

Establishing Corporate Business Process Management at Nycomed

Dr. Kai A. Simon

Business Process Manager

Corporate IT Office

Table of Content

Introduction to NYCOMED

BPM drivers and issues

The NYCOMED approach to BPM

- Overview
- Process map design
- BMP framework
- Standardized Platform
- Process Release-cycle
- Regulatory process documentation

Critical Success Factors and Conclusions

The New NYCOMED



ALTANA Pharma AG



Founded 1873 by Dr. Heinrich Byk
in Berlin



2007 NEW



Founded 1874 by Morten Nyegaard
in Norway



~13.000 employees world-wide

€ +3 bn annual turnover

Key markets Western Europe, USA, Russia-GUS

HQ in Zürich, major sites in Konstanz (D) and Roskilde (DK)

Table of Content

Introduction to NYCOMED

BPM drivers and issues

The NYCOMED approach to BPM

- Overview
- Process map design
- BMP framework
- Standardized Platform
- Process Release-cycle
- Regulatory process documentation

Critical Success Factors and Conclusions

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 not a one-off event

BPM is about performance improvement in business processes, i.e. it requires IT and business alignment

BPM provides framework and tools, but a fool with a tool ...

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

BPM Drivers in the Pharmaceutical Industry

Regulatory requirements & standards

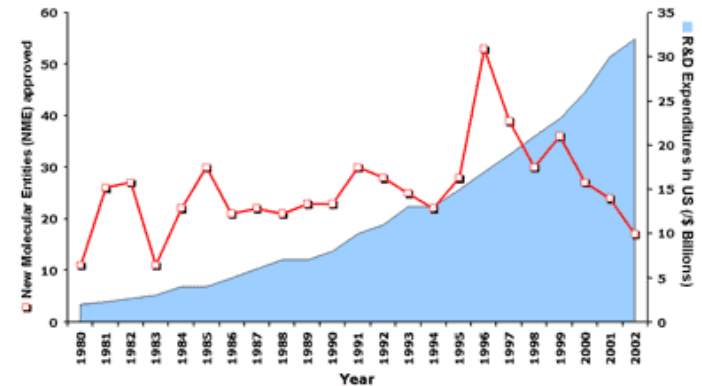
- GxP: Good Practices in Laboratory, Clinical, Manufacturing
- 21CFR Part 11: Electronic Records and Signatures (FDA)
- SOX: Sarbanes Oxley Act (sections 302, 404)
- Official and de-facto standards, e.g. CDISC, E2B

“Need for speed”

- Development cost ~800 M\$
- Development cycle time 8-12 years
- Patent protection period
- Globalization and harmonization of processes

Governmental pressure

- Price reductions
- Fewer approvals in highly populated disease areas



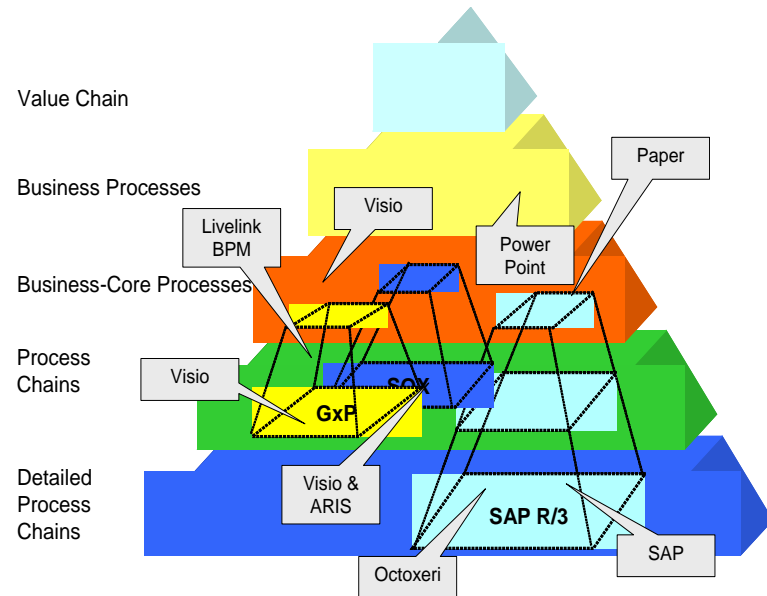
Typical Starting Situation

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



Where is the Home of BPM?

IT has a perspective that spans across borders within and across the organization

IT has no functional stakes to defend

BPM competence in IT is higher than in many consulting firms

Eat your own dog food: IT is transforming itself into a process organization

IT is already heavily involved in SOX and R&D improvement

Business has a much deeper understanding of its processes and needs

Business units need to drive their own transformation

Since when does IT know anything about Business Processes?

IT should get its own processes and delivery capabilities right first

IT should limit its role to provide the necessary infrastructure

Table of Content

Introduction to NYCOMED

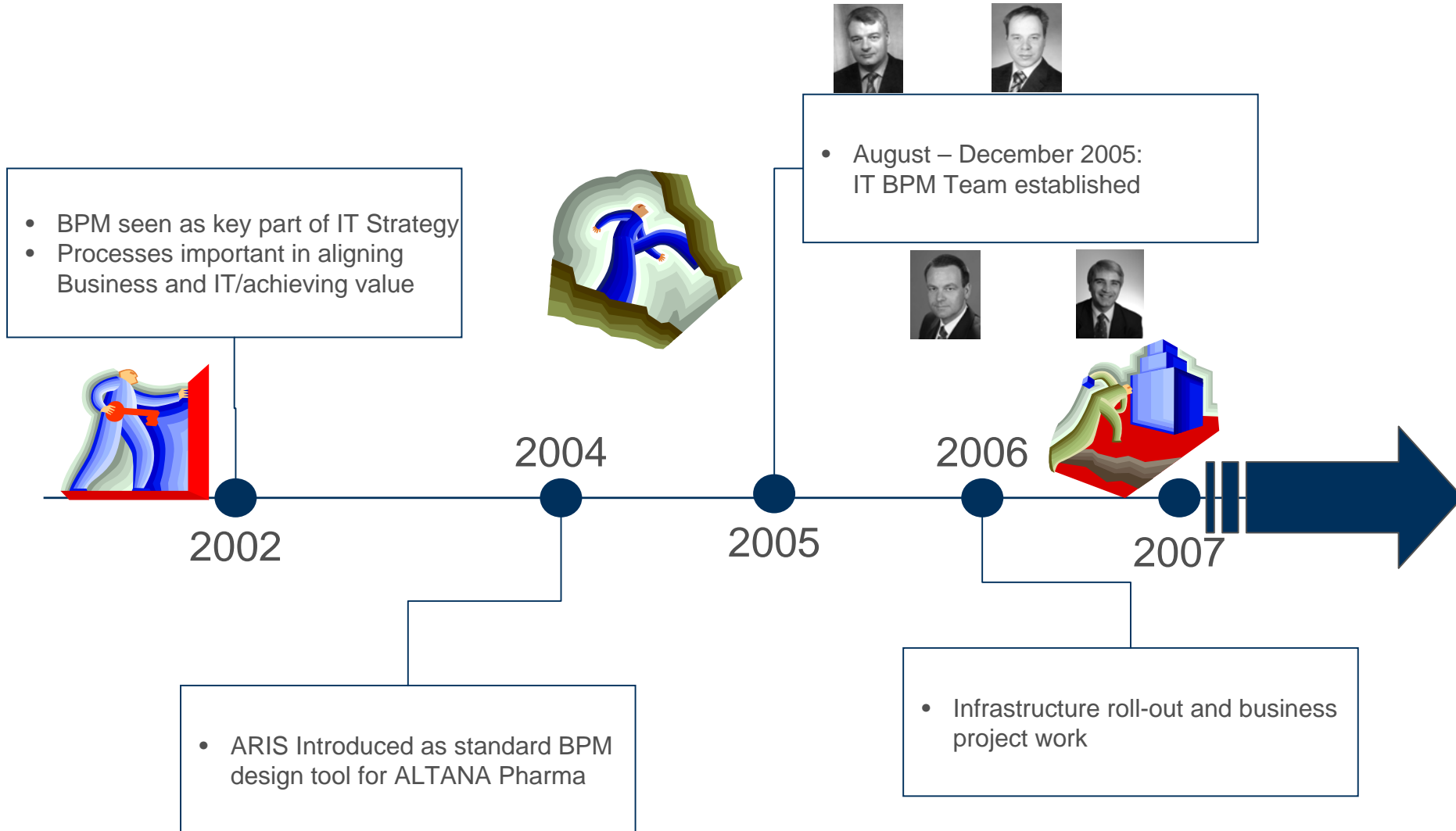
BPM drivers and issues

The NYCOMED approach to BPM

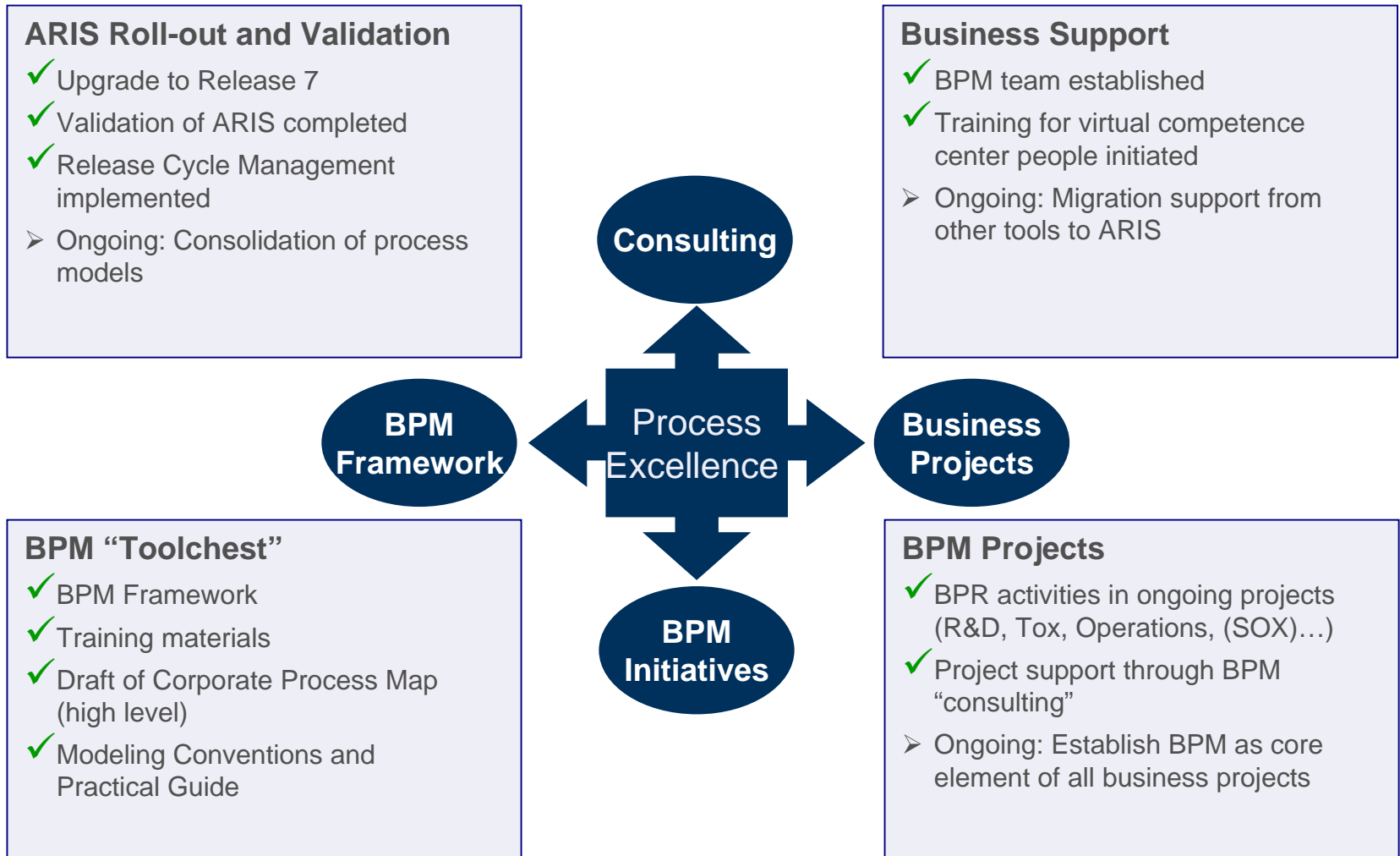
- Overview
- Process map design
- BMP framework
- Standardized Platform
- Process Release-cycle
- Regulatory process documentation

Critical Success Factors and Conclusions

History of BPM @ NYCOMED (APAG)

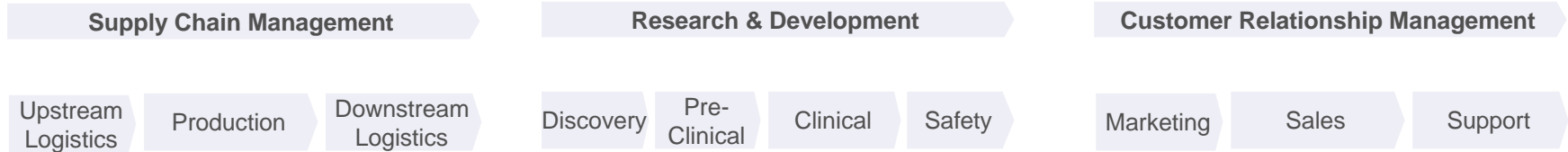


Overview and Status of BPM @ NYCOMED

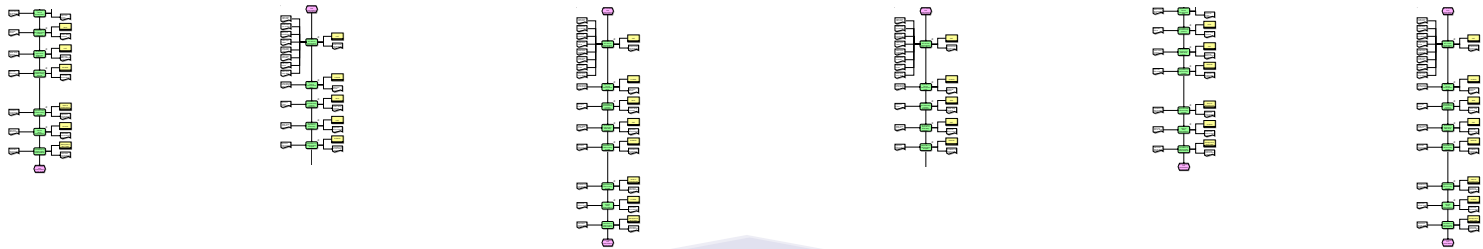


Approach to Process Map Design

Top-down analysis
 Identification of high level processes and definition of process map



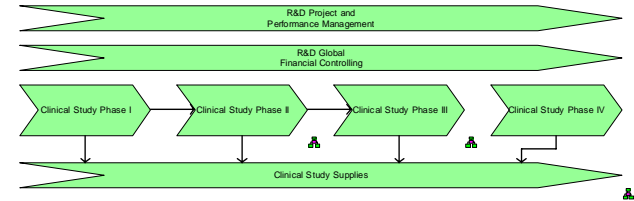
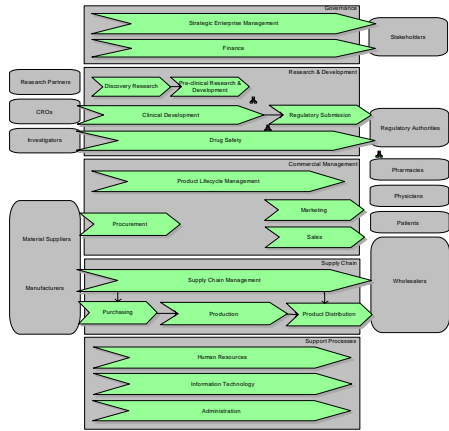
Bottom-up synthesis
 Integration of already defined and documented processes



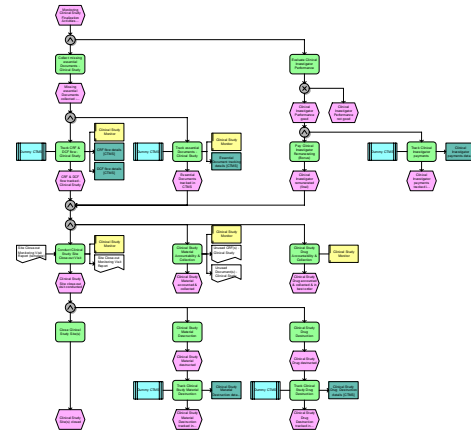
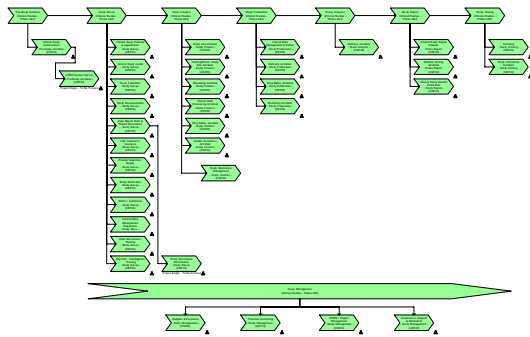
Definition
 Documentation of additional processes within projects

Process Map Design top-down vs bottom-up

BPM lead



Business lead



Defined Redesign Steps to maintain Consistency

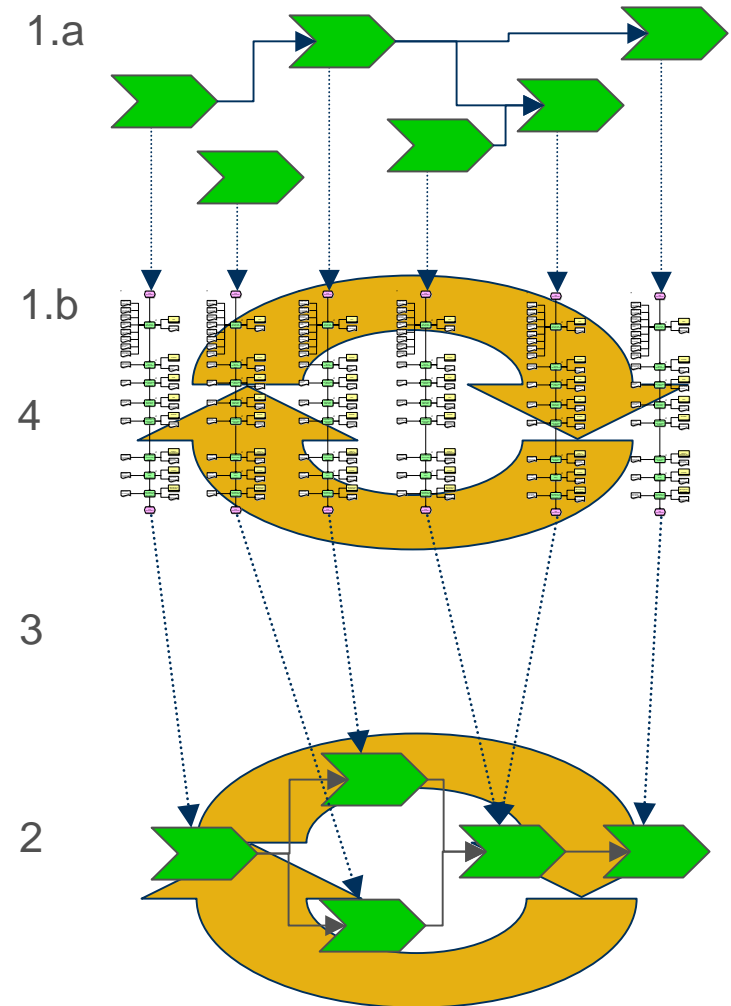
Document as-is processes top-down

- VACs - Value-added chains (WKD)
- ePCs - Process-chains (ePK)

Design to-be VAC structure

Assign as-is ePCs to new VAC structure

Redesign ePCs, following the new VAC structure



Process Map Design Issues

Top-down design of high-level maps led by BPM team in coordination with management

Lower-level maps designed by business, if required with support from BPM team

Interface (hand-over) design across main processes coordinated by BPM team

No pre-determined depth (# of levels) for analysis and design

- There is no „one size fits all“ approach
- Interfaces can be included across process levels

Strip-down of ARIS method to a limited number of possible objects

Training and Practical Guide

Process Designers receive a 2-day hand-on training. “Viewers” with read-only access get a walk-through.

Current access for all users via Business Designer, in the future via Web-Browser (and Business Publisher)

Training material

- Equivalent to IDS material for ARIS training
- Customized to fit Nycomed’s needs
- Used in a 2-day hands-on training for Process Designer

Practical Guide

- Describes conventions, objects, relations, attributes, ... according to the customized filter
- Contains a glossary of all relevant terms
- Extension with „Tips and Tricks“ planned

BPM Framework

Starting situation and context

- BPM definition and context
- Drivers, benefits
- Current situation of Nycomed

Governance

- Committees
 - AIC and ITC
 - 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

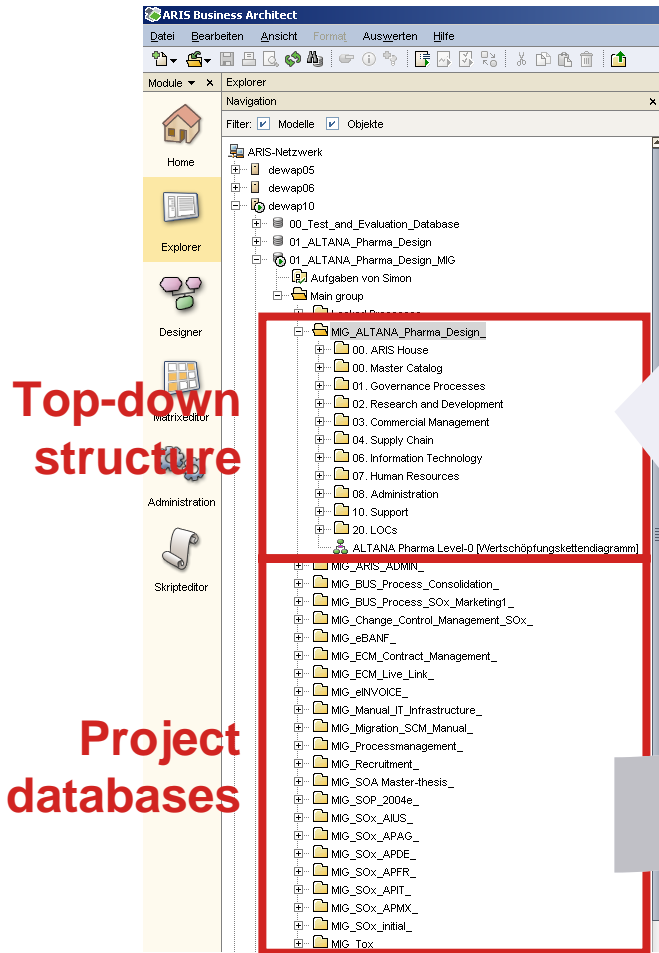
Administrative processes

- Technical infrastructure (incl. SLA, OLA, UC)
- User management
- Conventions -> Reference to PG
- Master data maintenance
- Training concept
- Validation

Delivery strategy

- Process Office
- Methodological approach

Consolidation of Process Models



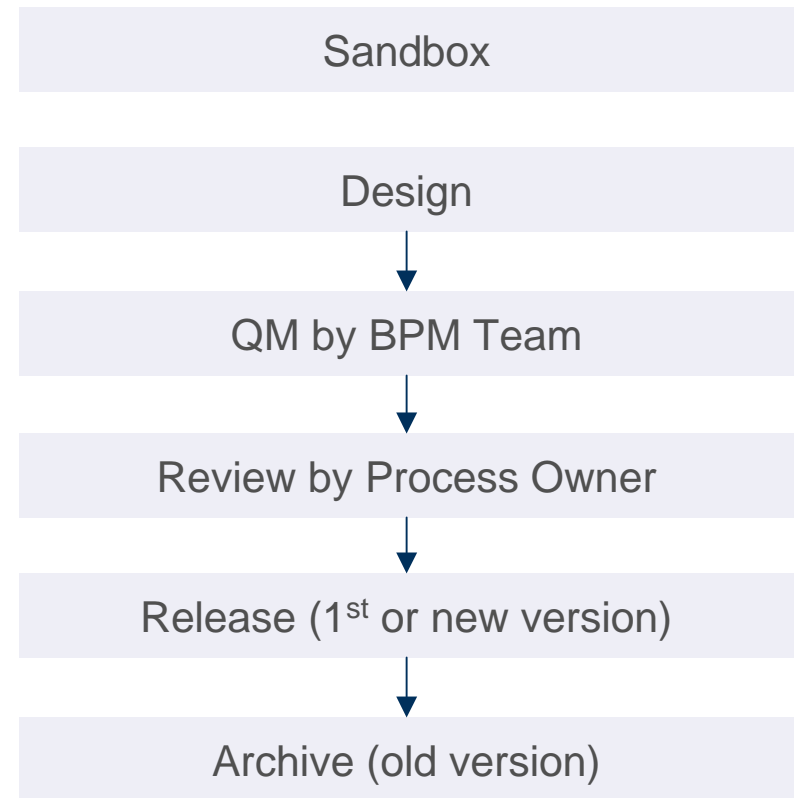
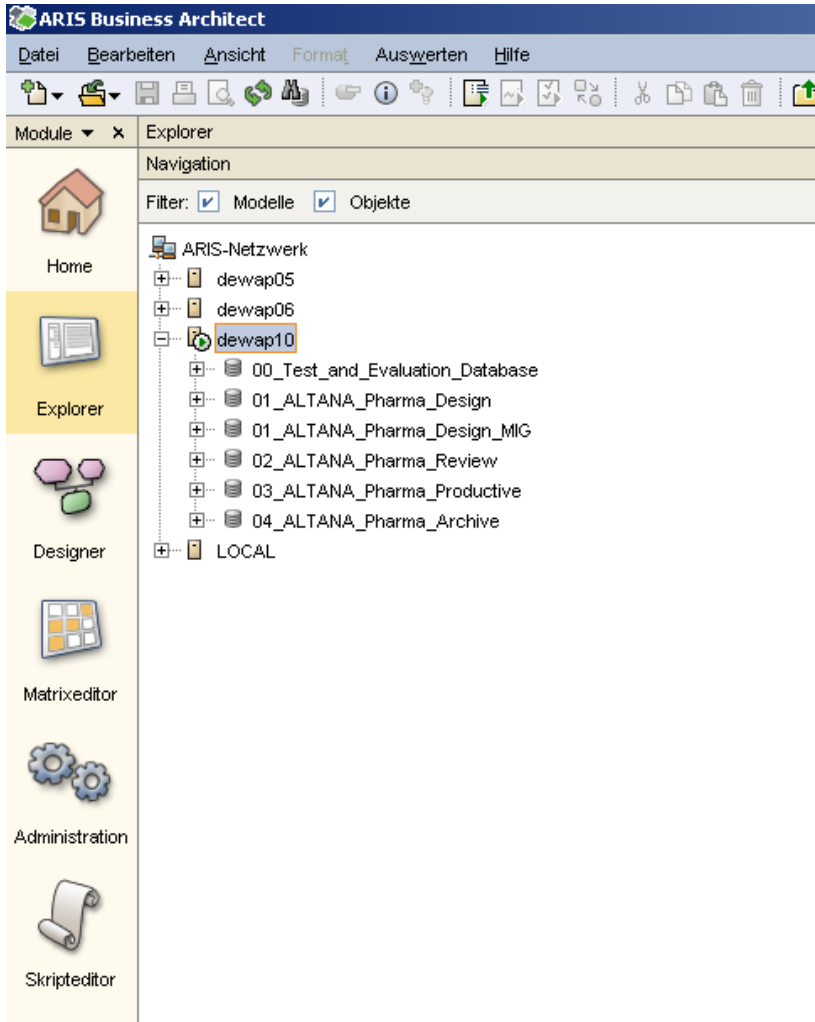
Consolidation of database

- Merge of project databases
- Sorting of processes into top-down structure
- Consolidation of master objects

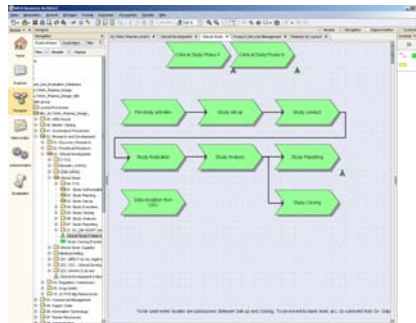
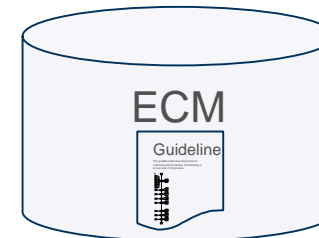
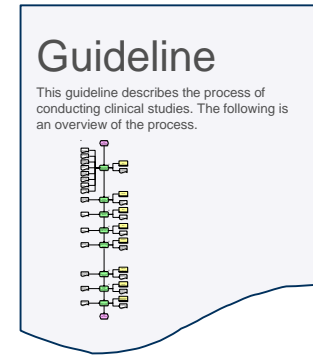
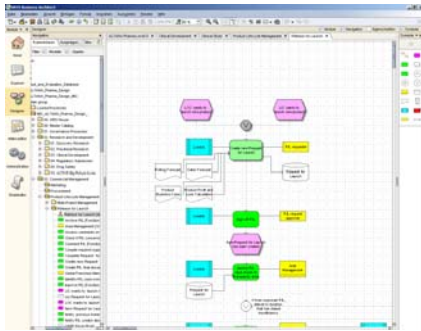
Open questions

- Should a strict process hierarchy applied, or should processes at certain level be grouped per function
 - Proposed solution: Function-wise grouping (e.g. Biometry) in DB with “dummy overview”, models grouped according to process hierarchy
- Process variations, e.g. LOCs or therapy area

Release Cycle Management



Covering Regulatory Requirements for Process Documentation



Availability of Process Documentation

Use of Business Publisher to provide process documentation to a large audience

- Replacement of current mechanisms, e.g. Notes-DB
- Integrated with Release-Cycle-Management
- Navigation across process models and functions

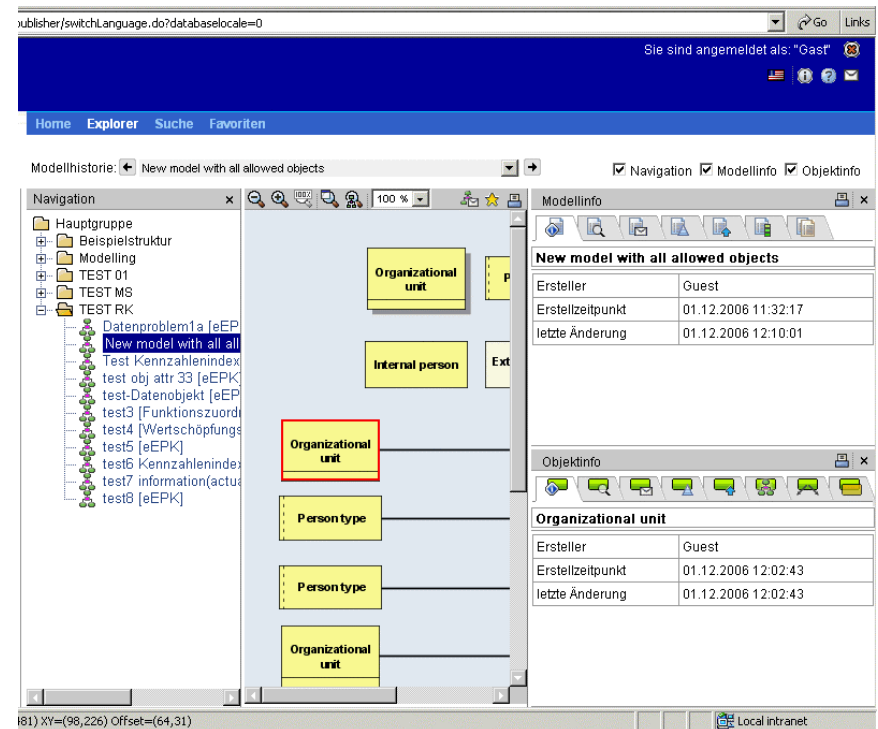


Table of Content

Introduction to NYCOMED

BPM drivers and issues

The NYCOMED approach to BPM

- Overview
- Process map design
- BMP framework
- Standardized Platform
- Process Release-cycle
- Regulatory process documentation

Critical Success Factors and Conclusions

Critical Success Factors

You've heard this many times before: Management commitment

- Senior management to promote and enforce, if necessary
- Middle management to use

Ability to demonstrate business benefits

- Quick-wins
- Long term benefits

Maintain balance between speed and consistency,
address break-out projects

Hand-over from project-work to maintenance

Network of ambassadors and designers throughout the business

Create inhouse-competence and use consultants for support

Some Conclusions – You might add your own

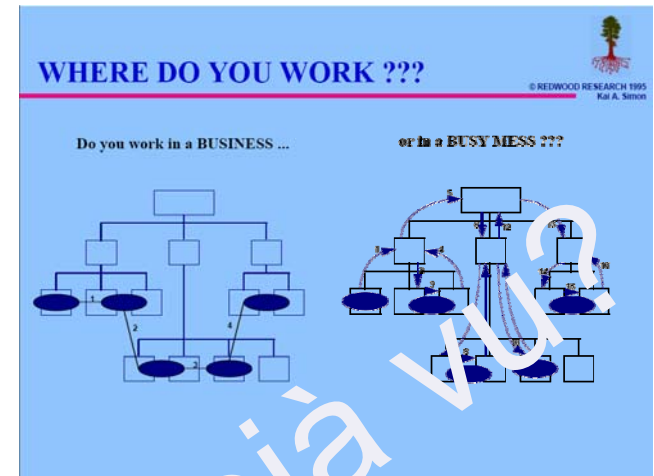
BPM is not only about performance, but also about politics

Remember: A fool with a tool is still a fool

BPM requires significant effort and is a never-ending story

Recall the lessons from the 1990s BPR wave

- It's about people
- Don't automate the busy mess
- No shortcuts and free lunches



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?