

# Monitoring ambijentalnih uslova u farmaceutskom lancu snabdevanja- od proizvođača, preko veleprodaja, do apoteka

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*VALENTINA D. MARINKOVIĆ*

*VMARINKOVIC@PHARMACY.BG.AC.RS*

# Sadržaj

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- ❖ Subjekti u farmaceutskom lancu snabdevanja
- ❖ Monitoring uslova tokom skladištenja i transporta
- ❖ Poverene aktivnosti u farmaceutskom lancu snabdevanja
- ❖ Standardi i smernice za regulaciju poverenih aktivnosti
- ❖ Alati i tehnike u upravljanju rizikom
- ❖ Kritični incidenti u farmaceutskom lancu snabdevanja

# Subjekti u farmaceutskom lancu snabdevanja

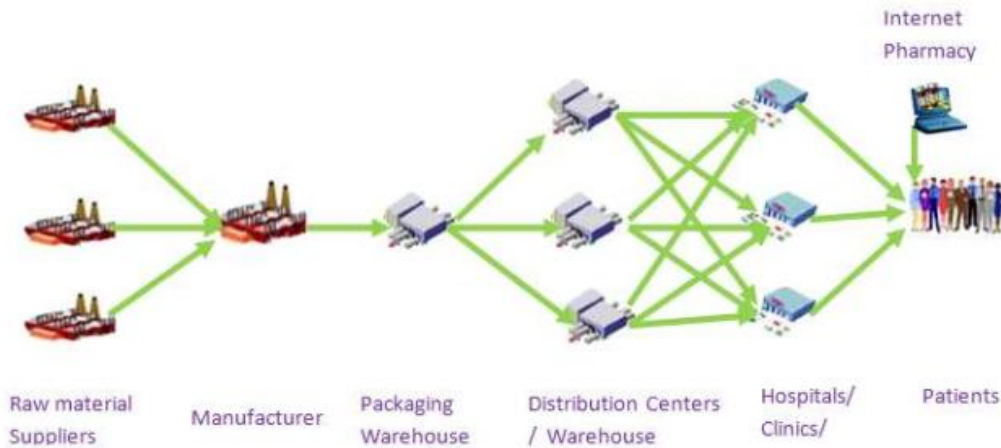


Figure 2-1 Forward Supply Chain of Pharmaceutical Industry

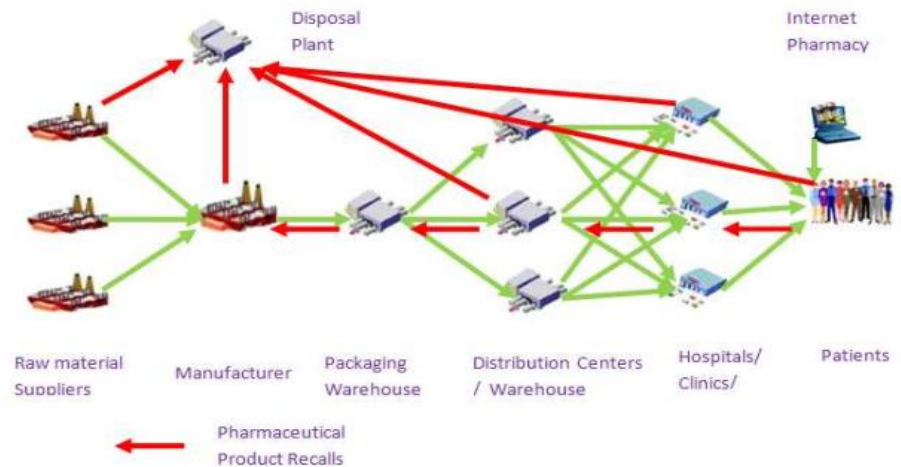


Figure 2-3 Reverse Supply Chain of Pharmaceutical Industry



# Kako pratiti uslove u farmaceutskom lancu snabdevanja?

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## **SKLADIŠTENJE**

- temperaturno mapiranje

(skladišta, materijalka, frižideri, hladne komore)

- redovni monitoring

Kontinuirani

Diskontinuirani

- Zapisi o primopredaji

## **TRANSPORT**

- temperaturno mapiranje

(vozila, cold box...)

- kvalifikacija transportne rute

- data logeri (u tercijernom pakovanju)

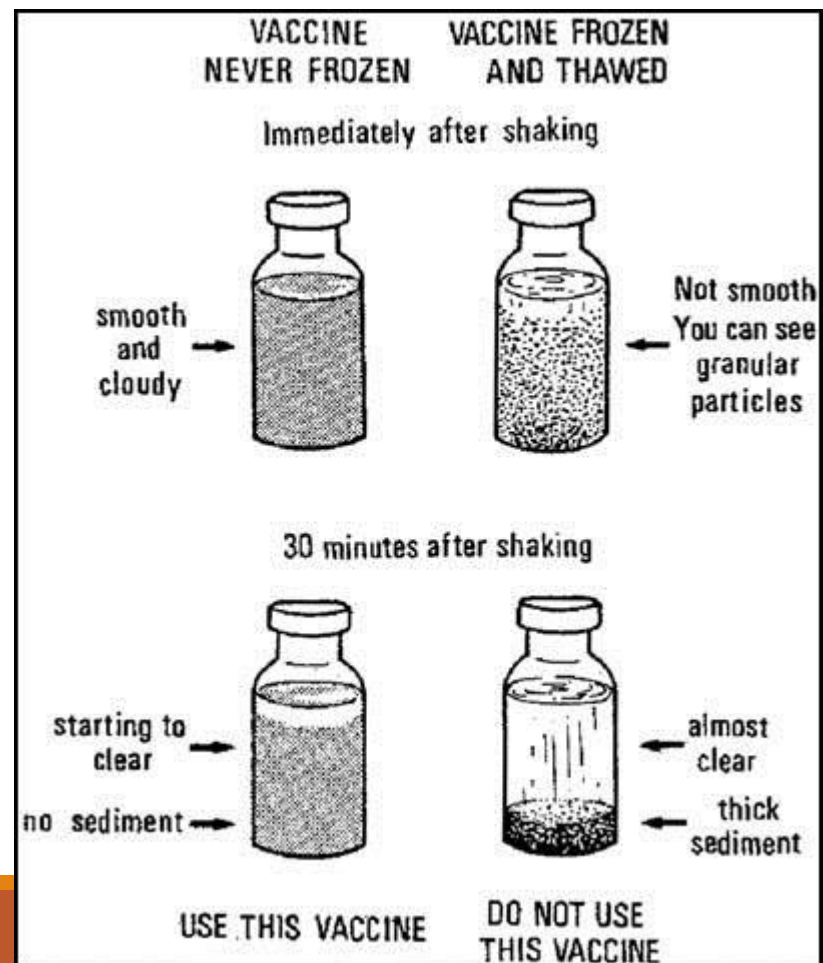
- Zapisi o primopredaji

# Osetljivost proizvoda na temperaturne uslove

## OSETLJIVI NA POVIŠENU TEMPERATURU



## OSETLJIVI NA ZAMRZAVANJE



# Pakovanja za otpremu

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**Pomoćni sistemi uz tercijarno pakovanje sa ciljem održavanja temperature tokom transporta.**

**Aktivni sistemi sa aktivnom kontrolom temperature kao što su teretni kontejneri za vazduh i vodu ili hladnjače**



**Pasivni sistemi bez aktivne kontrole temperature kao što su izolovani kontejneri od polistirena ili poliuretana sa ili bez rashladnih sredstava:**



# Data logeri

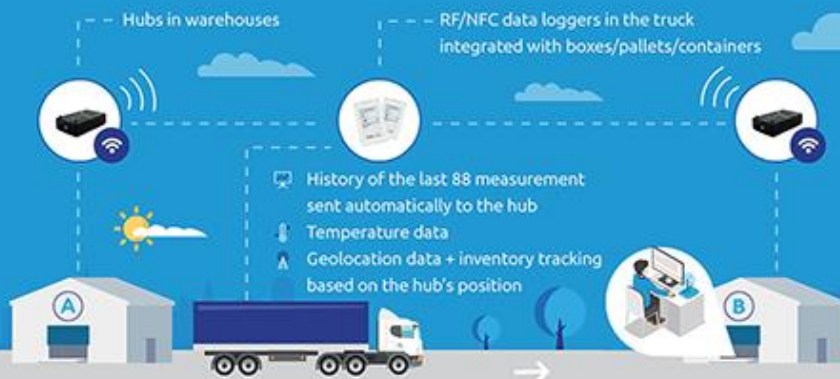
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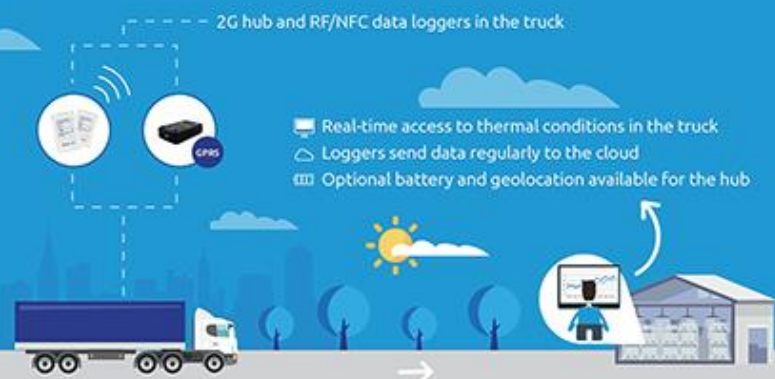


# Aktivni data logeri

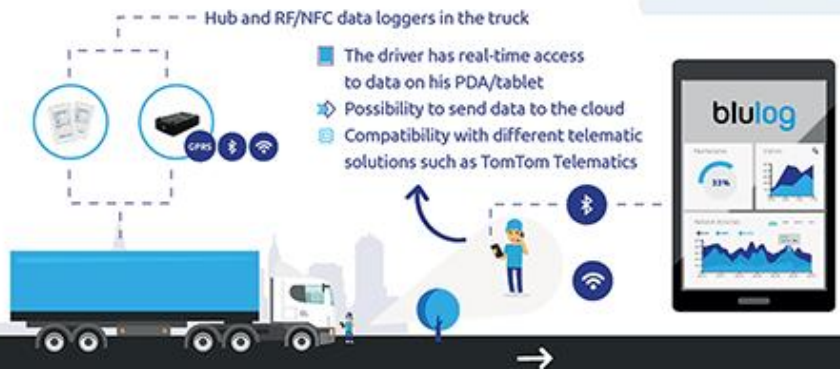
## 1 Measurement history of the entire delivery cycle



## 2 Real-time remote monitoring



## 3 Local view of the data



## 4 NFC loggers in boxes



# Šta je *outsourcing*?

Poverene aktivnosti

Spoljne usluge

Autsors



Copyright by Signe Wilkinson

**Outsourcing** je poslovna praksa koja podrazumeva poveravanje aktivnosti, zadataka, poslova ili procesa eksternim kompanijama u cilju smanjenja troškova i povećanja efektivnosti.

**Outsourcing** se odnosi na poveravanje poslova drugoj organizaciji („trećoj strani“ dok je **offshoring** poveravanje poslova organizaciji koja se nalazi u drugoj zemlji.

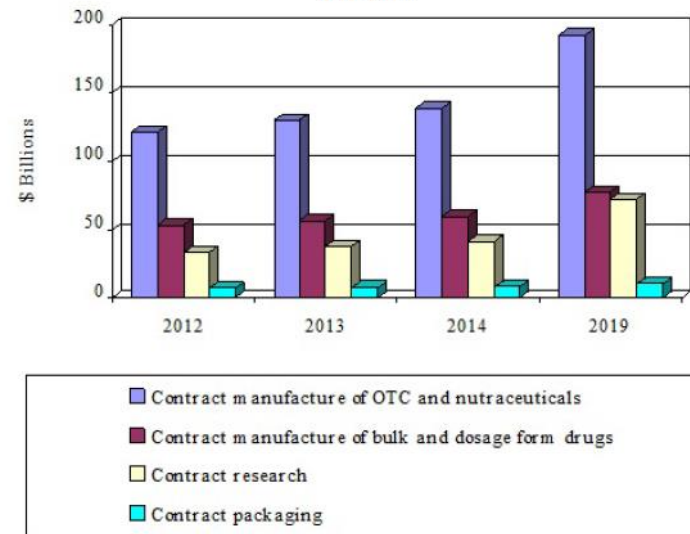
**Tradicionalni outsourcing** se zasniva na poslovnoj taktici koja podrazumeva smanjenje troškova i povećanje efikasnosti i fleksibilnosti

**Transformacijski outsourcing** se fokusira na inovaciji i poslovnim poboljšanjima, gde je osnovni cilj zajednika **poslovna promena**

# Organizacione promene u farmaceutskom poslovanju

- Proesi liberalizacije i globalizacije
- Podsticaj konkuretnosti na svim nivoima
- Spajanja i akvizicije
- **Outsourcing** je najpogodniji biznis model i deo uspešnih biznis strategija
- **Outsourcing** je jedna od najkompleksnijih zadataka u poslovnom svetu

SUMMARY FIGURE  
GLOBAL MARKET FOR CONTRACT PHARMACEUTICAL MANUFACTURING, RESEARCH AND PACKAGING BY SEGMENT, 2012-2019  
(\$ BILLIONS)



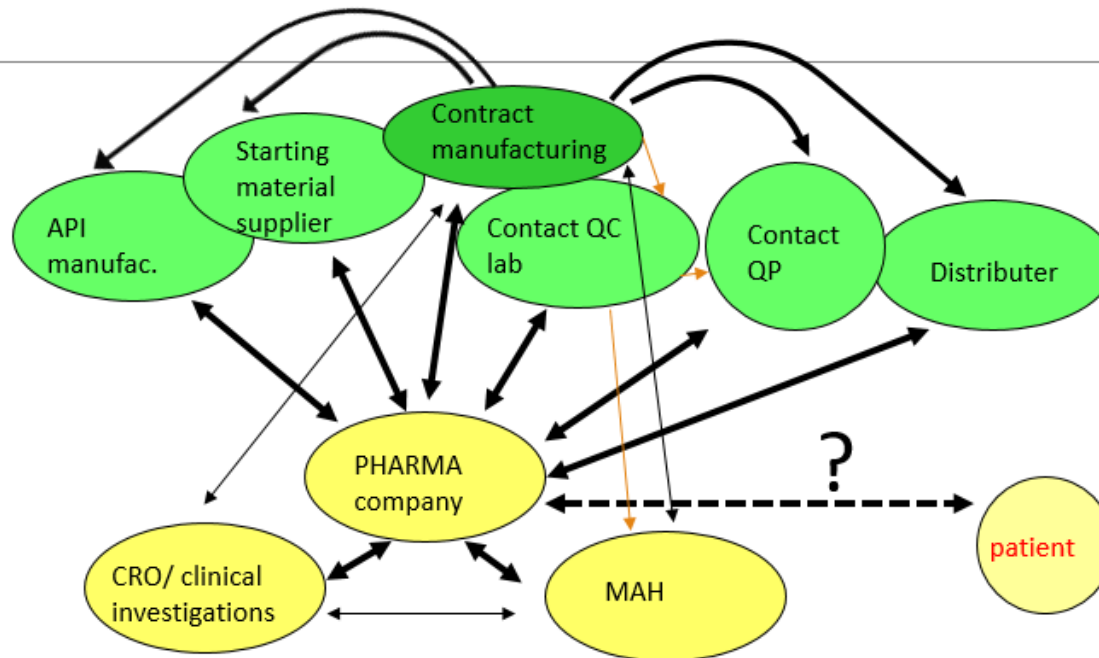
Choi TM, Wallace SW, Wang Y, Risk management and coordination in service supply chains: information, logistics and outsourcing, *Journal of the Operational Research Society* 2016; 67(2): 159–164

BCC Research Pharmaceutical Report overview, Global Markets for Contract Pharmaceutical Manufacturing, Research and Packaging, June 2015

<https://www.bccresearch.com/market-research/pharmaceuticals/contract-pharmaceutical-manufacturing-research-packaging-global-markets-report-phm043f.html>

# Outsourcing i rizik po pacijenta?

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# Standardi & Smernice

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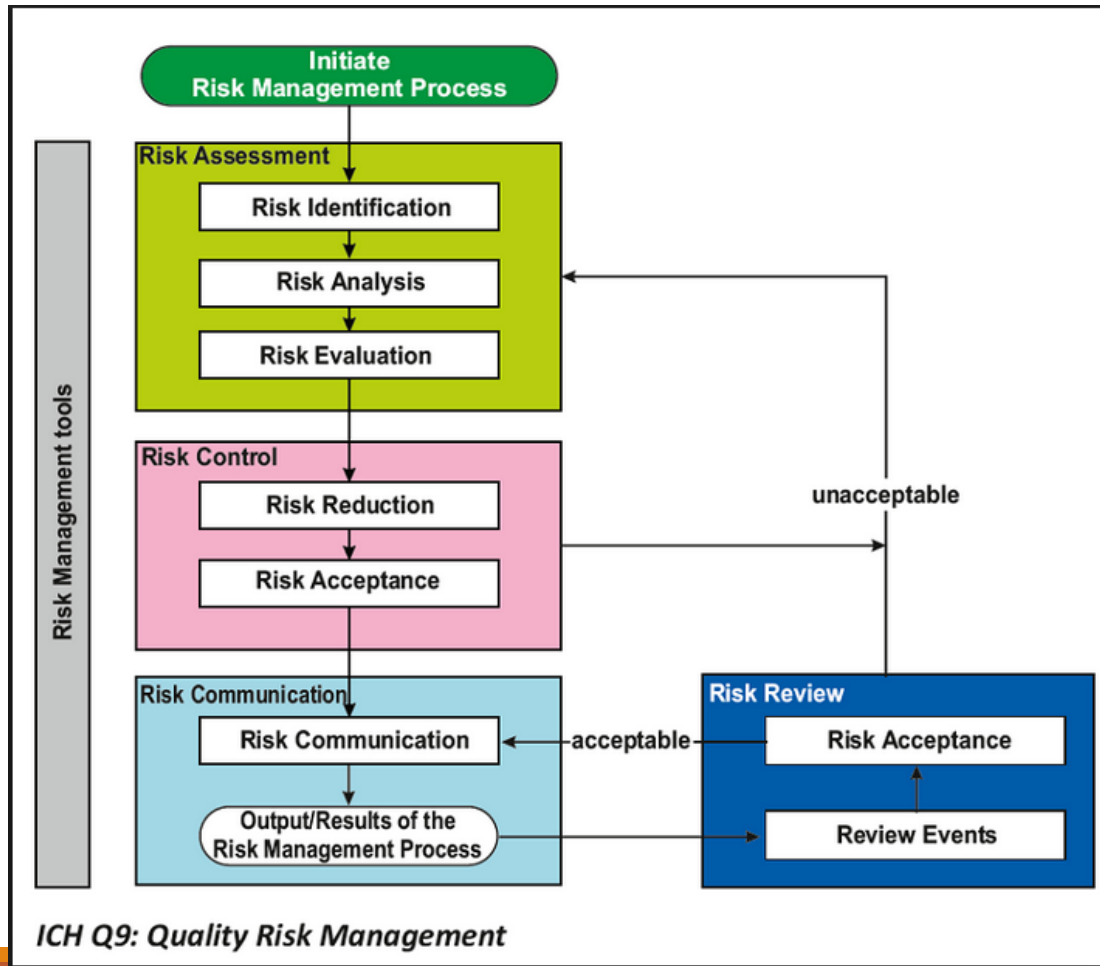
- ISO 9001:2015 Quality Management system
- ISO 14 971:2007 Medical devices -- Application of risk management to medical devices
- ISO 37500:2014 Guidance on outsourcing
  
- Good manufacturing Practice- poglavlje 7
- Good Distribution Practice- poglavlje 7
  - Tehnički ugovori
  - Kvalifikacija transportne rute
  - Upotreba data logera
  - Kvalifikacija dobavljača
- Kvalifikacija kupaca



# Rizici u *outsourcing*-u

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- ❖ GUBITAK STRATEŠKE KONTROLE
  - ❖ SKRIVENI TROŠKOVI
  - ❖ PROBLEMI U KVALITETU USLUGE
  - ❖ NEISPUNJENJE REGULATORNIH OČEKIVANJA

# Kako upravljati rizicima?



# Identifikacija rizika

1. Učiti iz prošlosti
2. Razumeti sadašnjost
3. Anticipirati budućnost

## Kategorije rizika u *outsourcing-u*:

- administrativni
- tehnički
- bihevioralni

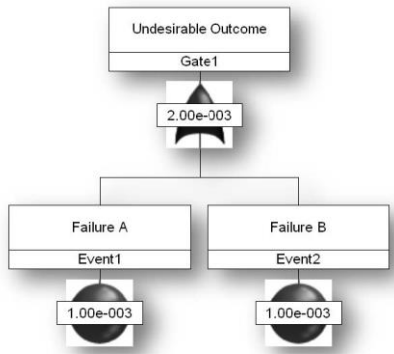
**Table 1. Categories of risks in Outsourcing Logistics**

Category	Risk
Operational: Storage and distribution processes	R1- Poor infrastructure and handling R2- Delivery delay R3- Poor service performance: failure in attaining an acceptable degree of responsiveness and flexibility R4- Disorder of operations at the transition phase R5- Medicinal products quality deterioration
Financial	R6- Unrealized savings with possible increased costs R7- Loss of customers due to the partner's poor service performance
Technology	R8- Poor information system integration leading to failure in product traceability
Information Related	R9- Strategic and operational information leakage R10- Latent information asymmetry between client and service provider. (Wang and Regan 2002)
Relational	R11- Poor supplier relations: Poor morale/employee issues R12- Reduced customer/supplier contact R13- Conflicts of culture
Internal	R14- Poor contract (unclear) or poor planning of outsourcing functions R15- Poor selection of partner R16- Unrealistic or high expectations regarding the service provide performance R17- Lack of skills to evaluate, manage and monitor outsourced functions R18- Loss of control over the service provider



# Procena rizika

## Prospektivni alati



### Risk Assessment - Creating FMEA

Process Function	Potential Failure Mode (How the X fails?)	Potential Effects of Failure on Product	SEV	Potential Cause(s) of Failure	OC	Current Process Controls	DET	RPN
								0
								0
								0

The FMEA process begins by identifying "Failure Modes," the ways in which a product, service or process could fail wrt **Customer Requirement**.

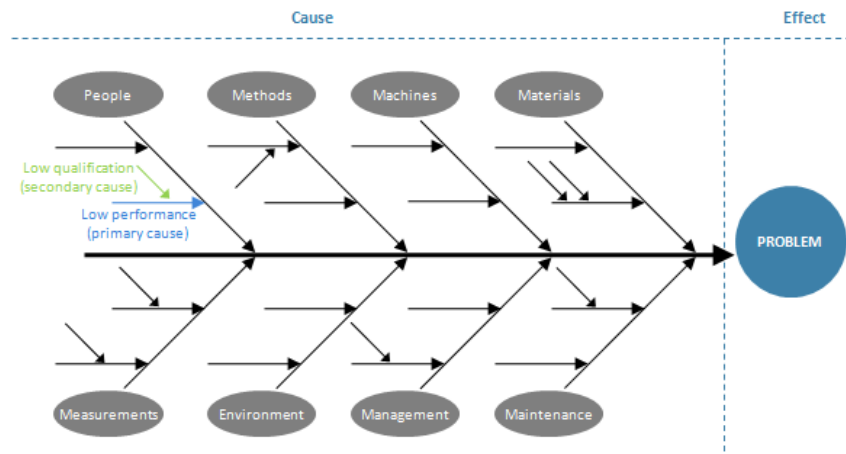
A project team examines every element of a service, starting from the **inputs** and **working** through to the **output** delivered to the customer.

Sandeep, LeanSixSigma

Likelihood	5	Almost certain	5	10	15	20	25
	4	Likely	4	8	12	16	20
	3	Possible	3	6	9	12	15
	2	Unlikely	2	4	6	8	10
	1	Rare	1	2	3	4	5
			Insignificant	Minor	Moderate	Major	Severe
			1	2	3	4	5
			Impact				

Green = Low  
 Yellow = Medium  
 Orange = High (Major)  
 Red = Critical

## Retrospektivni alati



# Komunikacija rizika

## Bihevioralni kontekst

Faktori koji vode ka uspešnom outsourcing.u

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- ❖ Pouzdanost
- ❖ Usaglašenost
- ❖ Odgovornost
- ❖ Fleksibilnost
- ❖ Bezbednost
- ❖ Empatija
- ❖ Sigurnost



# Faktori koji vode ka neuspešnom *outsourcing-u*

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**Nedostatak kompetentnosti zaposlenih**

**Odstustvo posvećenosti menadžmenta**

**Loša komunikacija**

**Razlika u organizacionoj kulturi**

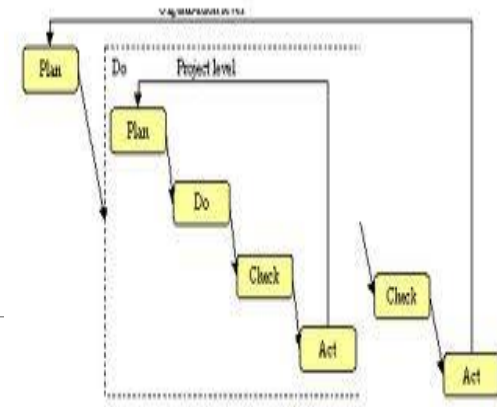
**Različit regulatorni okvir**

# Focus ka kvalitetu

## PDCA model

**Table 1: Conceptual PDCA model of outsourcing in pharmaceutical supply chain**

<b>PLAN phase</b>	<ul style="list-style-type: none"> <li>- Project task</li> <li>- Due diligence</li> <li>- Risk assessment</li> <li>- Pharmaceutical contract negotiation</li> </ul>
<b>DO phase</b>	<ul style="list-style-type: none"> <li>- Regulatory requirements compliance (variations, audits)</li> <li>- Pharmaceutical contract execution</li> <li>- Defining of KPIs referred to outsourcing organisation</li> </ul>
<b>CHECK phase</b>	<ul style="list-style-type: none"> <li>- Follow up of KPIs</li> <li>- Audits of service supplier on regular basis</li> </ul>
<b>ACT phase</b>	<ul style="list-style-type: none"> <li>- Objectives review</li> <li>- Contract review</li> <li>- Defining, implementation and tracking of preventive and corrective actions</li> </ul>



**Table 2: PDCA model for outsource of medicine transport**

<b>P</b>	<ul style="list-style-type: none"> <li>- Project task</li> <li>- Due diligence</li> <li>- Contract and technical agreement negotiation</li> </ul>	<ul style="list-style-type: none"> <li>- Risk/benefit analysis</li> <li>- Transport compliance evaluation in accordance with stability study (cold chain)</li> <li>- Transport company selection</li> <li>- Commercial and technical contract drafts preparation and defining responsibilities</li> </ul>
<b>D</b>	<ul style="list-style-type: none"> <li>- Regulatory requirements completeness (variation, audits)</li> <li>- KPI identification</li> <li>- Contract execution</li> </ul>	<ul style="list-style-type: none"> <li>- Defining of KPIs - example:                             <ul style="list-style-type: none"> <li>- 100% of deliveries according to the plan,</li> <li>- 0 % delivery with more than 15 days late</li> <li>- 0 % delivery with temperature deviation</li> <li>- not more than 0.2% non compliant product during the transport</li> </ul> </li> </ul>
<b>C</b>	<ul style="list-style-type: none"> <li>- KPI monitoring in regular periods</li> <li>- Outsource company audits in regular periods</li> </ul>	<ul style="list-style-type: none"> <li>- KPI trends analysis</li> <li>- Transport company audit</li> </ul>
<b>A</b>	<ul style="list-style-type: none"> <li>- Goals review</li> <li>- Contract review</li> <li>- Corrective and preventive action review- changes defining and execution</li> </ul>	<ul style="list-style-type: none"> <li>- Changes defining and execution</li> </ul>

# Focus ka upravljanju promenama?

ISO 37500:2014(E)

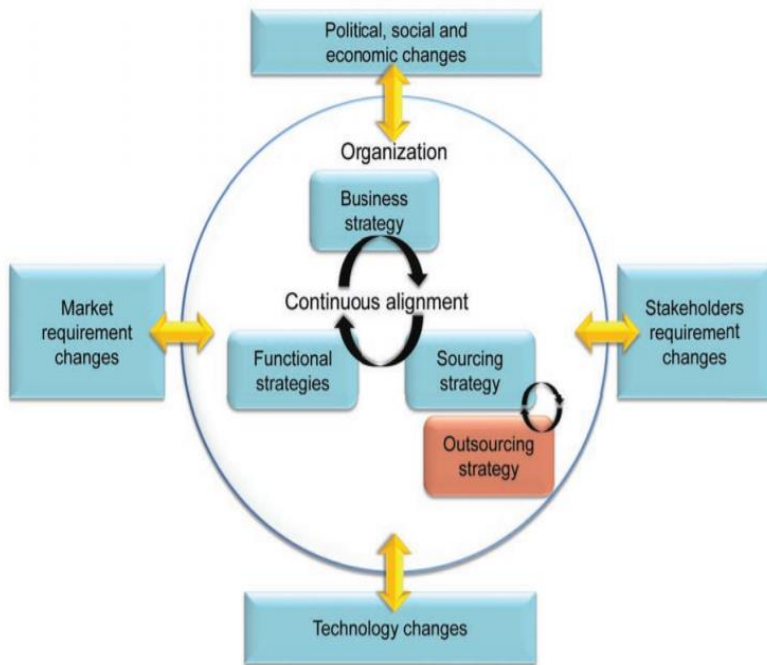


Figure 1 — Contextual model of outsourcing

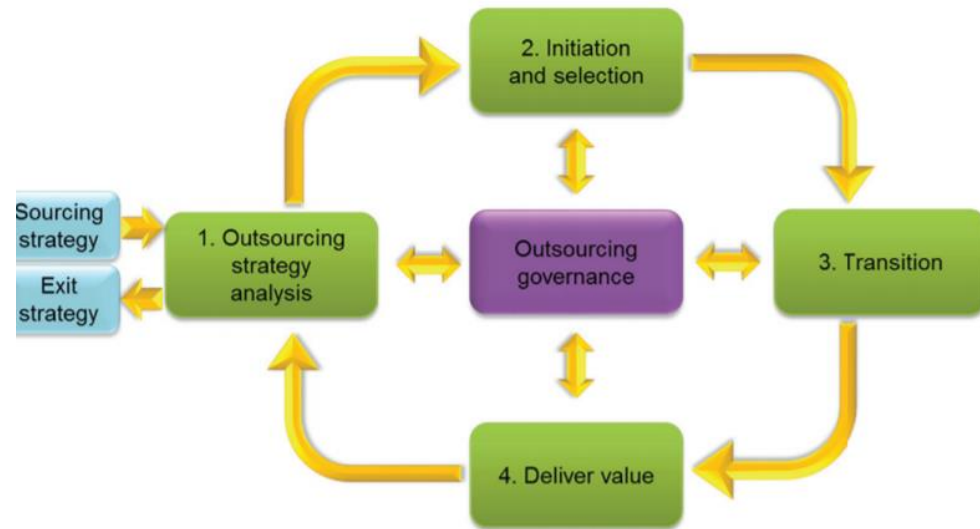


Figure 2 — Outsourcing life cycle model

Hvala!