Ελληνική Εταιρεία Συστημικών Μελετών
CSAP Mastering in Systemic Management
Επαγγελματική Πιστοποίηση Μεταπτυχιακού Επιπέδου
ISO 9001 Certified
European Union For Systemics

Systemic Restructuring of Business Continuity in a Pharmaceutical Company

Implementation of DCSYM, Dynamic Modeling and VSM

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Why the study and what was the problem

Why the study

- Requirement to shield the company against crises in order to ensure its survival
- Business Continuity Plans (BCPs) assigned to the 4 Department Directors, resulting in 4 standalone, unconnected plans

Current situation (as-is)

1. Overlaps and critical gaps at the interfaces between departments
2. Organizational silos: no common impact analysis (BIA) or central crisis management
3. Information overload at the General Management, with no integrated control
4. Critical asset at risk: vaccine storage with no backup power supply

Estimated BCP activation time: 72 hours

Company structure and reporting lines

~1,200 employees
35 years of operation

ISO 9001 · ISO 13485
GMP compliance

General Management
General Manager · Deputy Manager

Biotechnology Department
- Research
- Medical (Drugs · Vaccines)
- Testing
- Quality Control

Production Department
- Preparation
- Packaging

Supply Chain
- Raw Materials
- Warehouse
- Distribution (Internal · External)

Administrative Services
- Marketing · Accounting
- Personnel
- Information Systems
- Legal

All 4 departments report directly to the General Management · there is no crisis coordination body

Legal and regulatory framework

EOF · National Organization for Medicines

EMA · European Medicines Agency

1. GMP rules (Good Manufacturing Practice)
2. Clinical trials
3. Adverse event reporting (pharmacovigilance)
4. Personal data protection (GDPR)
5. Environmental regulations

Continuity of supply: a legal obligation (Directive 2001/83/EC, Article 81) and EMA guidelines

The company's environment: PESTEL

P Political

Stable legal framework, increased EOF / EMA inspections

E Economic

Raw material costs, price pressures, economic instability

S Social

Increased demand for vaccines, ageing population, chronic diseases

T Technological

Production digitalization, AI, automation, IoT

E Environmental

Sustainable production, reduced waste and footprint

L Legal

Strict regulations: recalls, adverse events, GMP, GDPR

Greatest impact: economic and legal factors → BCM is a necessity

Purpose and methodological approach

1

SSM

Understanding the unstructured problem

2

DCSYM

Structure, communications, control

3

System Dynamics (VENSIM)

Dynamics and cost of delay

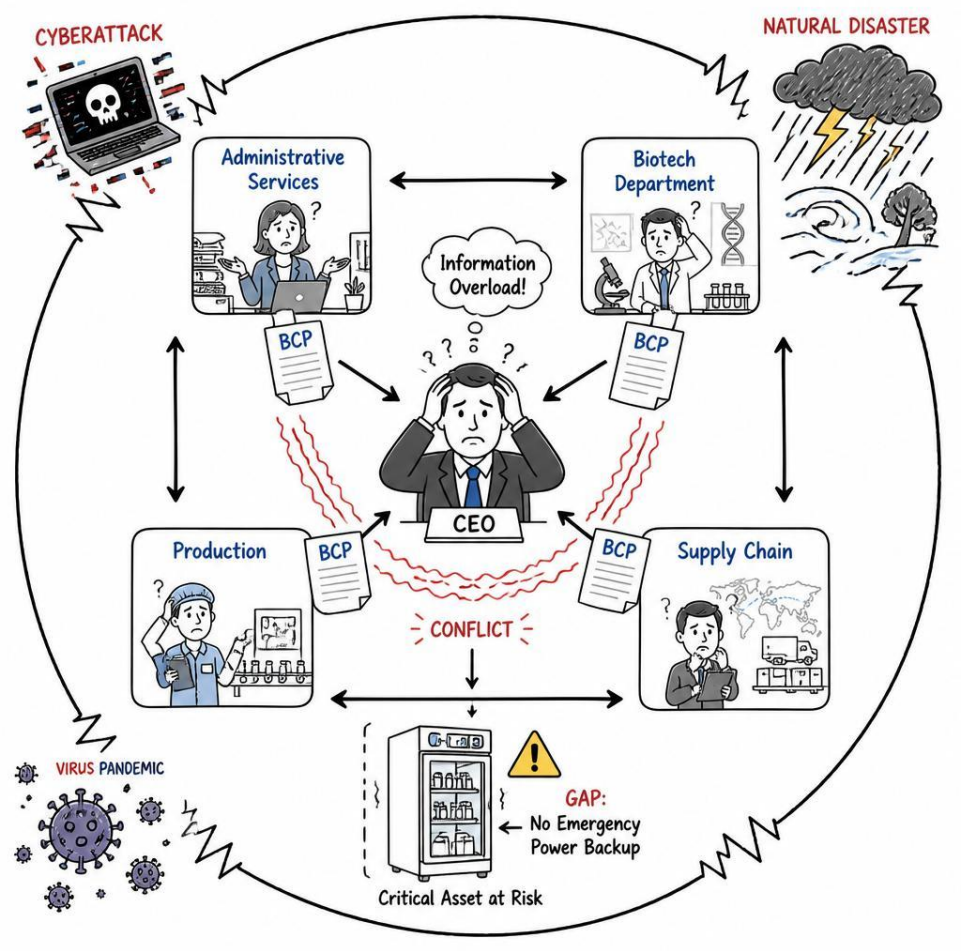
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VSM

Viability of the new structure

Hybrid approach (multi-methodology) to a business problem

SSM: from confusion to shared understanding



Transformation

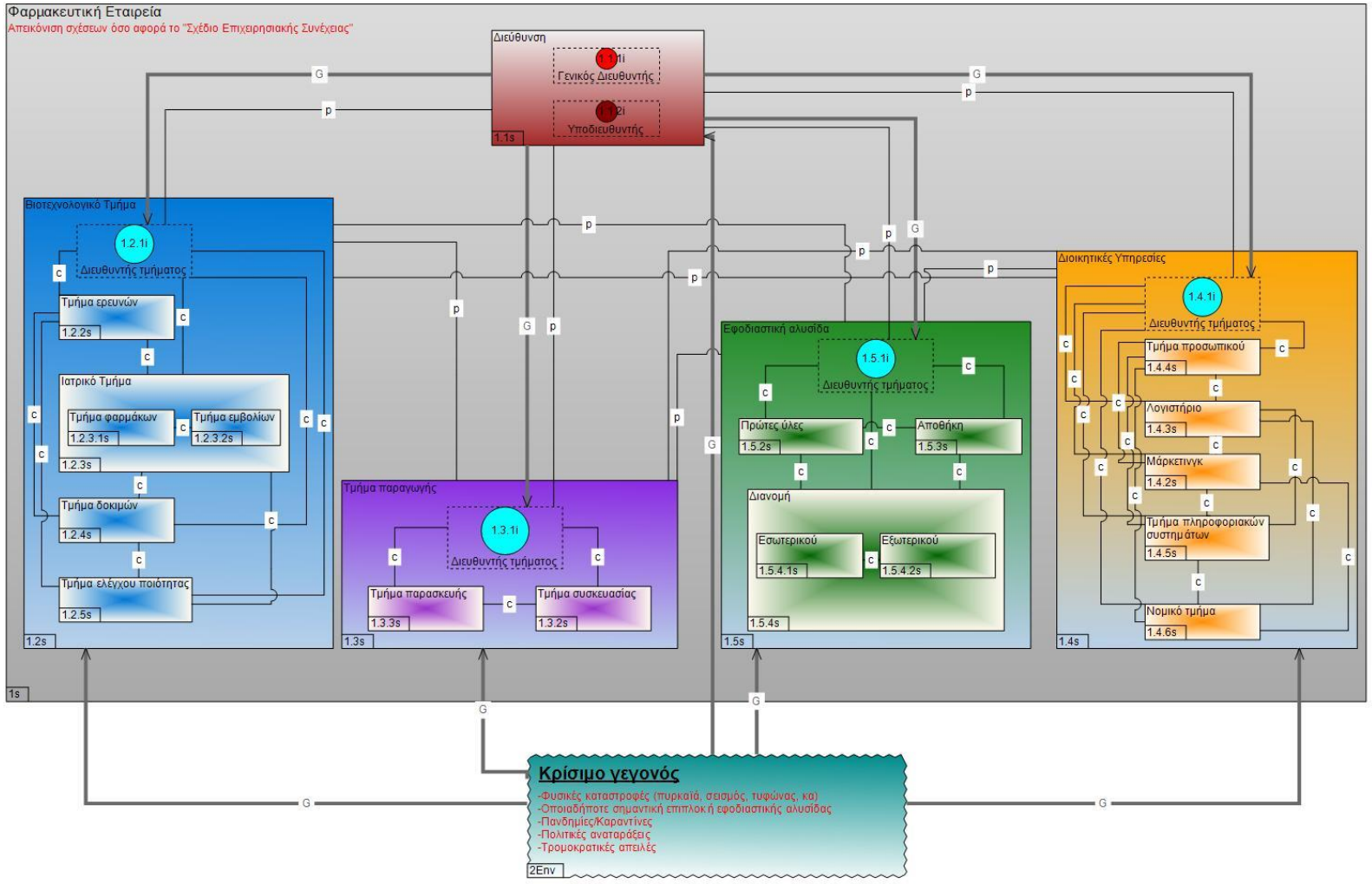
4 fragmented BCPs → 1 unified Enterprise BCP with central coordination

W Continuity is a systemic property, not the responsibility of each department

O General Management and Board approve and allocate resources

E Budget, GMP regulations, resistance to change

DCSYM: Current State (CS)

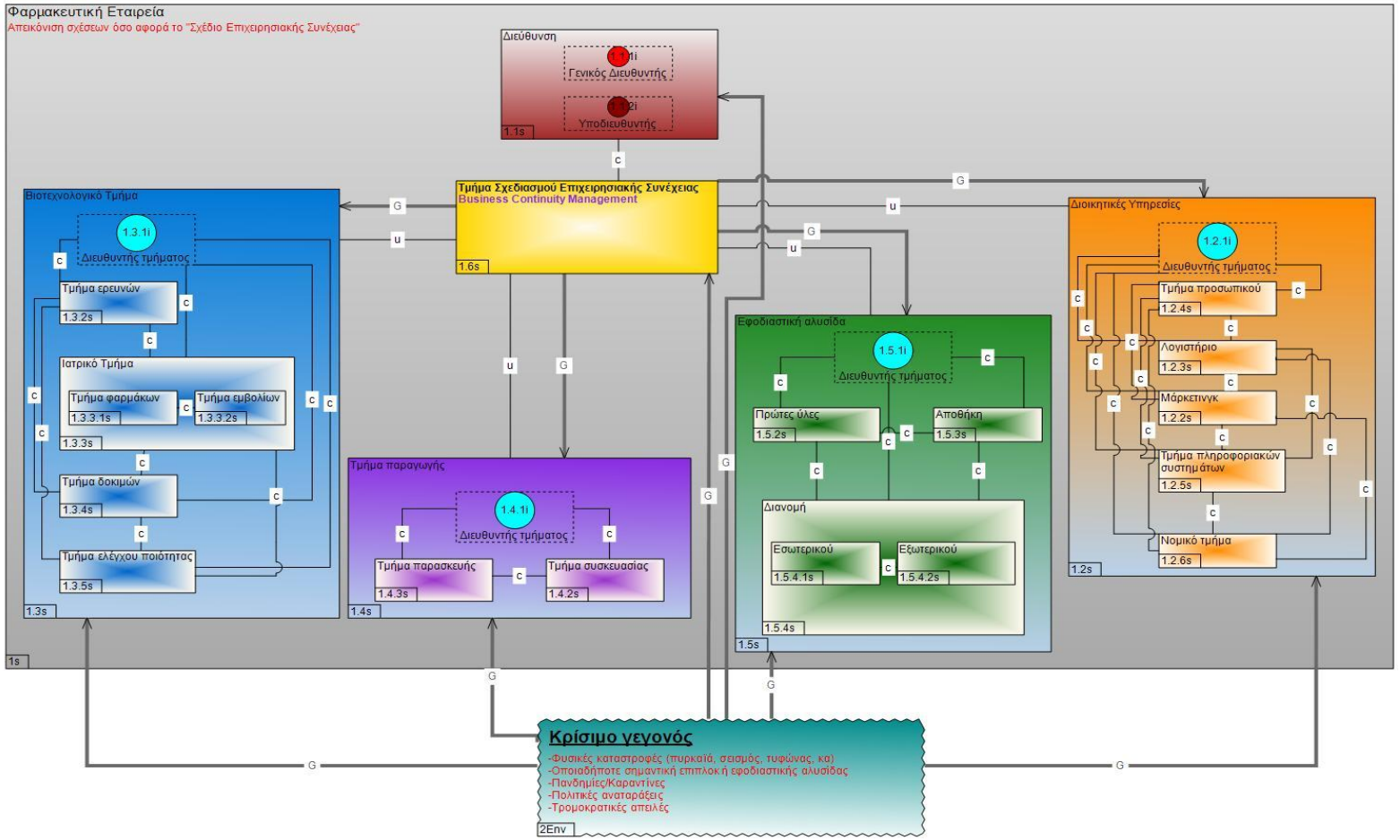


46 communications among 24 systems

10 type p communications (potential conflict)

G unstructured control by the General Management

DCSYM: Proposed Improvement (PI)



46→41 communications

10→0 p (conflict) communications

G→u unstructured control → targeted action

New BCM Department: central coordination hub, reporting to the General Management

Causal loops: vicious cycle and balancing

R1 · Vicious cycle of inertia

Decentralized BCPs → **Overlaps and gaps** → **Decision-making time** → **Activation delay** → **Confusion and errors**

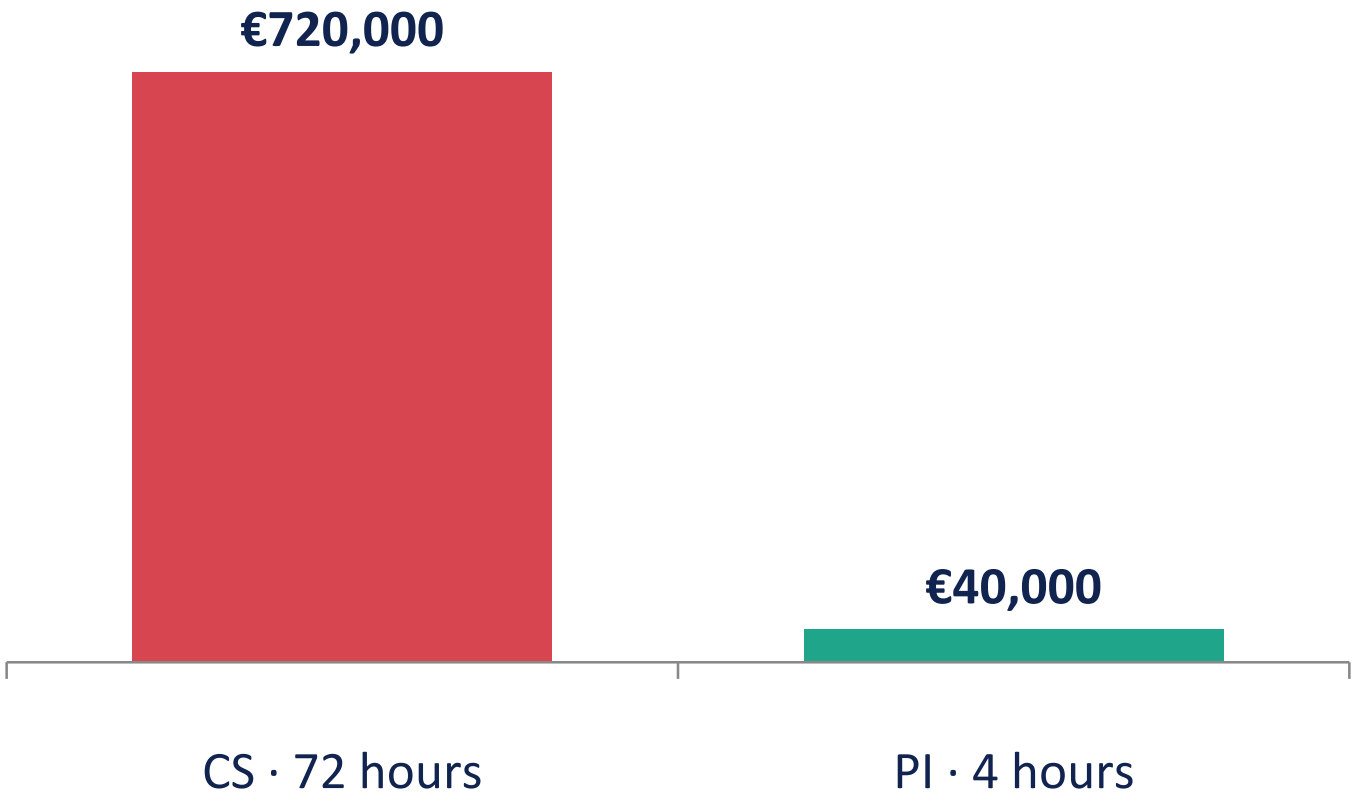
↻ *confusion feeds the overlaps again*

B1 · Stabilizing mechanism

Central BCM → fewer overlaps → faster decisions → less confusion

Leverage point: the establishment of the BCM

Results: the cost of delay



Model assumptions: €10,000/hour · delay of 72 hours (CS) and 4 hours (PI) · anonymous case-study company

–94%
cost of delay per crisis

€10,000/hour
model assumption for the cost of delay

€680,000
saved per crisis (under the assumptions), against a project cost of €250,000

CS vs PI: summary comparison

Criterion	Current (CS)	Proposed (PI)
Number of BCPs	4 fragmented	1 unified
Type p communications	10	0
General Management control	Unstructured (G)	Via BCM (u)
BCP activation time	72 hours (estimate)	4 hours (target)
Cost of delay	€720,000	€40,000
Staff training	Untrained	Training and exercises
Viability (VSM)	Not viable	Viable

VSM: viability diagnosis after the PI

S1	**Operations**	4 autonomous departments, with a horizontal link to the BCM
S2	**Coordination**	The BCM as a “traffic controller”: an end to organizational silos
S3	**Control**	Continuity control at the BCM, strategic oversight by the GM
S4	**Intelligence**	Preventive scenarios: pandemic, geopolitical disruptions
S5	**Policy**	Business Continuity becomes a core value of the culture

Implementation: 6-month project, €250,000 budget

1. **Strategic planning and approval**
2. **Impact and risk analysis (BIA)**
3. **Staffing and infrastructure**
4. **Unified BCP and algedonic channel**
5. **Training and simulations**
6. **Handover to operations**

BCM Manager + 2 analysts + liaisons from each department · Sponsor: General Management

Innovation and adaptability

1

Hybrid methodology

DCSYM for structure, System Dynamics for dynamics, VSM for viability

2

Quantifying “confusion”

A qualitative problem becomes a measurable financial quantity

3

Potentially transferable model

Applicable, according to the study's assessment, to organizations with decentralized BCPs: banks, logistics, energy

Conclusions and next steps

Conclusions

- Systemic thinking is an operational necessity
- A small, targeted structure (BCM) reduces, according to the model, losses of hundreds of thousands of € per crisis
- Stakeholder participation (SSM) is a prerequisite for change

Future research

- Testing with real data (the study's cost figures are based on assumptions)
- Agent-Based Modeling of behavior in crisis
- Automatic BCP activation with AI and IoT

Thank you for your attention

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