

Business Process Management @ ALTANA Pharma

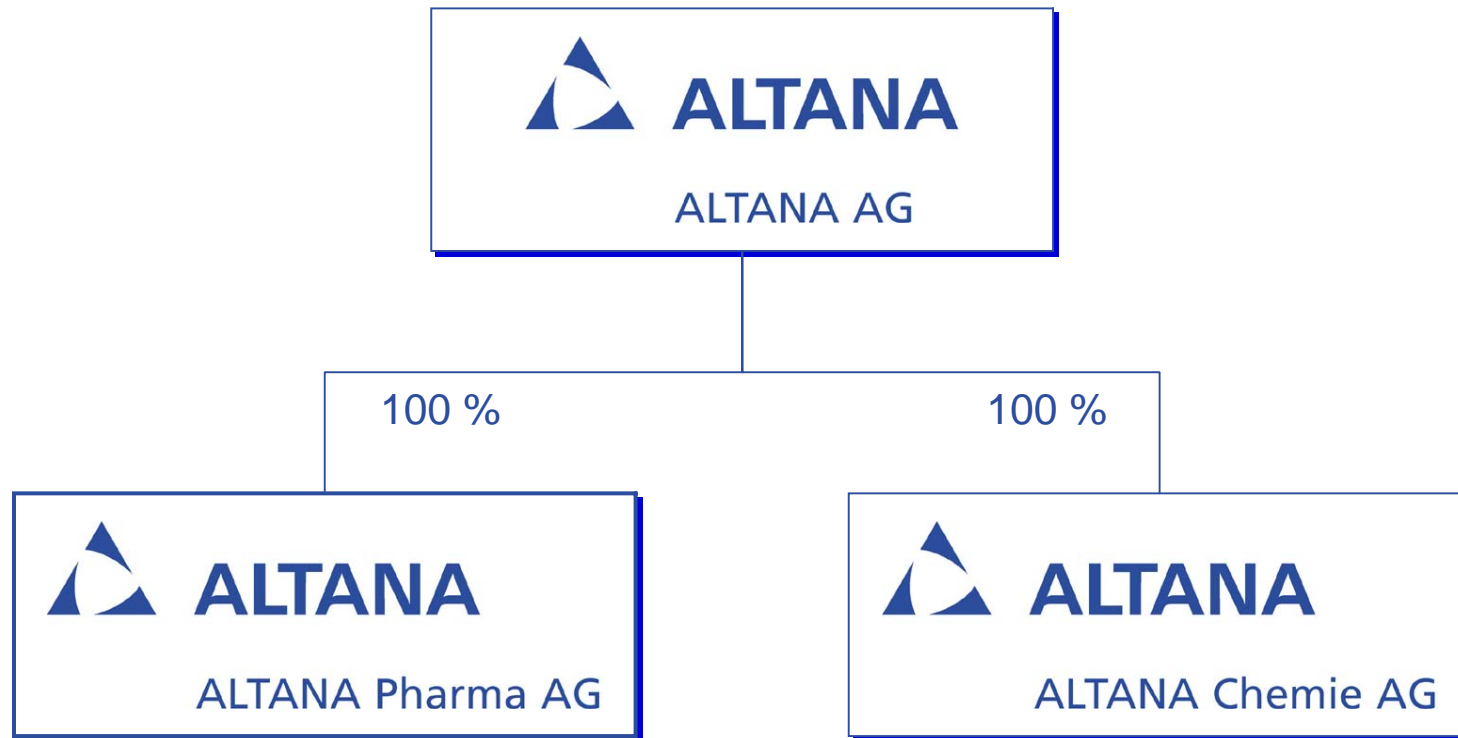
Kai A. Simon, PhD

Business Process Manager
Corporate IT Strategy, Processes and Patterns

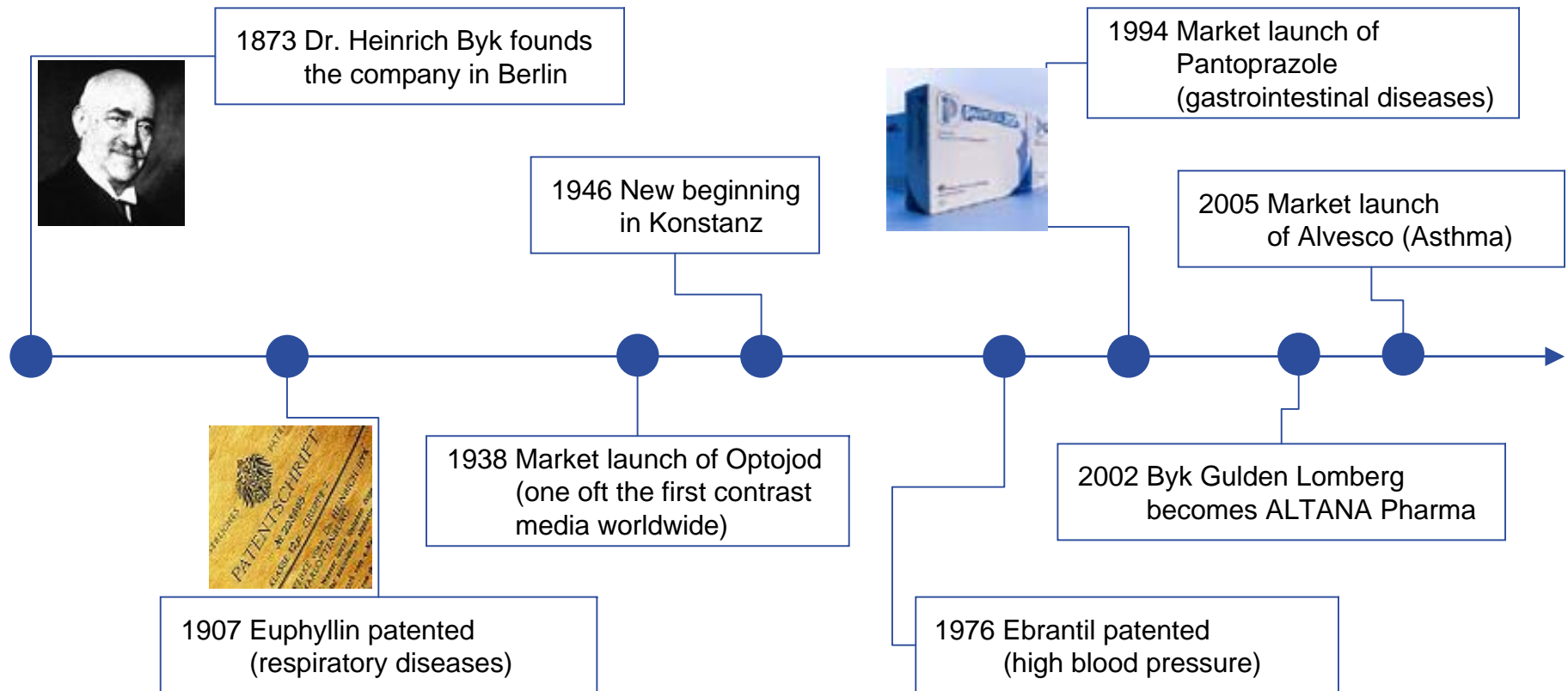
Table of Content

- Introduction to ALTANA Pharma
- BPM drivers and issues
- The ALTANA Pharma approach to BPM
- Some practicalities

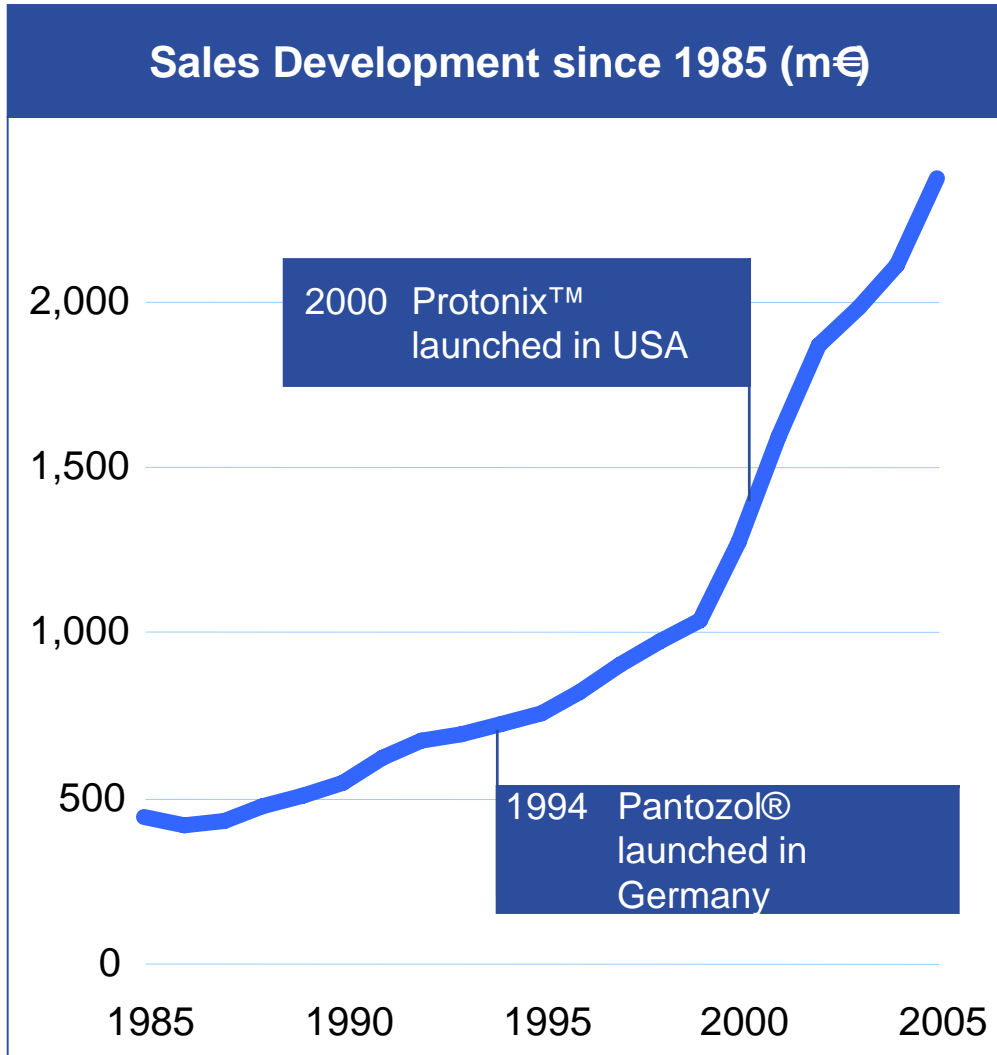
ALTANA Group



Over 130 Years of Innovative Medicines



Sustained Growth Over Two Decades



- Another record performance in 2005
- Sales at 2.4 bn€, up 12 percent on 2004
- EBIT-margin of 26 percent places us among the top tier pharmaceutical companies in Europe
- Successful products and promising new developments ensure the long-term basis for further growth

Strategic Goals

- Focus on business offering the highest value
 - Innovative therapeutics
- Focus on relevant markets
 - Europe, USA, Japan
 - Partnering is key
- Focus on well-defined and selected R&D areas
 - Gastrointestinal diseases
 - Respiratory diseases
 - Oncology
- Internationalization of research and development

Table of Content

- Introduction to ALTANA Pharma
- BPM drivers and issues
- The ALTANA Pharma approach to BPM
- Some practicalities

Short Definition of BPM

Business Process Management (BPM) is itself a process that ensures continued improvement in an organizations performance. It is thus the meta-process that defines the framework and provides the tools for driving and improving performance in business processes.

- BPM is an ongoing process and applies its methods on itself
- BPM is about performance improvement in business processes, i.e. it requires IT and business alignment
- BPM provides framework and tools ... but the thinking is all yours

Source: Simon, K.: Some aspects on Business Process Management in the Pharmaceutical Industry (forthcoming)

Dr. Kai A. Simon, 27-09-2006, 8

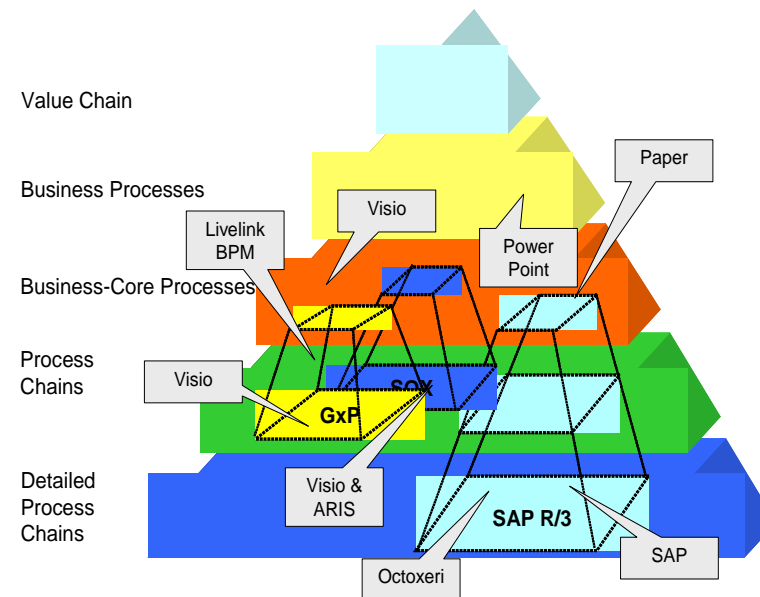
BPM Drivers in the Pharmaceutical Industry

- Regulatory requirements & standards
 - GxP: Good Practices in Laboratory, Clinical, Manufacturing
 - 21CFR Part 11: Electronic Records and Signatures (FDA)
 - SOX: Sarbanes Oxley Act (sections 302, 404)
 - Standards: eCTD, CDISC
- “Need for speed”
 - Development cost ~800 M\$
 - Development cycle time 8-12 years
 - Patent protection period
 - Globalization and harmonization of processes
- Governmental initiatives
 - Price pressure from governments
 - Fewer approvals in highly populated disease areas

Typical Starting Situation

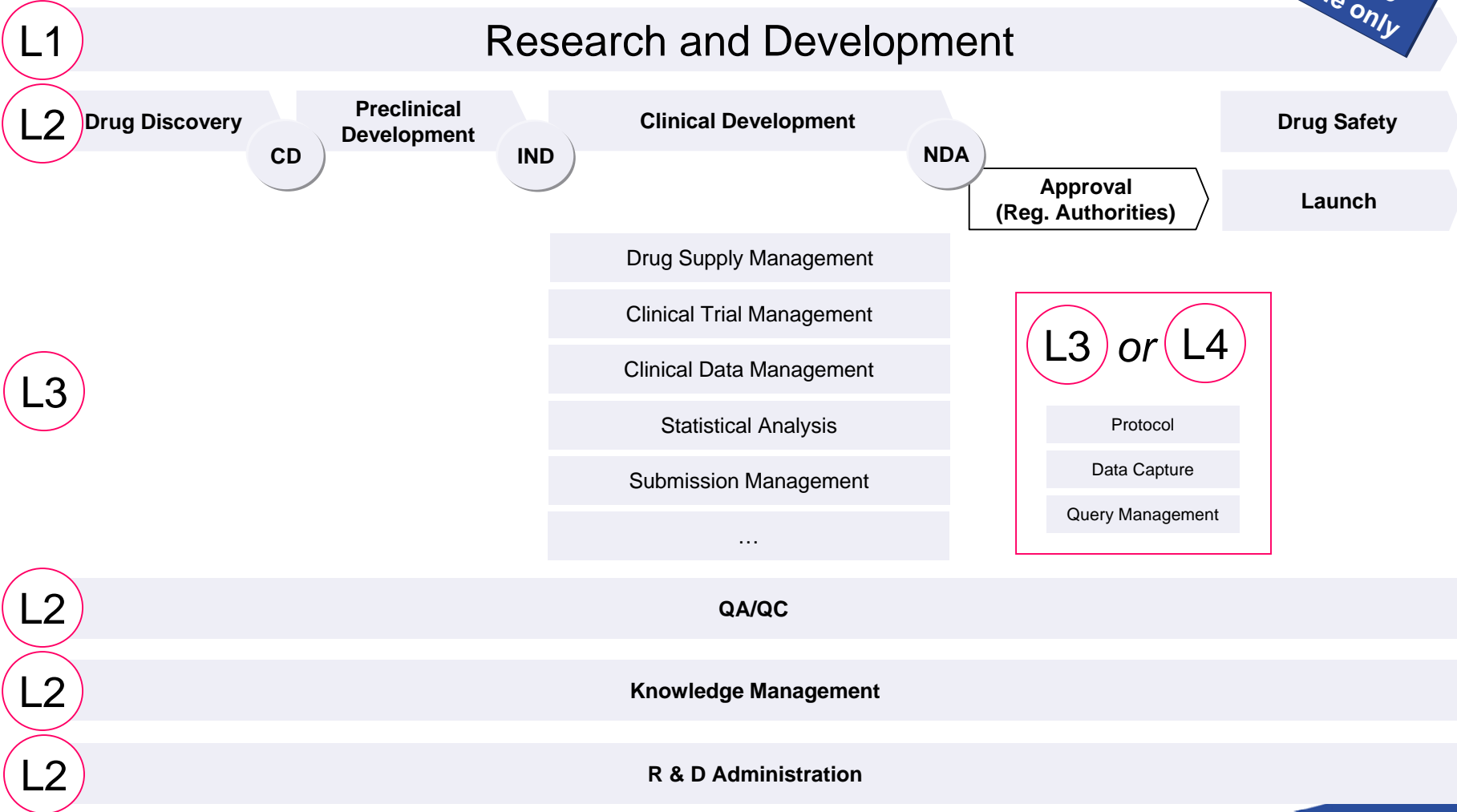
- Multiple tools and conventions
- No central repository for process documentation across functions and geographic areas
- Variation of process documentation granularity and compliance maturity

➔ Difficult to reap process and technology synergies



The Granularity Issue

Illustrative example only



The Granularity Issue

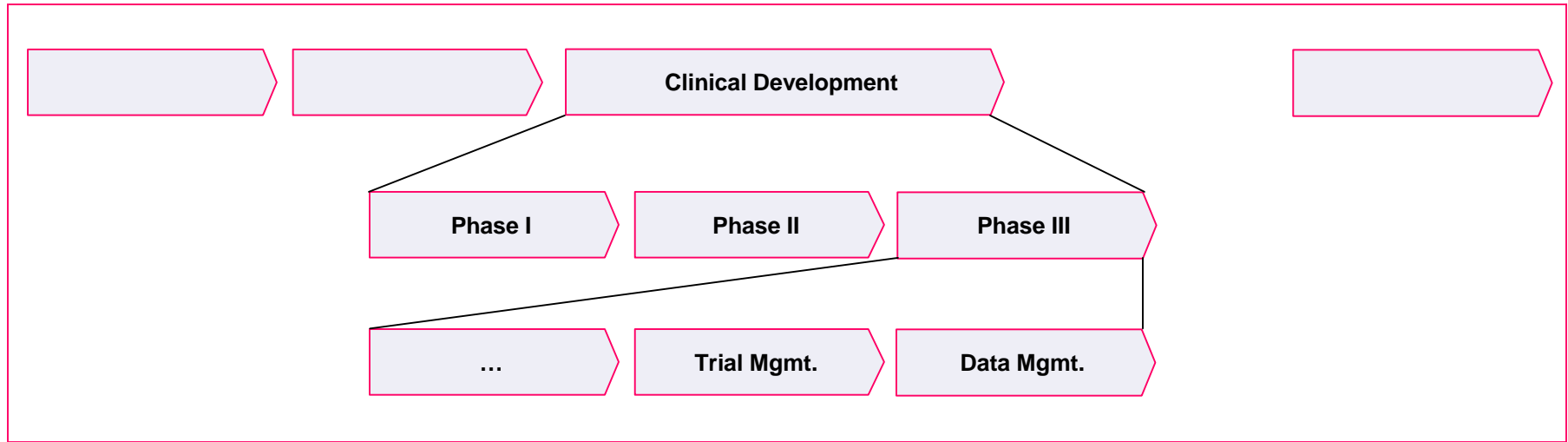
- The appropriate level of decomposition is not clear
- The issue can be addressed in different ways, depending on the purpose
- Is there a best practice?
 - Depending on specific organization
 - Hierarchical depth is not prescribed
- Modelling conventions can be used, but do not need to include modelling levels
- Typical levels are
 - Level 0: Overall map (“board level map”)
 - Level 1: Main process overview
 - Level 2: Details of sub-processes
 - Level 3: Detailed description starts typically here
 - Organizational entities can be associated at higher levels
 - IT systems are associated at level 2+

The Missing Link Issue

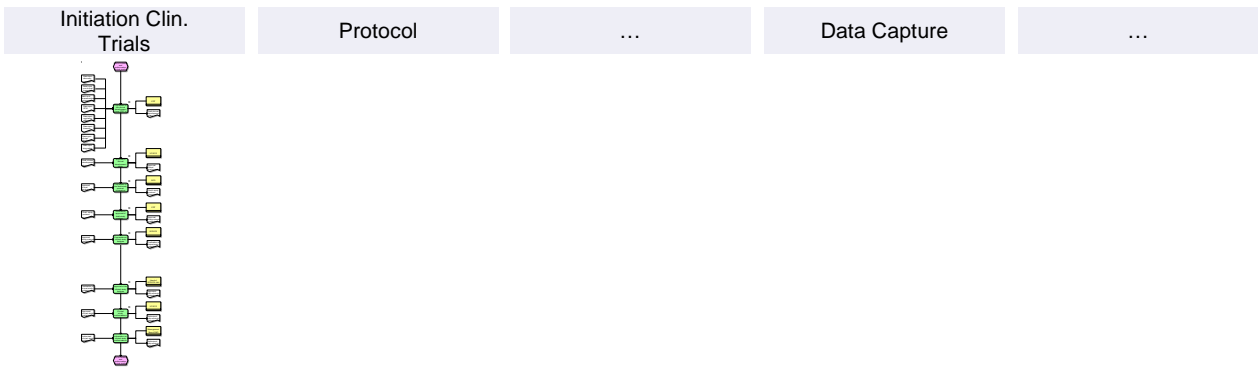
Illustrative example only

L1

Research and Development



Ln

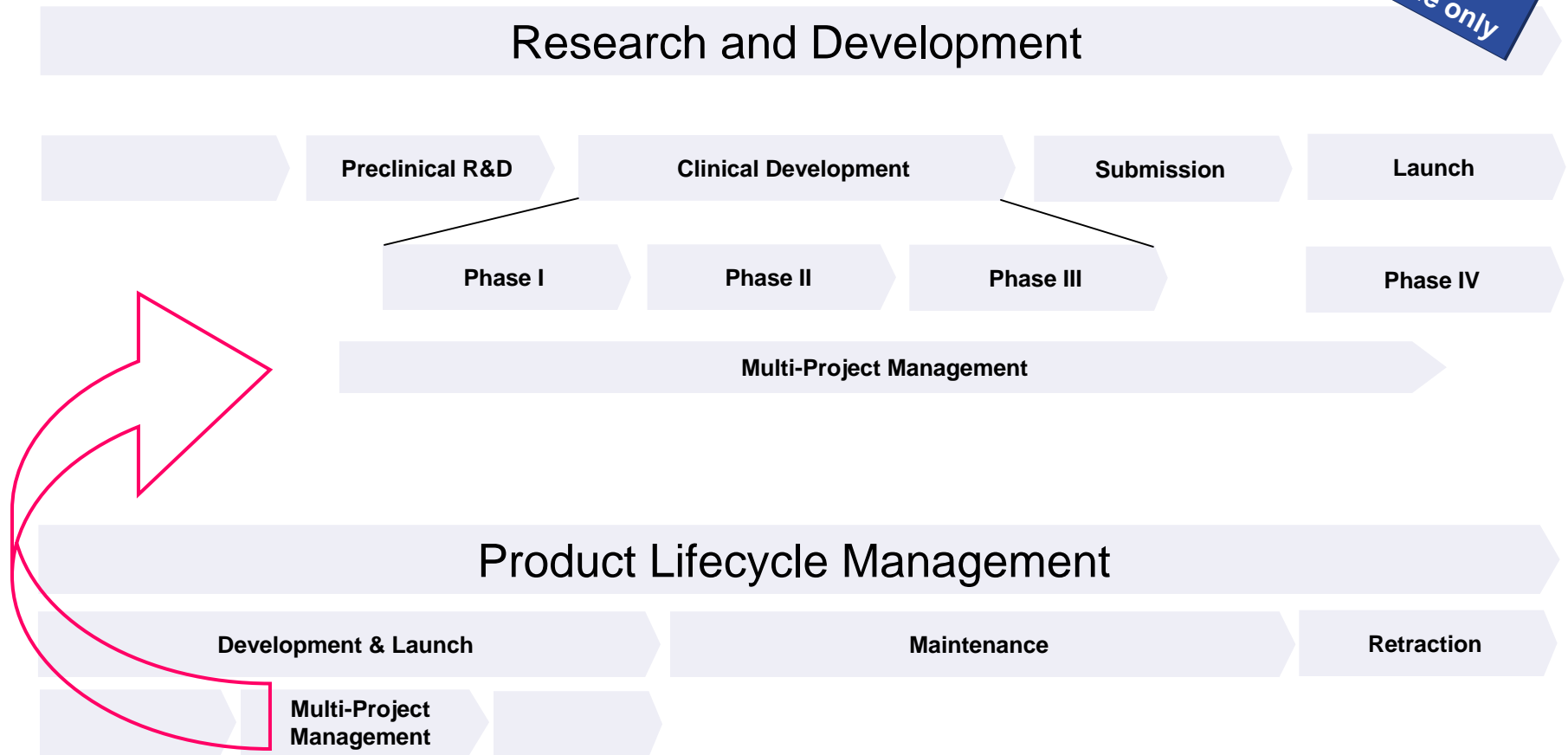


The Missing Link Issue

- There is no process documentation at all levels – this phenomenon comes in two flavors
 - High level maps are not further broken down (processes exist at board level)
 - Operational processes, e.g. SOX relevant processes, are described in detail, but are not synthesized
- The typical result is a fragmented process map, where process relations and interfaces are not visible
- This issue is addressed by filling the gaps in the map through analysis and synthesis

The Process Allocation Issue

Illustrative example only

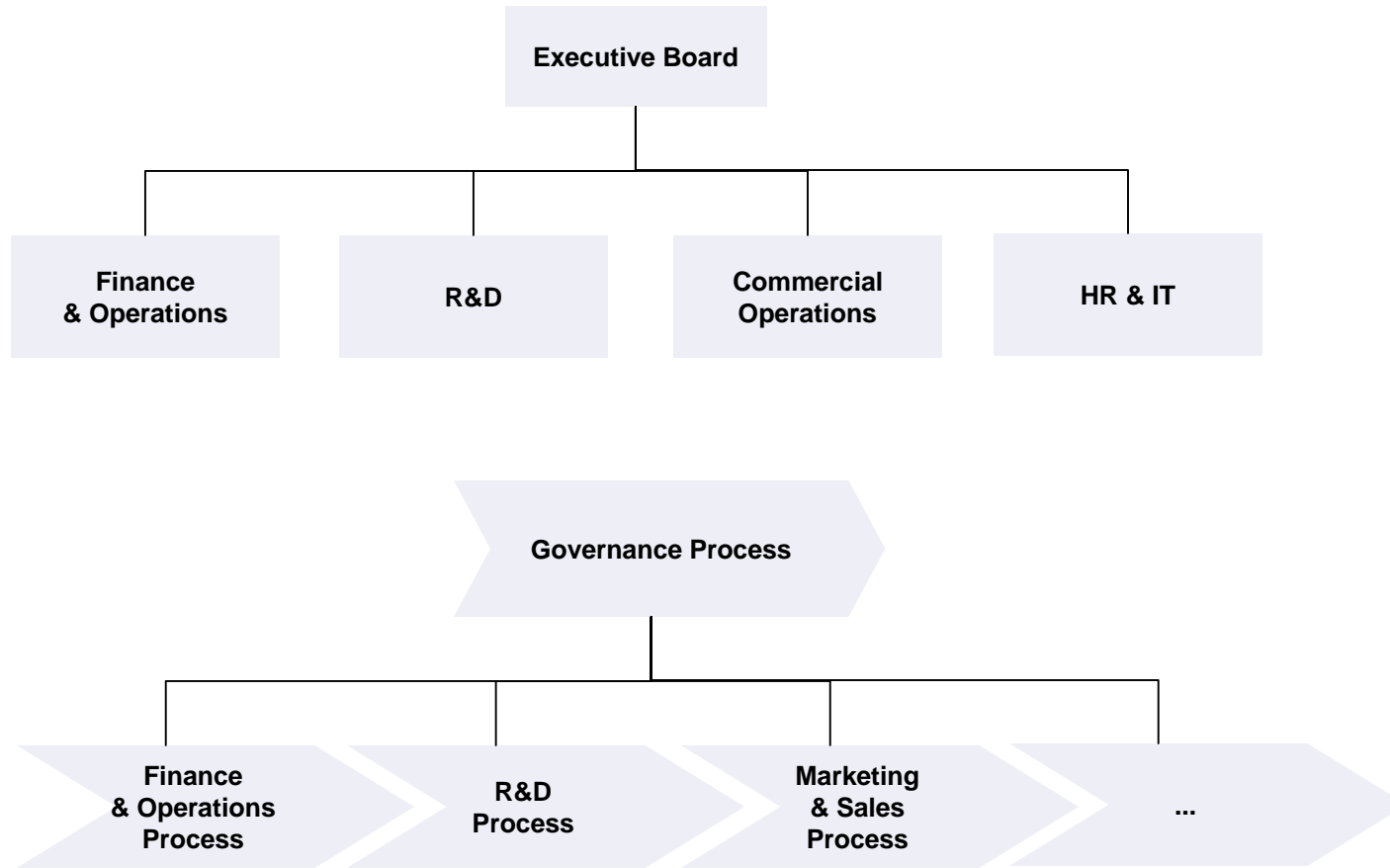


The Process Allocation Issue

- Processes belong hierarchically to one main-process process, but are performed within another main-process
 - Corresponds to the matrix-organization problem
 - Governance and goal congruence are crucial topics
- Processes can be shared and need to be integrated into multiple super-processes
- This issue easily becomes political
 - *„My“ process is not part of somebody elses.*

The 90 Degree Issue

Illustrative example only

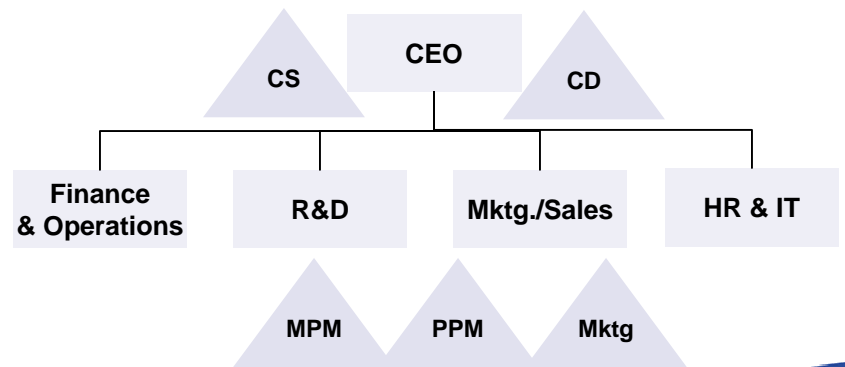
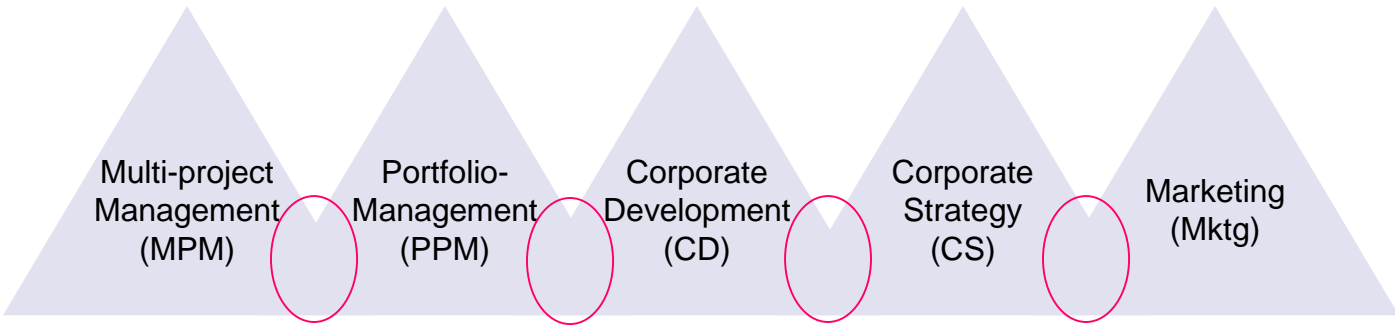
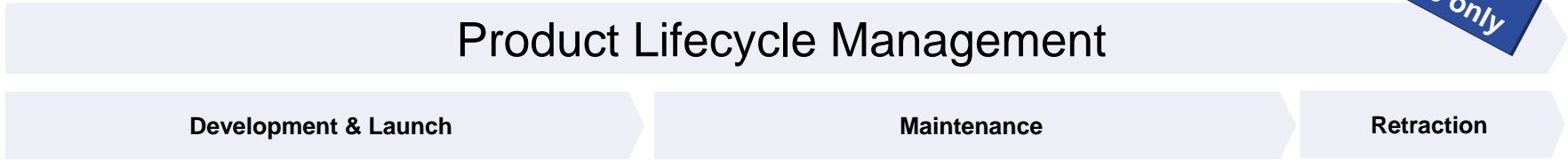


The 90 Degree Issue

- Typically, the organization structure is turned by 90° and the hierarchical structure is declared as being process oriented
 - An easy way to pass by problematic discussions and keeps everybody satisfied, since no real change is taking place
- It is necessary to establish a clear conceptual distinction between processes and structural elements of the organization
 - This might change roles and responsibilities and not everybody is going to be a winner

The Structural Overlap Issue

Illustrative example only



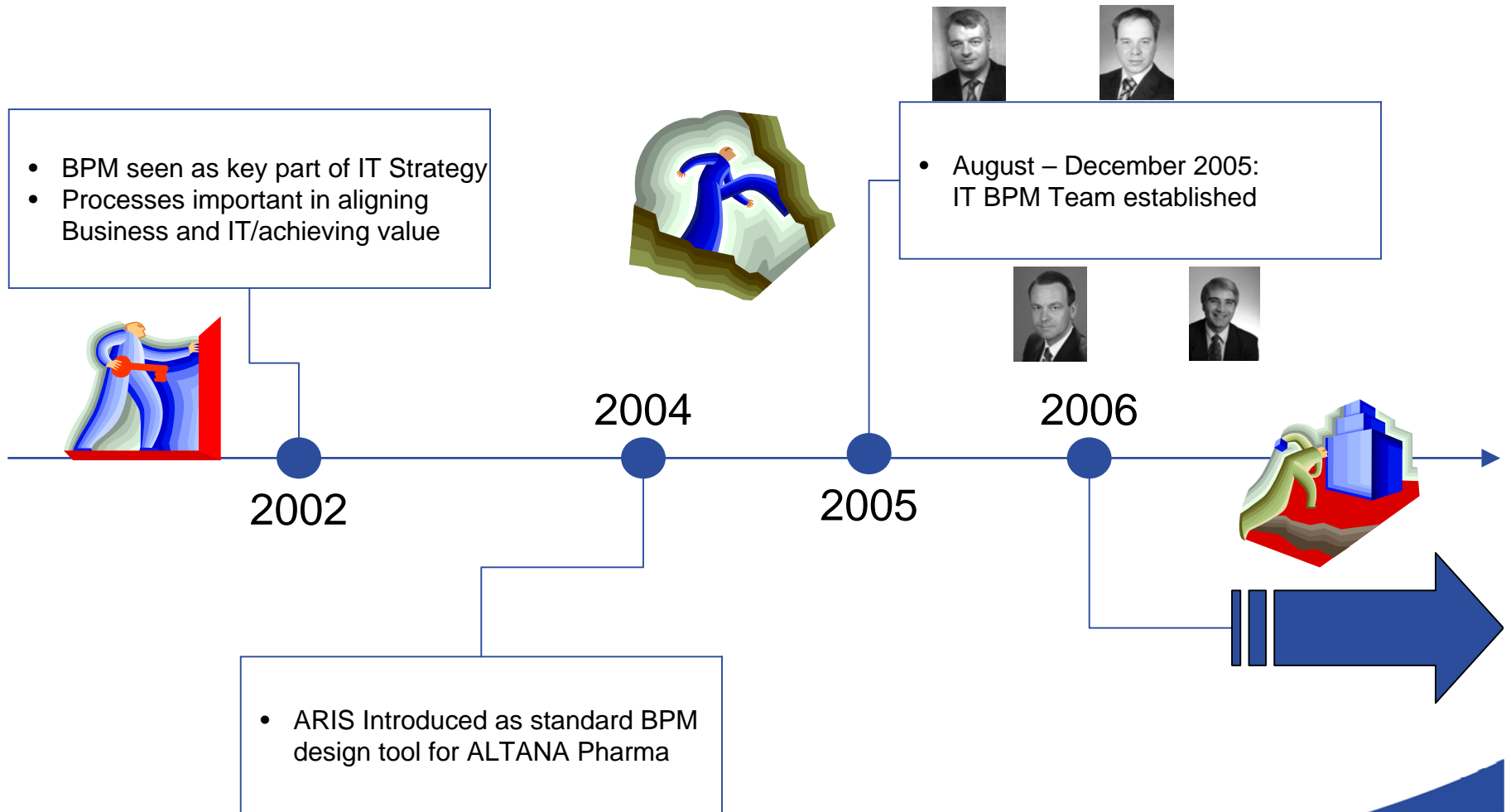
The Structural Overlap Issue

- There are multiple stakeholders for a process
- Process responsibilities and governance structures are not congruent with organizational structures
 - Similar tasks are performed within different units
 - Responsibilities for processes are not clearly assigned
- The responsibilities for processes must be clearly defined and established
 - Are structures or processes the predominant elements?
- Also this issue tends to become political

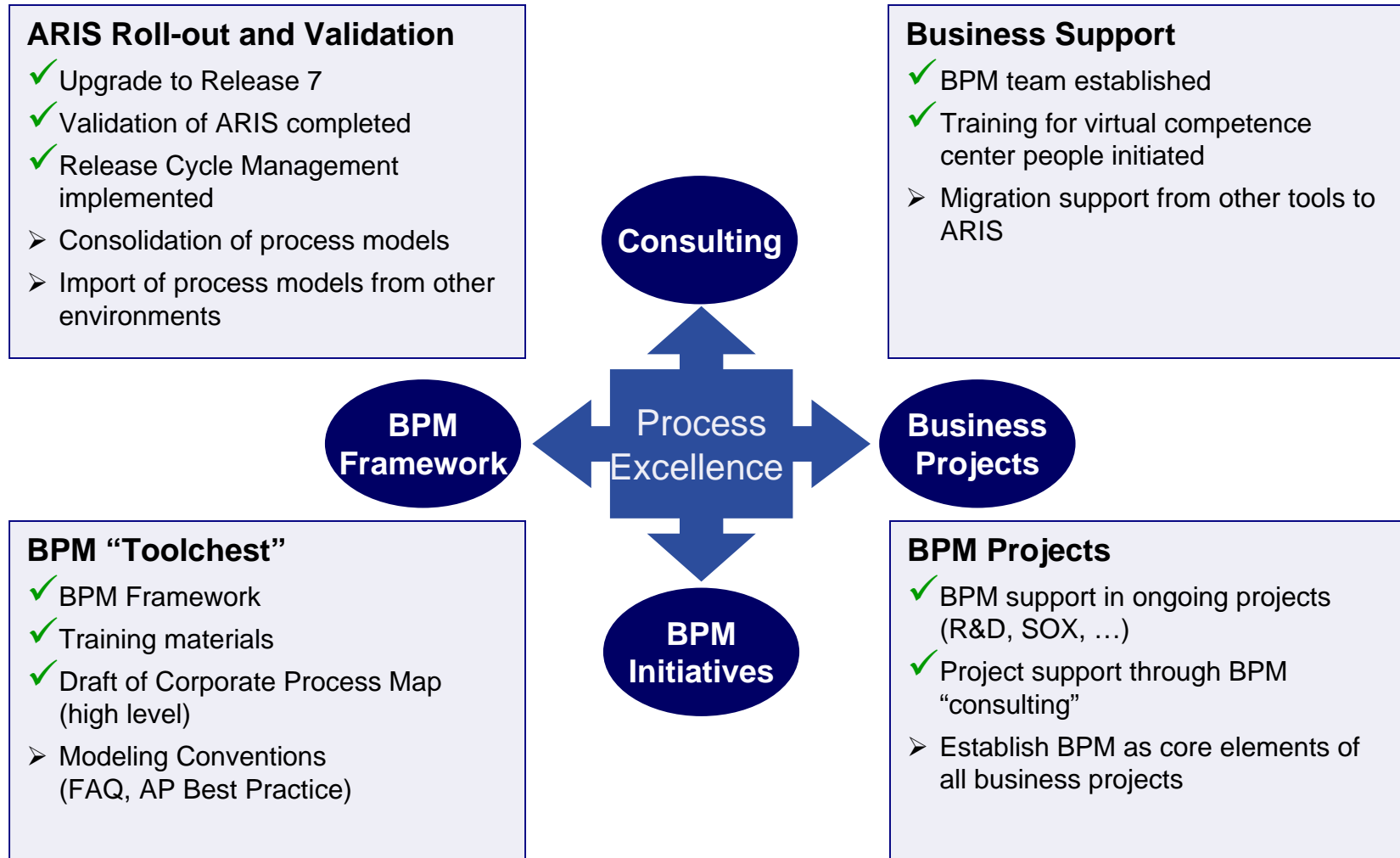
Table of Content

- Introduction to ALTANA Pharma
- BPM drivers and issues
- The ALTANA Pharma approach to BPM
- Some practicalities

History of BPM @ ALTANA Pharma



Status of BPM @ ALTANA Pharma



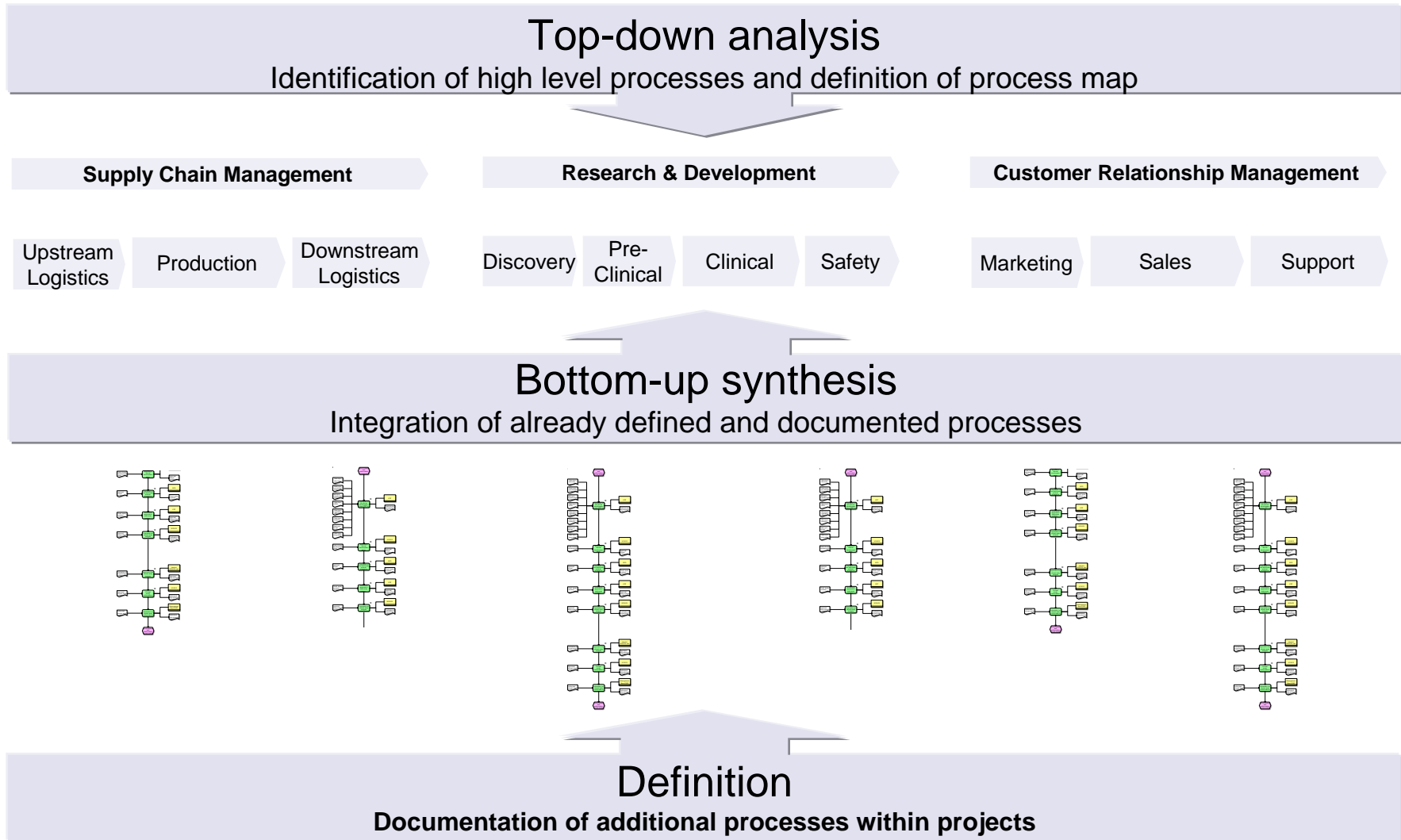
The Foundation is laid, but there is more to do

- One repository for consistency in notation, integration and reusability:
 - Integration with ECM, Electronic Signing, Web Publishing
 - Repository consolidation, process migration
- Consistency across various model types and levels, such as high level processes (value-added chains), detailed process descriptions and UML models
- Requirements definition becomes process lead
- Process view becomes integral part of our architectural perspective, i.e. continuity from business process down to systems (BP, BPEL, SOA, NetWeaver, SAP, ...)
- Simulation, process KPIs and tracking of process performance for continuous improvement
- Direct link to AuditManager for documented process compliance

Table of Content

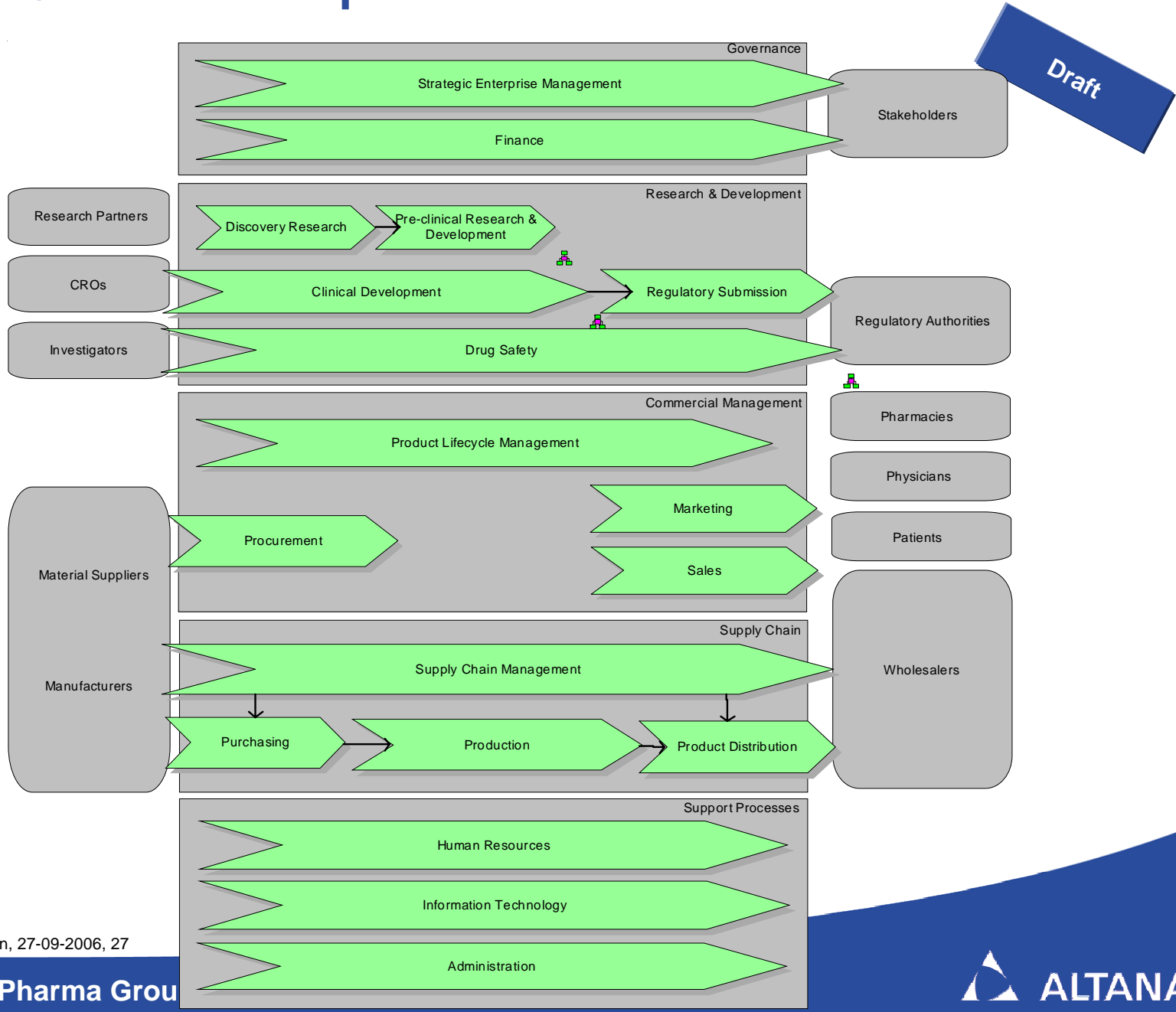
- Introduction to ALTANA Pharma
- BPM drivers and issues
- The ALTANA Pharma approach to BPM
- Some practicalities

Multiple work streams to develop the process map



Dr. Kai A. Simon, 27-09-2006, 26

Level-0 Process Map

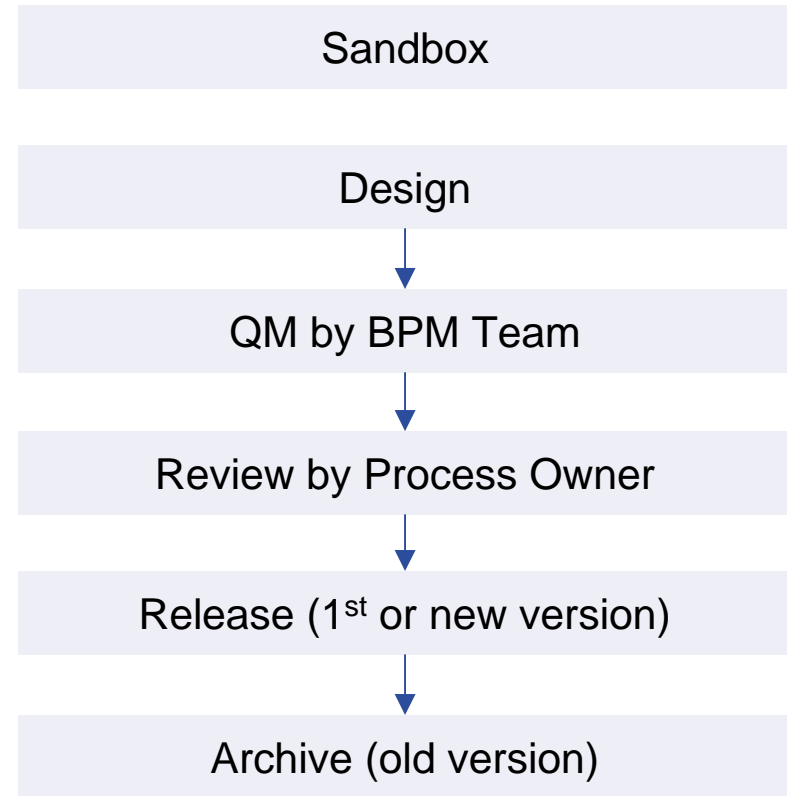
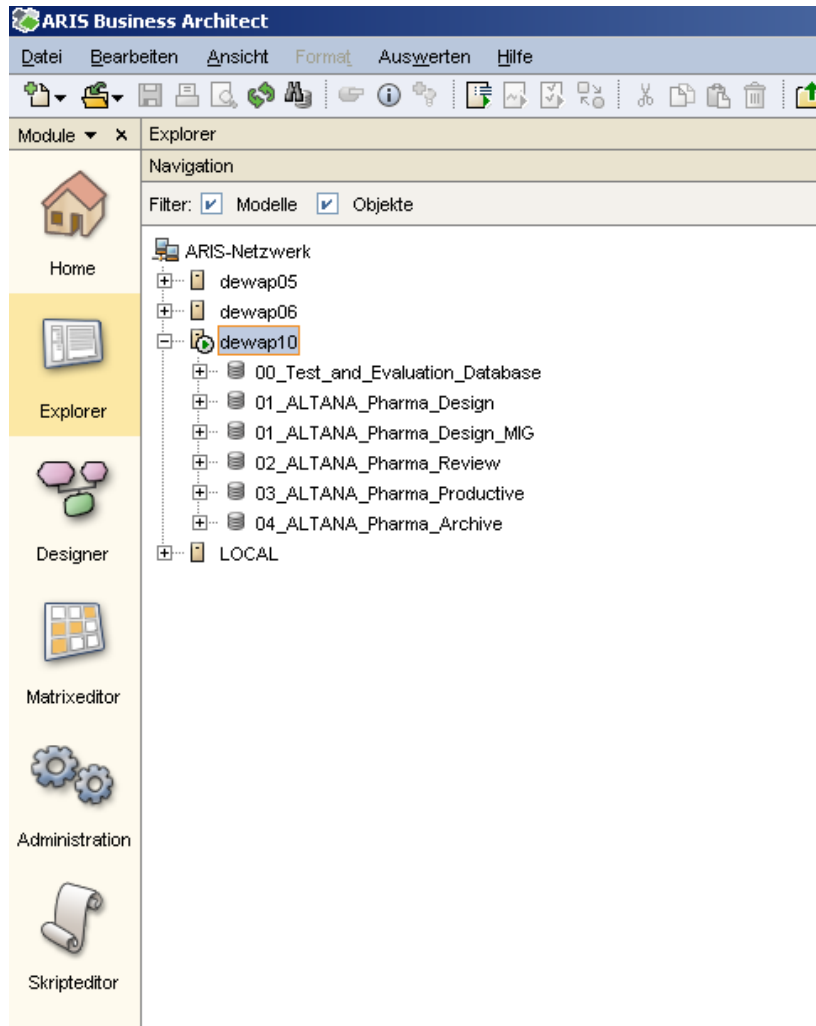


Dr. Kai A. Simon, 27-09-2006, 27

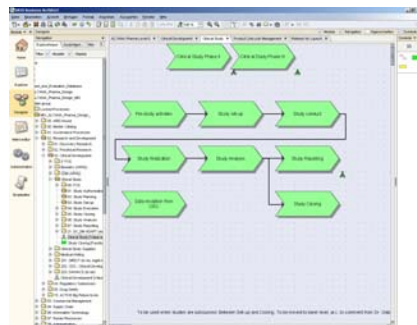
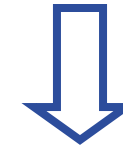
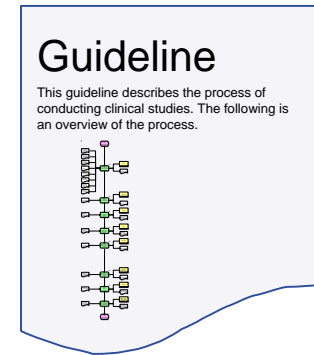
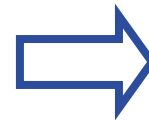
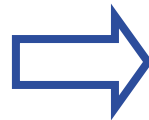
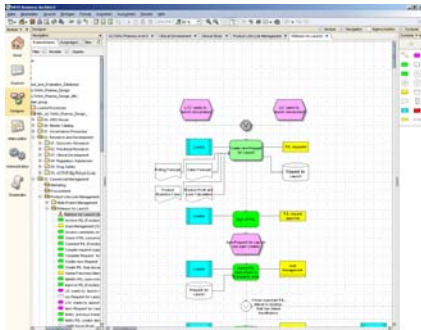
BPM Framework

- Starting situation and context
 - BPM definition and context
 - Drivers, benefits
 - Current situation of ALTANA Pharma
- Governance
 - Committees
 - ITC and AIC
 - BPM Control Committee
 - BPM Team responsibilities
- Role Concept
 - Process Owner
 - Process Sponsor
 - Process Executive
 - Process Designer
 - BPM Team Member
 - BPM CC Member
- Managing processes
 - Business Process Lifecycle
 - Process Review Lifecycle
 - Change Process
- Administrative processes
 - Technical infrastructure (incl. SLA, OLA)
 - User management
 - Conventions
 - Master data maintenance
 - Training concept
 - Validation
- Delivery strategy
 - Process Office
 - Methodological approach

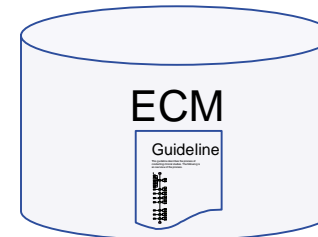
Databases and RCM Process



Future Guideline and SOP Management

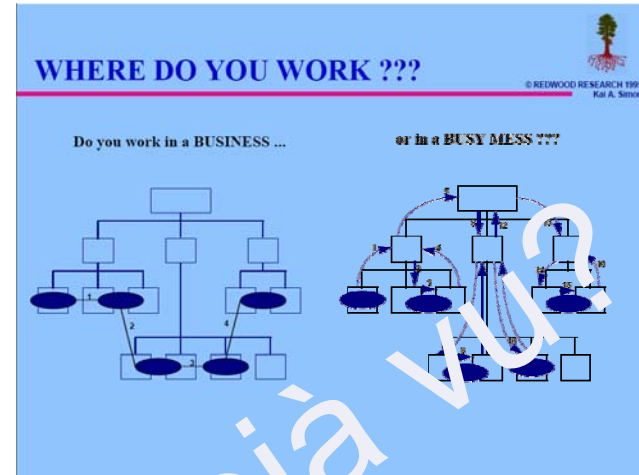


Hyperlink to content element



Conclusions

- BPM requires
 - commitment at all levels throughout the organization
 - significant effort
- As Business Process Manager you need to
 - eat your own dog food (or sip your own champagne)
 - show BPM potentials and benefits
- Remember that
 - a fool with a tool is still a fool
 - you cannot make love through a consultant
 - BPM is a never-ending story



WORDS FOR THE DAY

© REDWOOD RESEARCH 1995
Kai A. Simon

- ◆ First redesign, then workflow support:
DON'T AUTOMATE YOUR BUSY MESS.
- ◆ You are not fighting a war:
IF YOU ONLY HAVE A HAMMER, THE WHOLE WORLD LOOKS LIKE A NAIL.
- ◆ There are no shortcuts:
NO GAIN WITHOUT PAIN.

*There is no one best way to organize.
Not all the ways are equally effective.*
Jay Galbraith

Thanks for your attention!
Any questions?