



TECTEM - The connection
between research and practice

Enablers and Challenges for Operational Excellence

Prof. Dr. Thomas Friedli – The Heidelberg PAT Conference, October 28th, 2008

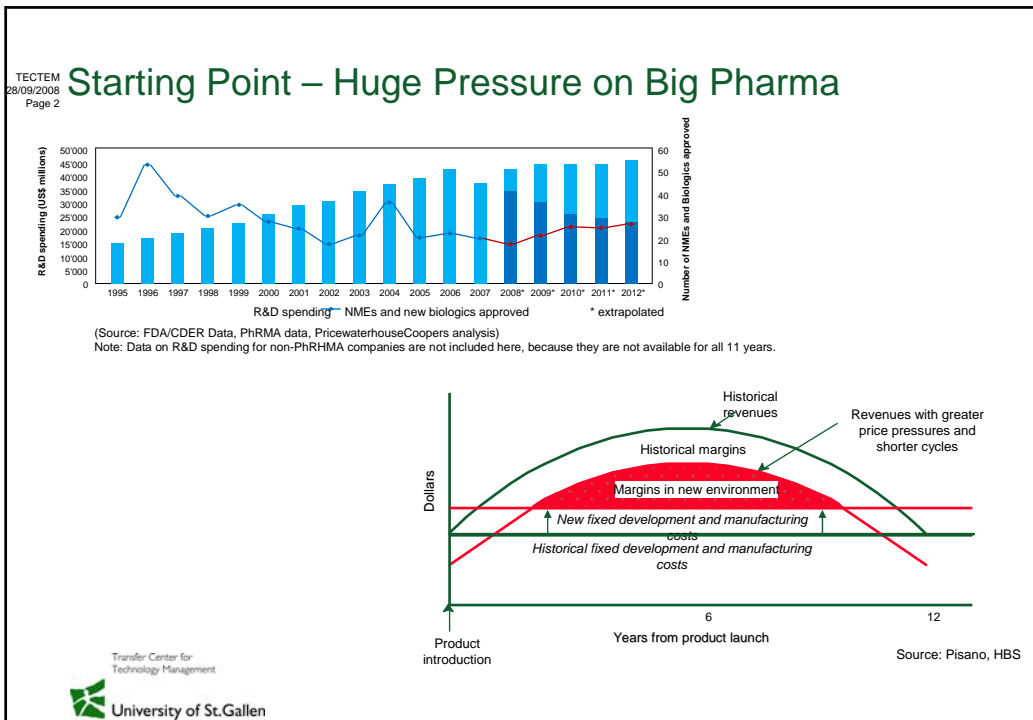
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Structure

- 1 Potential of Operational Excellence**
- 2 A Model for a Sustainable Implementation**
- 3 How could Excellence have an Impact on the Regulatory Environment?**
- 4 Summary and Discussion**





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FDA supports Paradigm Change in Industry!

- FDA revised their Process Validation Policy (March 12, 2004), where FDA's intent to reward process understanding can be seen
- FDA PAT (Process Analytical Technology) Guidance
*„This guidance ... will encourage the **voluntary development and implementation of innovative pharmaceutical manufacturing and quality assurance.***

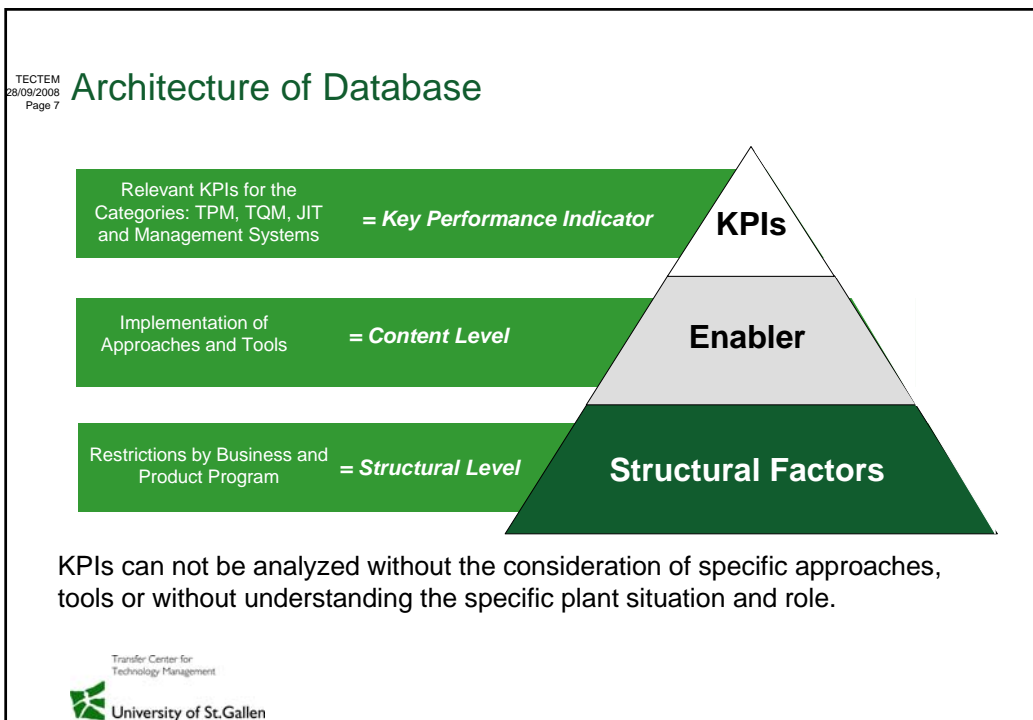
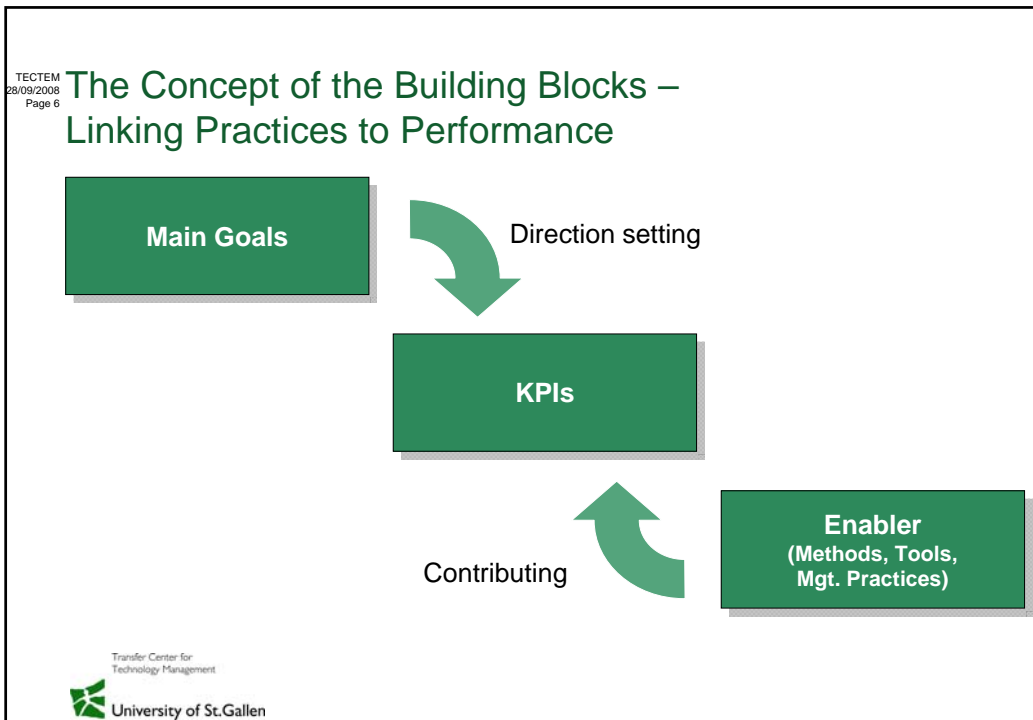
*„(PAT) ... is a system for designing, analyzing and controlling manufacturing through timely measurements (i.e., during processing) of **critical quality and performance attributes** of raw and in-process materials and processes with the goal of ensuring final product quality.“*

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- Moving
 - from **compliance with specification**
 - to **process understanding**
- Process understanding leads
 - from **corrective action**
 - to **continuous improvement**

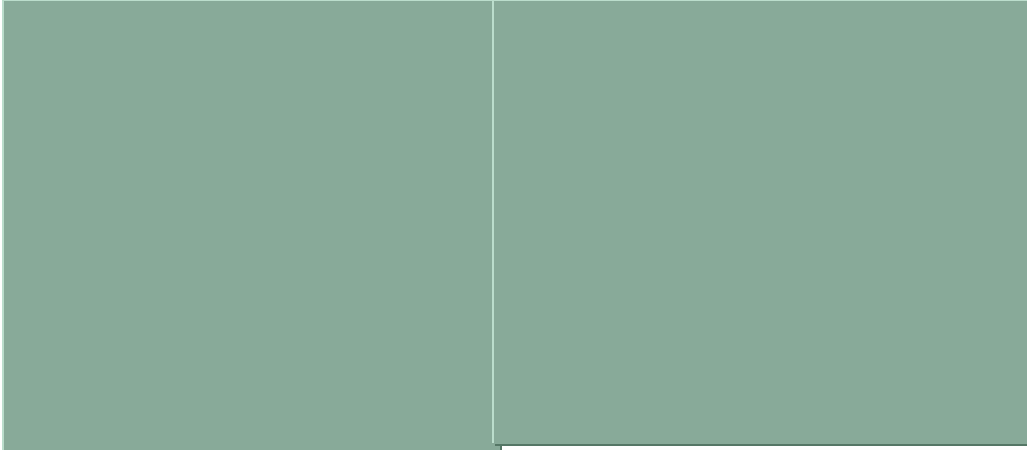
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Source: Dr. Ajaz Hussain, FDA




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Example Evaluation of TQM Enablers



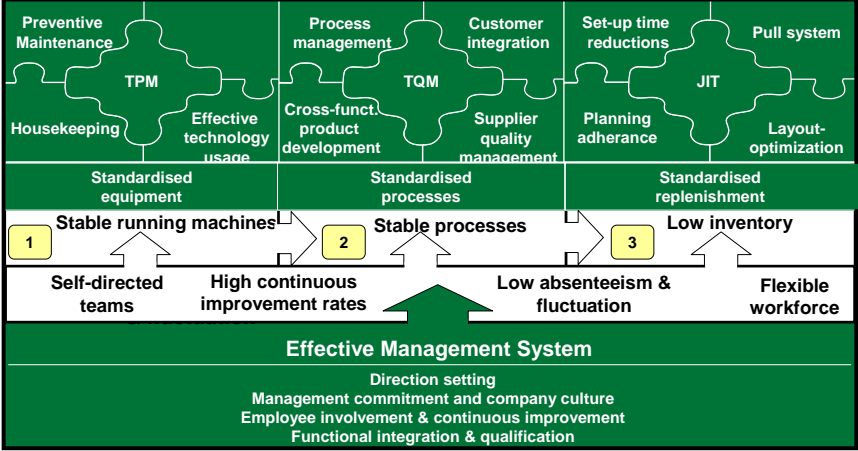
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Stages of Operational Excellence

Logical sequence: effectiveness before efficiency



Operational performance

TPM
Preventive Maintenance, Housekeeping, Effective technology usage

TQM
Process management, Cross-funct. product development, Supplier quality management

JIT
Customer integration, Set-up time reductions, Planning adherence, Pull system, Layout-optimization


Standardised equipment, Standardised processes, Standardised replenishment

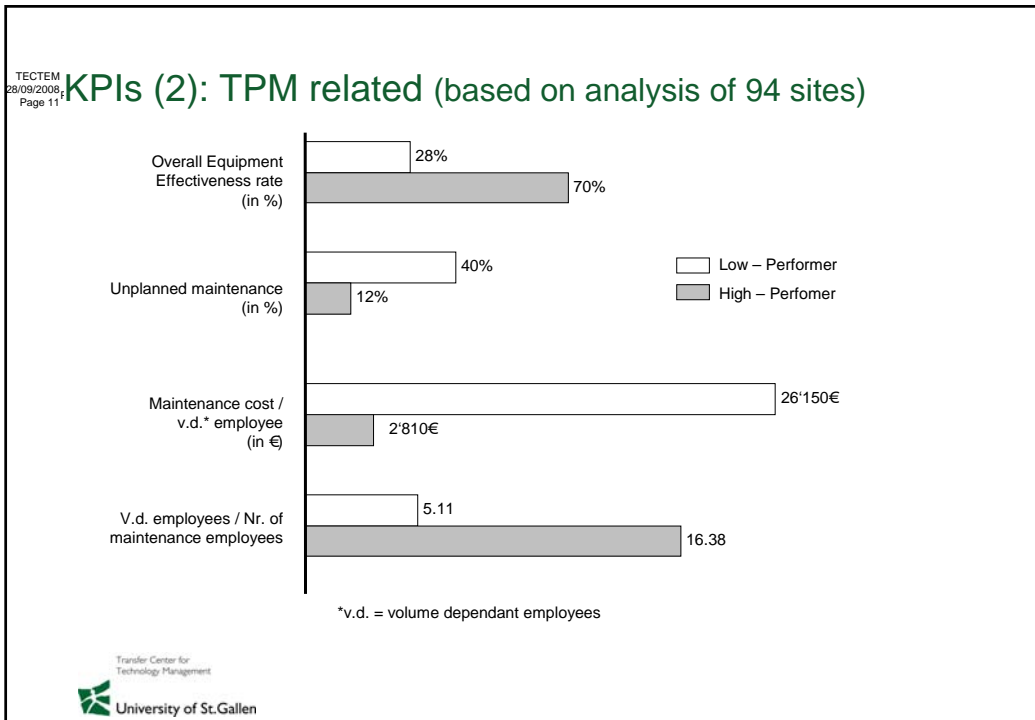
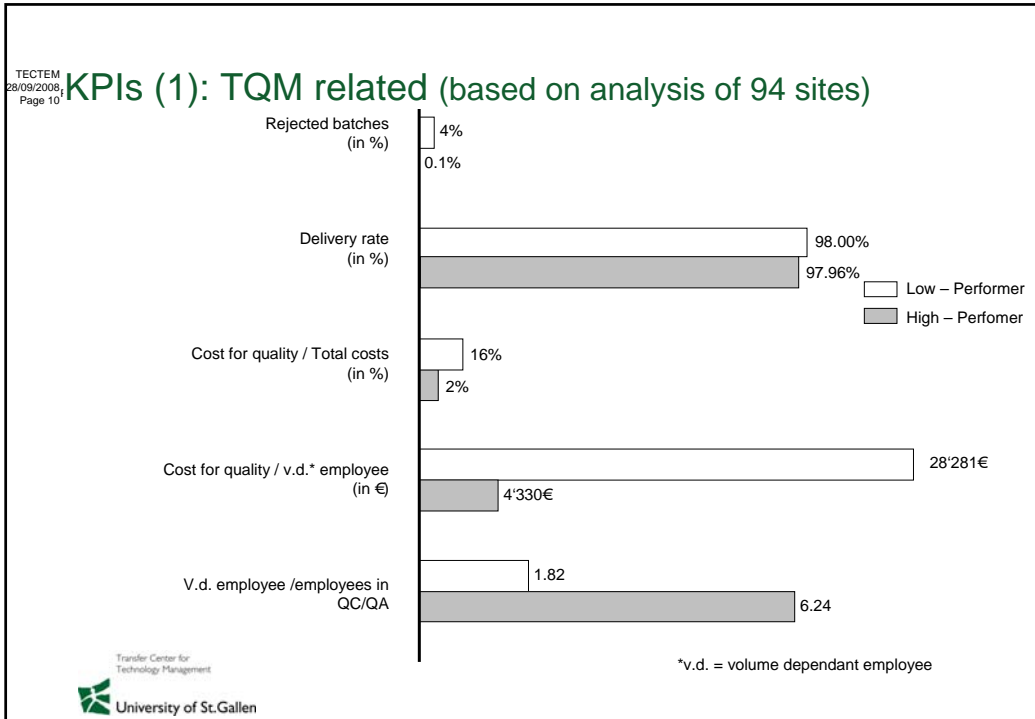
1 Stable running machines, 2 Stable processes, 3 Low inventory

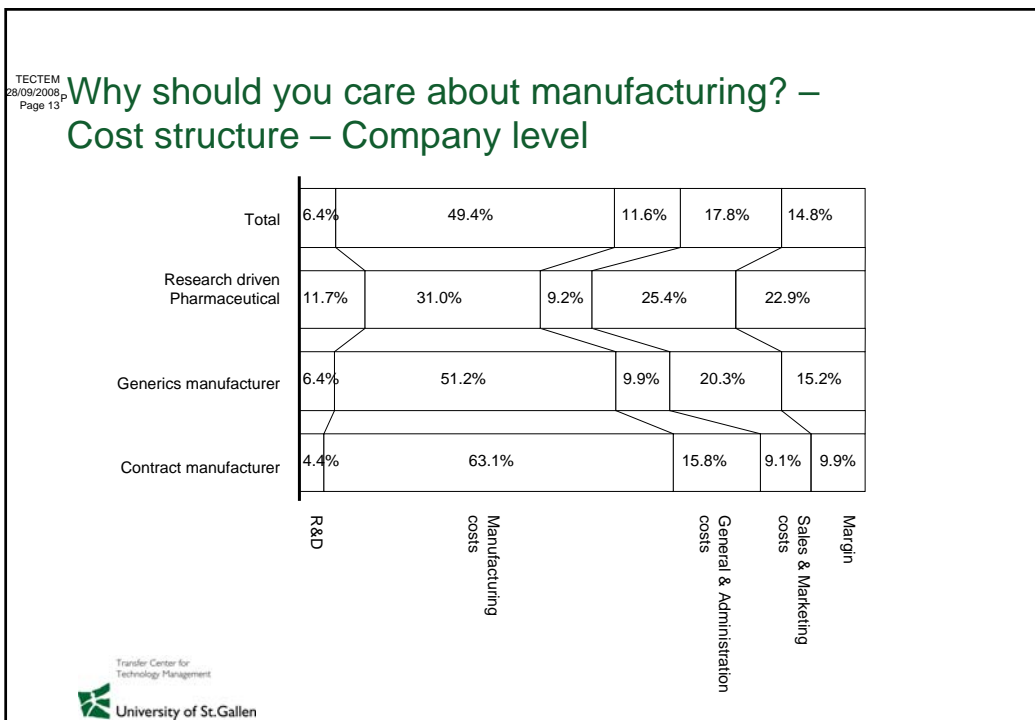
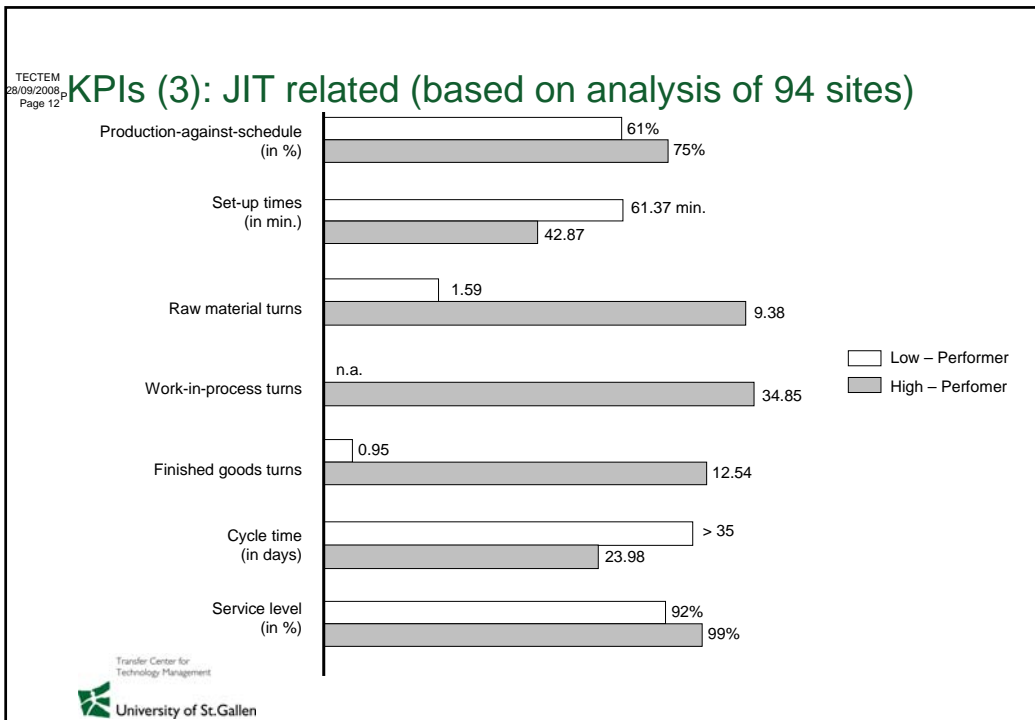
Self-directed teams, High continuous improvement rates, Low absenteeism & fluctuation, Flexible workforce

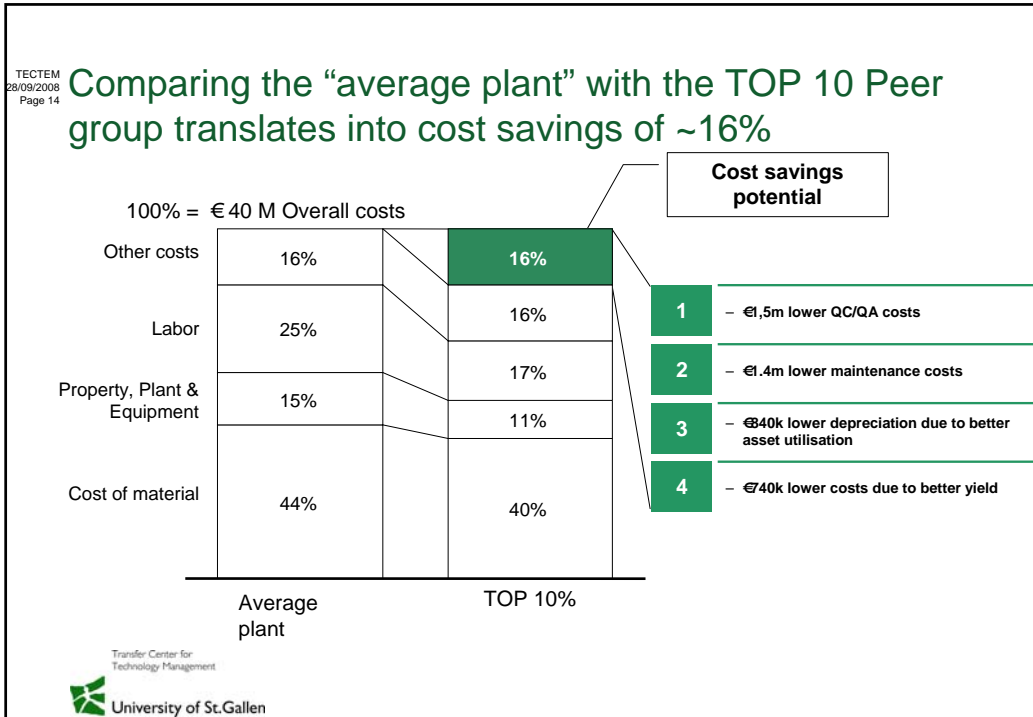
Effective Management System
Direction setting
Management commitment and company culture
Employee involvement & continuous improvement
Functional integration & qualification

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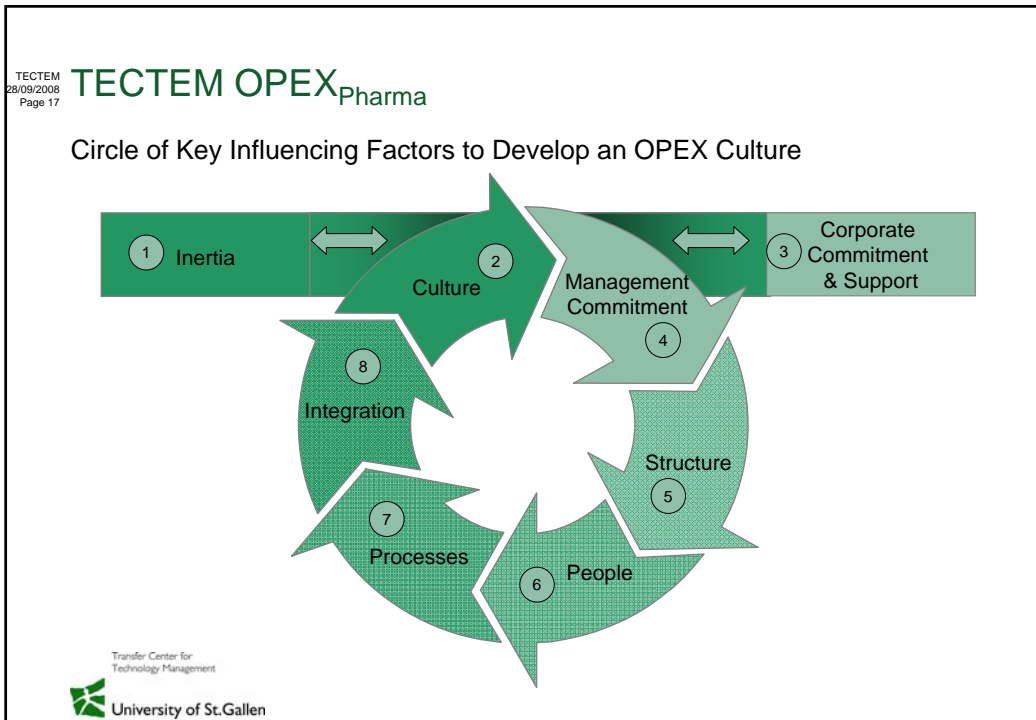
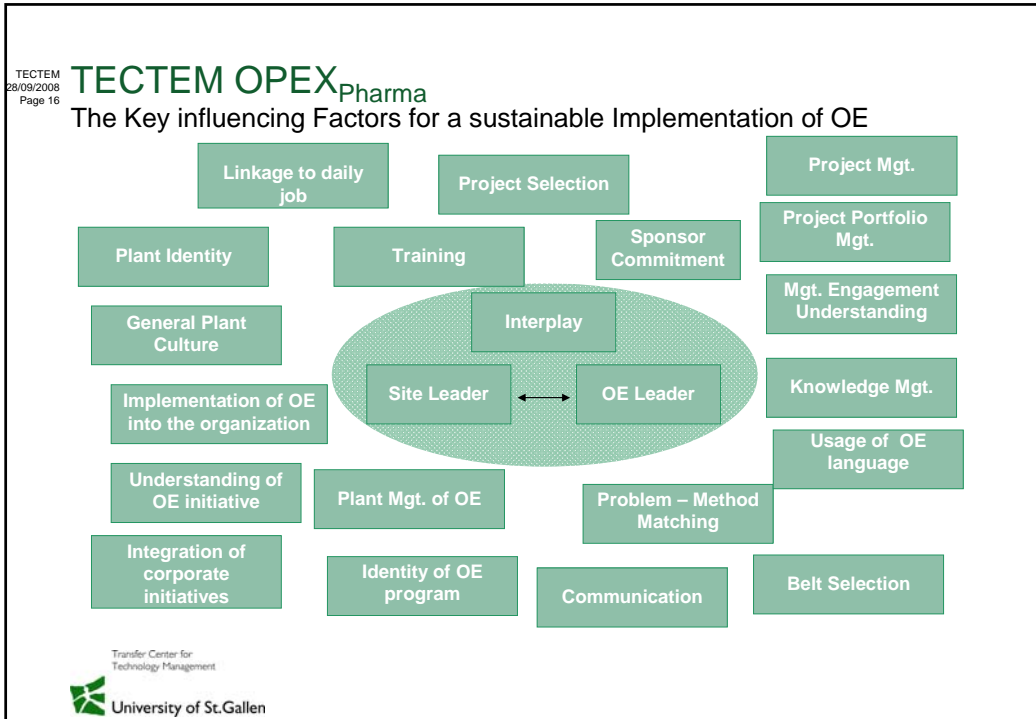


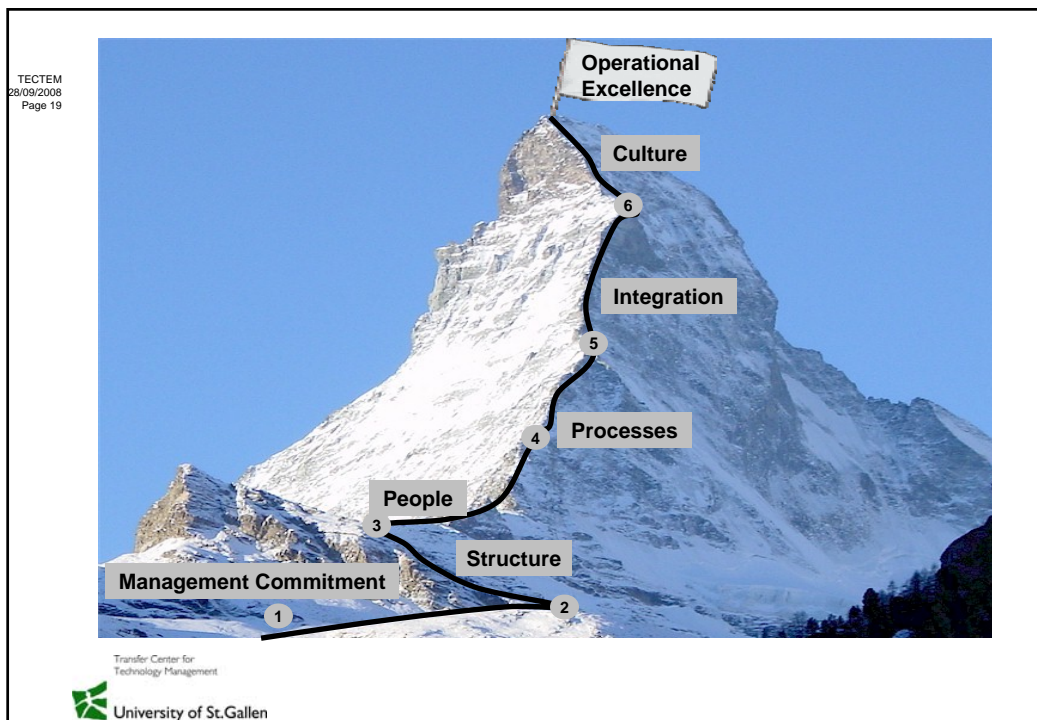
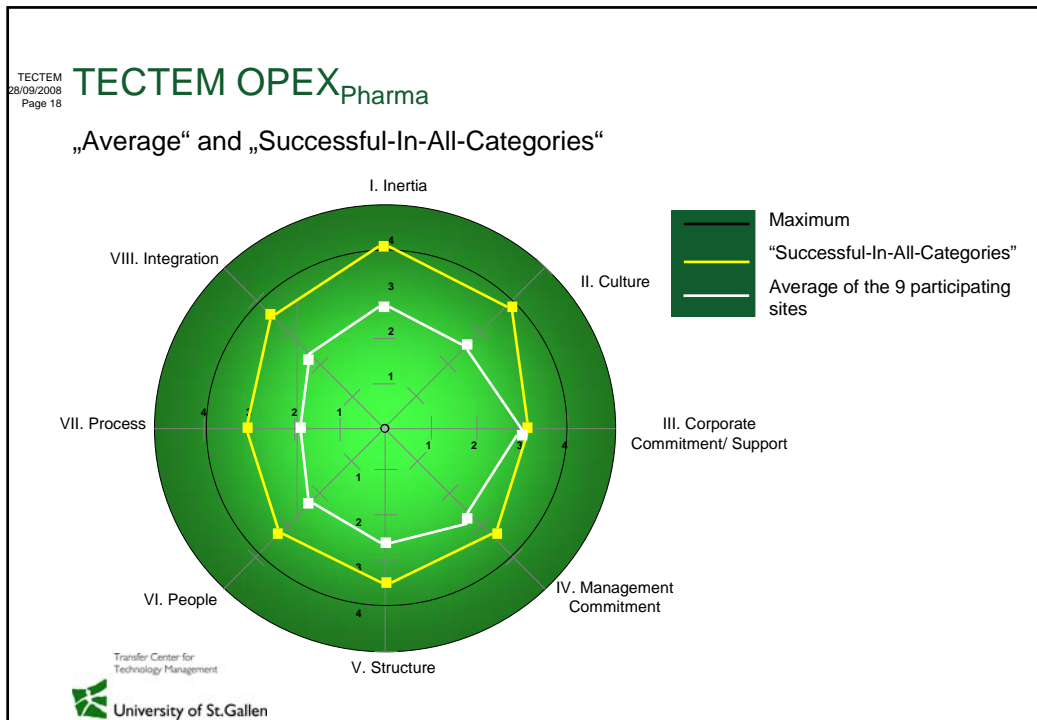
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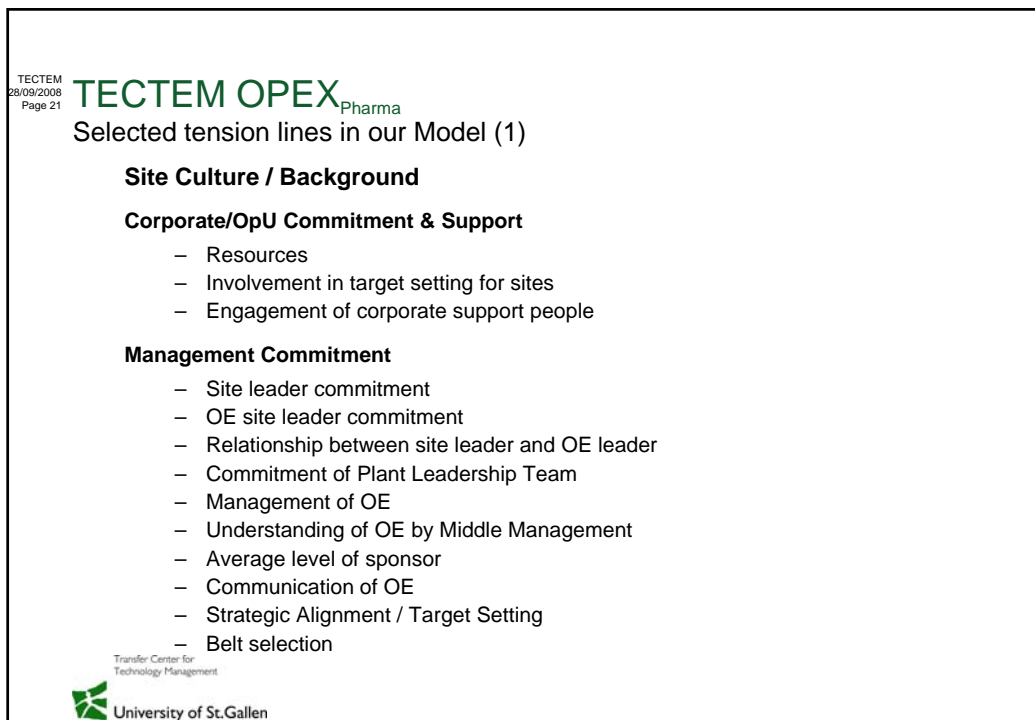
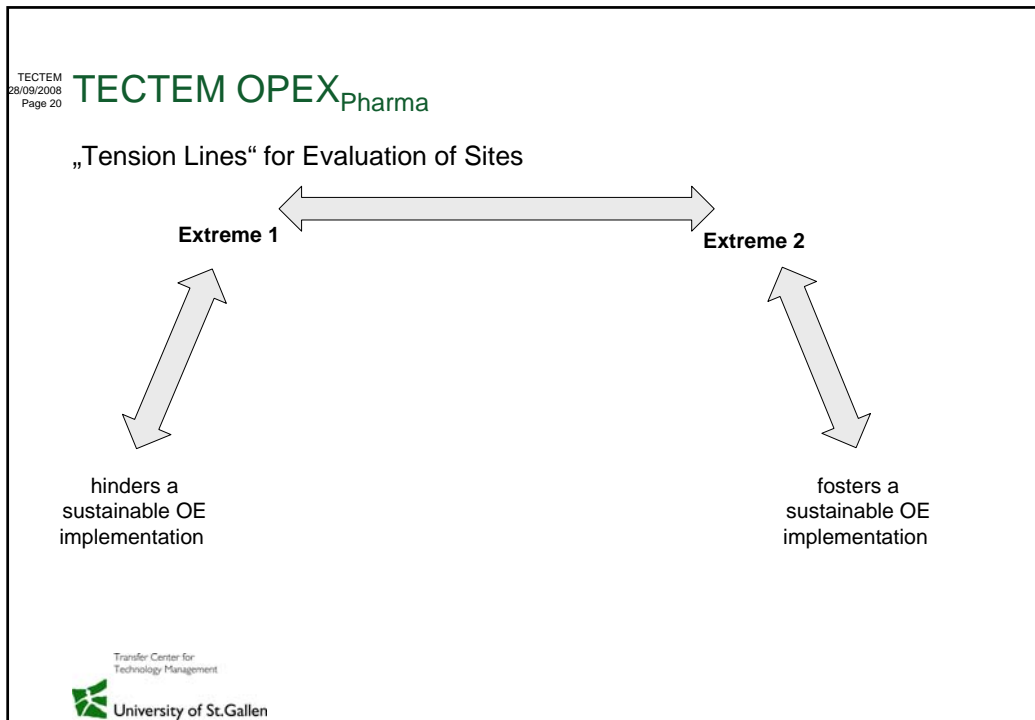
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Selected tension lines in Model (2)

Structure

- Availability
- Organizational Integration
- OE-dedicated Resources
- Steering Committee

People

- Understanding by Shop Floor
- Spread of Projects over the Organization
- Number of trained people


Process

- Project Engagement
- Standardization of OE-Processes
- Training
- Pipeline Management
- Knowledge Management

Integration

- Link to day-to-day job
- Alignment of OE with other Initiatives
- Integration of HR and Learning Strategy

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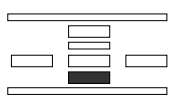


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Examples tension lines




Examples Tension lines

OE Site Leader




Not involved in Site Strategy Setting	Delivers inputs for Site Strategy Setting	Partly involved in Site Strategy Setting	Fully involved in Site Strategy Setting
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Relationship between Site MD and OE Leader

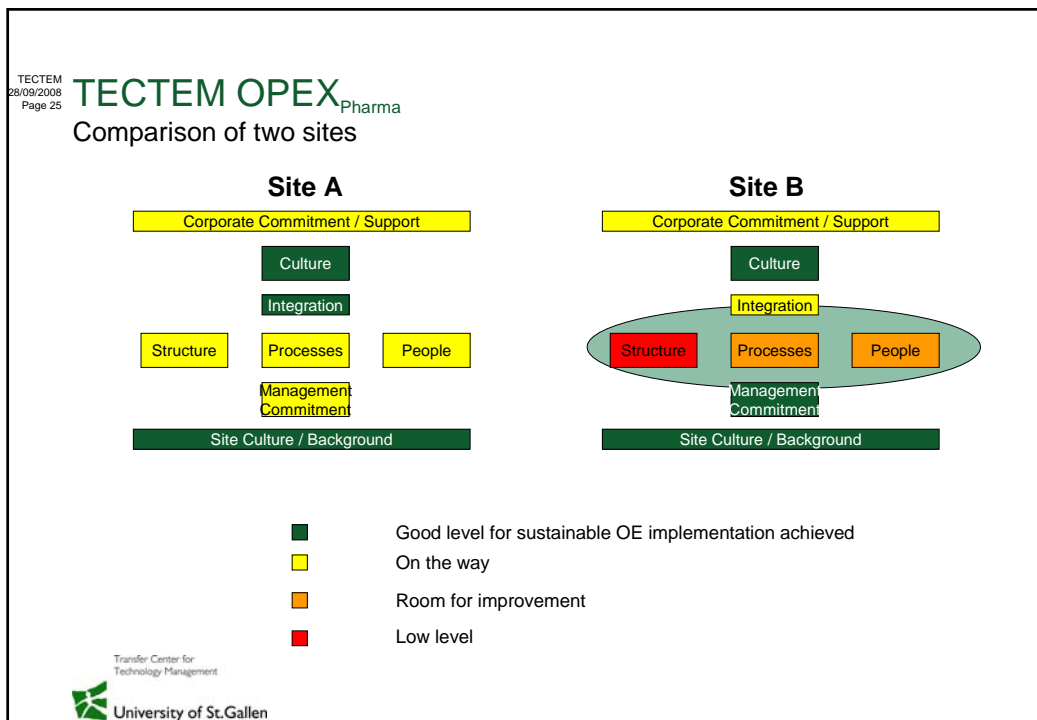
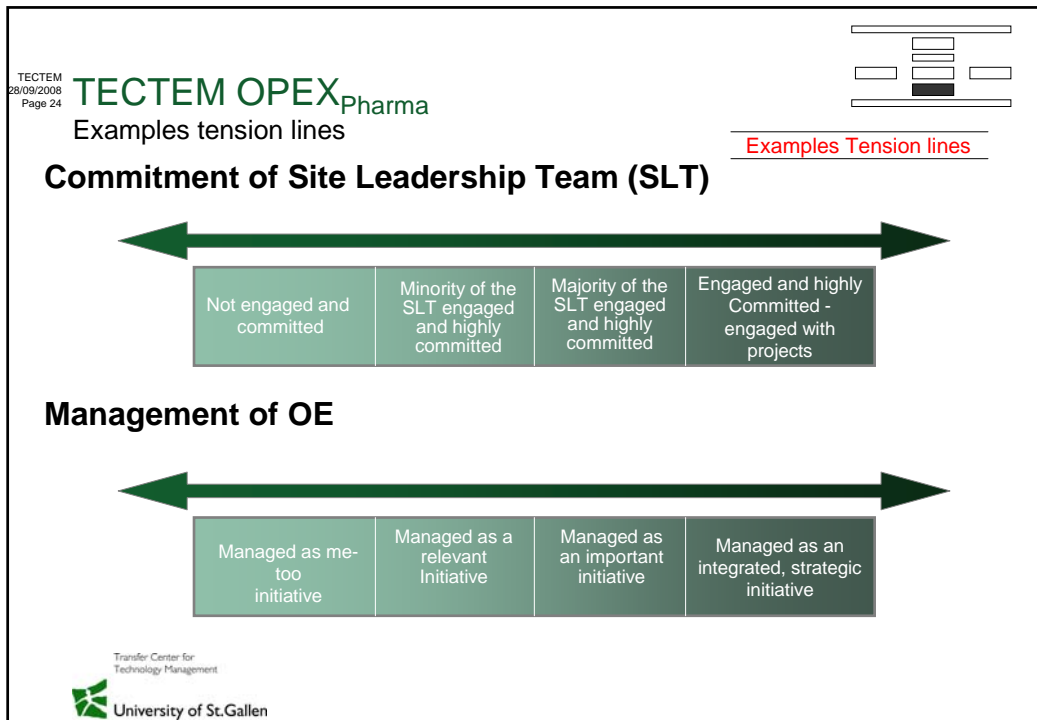


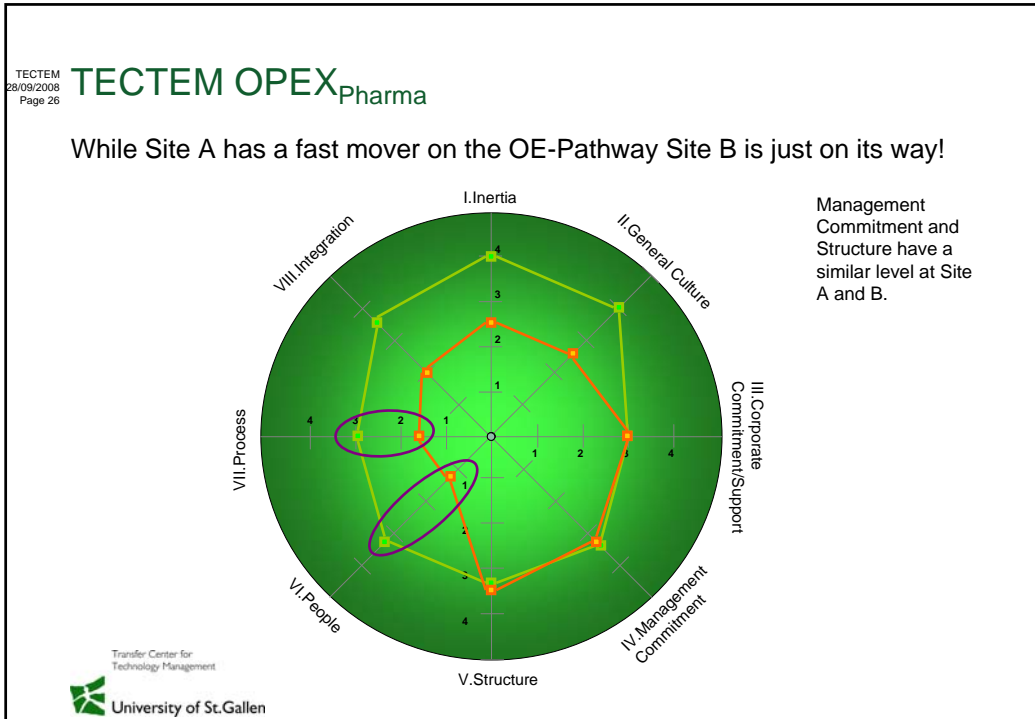
Contradictory, Not the same agenda	Different positions on several strategic issues	Different positions on several tactical issues	Complementary, completely aligned, synergistic
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Overview of European Sites

Site	Corporate Support	Culture	Integration	Structure	Processes	People	Management Commitment	Heritage
A	Yellow	Green	Yellow	Yellow	Orange	Yellow	Green	Green
B	Yellow	Red	Red	Orange	Red	Orange	Orange	Orange
C	Yellow	Red	Yellow	Yellow	Orange	Yellow	Yellow	Yellow
D	Yellow	Green	Green	Yellow	Orange	Yellow	Yellow	Green
E	Yellow	Yellow	Orange	Yellow	Orange	Yellow	Yellow	Orange
F	Yellow	Yellow	Orange	Yellow	Yellow	Red	Yellow	Orange
G	Yellow	Red	Orange	Yellow	Red	Orange	Orange	Green
H	Yellow	Orange	Orange	Yellow	Red	Orange	Orange	Orange
I	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow

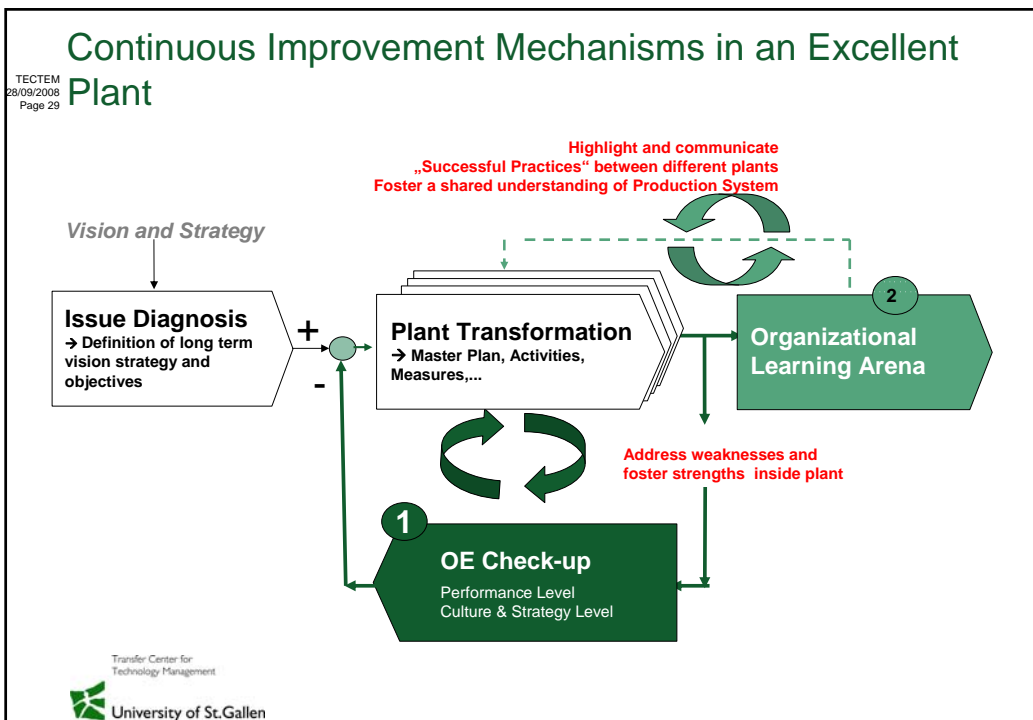
good level
 on the way
 room for improvement
 low level

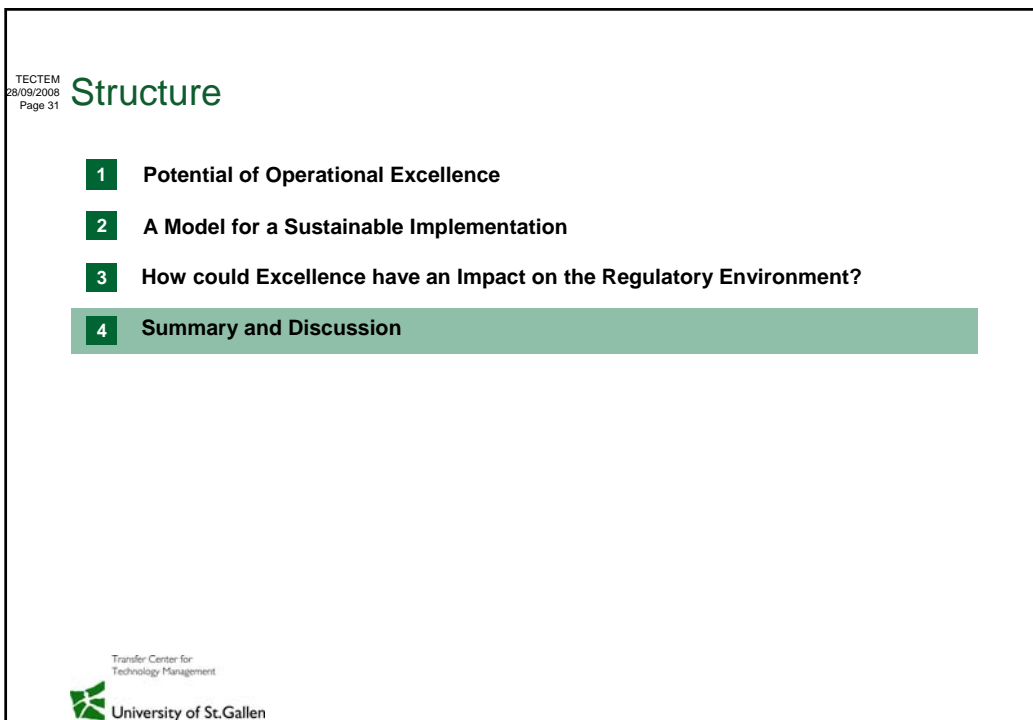
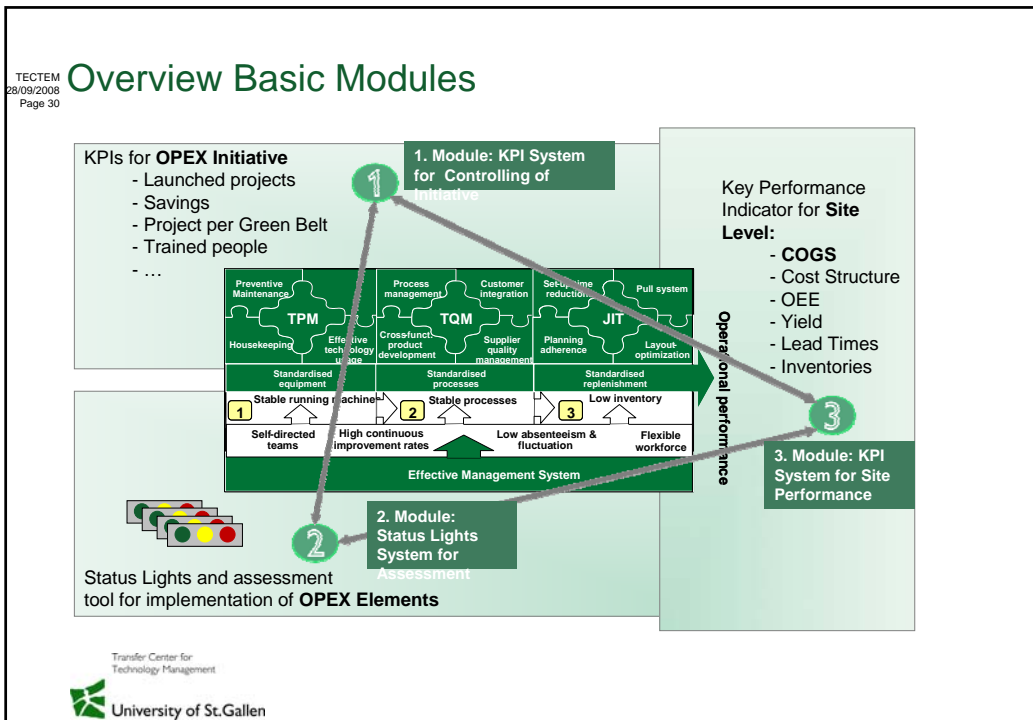
⇒ With regard to Structure / Processes and People there is no site that already has reached a good level!

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Summary

- The improvement potential coming from Operational Excellence is huge!
- Operational Excellence is not achieved overnight!
- QbD should be part of Operational Excellence!
- The cultural challenges are the biggest hurdles for a sustainable implementation at the moment!
- A regulatory Vision for the Future could be to define the Design Space for the entire Plant no longer for a single process so as fostering the motivation to strive for Operational Excellence!