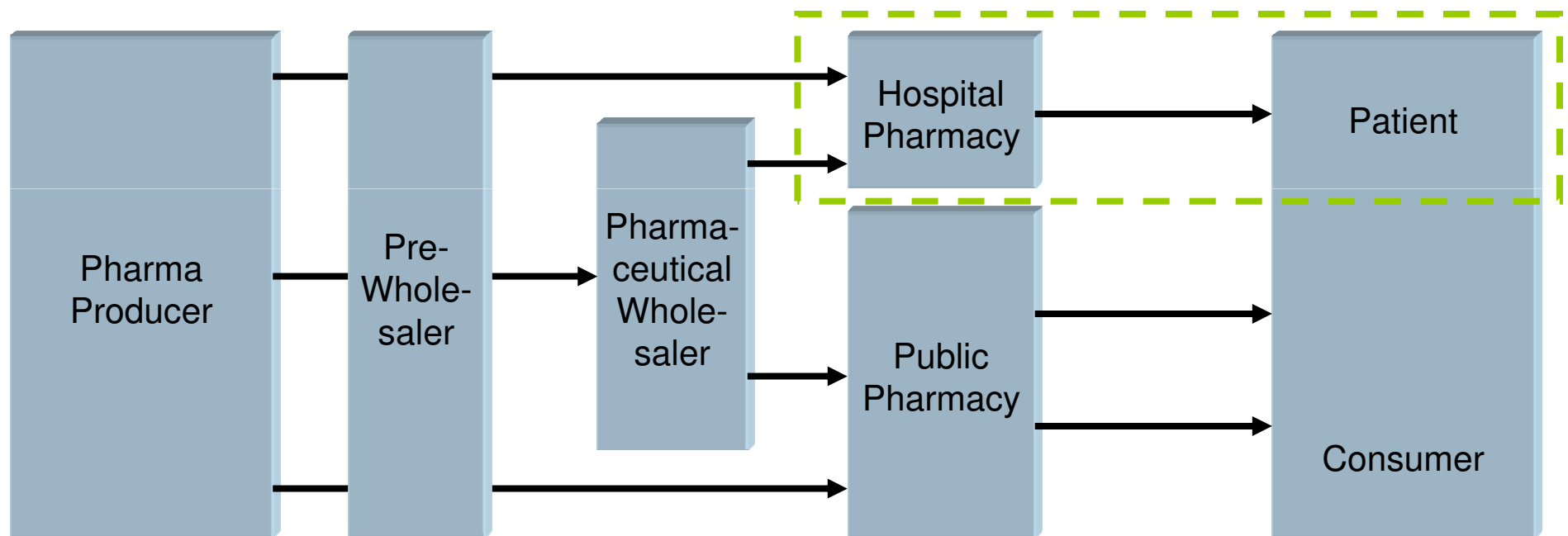
Educational Goals

- Understanding the supply chain
- Knowledge of methods to avoid counterfeits along the supply chain
- Knowledge of the definition of logistics (phases, activities)
- Knowledge of the „6 Rights“ of logistics (5 Rights of drug provision)
- Knowledge of main logistics costs
- Knowledge of logistics service components
- Understanding the „available stock“
- Able to draw the „Ideal Model“ of order point planning
- Knowledge of consumption models
- Understanding the method „exponential smoothing“

Supply Chain and Economic Indicators - Fundamentals -

Supply Chain of Drugs

our main focus



Supply Chain and Economic Indicators - Fundamentals -

Challenge of the Future: Combat counterfeit drugs along SC

Examples of security systems for securing traceability:

- 2D Barcodes, e.g. Datamatrix code



- RFID, Radio Frequency Identification

expanded memory →

possible to safeguard authentication,

Stored information: company prefix, article number,

unique serial number, locked by the

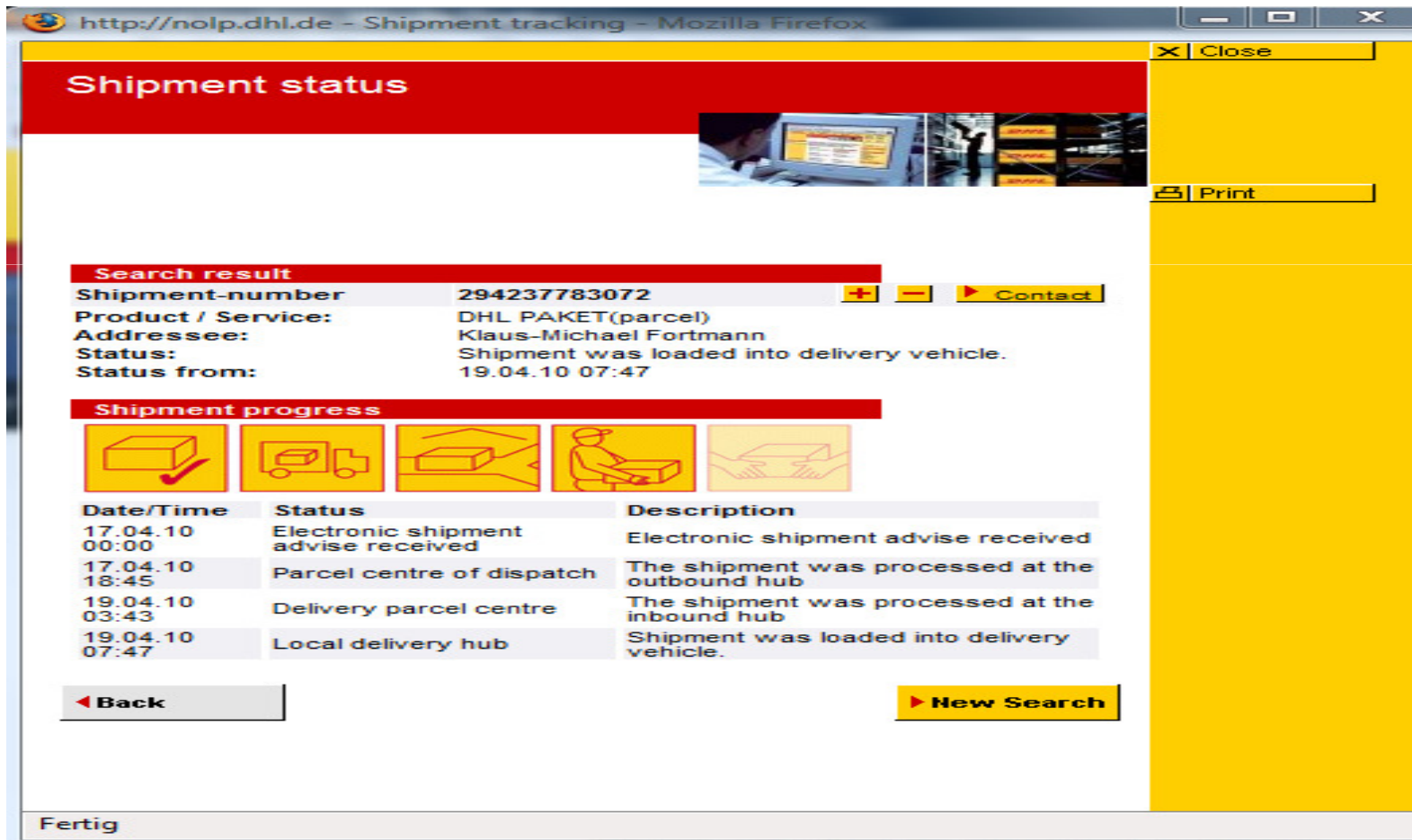
pharmaceuticals manufacturer with a specific code

- **Variable security printing**

each label provided with a unique randomly selected code, code stored in a database. All affected parties in the supply chain are able to read off and verify this code against the database

Supply Chain and Economic Indicators - Fundamentals -

Tracking & Tracing is Normal in other Fields of Distribution



The screenshot shows a web browser window with the address bar displaying "http://nolp.dhl.de - Shipment tracking - Mozilla Firefox". The page title is "Shipment status". Below the title, there is a "Search result" section with the following information:

- Shipment-number: 294237783072
- Product / Service: DHL PAKET(parcel)
- Addressee: Klaus-Michael Fortmann
- Status: Shipment was loaded into delivery vehicle.
- Status from: 19.04.10 07:47

Below the search result, there is a "Shipment progress" section with a progress bar and a table of events:

Date/Time	Status	Description
17.04.10 00:00	Electronic shipment advise received	Electronic shipment advise received
17.04.10 18:45	Parcel centre of dispatch	The shipment was processed at the outbound hub
19.04.10 03:43	Delivery parcel centre	The shipment was processed at the inbound hub
19.04.10 07:47	Local delivery hub	Shipment was loaded into delivery vehicle.

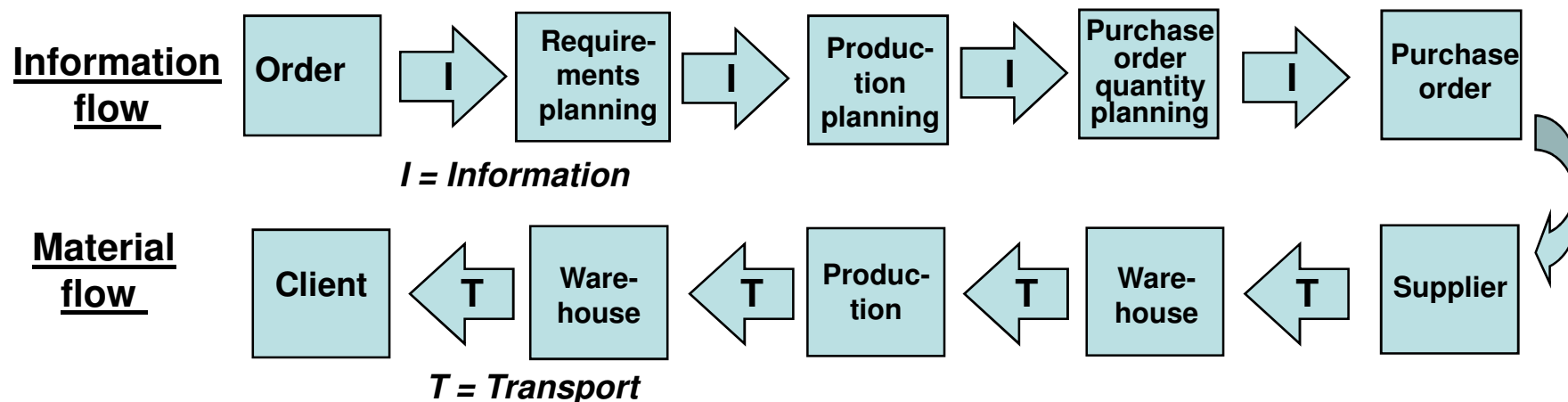
At the bottom of the page, there are buttons for "Back" and "New Search". The word "Fertig" is visible in the bottom left corner of the browser window.

Supply Chain and Economic Indicators - Fundamentals -

General Definition of Logistics

Logistics is defined as the integrated planning, realising, usage and control of

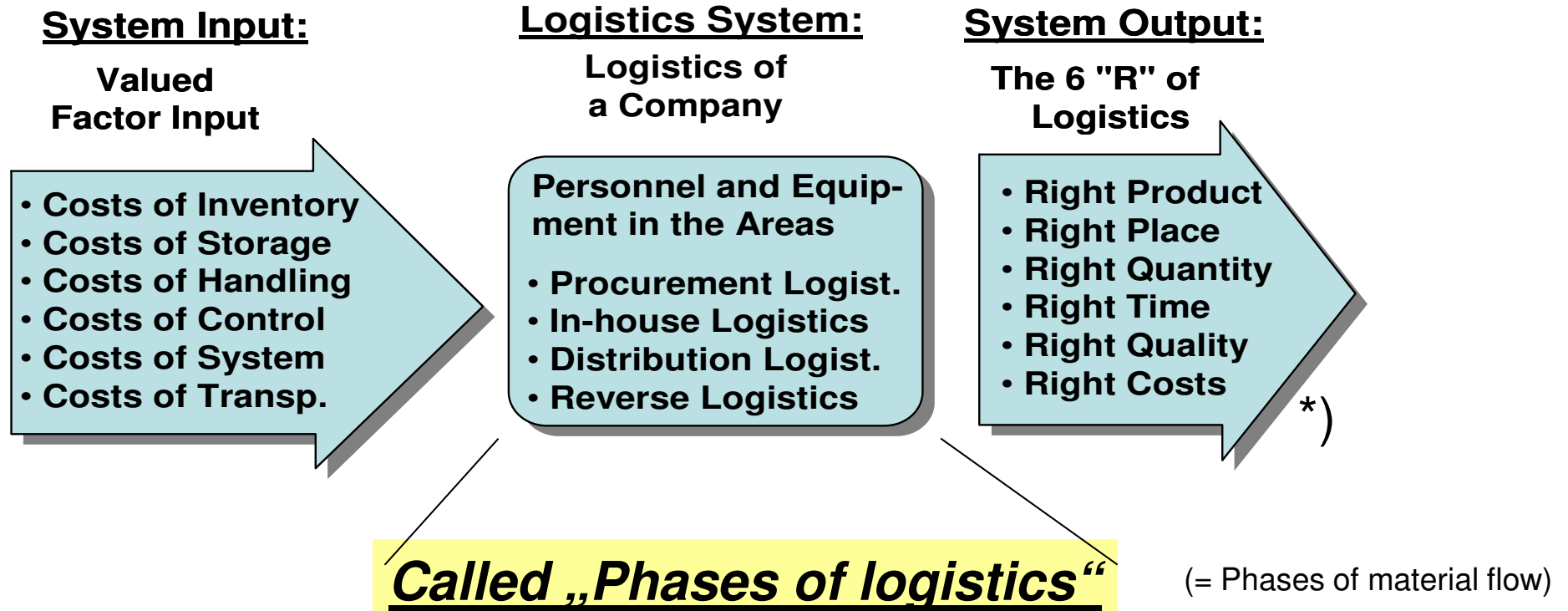
- all kinds of transport processes,
- the storage of goods and
- the corresponding information processes within companies and between companies.



Supply Chain and Economic Indicators - Fundamentals -

Main Aim of Logistics: Optimisation the Efficiency of Logistics

Efficiency of Logistics = Output/Input Ratio of the Logistics System



*)Variant: The 5 rights: the right patient, right medicine, right dose, right route and right time

Supply Chain and Economic Indicators - Fundamentals -

Components of Logistics Service

Delivery Time = Time between issue of order and availability for the client

Delivery Reliability (*on-time delivery performance*) = Percentage of keeping the guaranteed delivery time

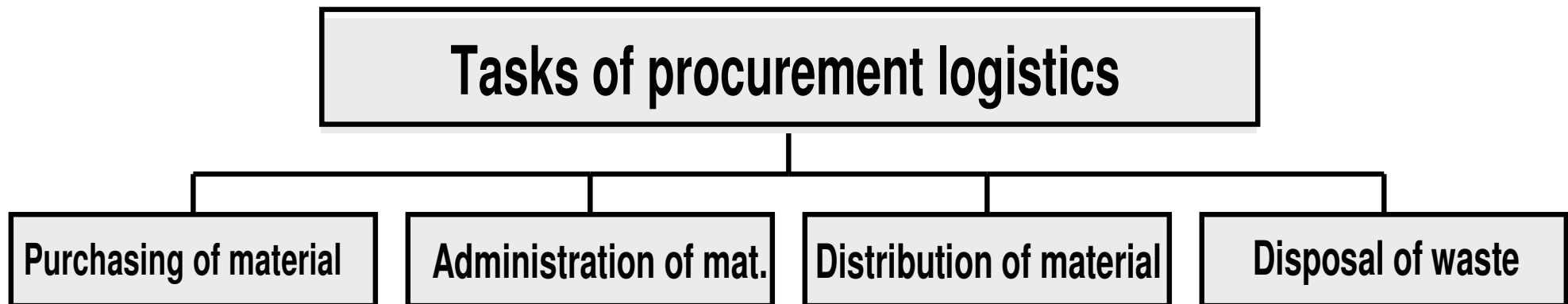
Delivery Service Level = Percentage of articles directly deliverable from warehouse

Quality of Delivery = Accuracy of delivery concerning type, quantity and quality of the delivered articles

Flexibility of Delivery = Possibility of consideration of special wishes of the clients concerning delivery time or delivery quantity

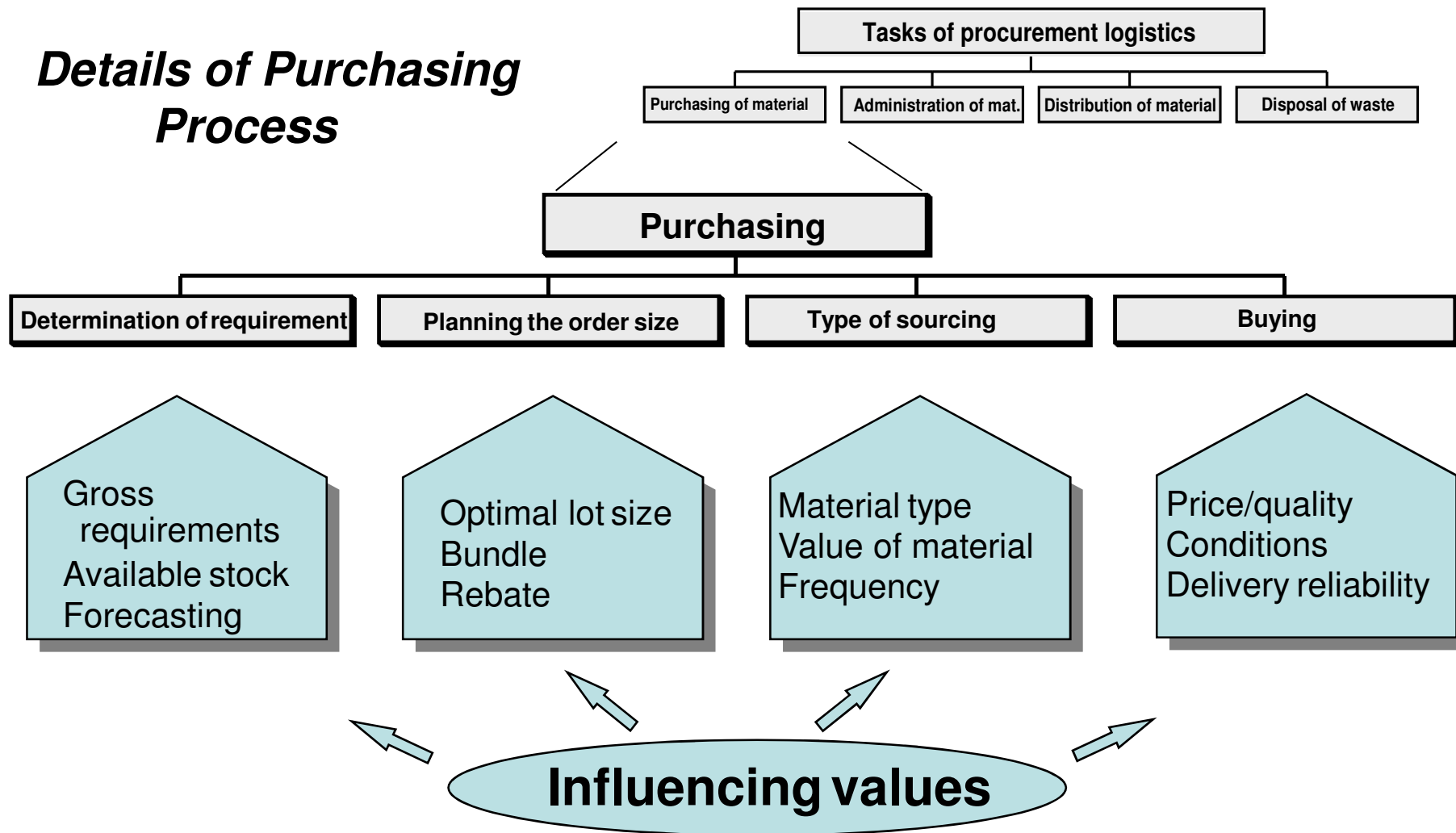
Supply Chain and Economic Indicators - Fundamentals -

Phase: Procurement Logistics



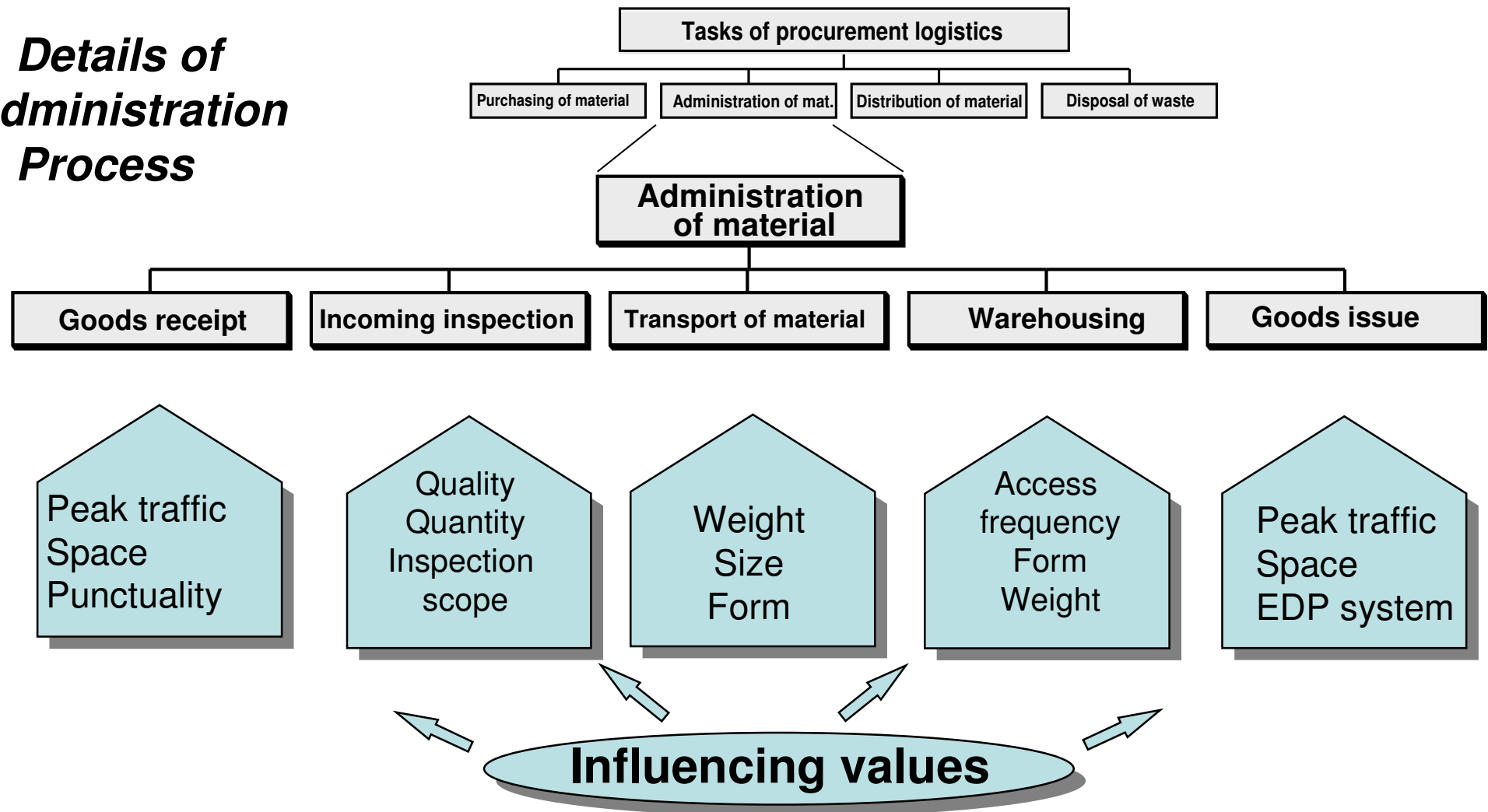
Supply Chain and Economic Indicators - Fundamentals -

Details of Purchasing Process



Supply Chain and Economic Indicators - Fundamentals -

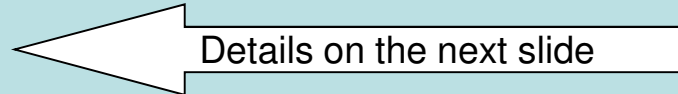
Details of Administration Process



Supply Chain and Economic Indicators - Fundamentals -

Tasks of the Purchasing Process in a Hospital Pharmacy

- Checking the bought products
- Evaluation of suppliers
- External price comparison
- Negotiation of prices and conditions
- Conclusion of contract
- Continuous revision of assortment
- Ordering
- Procurement of not-listed medicaments in special cases
- Ecological checking: packing, disposal



Supply Chain and Economic Indicators - Logistic Tools -

Value Benefit Analysis for Suppliers as Part of the Buying Process

Suppliers \ Criteria	Weight	Supplier Miller		Supplier Mayor		Supplier Smitt	
	1....5	Points 1...5	PxG	Points 1...5	PxG	Points 1...5	PxG
Product Quality	5	3	15	4	20	5	25
Price	2	5	10	4	8	2	4
Delivery Time	4	4	16	2	8	1	4
Fulfillment of Contract	1	2	2	3	3	5	5
Delivery Date Reliability	4	2	8	3	12	5	20
Quantity Reliability	2	1	2	5	10	3	6

**Sum
Rank**

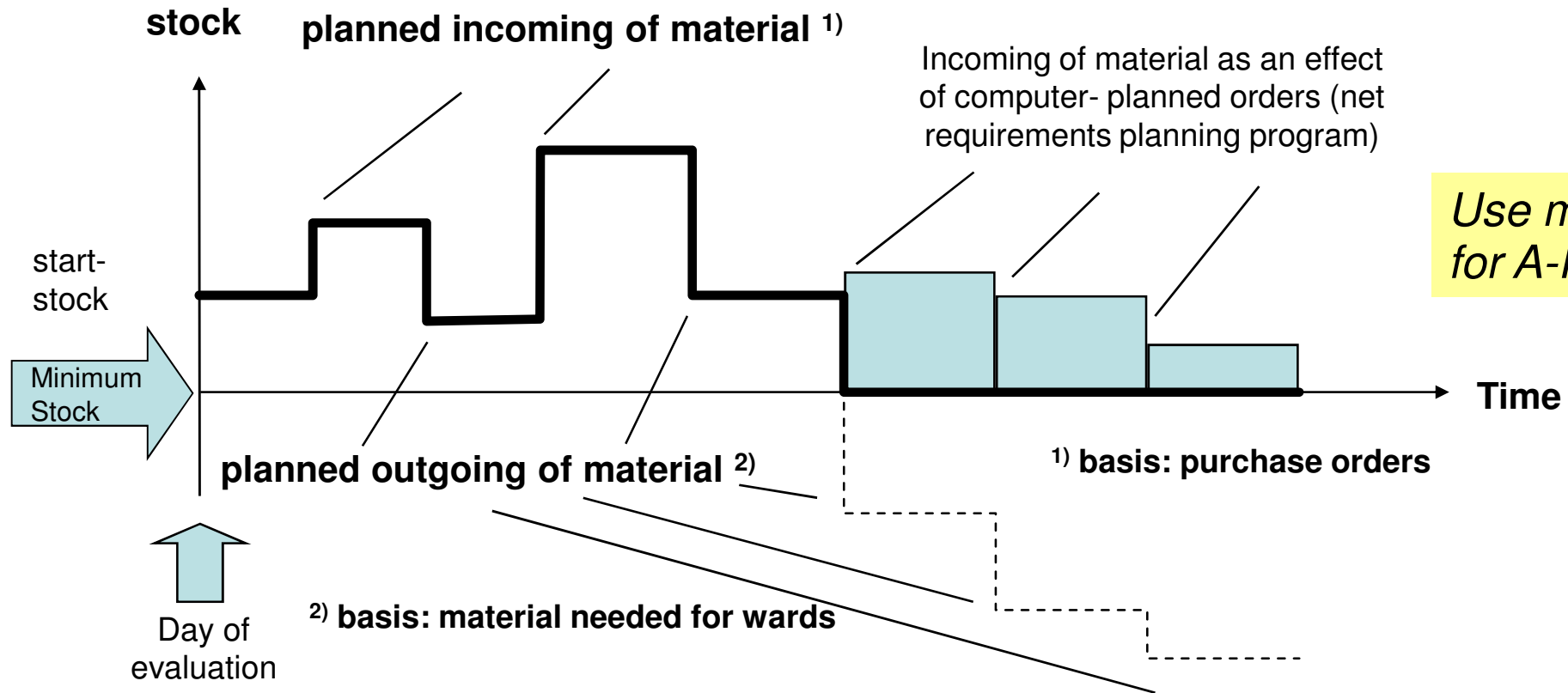
**53
III.**

**61
II.**

**64
I.**

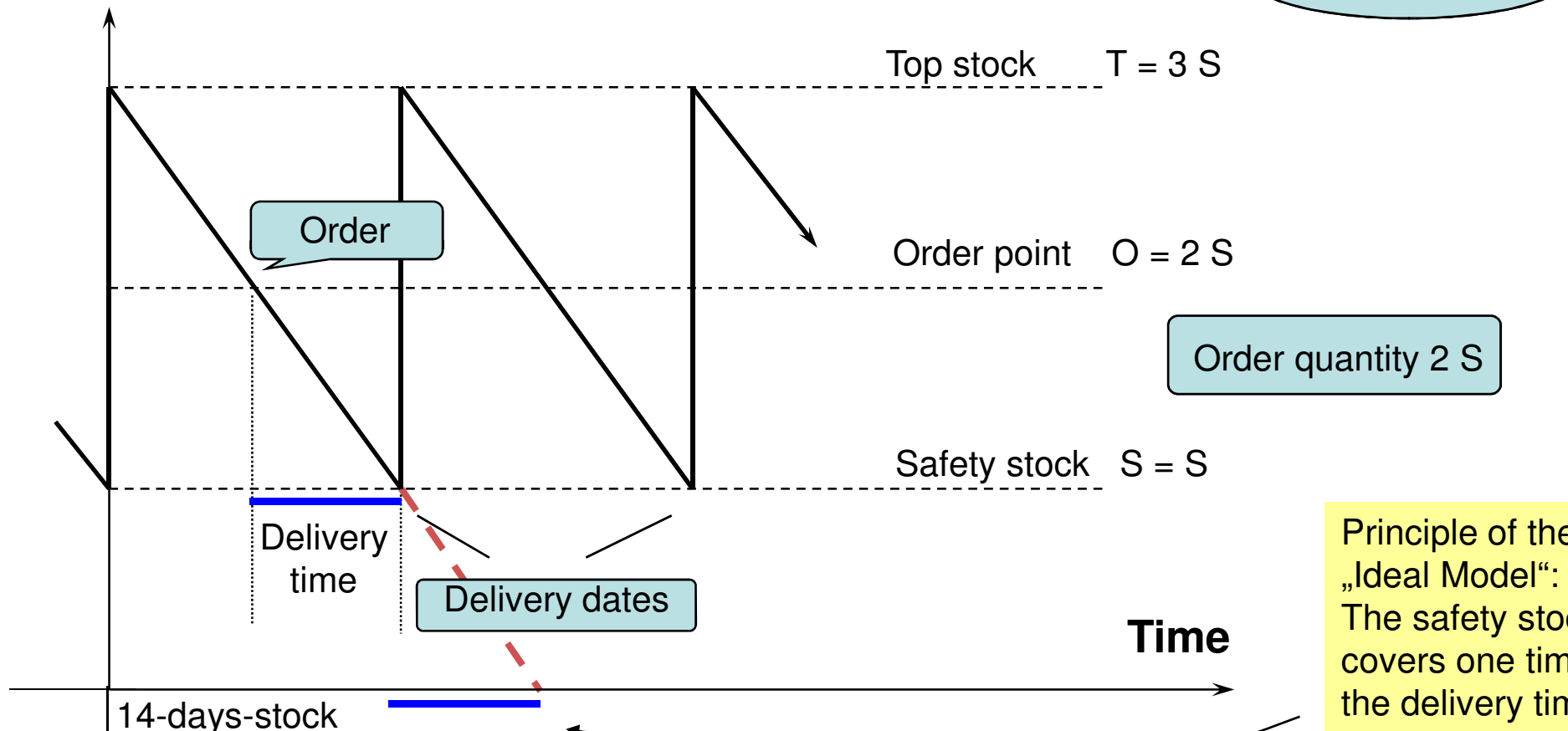
Supply Chain and economic Indicators - Logistic Tools -

Calculation of Material-Availability in the Future by Means of a Simulation of the Function „Stock over Time“, Dependent on Events



The Order Point System

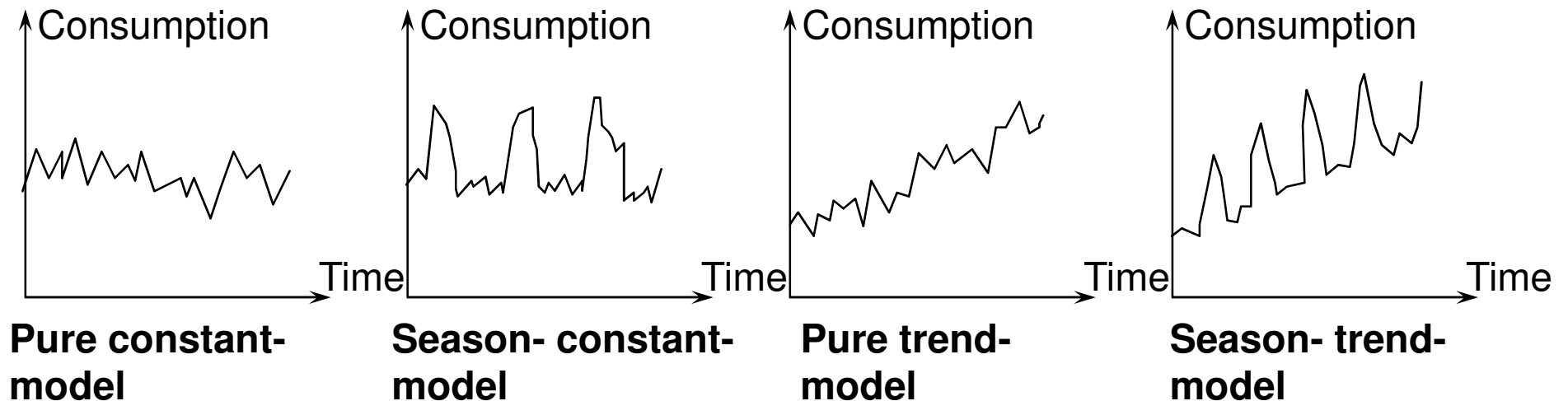
Stock of a definite material



Supply Chain and Economic Indicators - Logistic Tools -

Stochastic Requirements Planning: Types of Models for Consumption

The stochastic requirements planning normally is used with lower-value parts (C-Parts) and is based on the consumption in the past.



Supply Chain and Economic Indicators - Logistic Tools -

Stochastic Requirements Planning: Forecast Methods

Moving average value = Average consumption over x past periods; at the beginning of each new period the oldest one is cancelled; suitable for the pure constant model

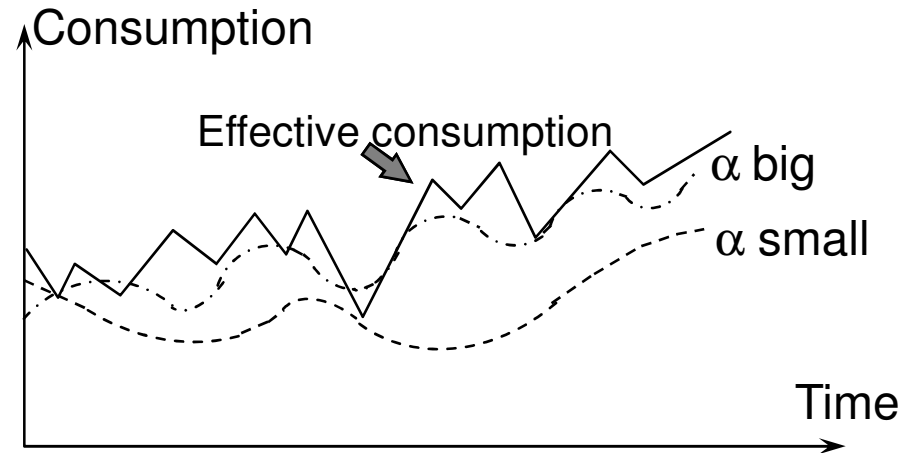
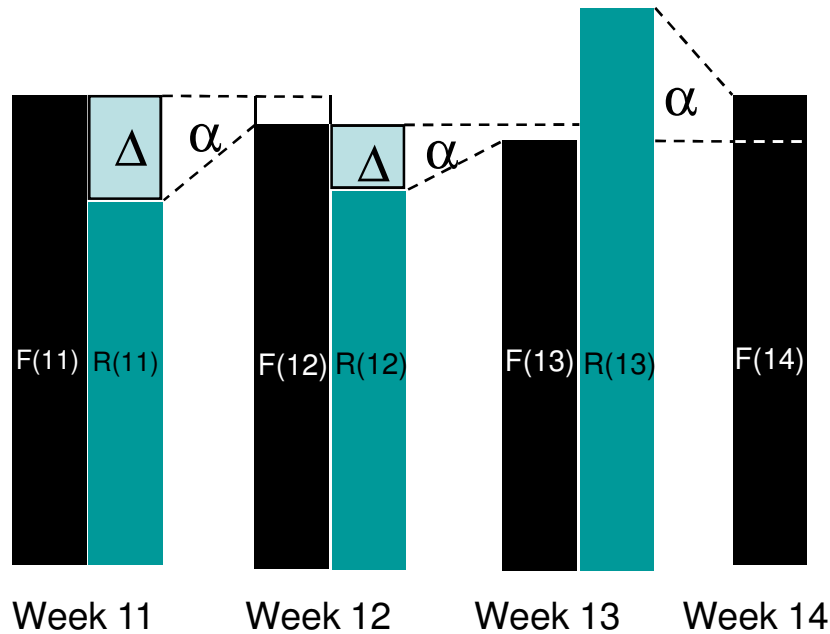
Weighted moving average value: Each period-consumption corresponds with weight factors: the oldest one receive the lowest weight; suitable for the pure constant model

Regression analysis = Used for the forecast with trend-type function;
linear case: $y=a+bt$; non-linear: polynomial of n-th order

Exponential smoothing: Most important stochastic method; the new forecast is built from the old one to which is added the with α weighted difference between the old actual value and the old forecast value; suitable for the pure constant model; with the exponential smooting of second order it is possible to take into account trend functions of the past-consumption values

For season models are suitable mathematic combinations of the above models.

Stochastic Requirements Planning: Exponential Smoothing



$$F_{t+1} = F_t + \alpha(R_t - F_t)$$

$$\alpha = 0,1 \dots 0,3$$

F_{t+1} : new forecast
 F_t : old forecast
 R_t : real consumption of the old period
 α : smoothing factor

α is an experience factor

Advantage:

Low calculating amount: Only the data of the month before are necessary (the total past is involved in the values of the earlier months).; Influence of the newest values is stronger than the effect of elder ones.

Supply Chain and Economic Indicators - Fundamentals -

Repetition

- Difference between supply chain management and logistics?
- Partners of SC of pharmaceuticals?
- Definition of logistics (phases, activities)?
- “6 Rights” of logistics (5 Rights of drug provision)?
- Type of logistics costs?
- Logistics service components?
- Explain the „available stock“
- Draw the „Ideal Model“ of order point planning
given: 2 weeks delivery time, consumption per week: 100 pieces
- Consumption models?
- Calculation of forecast F_{15} using the „exponential smoothing“
- given $\alpha = 0,3$ $F_{14} = 200$ $R_{14} = 180$

Supply Chain and Economic Indicators

- *Logistic tools*

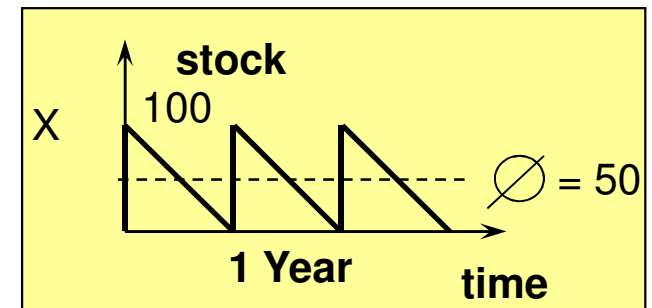
Supply Chain and Economic Indicators - Logistic Tools -

Educational Goals

- Understand the Andler formula
- How to calculate an ABC analysis (method, advantages)
- How to calculate a XYZ analysis (method, advantages)
- Knowledge of using the ABC/XYZ analysis
- Method of material flow analysis
- Knowledge of important rules for designing the material flow

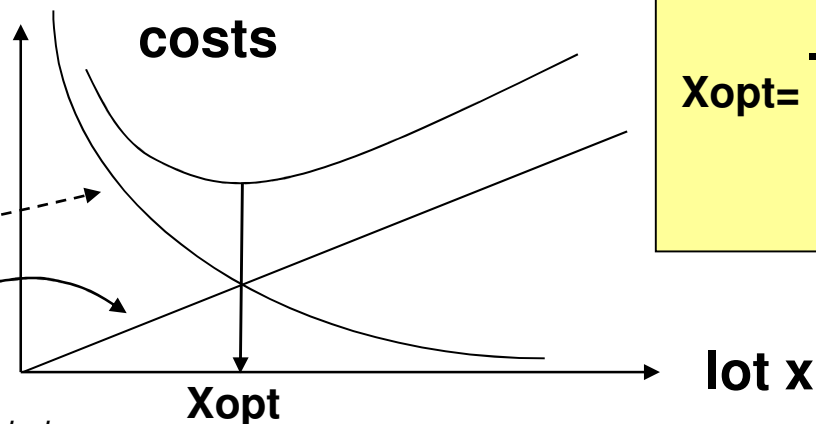
Simplified Derivation of the Andler Formula

- J: annual requirement of bought-in material
- F: fixed costs of the purchase process for one orderline
- E: price per piece
- TWER: costs of all storage activities as percentage from bounded capital



The half of the lot x is equal to the average stock (assumption: linear consumption).
So the average stock value is equal to $x/2 * E$. The costs of average stock is $x/2 * E * TWER[\%]/100$.
The minimum value of the sum of both types of costs can be found at the point of intersection.
Both functions will be equated, so we find X_{opt} , the optimal lot size.

$$\frac{J}{x} F = \frac{x}{2} E \frac{TWER}{100}$$



$$X_{opt} = \sqrt{\frac{200 \cdot J \cdot F}{E \cdot TWER[\%]}}$$

TWER = Total warehousing expense ratio, explanation see below

Supply Chain and Economic Indicators - Logistic Tools -

Optimal Order Quantity Formula, Developed by ANDLER :

Optimal Order Quantity (pieces, unit) =
$$\sqrt{\frac{200 \times J \times F}{E \times \text{TWER} [\%]}}$$

J: annual requirement of bought-in material
F: fixed costs of the purchase process for one orderline
E: delivered price per piece (unit)
TWER: Costs of all storage activities [%]

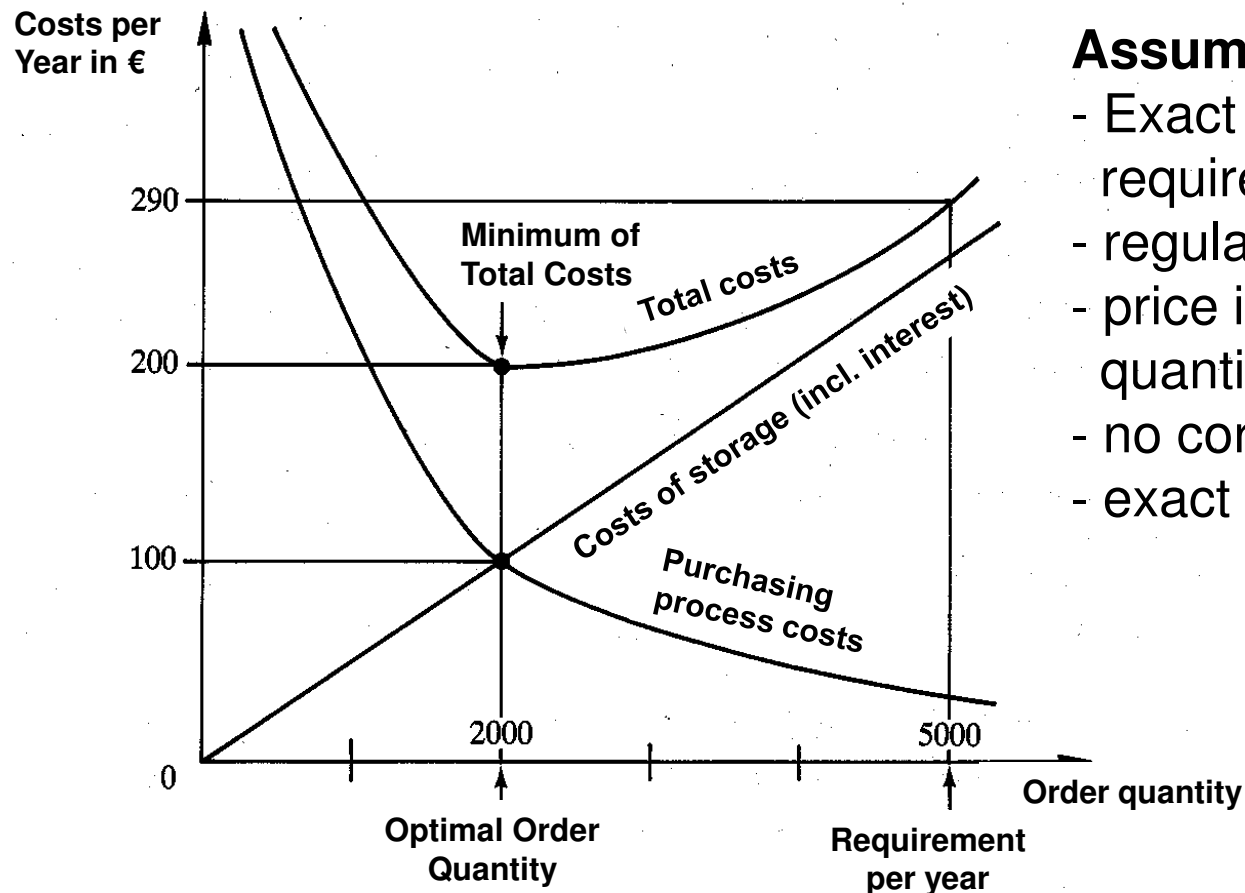
Similarly is valid for in-house-products:

Economic Lot Quantity (pieces, unit) =
$$\sqrt{\frac{200 \times J \times \text{SC}}{\text{MC} \times \text{TWER} [\%]}}$$

J: annual requirement of in-house material
SC: costs of the set-up process at the production machine: once per lot
MC: manufacturing costs for the considered in-house part
TWER: Costs of all storage activities [%]

TWER = Total warehousing expense ratio, explanation see below

Graphical Interpretation of the ANDLER Formula



Assumptions for the Validity:

- Exact knowledge of the requirement per year
- regular consumption
- price independent of the lot quantity
- no corresponding parts
- exact knowledge of costs

Supply Chain and Economic Indicators - Logistic Tools -

ABC Analysis

Main question: Which bought-in products correspond with the most expenses?

1) Build a list of articles and expenses

article	annual expenses in Euro
product 1	23.478,00
product 2	304.536,00
product 3	45.676,00
product 4	1.207,00
product 5	33.426,00
product 6	2.234,00
product 7	87.689,00
product 8	77.589,00
product 9	234.234,00
product 10	123.321,00
product 11	678.654,00
product 12	3.456,00
product 13	5.432,00

2) Sort the list by decreasing expenses

3) Accumulate the expenses

4) Classify the articles

article	annual expenses in Euro	accumulated expenses	percentage from total	class
product 11	678.654,00	678.654,00	41,87	A
product 2	304.536,00	983.190,00	60,66	A
product 9	234.234,00	1.217.424,00	75,11	A
product 10	123.321,00	1.340.745,00	82,71	B
product 7	87.689,00	1.428.434,00	88,12	B
product 8	77.589,00	1.506.023,00	92,91	B
product 3	45.676,00	1.551.699,00	95,73	C
product 5	33.426,00	1.585.125,00	97,79	C
product 1	23.478,00	1.608.603,00	99,24	C
product 13	5.432,00	1.614.035,00	99,57	C
product 12	3.456,00	1.617.491,00	99,79	C
product 6	2.234,00	1.619.725,00	99,93	C
product 4	1.207,00	1.620.932,00	100,00	C
sum	1.620.932,00			

A ≤ 80 %

B > 80 %
≤ 95 %

C > 95 %
≤ 100 %



Supply Chain and Economic Indicators - Logistic Tools -

ABC Analysis

What are the consequences?

3 from 13 articles
are A-products
→ 23,1 %

3 from 13 articles
are B-products
→ 23,1 %
(casually the same
value as above)

7 from 13 articles
are C-products
→ 53,8 %

article	annual expenses in Euro	accumulated expenses	percentage from total	class
product 11	678.654,00	678.654,00	41,87	A
product 2	304.536,00	983.190,00	60,66	A
product 9	234.234,00	1.217.424,00	75,11	A
product 10	123.321,00	1.340.745,00	82,71	B
product 7	87.689,00	1.428.434,00	88,12	B
product 8	77.589,00	1.506.023,00	92,91	B
product 3	45.676,00	1.551.699,00	95,73	C
product 5	33.426,00	1.585.125,00	97,79	C
product 1	23.478,00	1.608.603,00	99,24	C
product 13	5.432,00	1.614.035,00	99,57	C
product 12	3.456,00	1.617.491,00	99,79	C
product 6	2.234,00	1.619.725,00	99,93	C
product 4	1.207,00	1.620.932,00	100,00	C

The knowledge of the A-parts is a good basis for negotiations with the suppliers; necessary is a perfect procurement planning

The purchasing process for C-parts must be rationalized because they represent only 5 % of the procurement volume.

XYZ Analysis: A Method for Analyzing the Fluctuation in Consumption, Necessary for a Good Procurement Decision

Definition:

X constant consumption

Y stronger fluctuations in consumption

Z completely irregular consumption

Coefficient of Variation

$$COV = \frac{1}{\bar{X}} \sqrt{\frac{1}{n} \sum_{i=1}^{i=n} (x_i - \bar{X})^2} * 100[\%]$$

Steps for Realizing a XYZ Analysis

- calculate the coefficient of variation (COV) per article along a predefined number of periods
- Sort the list by increasing COV
- Graphical interpretation

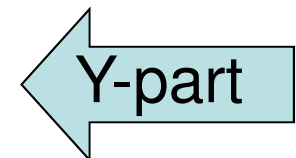
Example:

Consumption of an article in month....			
May	June	July	August
800	1.100	900	1.200

Class Limits:

for X: <= 10 %
for Y: <= 25 %
for Z: the rest

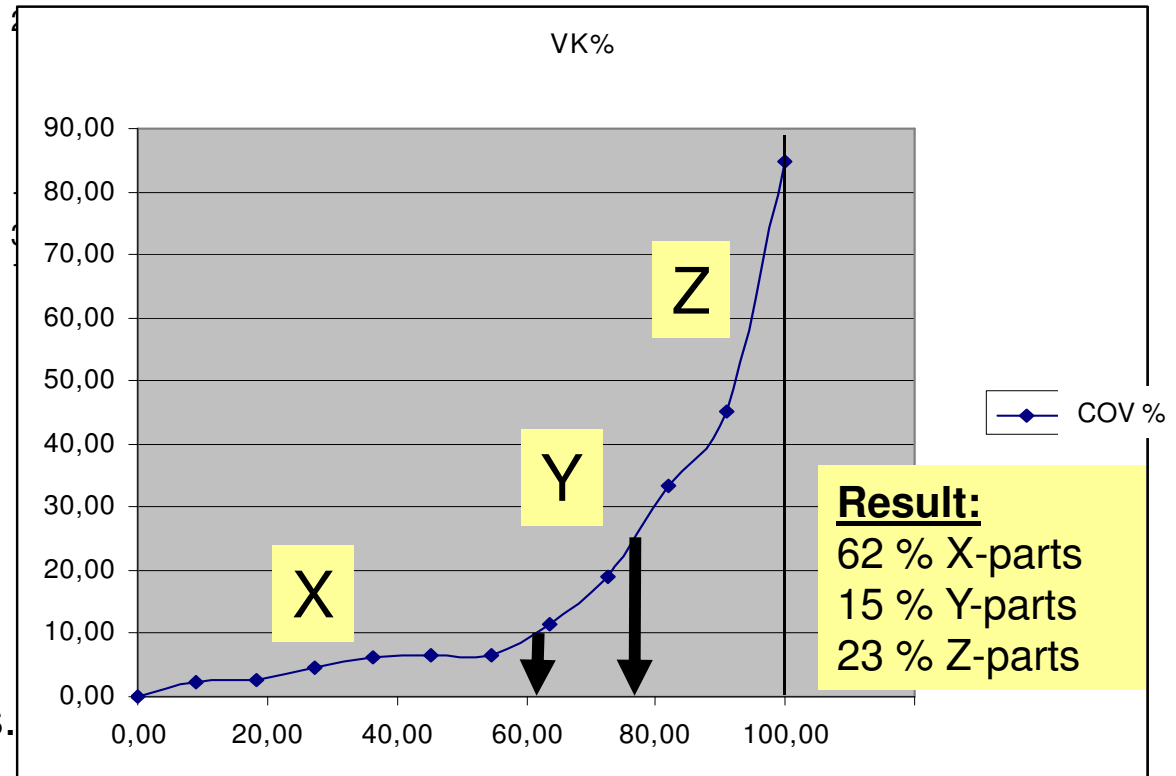
Calculation of COV				
Average	(800-1000) ²	(1100-1000) ²	(900-1000) ²	(1200-1000) ²
1.000	40.000	10.000	10.000	40.000
	Sum of squares	Sum / 4	Square root	COV [%]
	100.000	25.000	158,114	15,81



Supply Chain and Economic Indicators - Logistic Tools -

Example of a XYZ-Analyse Including a Graphical Interpretation

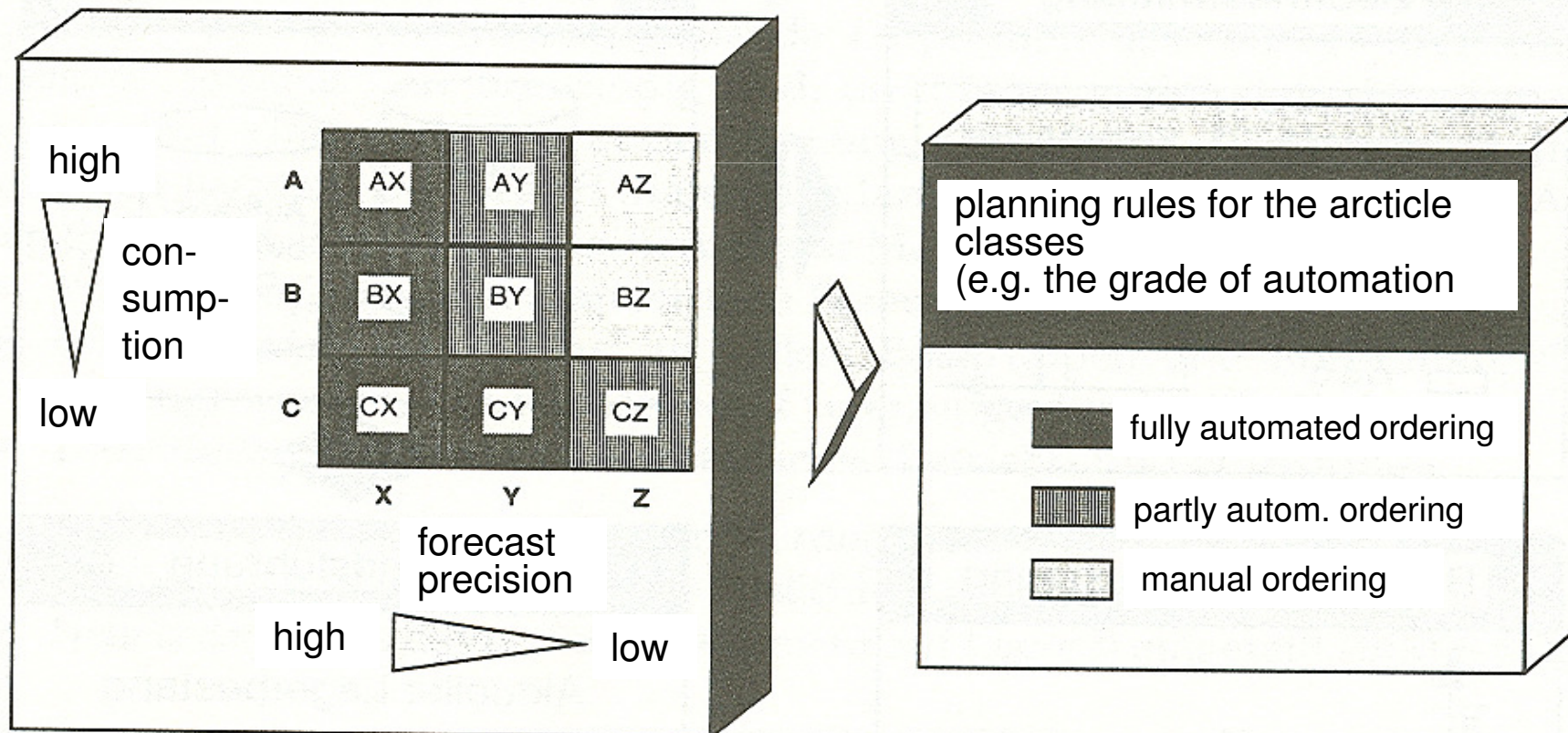
Article	No.	A%	COV%	Consumption per month													
				1	2	3	4	5	6	7	8	9	10	11	12		
		0,00	0,00														
976	1	9,09	2,28	X	8987	8998	8765	8438	8698	9001	8987	8675	8453	8564	8867	8732	
4532	2	18,18	2,75		5543	5556	5567	5678	5432	5364	5867	5675	5879	5647	5435	5534	
1231	3	27,27	4,49		311	312	334	323	345	334	345	344	332	324	347	365	
7869	4	36,36	6,38	Y	2345	2322											2314
4536	5	45,45	6,38		123	122											131
5647	6	54,55	6,44	Z	355	345											387
6754	7	63,64	11,40		10	11											11
4812	8	72,73	19,00		200	213											322
4356	9	81,82	33,44		2342	1213											3345
4567	10	90,91	45,07		2213	2456											5678
4711	11	100,00	84,62		1123	12234											3345



Hint:
The graphically shown results are not represented by real articles in the table above, because there are only 11 values. In bigger tables are many points along the curve, so they may nearly match real points.

Influence of ABC / XYZ Classification

The combination ABC/XYZ leads to rules for requirement planning

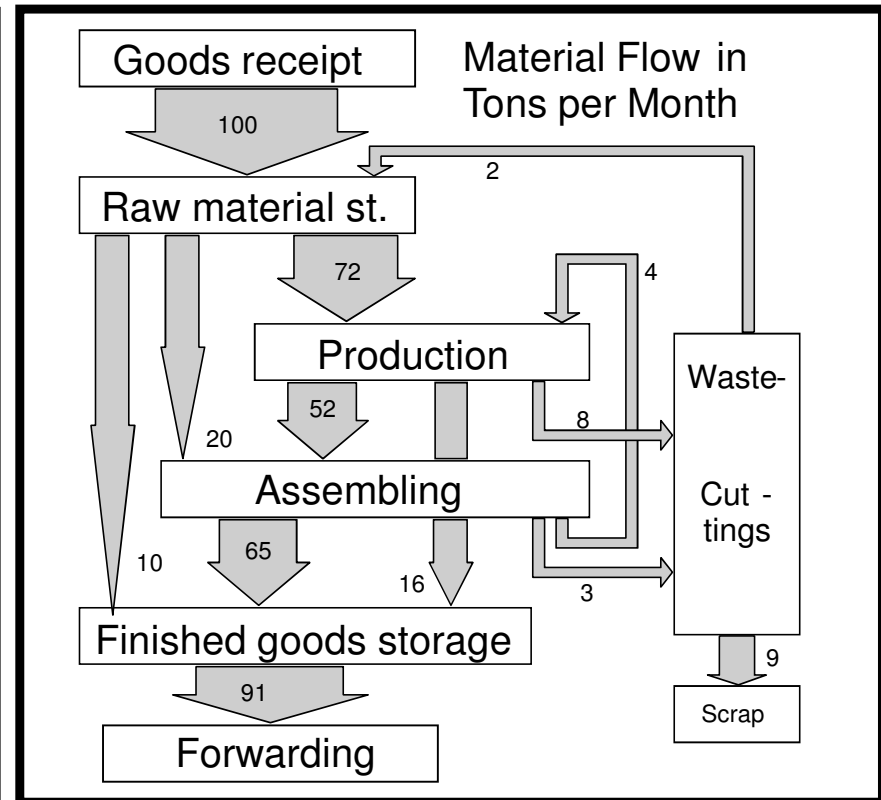


Supply Chain and Economic Indicators - Logistic Tools -

Principles for Optimizing the Material Flow in a Hospital Pharmacy Analogous to the Methods Used in Industry

Transport Matrix and Sankey-Diagramm¹

To From	Raw material storage	Production	Assembling	Finished goods stor.	Waste, cuttings	Forwarding	Scrap	Sum
Goods receipt	100							100
Raw material storage		72	20	10				102
Production			52	16	8			76
Assembling		4		65	3			72
Finished goods storage						91		91
Waste, cuttings	2						9	11
Sum	102	76	72	91	11	91	9	

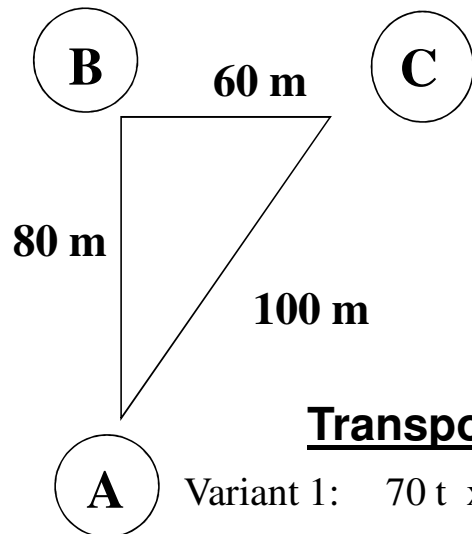


Supply Chain and Economic Indicators - Logistic Tools -

Principles for Optimizing the Material Flow in a Hospital Pharmacy Analogous to the Methods Used in Industry

The Transportation Work depends on the Allocation of the Machines

Distances between the locations of the production facilities



Tons per month between the Production machines

	To	2	3
From			
1		70	40
2		X	50

Variations of allocation of the production machines to the production facilities

	A	B	C
V1	1	2	3
V2	3	1	2
V3	2	3	1

Transportation work for the alternatives:

Variant 1: $70 \text{ t} \times 80 \text{ m} + 40 \text{ t} \times 100 \text{ m} + 50 \text{ t} \times 60 \text{ m} = 12.600 \text{ tm}$

Variant 2: $70 \text{ t} \times 60 \text{ m} + 40 \text{ t} \times 80 \text{ m} + 50 \text{ t} \times 100 \text{ m} = 12.400 \text{ tm}$

Variant 3: $70 \text{ t} \times 100 \text{ m} + 40 \text{ t} \times 60 \text{ m} + 50 \text{ t} \times 80 \text{ m} = 13.400 \text{ tm}$

optimal ←

Supply Chain and Economic Indicators - Logistic Tools -

Design Principles of Material Flow

- The design of material flow should be linear
- Clear structure in using of the available space
- Opposite transports should be avoided
- Avoid crossings in material flow

Supply Chain and Economic Indicators

- *Storage systems on wards*
- *Storage condition monitoring*

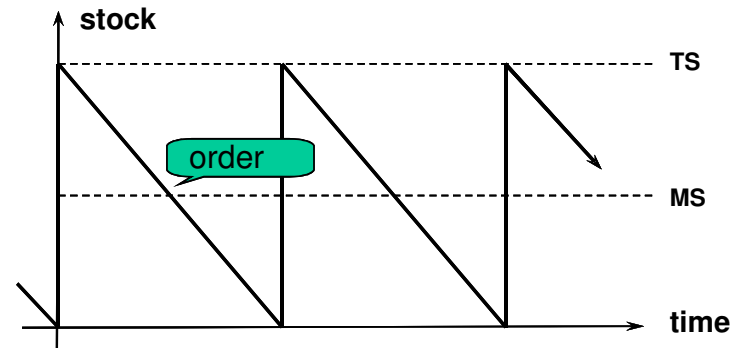
Supply Chain and Economic Indicators - Storage On Wards / Stor. Cond. Mon.-

Educational Goals

- Understanding the principle of module systems
- Knowledge of functions of electronic cabinets
- Knowledge of GSP as part of GMP
- Methods of storage condition monitoring

Supply Chain and economic Indicators - Storage Systems on Wards -

Module System



Organisation:
first in first out



The quantities within the baskets must be defined (minimum stock, top stock (=2 MS))



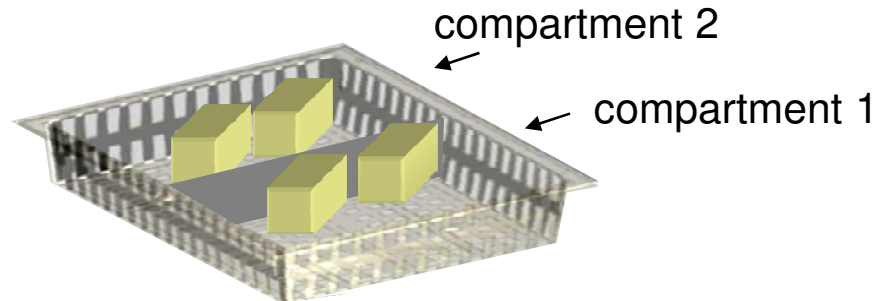
A barcode reader scans the requirement



Module system also within the several service trolleys

Supply Chain and economic Indicators - Storage Systems on Wards -

Module System



Principle: a defined quantity for a defined time at a defined location

Example:

- Calculate the average requirement for 7 days
- This 7-day-quantity is called minimum stock MS
- This stock is twofold stored within the basket
e.g. the reserve has the same value MS

Rules:

- Begin withdrawing from compartment 1,
- when empty, withdraw from comp. 2,
- never use articles from comp. 2, when there is a rest in comp. 1
- never rearrange articles from comp. 2 to comp. 1

Supply Chain and economic Indicators - Storage Systems on Wards -

Electronic Cabinet

OMNICELL Inc.

Controlled Substance Management



Improve distribution and record keeping for controlled substance inventory



Omniceil's SecureVault™ system combines cabinet security with software that enables the pharmacy to trace and monitor the movement of controlled substances along all points in the distribution process. Every transaction is automatically recorded, ensuring a complete audit trail.

Supply Chain and economic Indicators - Storage Systems on Wards -

Electronic Cabinet

PAR Excellence Systems



PAR Secure can be used in conjunction with any of the following products to identify the patient or department to which the supplies are being dispensed: PAR Display, PAR Select, PAR Record PAR Replenish. To gain access to secured supplies, the caregiver simply enters an access code. Upon opening the door, the user indicates supplies dispensed by touching the iTag associated with the item.

Supply Chain and economic Indicators - Storage Systems on Wards -

Electronic Cabinet



The caregiver utilizes any PAR Excellence product to select the patient name, then enters a code to unlock the cabinet.

PAR Secure System



Then the caregiver touches the iTag or scans the Barcode for items dispensed from the cabinet or from those maintained outside the cabinet.



The information is downloaded when the probe is returned to the downloader.

Process steps

Supply Chain and economic Indicators - Storage Systems on Wards -

AcuDose-Rx

McKesson

Electronic Cabinet



Key Benefits

- Highest storage capacity of any cabinet on the market
- Specifically designed for maximum reliability and durability
- Modular software and hardware updates to extend investment
- Supports the ISMP recommended core processes
- Only cabinet with certified biometrics identification method—FastEntry™
- Most flexible and configurable cabinet system available today

Reliable, Safe, Fast and Efficient Medication Dispensing

AcuDose-Rx® is an automated medication dispensing cabinet solution that provides caregivers with fast, safe and secure access to patient medications. The system supports all hospital distribution models to streamline nursing workflow, improve inventory management, and strengthen compliance. Offering more capacity than any other cabinet available, AcuDose-Rx reduces stock outs and ensures medication availability for patients.

Video link: supply chain management
between ward and hospital pharmacy

<http://video.mckesson.com/services/player/bcpid10043455001?bclid=9203093001&bctid=8789317001>

Supply Chain and economic Indicators - Storage Condition Monitoring -

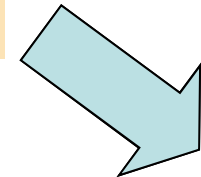
The WHO, WORLD HEALTH ORGANIZATION Defines Rules for Good Storage Practice Including Storage Condition Monitoring

„In order to maintain the original quality, every activity in the distribution of pharmaceutical products should be carried out according to the principles of good manufacturing practice (GMP), good storage practice (GSP) and good distribution practice (GDP).“ ¹⁾

Good Storage Practices

„Good Storage Practices are that part of quality assurance that ensure that the quality of a pharmaceutical products is maintained through adequate control throughout the storage.“ ¹⁾

Focus here: GSP



1) Source: WORLD HEALTH ORGANIZATION, Working document QAS/04.068/Rev.2, „DISTRIBUTION PRACTICES (GDP) FOR PHARMACEUTICAL PRODUCTS“ page 4 and 8

Supply Chain and economic Indicators - Storage Condition Monitoring -

GSP Good Storage Practices for Pharmaceuticals

Personnel

- qualified personnel to achieve pharmaceutical quality assurance objectives
- trained in relation to good storage practice, regulations, procedures and safety
- high levels of personal hygiene and sanitation
- wear suitable protective or working garments (special clothes)

Storage area

- only authorized persons
- sufficient capacity of storage areas
- adapted to ensure good storage conditions (clean, dry, acceptable temperature)
- provide, check, monitor and record special storage conditions (e.g. temperature, relative humidity), when these are obligatory

Supply Chain and economic Indicators ***- Storage Condition Monitoring -***

GSP Good Storage Practices for Pharmaceuticals

Storage area (continuation)

- clean areas, free from accumulated waste and vermin, written sanitation programme (frequency and methods of cleaning and pest control)
- receiving and dispatch bays free from influence of weather
- quarantine areas separate, clearly marked, only authorized personnel
- separate sampling areas for starting materials, avoid cross-contamination by means of adequate cleaning procedures
- separated and good identifiable area for segregated products (rejected, expired, recalled, returned materials or products)
- dedicated areas with additional safety and security measures for high risky products (e.g. radioactive, high active, narcotics ...)
- handling and distribution of materials and pharmaceuticals according to GMP (Good Manufacturing Practise)
- prevent contamination, mix-ups and cross-contamination
- assure the principle „first expiry/first out (FEFO)

Supply Chain and economic Indicators - Storage Condition Monitoring -

GSP Good Storage Practices for Pharmaceuticals

Storage area (continuation)

- separate storage of rejected materials and pharmaceutical products
- narcotic drugs must be stored according to international conventions and national laws
- damaged items must be separated
- adequate lighting at all storage areas

Storage conditions and monitoring of storage conditions

- compliance with the labelling on pharmaceutical products and materials
- recording of temperature for later control
- periodically checking, calibration and documentation of the monitoring equipment
- storage of the recorded data more than 1 year after shelf-life

Supply Chain and economic Indicators - Storage Condition Monitoring -

GSP Good Storage Practices for Pharmaceuticals

Documentation: written instructions and records

- instructions according to material flow, handling of expired stock and organization in case of product recall
- written information concerning storage conditions and retest dates
- storage of data about each delivery: goods, quality, quantity, supplier, batch number (of supplier and /or assigned), date of receipt, expiry date; storage duration of the data: shelf-life of the products plus 1 year
- storage of all data about receipts and issues, using the batch number

Labelling and containers

- storage of materials and pharmaceutical products in adapted containers (ensure quality, free from external influences)
- clear labelling: name of material, batch number, expiry date, retest date, storage conditions, reference to the pharmacopoeia

Supply Chain and economic Indicators - Storage Condition Monitoring -

Examples for labelling

GSP Good Storage Practices for Pharmaceuticals

Normal storage conditions

- dry, well-ventilated, temperatures of 15–25 °C or, depending on climatic conditions, up to 30 °C
- extraneous odours, other indications of contamination, and intense light must be excluded

Defined storage instructions

- “Do not store over 30 °C” from +2 °C to +30 °C
- “Do not store over 25 °C” from +2 °C to +25 °C
- “Do not store over 15 °C” from +2 °C to +15 °C
- “Do not store over 8 °C” from +2 °C to +8 °C
- “Do not store below 8 °C” from +8 °C to +25 °C
- “Protect from moisture” no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moistureresistant container.
- “Protect from light” to be provided to the patient in a light-resistant container.

Supply Chain and economic Indicators - Storage Condition Monitoring -

Stability Storage/Testing

Stability storage and testing is required in order to assign expiration dating. We offer many temperature and humidity conditions for storage, both ICH and custom. A variety of light studies can be performed as well. Analysis of products at client specified time intervals are normally conducted. In some cases, samples are returned to a client for subsequent testing.



Walk-in and Reach-in Chambers
Storage Conditions
25° C/60% RH
30° C/65% RH
40° C/75% RH
5° C
-20° C
Freeze/Thaw
Photo Stability
Specialty conditions may be arranged:
40° C/Ambient
25° C/Low Humidity
50° C
Others

ICH

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

(<http://www.ich.org/cache/compo/276-254-1.html>)

Supply Chain and economic Indicators - Storage Condition Monitoring -

Stability Chambers

Our state-of-the-art stability chambers offer continuous mapping with up to 26 fixed sensors to capture electronic data. Electronic calculation of MKT by an individual sensor or weighted average by multiple sensors at any time period may be selected.

Your stability studies are safe and secure with our alarm notification system. In the event of a set point failure all appropriate supervisory personnel are notified by e-mail and alarm monitoring services.

All maintenance and service is provided by qualified engineering support. Maintenance records and monitoring data can be viewed during an audit. To reduce down time from potential chamber failures all parts are inventoried on site.

The automated explosive gas venting system is designed to prevent damage from gas build-up and eliminate product or client liability due to hazardous product leakage from alcohol based products, unusual gases, aerosol products, etc.

Stability Chamber Features Include:

Storage – ICH



Supply Chain and economic Indicators - Storage Condition Monitoring -

PC based controlling process control

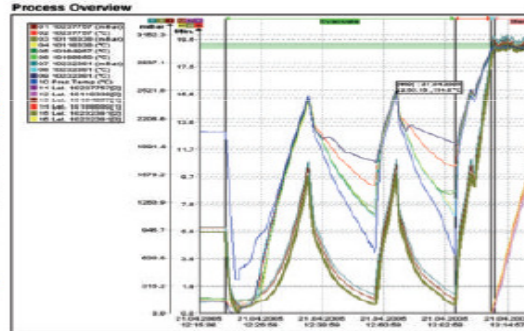
Only 3 Easy Steps

... ebro® validation systems

Setup
1

Evaluate
2

Report
3



The report provides a detailed overview of the validation process, including parameters such as temperature, humidity, and time. It includes a table with columns for 'Date/Time', 'Value', 'Unit', and 'Status'. The table contains multiple rows of data points, likely representing individual sensor readings or process steps.

Quick and easy validation

ebro® Winlog validation system is a combination of high accuracy wireless measurement technology and powerful programming and reporting tools.

The system consists of:

EBI series Data Loggers:

Wireless sensors to measure and record process conditions (temperature, rH, pressure, time)

USB Interface:

To provide simultaneous readout of up to 8 loggers at once. Additional interfaces can be connected to increase productivity.

Winlog.pharm Software:

Easy-to-use software for programming, evaluation, calibration and report generation

Supply Chain and economic Indicators - Storage Condition Monitoring -

Automatic functions of Winlog.pharm:

Automatic report generation

The Software automatically generates clear, precise reports for setup and validation. The reports can be adapted to the specific needs of the user and the data can be exported in Excel for further evaluation.

Automatic user-defined calculation

Statistical calculations such as lethality, difference, fluctuation and variance are pre-programmed into the system. The user can freely select the calculations that are relevant to the specific validation study.

Automatic recognition of process cycles

The powerful cycle detective makes it easy to generate reports, as critical process cycles are recognized automatically.

Automatic completion of validation processes

The software database allows validations to be evaluated according to national and international standards.

Creation of user-specific templates for specific devices and thermal processes

The Explorer-similar interface makes it easier to create, select, archive and view the different devices. Frequently used validation configurations can be saved. Re-validation is made easier by calling up a saved configuration from the data base.

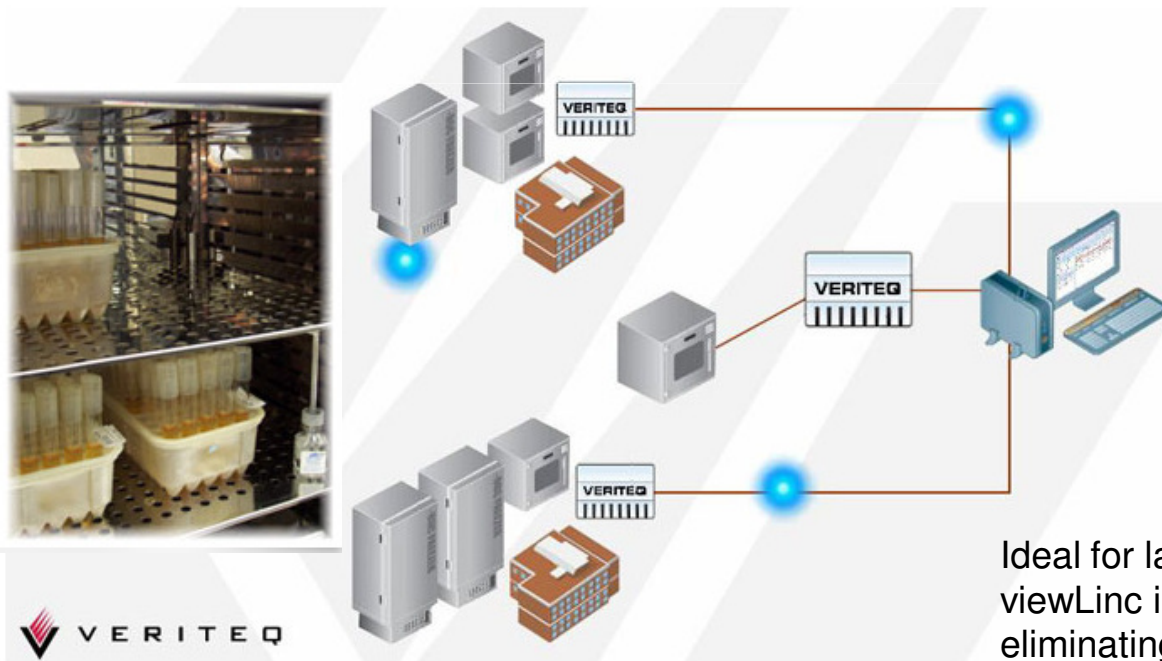
*Documentation templates SOP, IQ/OQ tailored to the needs of the pharmaceutical industry
DKD (NIST) Validation Standard FDA 21 CFR Part 11 compliant*

Supply Chain and economic Indicators - Storage Condition Monitoring -

Validatable Relative Humidity & Temperature Data Loggers

Veriteq's VL 2000 series loggers are fully validatable and designed for regulated industries/pharmaceutical applications — with NIST-traceable, ISO/IEC 17025 calibration, cGMP/FDA compliant measurement and redundant recording of temperature and humidity. All data are recorded in real-time and maintained in a secure format for later review and reporting

PC
phone
eMail
SMS
pager



viewLinc™ Monitoring, Alarming & Reporting

For monitoring with alarming, real-time and historical data trending
Compliant with the requirements of all major regulatory bodies, including **FDA (Part 11), CBER, ISO 17025, the Joint Commission, and AATB**

Ideal for large-scale systems and standalone applications, viewLinc integrates with your existing infrastructure, eliminating the cost of installing and maintaining a dedicated network. Connect with your existing Ethernet, PoE, WiFi or combination.



Supply Chain and Economic Indicators

- Storage models
- Results and discussion

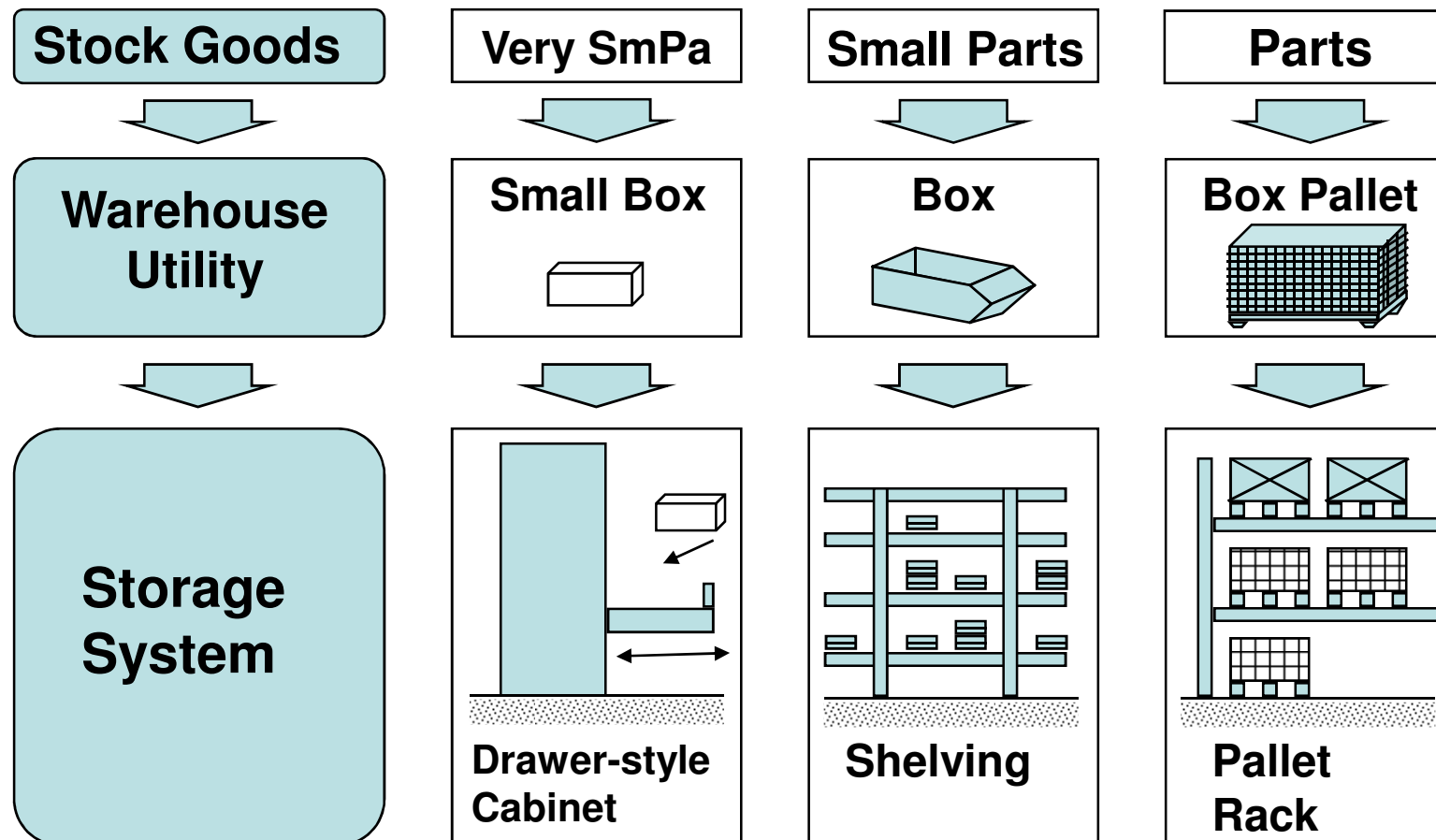
Supply Chain and Economic Indicators - Storage Models / KPIs -

Educational Goals

- Understanding the order to select the suitable storage system
- Knowledge of storage principles
- Knowledge of types of racks
- Knowledge about advantages of stock centralisation
- Ability to use the „square root law“
- Knowledge of paternoster warehouse
- Understanding pick to light principle
- Knowledge about paperless order picking
- Understanding the batch flow method
- Knowledge about the advantages and problems of Unit Doses
- Ability to calculate KPIs and the several kinds of average stock
- Understanding the KPI-report for a hospital pharmacy

Supply Chain and economic Indicators - Storage Models -

Selection Criteria for the suitable Storage System



Supply Chain and economic Indicators - Storage Models -

Storage Principles

Random storage, chaotic storage: no fixed places for articles

- needs a good and secure organisation (normally computer aided)
- advantage: saves place in warehouse
- risk: big efforts for inventory when information about articles<->bins is lost

Fixed storage bin principle: each article has its own, fixed place

- advantage: with increasing experience, the warehouse worker finds articles very quick
- disadvantage: a fixed, but empty bin cannot be used by another article

Alphabetic order:

- advantage: each person can find articles quickly without experience
- disadvantage: when names of articles change, they must be rearranged

Order by API (active pharmaceutical ingredient):

- advantage: name-changes do not affect the storage order
- disadvantage: physicians, nurses and pharmacists must learn a new principle ¹⁾

1) **Details:** http://www.medicalorder.de/uploads/media/KH_Pharmazie_Lagerung_Wirkst.pdf

Supply Chain and economic Indicators - Storage Models -

**E
x
a
m
p
l
e
s**



Shelving



Gravity flow rack



Drawer style cabinet



Pallet rack



Pallet rack



Fully automated
small-parts warehouse
„Miniload warehouse“

Supply Chain and economic Indicators - Storage Models -

Advantages of a Central Warehouse

Advantages of central Storage versus decentral Storage:

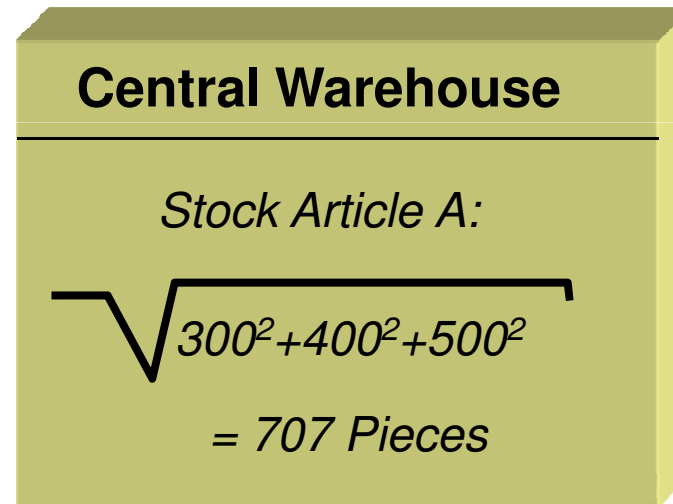
- Stock lower than the sum of decentral stock
- Minimum stock lower than the sum of minimum stock decentral
- Lower capital lockup
- Better use of room
- Higher turnover: therefore lower perishableness
- Personnel placement more economic
- Use of storage devices more efficient

Supply Chain and economic Indicators - Storage Models -

Decentral Stock versus Central Stock



1200 Pieces - 707 Pieces = 493 Pieces is equivalent to 41 % Reduction of Stock, when centralized



General Conditions:

- Optimal disposition of Stock and further supplies
- Same turnover decentral and central
- Same assortment decentral and central

Additional correction factor, when more technical performance is installed in the central warehouse than in the decentral locations:
0,7 bis 0,8 (that means for example: 0,7x707 pieces)

Supply Chain and economic Indicators - Storage Models -

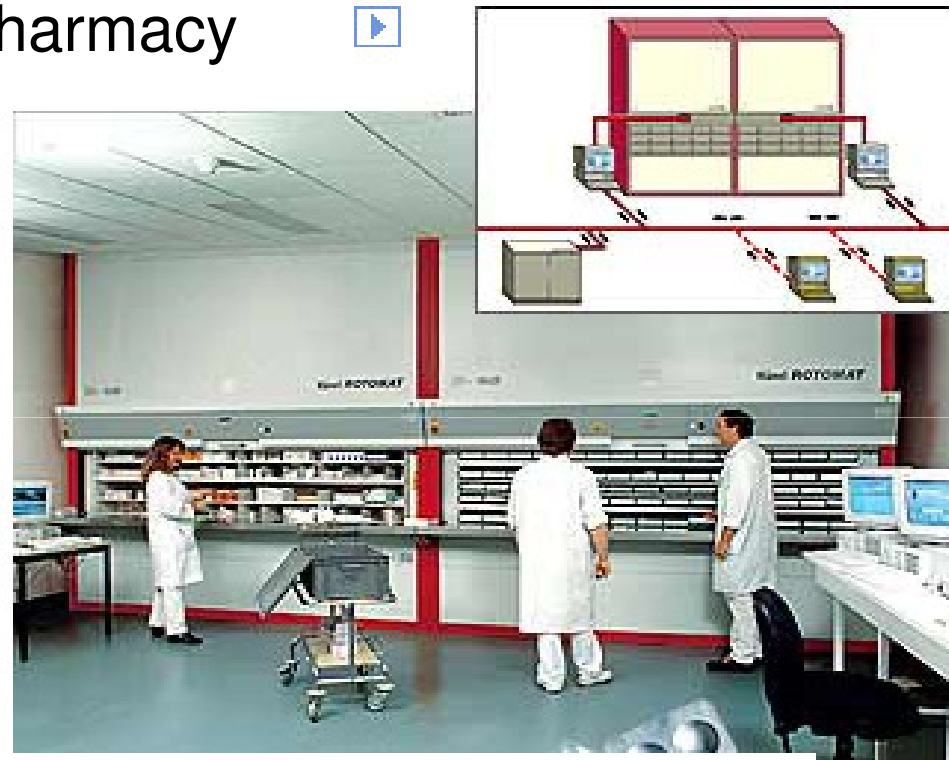
Storage Example Central Pharmacy

EDP controlled central pharmacy in 2 ROTOMAT Lifts (vertical paternoster principle).

Advantage: permanent overview about total stock with low time amount for withdrawing and filling.

The HÄNEL Software administrates the entire pharmacy and controls the two ROTOMAT Lifts.

The Software is connected to the Hospital Information System, so all kinds of data exchange are possible



Advantages

- More than 60% space saving in comparison with conventional storage
- considerable saving of working hours by means of simply and quick operation
- permanent stock overview
- better organization of drug issue
- protection and security for the stored drugs

source: <http://www.haenel.de/pc/ie/de/kontakt/index.htm>



Supply Chain and economic Indicators - Storage Models -

Advantages of Paperless Order Picking

- productivity higher
- personnel costs lower
- reducing of mix-up of articles
- reducing of control effort
- short order picking time
- better keeping of delivery dates
- lower stock level within the pick order area
- no costs for printing and distribution of order picking papers
- optimizing the order picking route
- better use of room resp. area
- lower stress for the personnel

Supply Chain and economic Indicators - Storage Models -

Pick-by-Light- Order picking

Gravity flow rack
first in first out
principle →

The picking person goes to the compartment with light on and picks the quantity, shown in the display. Then she must push the button; the computer program then reduces the stock.



Supply Chain and economic Indicators - Storage Models -

AXON System in the Stauferklinik Mutlangen

Batch oriented order picking

5 Hospitals
1300 Beds

Manual order
picking,
using PDA



Supply Chain and economic Indicators - Storage Models -

Batch Flow System

Company: P@P Systems GmbH
Schafhofstraße 10
D 90411 Nürnberg



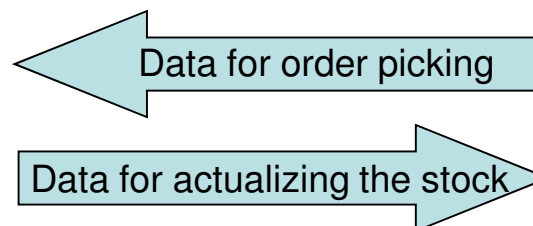
Left can be seen the control unit with the WiFi access point, in front are the container for the wards, in background the gravity flow racks



The PDA leads the employee to the picking points



Linear sorter, filling the ward containers



Connection to
SAP-System

Supply Chain and economic Indicators - Storage Models -

Fully automated Order picking in Lukas Hospital Neuss (near Düsseldorf.)

- automated handling of drugs and medical products in containers for several wards
- contains up to 80.000 drug parcels, maximum 2.500 per hour,
- about 1.000 different drugs, partly with high turnover
- exactly Cooled warehouse area included



filling the order picking automat



exterior view

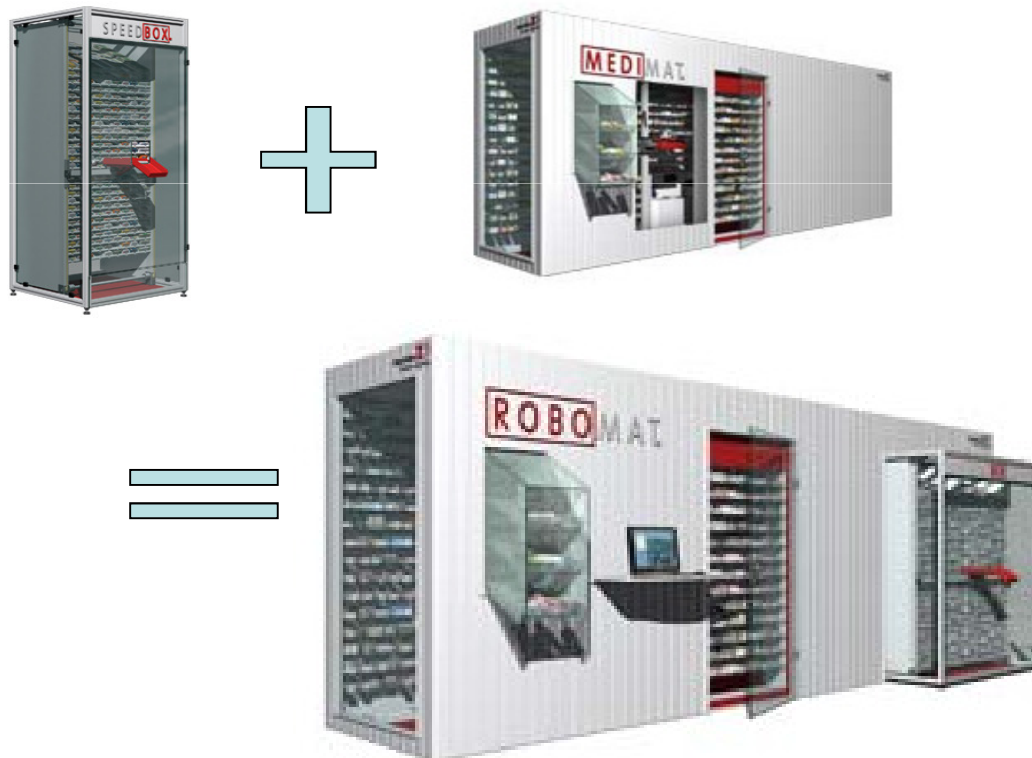


interior view with cooled area

Städtische Kliniken Neuss ·
Lukaskrankenhaus GmbH ·
Preussenstr. 84 · 41464 Neuss ·
Telefon: 0 21 31 / 8 88-0 ·
Telefax: 0 21 31 / 8 88-79 99
E-Mail:
information@lukasneuss.de

Supply Chain and economic Indicators - Storage Models -

Parcel Oriented Order Picking Solutions



Technische Daten ROBOMAT®	
Maße ROBOMAT®	
Höhe:	1,95 m bis 2,95m
Länge:	4,0 m bis 13,0 m
Breite:	1,30 m
Kapazität:	ca. 3.200 Packungen (bei sortenreinen Kanälen) pro Meter Regal
Leistung	
Auslagerung:	1200 Pack/h
Einlagerung:	330 Pack/h manuell
	150 Pack/h autom.
Personaleinsatz	Mit vollautomatischer Scannung ca. 1 Sekunde pro Packung Mit manueller Scannung ca. 3 Sekunden pro Packung

Supply Chain and economic Indicators - Storage Models -

Characteristics of THERIAK ¹⁾ and Unit Dose Principle

- Cross interaction between drugs are avoided
- allergic reaction are avoided using anamnesis data
- dosis is adapted to patient weight
- avoiduing of kidney damage
- Theriak is connected via interface to the HIS Hospital Information System
- Stockage of Unit Doses in the pharmacy only 3-5 days
- Providing security is givenn by using redundant technique
- for short term demand (the patient comes in the afternoon) exists a ward stockage of Unit Doses, e.g. 20 sachets (each contaning 1 pill)
- Sachets are continuous scanner-controlled
- Non-used sachets are restored to the pharmacy warehouse
- Application of drugs in the right order by means of patient tag

1) THERIAK TMM prescription software; runs independant from producer of the unit dose system
source: <http://cis-healthcare.com/Theriak/introduction.aspx>

Supply Chain and economic Indicators - Storage Models -

UNIT DOSE for Pills, Capsulas, Dragées, Phials

Unit Dose
decentral



Giving



Patient bracelet
Barcoding



Prescription



THERIAK
TMM
Prescription
Software

UNIT-DOSE=
closed-loop
process of
drug logistics

Controlling/Optimizing



Unit Dose



Order Picking



Packaging/Storage



Not used drugs
can be restored

„Drugnest“

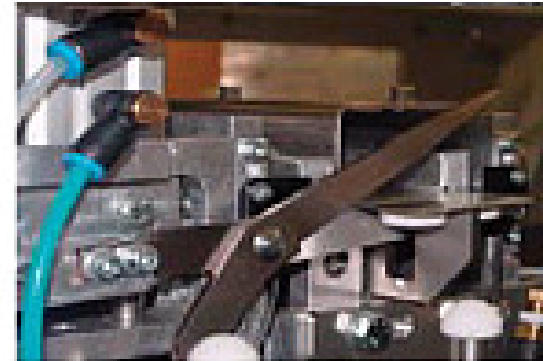


swisslog

www.swisslog.com

Supply Chain and economic Indicators - Storage Models -

UNIT DOSE mit Swisslog



Cutting of blister packs

Bulk drugs



Drug nest



Collecting the Unit Doses for one patient



Supply Chain and economic Indicators - Storage Models -



BAXTER FDS 330 (Fast Dispensing System) „Krankenhaus der Barmherzigen Brüder“ Linz, Austria

Advantages of Unit Dose

- The patient is able to control his drug
- Fully controlled and documented way of drugs
- Less medication errors
- Less manual work on wards
- More time for patients
- More transparency and standardization of drug prescription
- Medication profiles are visible via networking, especially important in case of emergency
- Reduction of drug consumption
- Lower stockage on wards
- Exact consumption control concerning cost units
- Less theft
- Less effort for inventory on wards
- Easier calculation of costs concerning DRGs



Characteristics:

- Administration of single pills
- No blister package
- Cross contamination possible
- Pills must be de-blistered

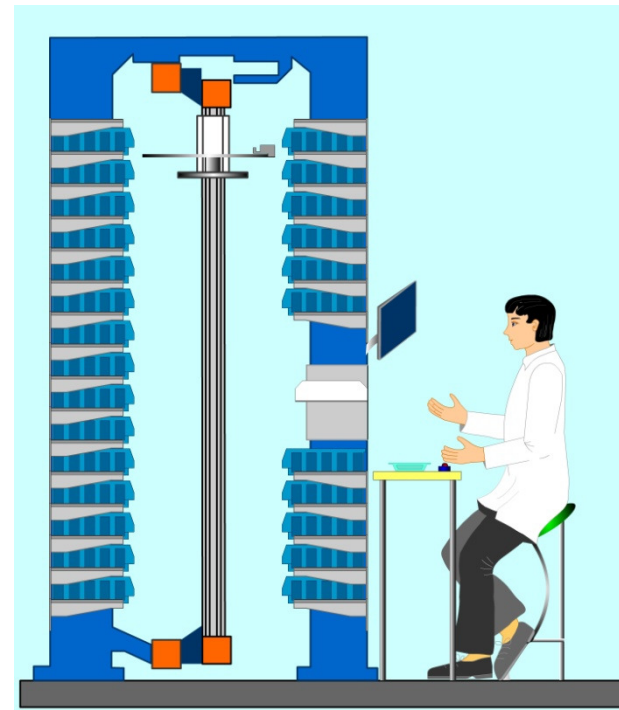
Supply Chain and economic Indicators - Storage Models -

Partially manual Unit Dose System

Pentapack HP500
Blister-Machine



P@P Unit Dose Machine



Patient tray



Supply Chain and economic Indicators - Storage Models -

Reduction of Medication Errors Using UNIT DOSE

Based on worldwide studies

Number of patients per year		70.000	
Medication error quota with longer lay time		3%	*
No. of patients affected by medication errors		2.100	
Prolongation of lay time in days		2	
Costs per day /Patient in EURO		500	
Total costs per year, based on medication errors		2.100.000	EURO

*) studies in Norway say up to 10%

Supply Chain and economic Indicators

- Economic Indicators -

„Logistics Performance Measurement“

= part of logistics controlling by
means of

Key Performance Indicators (KPIs)

Supply Chain and economic Indicators

- Economic Indicators -

The most important KPIs within Procurement Logistics

$$\text{Purchase performance} = \frac{\text{total order value p.a. in EUR}}{\text{costs of the purchasing department p.a. in EUR}}$$

This KPI evaluates the performance of the purchasing department; it indicates, which order value was realised per 1 EUR costs of the purchasing department. It is difficult to manipulate this KPI. Example: **50:1**

$$\text{Costs per order item} = \frac{\text{costs of the purchasing department p.a. in EUR}}{\text{number of order item p.a.}}$$

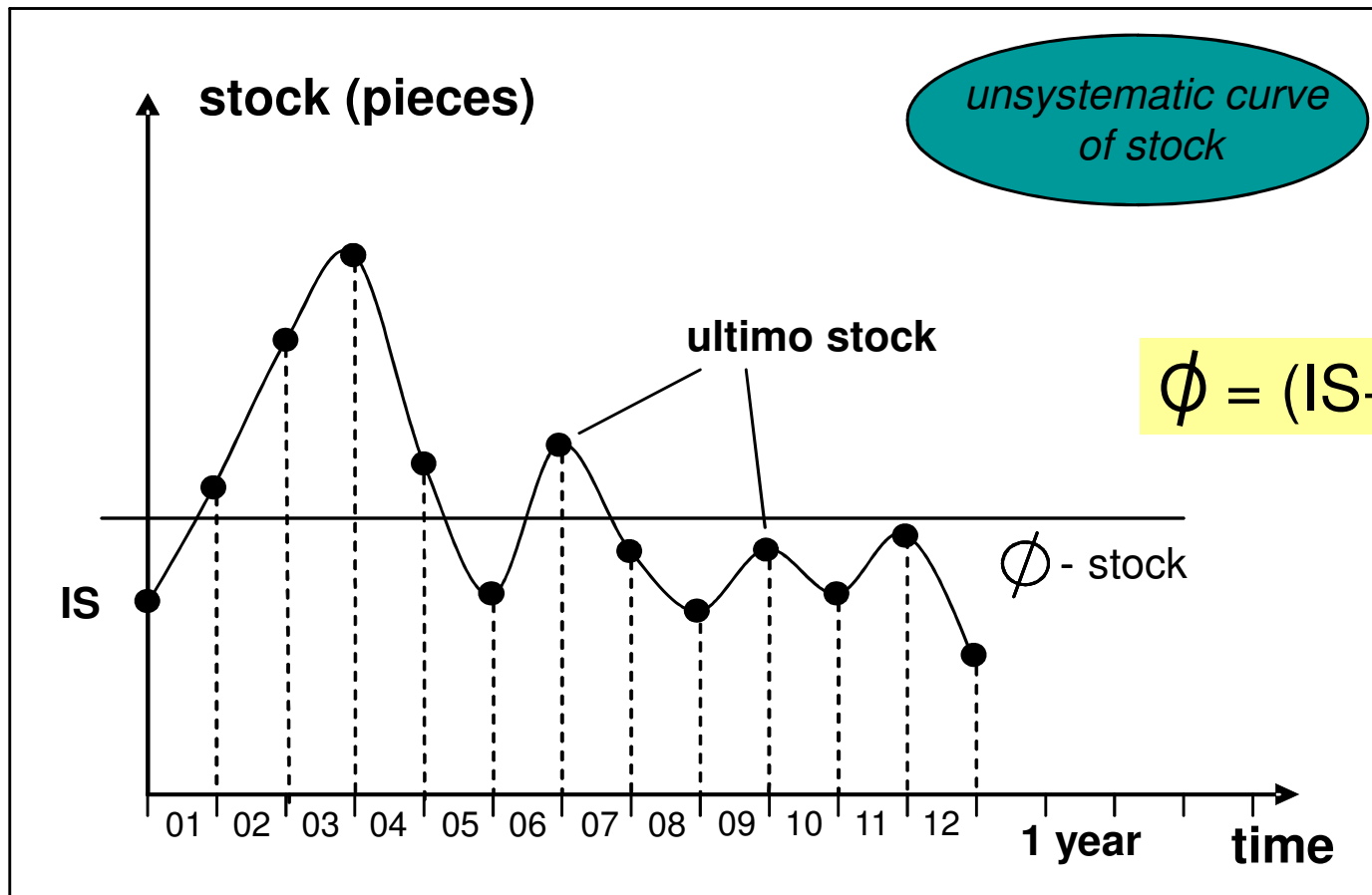
This KPI is necessary for the ANDLER-formula

$$\text{Purchase success} = \text{sum of price deviations} / \text{sum of planned prices} \times 100 [\%]$$

A negative value indicates a negotiation success because the paid prices were lower than the planned prices.

Supply Chain and economic Indicators - Economic Indicators -

Calculation of the average stock Version 1

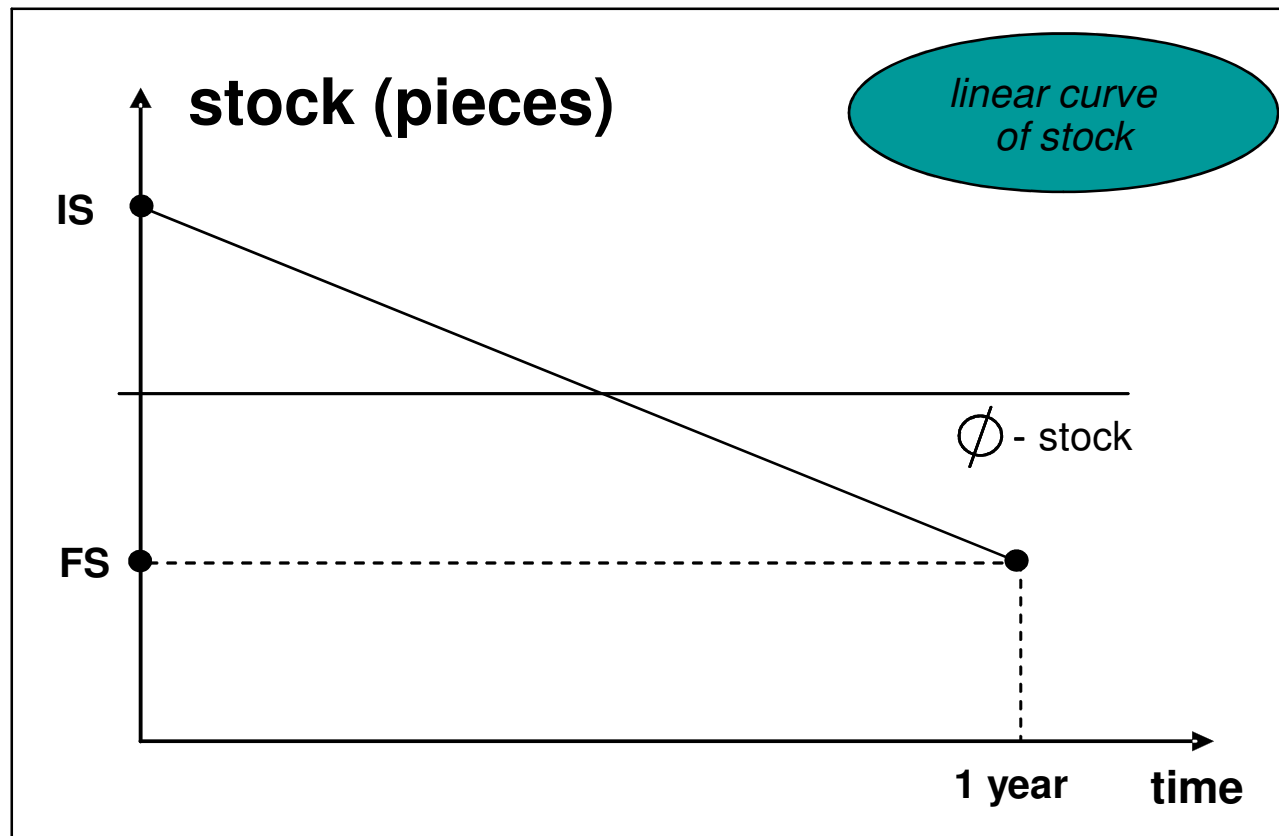


IS=initial stock
US=ultimo stock

Supply Chain and economic Indicators

- Economic Indicators -

Calculation of the average stock Version 2

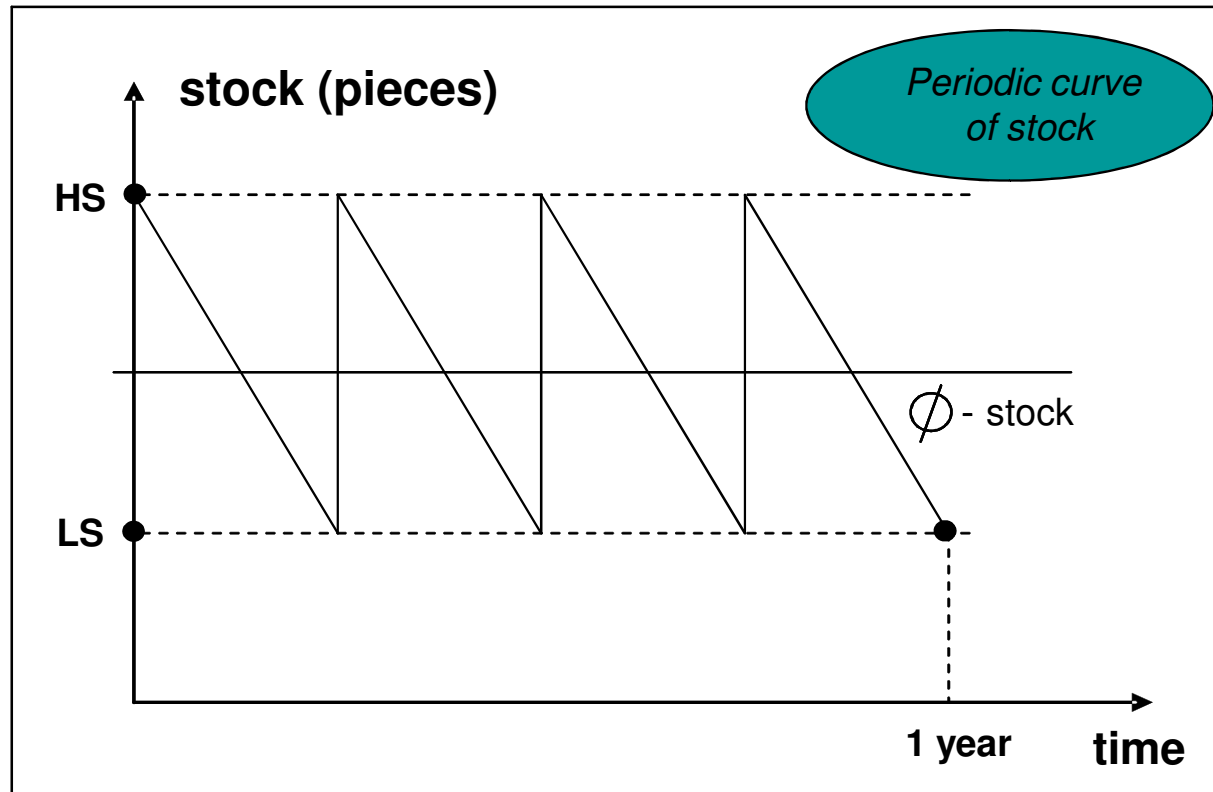


$$\phi = (IS+FS)/2$$

IS=initial stock
FS=final stock

Supply Chain and economic Indicators - Economic Indicators -

Calculation of the average stock Version 3



$$\phi = (LS+HS)/2$$

Supply Chain and economic Indicators - Economic Indicators -

The most important KPIs for warehousing

$$\text{Average stock} = (\text{start stock} + 12 \text{ ultimo stocks}) / 13$$

$$\text{Warehouse expense ratio (WER)} = \frac{\text{total costs of warehousing p.a.}}{\text{average stock (capital lockup)}} \times 100 [\%]$$

The costs of warehousing do not contain the interest costs of the capital lockup.

$$\text{Total warehousing expense ratio (TWER)} = \text{WER} + \text{interest for capital lockup}$$

This KPI is necessary for the ANDLER-formula; normal value range: 15 – 25 %

Supply Chain and economic Indicators - Economic Indicators -

The most important KPIs for warehousing

**Inventory turnover = warehouse sales p.a. (pieces resp. value) /
average stock (pieces resp. value)**

The inventory turnover is one of the mostly used KPI.

The average turnover over the full assortment must be built only via values!

Range of inventory in months = 12 months / inventory turnover

The range of inventory tells us, how long the average stock meets the normal demand without replenishment. The average range must be built using the average turnover.

Supply Chain and economic Indicators - Economic Indicators -

The most important KPIs for warehousing an logistics

$$\text{Delivery service level} = \frac{\text{directly delivered number of pieces of an article}}{\text{demand of the customer}} \times 100 [\%]$$

Average delivery service level: sales realised / wished sales * 100 [%]

$$\text{Logistics cost rate} = \text{costs of logistics} / \text{sales} \times 100 [\%]$$

Costs of logistics = depend on the definition, what logistics is: planning of materials, purchasing, goods receipt, included quality control, warehousing, in-house transport, External transport, order picking, packaging, shipping, logistics-IT-system, order processing, production planning and control (PPC) etc.

Supply Chain and economic Indicators

- Economic Indicators -

The most important KPIs for warehousing and logistics

$$\text{Pick-Rate} = \frac{\text{number of picked colli}}{\text{man hours}} \quad [\text{pieces per hour}]$$

Delivery Time = time between issue of order and disposability for the client

$$\text{Delivery reliability} = \frac{\text{number of on-time delivered positions}}{\text{total number of delivery positions}} \times 100 [\%]$$

Supply Chain and economic Indicators

- Economic Indicators -

Most Important Key Performance Indicators in a Hospital Pharmacy					
General Data		Key Performance Indicator		KPI	Remark
Sales volume in €	5.000.000	turnover per sqm	8.333		
thereof for drugs	3.000.000				
number of provided hospitals	3				
number of beds	1.100	turnover per bed	4.545		
number of DRG cases	30.000	turnover per DRG case	167		DRG-relevant
personnel (full time) incl. chief	12	turnover per person	416.667		
thereof procurement	2	percentage	16,7		
thereof goods receipt	0,5	percentage	4,2		
thereof warehousing	1	percentage	8,3		
thereof order picking	3	percentage	25,0		
thereof goods issue	0,5	percentage	4,2		
thereof inventory control	1	percentage	8,3		
thereof preparation	2	percentage	16,7		
thereof transport to wards	1	percentage	8,3		
total area in square meters sqm	600				
Numbers of articles					
numb. of active pharmac. ingredients	700	number of APIs per bed	0,64		decreases by help of standardization
number of article numbers for drugs	2.000	number of drugs per bed	1,82		decreases by help of standardization
numb. of art. numb. for medical products	4.000	number of medical products per bed	3,64		decreases by help of standardization

Supply Chain and economic Indicators

- Economic Indicators -

Data for warehousing		Key Performance Indicator	KPI	Remark
average stock in €	600.000	Inventory turnover (IT)	8,33	
		Range of inventory (RI) in weeks	6,24	<i>RI=52/IT</i>
depreciation	20.000	percentage of turnover %	0,40	
theft	10.000	percentage of turnover %	0,20	<i>Theft</i>
storage area in sqm	300	stock per sqm in €	2.000,00	
thereof drugs	120			
personal capacity in warehouse	1			
full cost per person	35.000			
warehouse rent in €/sqm per month	10			
room costs for warehousing	36.000	warehouse expense ratio WER %	11,83	<i>(room costs+personnel costs)/capital lockup</i>
interest for capital lockup in %	6	total WER in %	17,83	<i>TWER=WER + interest</i>
Date for procurement				
office area in sqm	40			
number of order item p.a.	40.000	costs per order item ="F" in Andler formula	2,62	<i>purchas.+goods receipt+invoice contr.+office rent</i>
thereof drugs	30.000	order item quota	1.667	<i>order items per employee per month</i>
thereof medical products	8.000	total order item performance	3.333	<i>total order items per month</i>
miscellaneous	2.000			
person.capac. Procurement	2,0			
pers.cap.Sampling goods receipt	0,2			
person.capac. goods receipt entry Buchu	0,2			
person.capac. invoice control	0,1			
full cost per person p.a.	40.000			
office rent in €/sqm per month	10			
room costs office procurement	4.800	€ per year		

Supply Chain and economic Indicators

- Economic Indicators -

Examples for optimal lot		Key Performance Indicator	KPI	Remark
number of pills <i>Paracetamol</i> p.a.	70.000	in Andler formula called "J"		
number of order items p.a.	5	lot quantity actual	14.000	
price per piece in €	0,01	in Andler formula called "E"	14.342	<i>Andler formula = SQRT((200*J*F)/(E*TWER))</i>
number of <i>Ti-Mesh</i> p.a.	77			
number of order items p.a.	5	lot quantity actual	15	<i>The optimal lot size is 5 or 6 but never 15!</i>
price per piece at 6	85	optimal lot	5	<i>Andler formula = SQRT((200*J*F)/(E*TWER))</i>
price per piece at 60	72	optimal lot	6	<i>Andler formula = SQRT((200*J*F)/(E*TWER))</i>
Procurement performance				
Planned budget	4.900.000	purchase success in %	-2,08	<i>minus indicates: better than planned</i>
as-is volume	4.800.000	purchase performance	60 :1	<i>for 1 € effort was made a purchase turnover of 60 €</i>
thereof over master agreement	2.000.000	master agreement quota in %	42	<i>easier purchasing process</i>
number of delivery notes p.a.	12.000			
number of working days	250			
av.number of items per deliv. note	5	number of goods receipt items per day	240	<i>productivity of goods receipt</i>
delivery time from producer in hours	24			
delivery time from wholesaler in h	4			
deliv. time taxi from public pharmacy	1			
Order picking performance				
number of order picking items p.a.	250.000	WA-Positionen per Tag	1.000	<i>productivity of order picking</i>
pers.capacity (incl. goods issue+control)	3,5	pick rate in picks per man-hour	41	<i>productivity of order picking</i>
full costs per person p.a. in €	35.000	costs per goods issue item in €	0,49	
number of man-hours per day	7			

Supply Chain and Economic Indicators

- Storage Models / KPIs -

Repetition

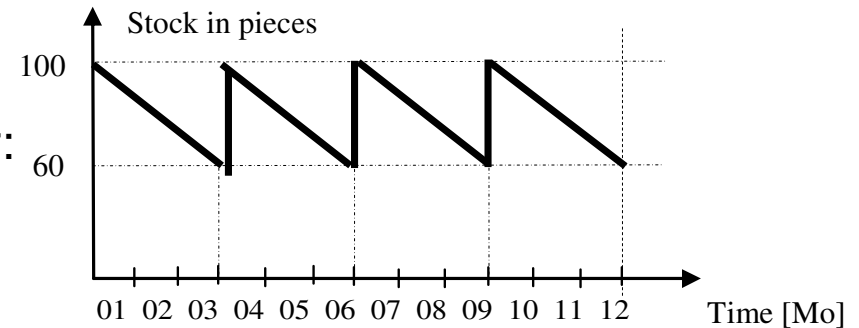
- Declare the steps to find the suitable storage system
- Explain advantages and disadvantages of several storage principles
- Explain some types of racks; what is the main advantage of a gravity flow rack?
- Calculate the central stock
given: in decentral warehouse: W1 300 pieces, W2 400, W3 500
- Give some examples, where the paternoster principle can be found
- Explain the pick to light principle
- Explain some advantages of paperless order picking
- Explain the advantages of batch flow method
- What are advantages and problems of Unit Doses?
- Ability to calculate KPIs and the several kinds of average stock
- Understanding the KPI-report for a hospital pharmacy

Supply Chain and Economic Indicators

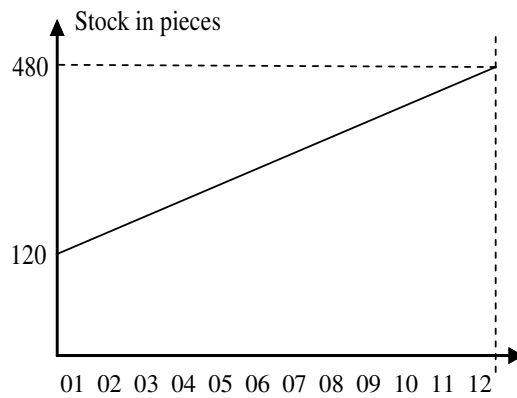
- Storage Models / KPIs -

Repetition

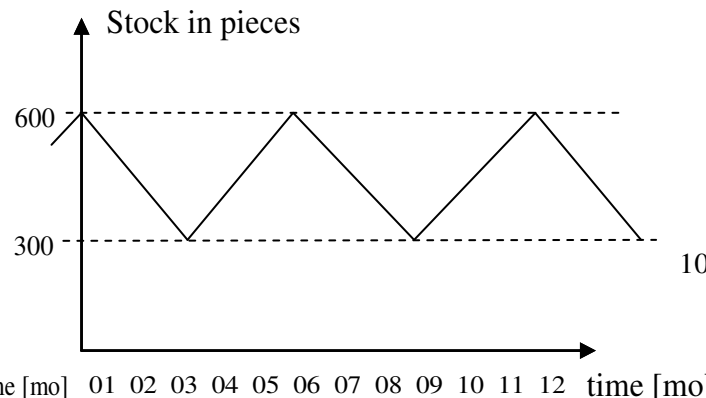
- Given is the following stock curve for one year:
Please calculate the inventory turnover



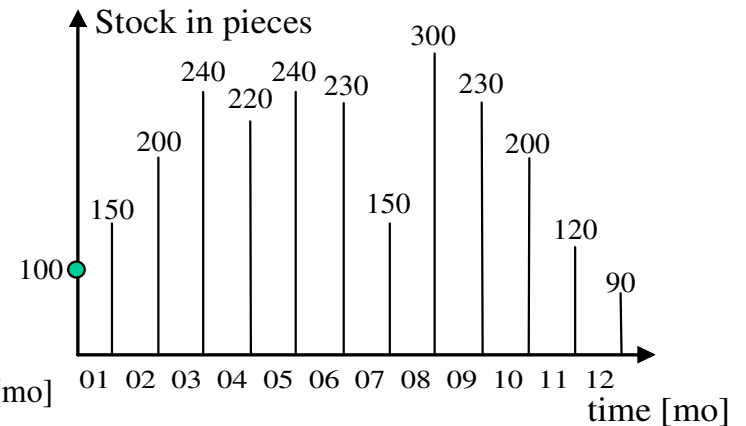
- Given are the following stock curves, each for one year.
Calculate in all cases the average stock!



$$\phi =$$



$$\phi =$$



$$\phi =$$