



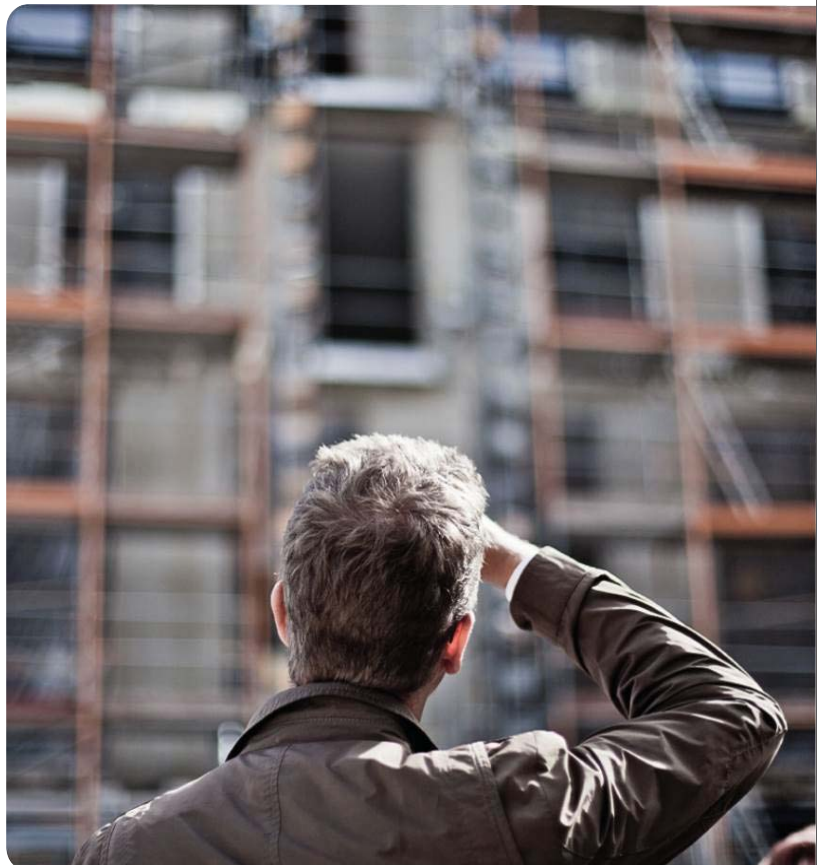
Form and Function in Concert

Managing Projects by Harald J. Geitz
ISPE Thailand conference on July 17-19th 2013

io Content

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1. Project structure
2. Targets of io-consultants project management
3. Elements of io-consultants project management
4. io-consultants project portal
5. Standardization
6. Examples
7. Success factors of a good project management



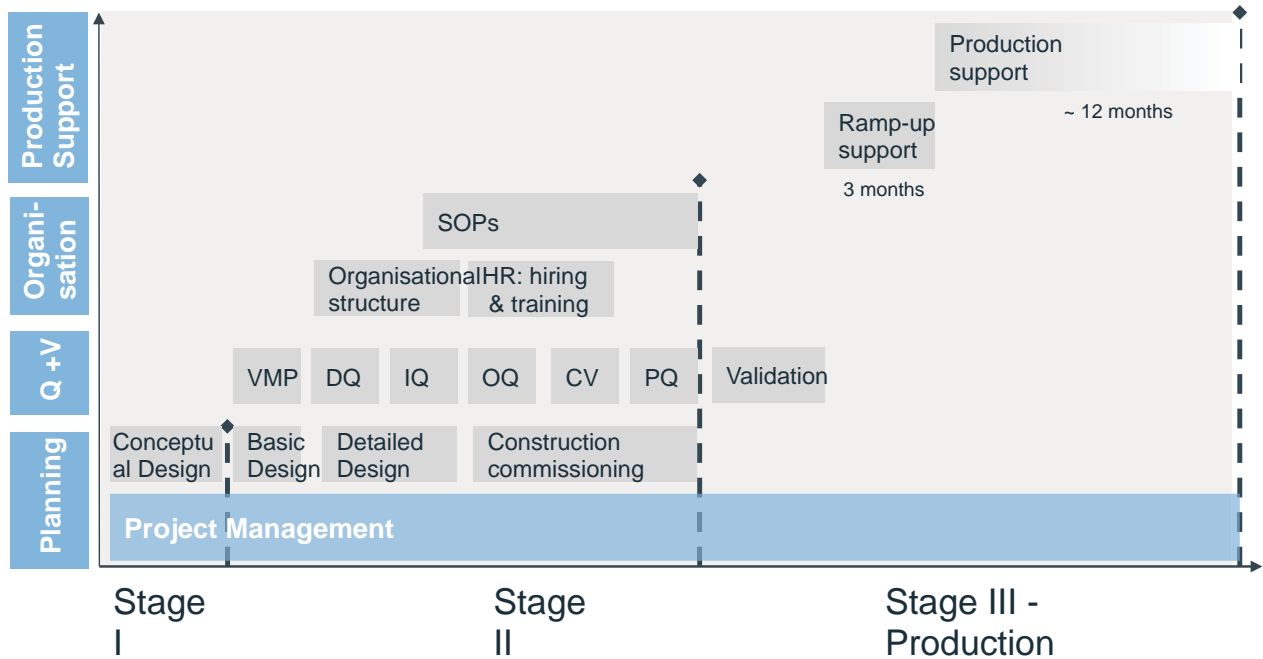
Project Structure

io Project Phases

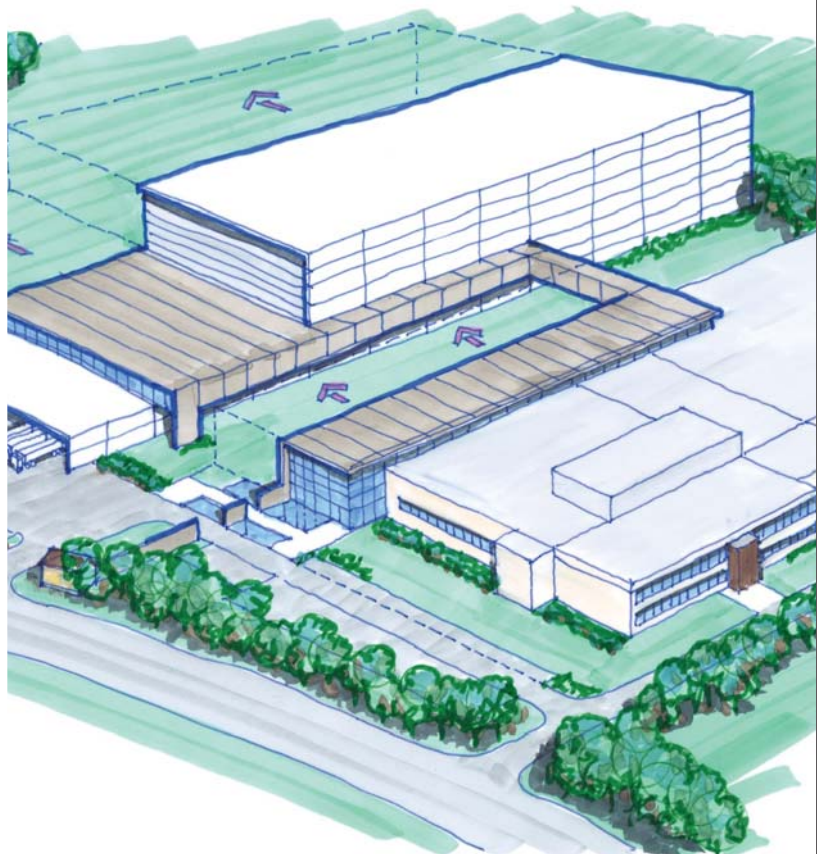
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- Project structure
- Conceptual design
- Basic/detailed design
- Supervision/handover
- Qualification/validation
- Experience





- Process and Packaging Technology
- Warehousing and Material Flow
- Area / Staff Requirements
- Master Plan Development
- Layout Alternatives 1:200
- Architectural / Structural Concept
- Building Services Concept
- GMP Requirements
- Rough Time Schedule
- Cost Estimate $\pm 25\%$





Project Phases - Basic / Detailed Design

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- Process Engineering
- Detailed Layout and Arrangement Drawings
- Work Centres 1:20
- HVAC / M&E / Utilities Engineering
- Architectural / Structural Design
- IT / Supply Chain
- Specification of Equipment
- Documentation of Regulatory Issues
- Refined Cost Estimate



Project Phases - Supervision / Handover

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- Factory Acceptance Tests (FAT)
- Site Management and Site Organisation
- Scheduling
- Supervision of Works according to GMP Requirements
- Supervision of Commissioning
- Supervision of Remedial Action
- Documentation and Handover





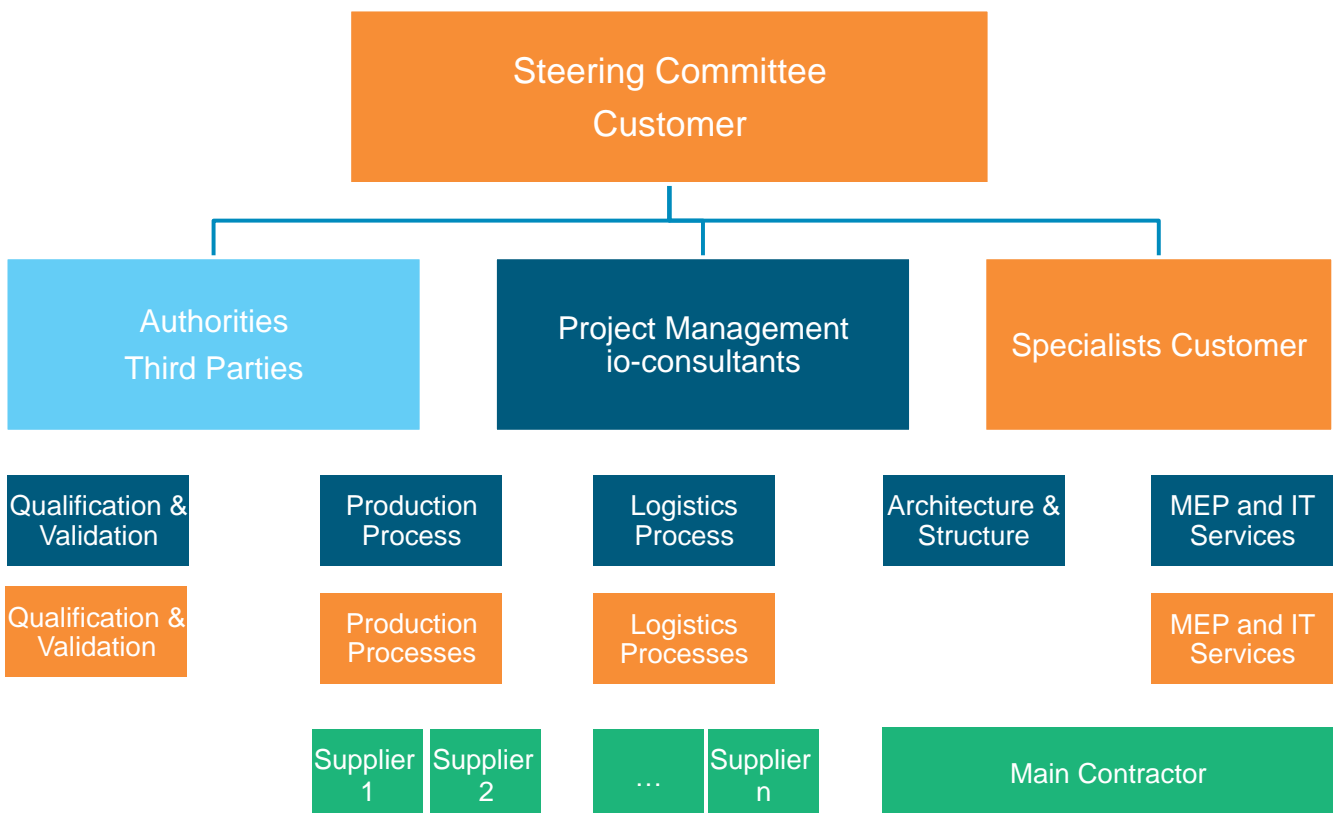
Project Phases - Qualification / Validation



- ▮ Validation Master Plan (VMP)
- ▮ User Requirement Specification (URS)
- ▮ Supplier Audit
- ▮ Design Qualification (DQ)
- ▮ Acceptance Tests (FAT / SAT)
- ▮ Installation Qualification (IQ)
- ▮ Operation Qualification (OQ)
- ▮ Performance Qualification (PQ)
- ▮ Computer Software Validation (CSV)
- ▮ Standard Operation Procedure (SOP)



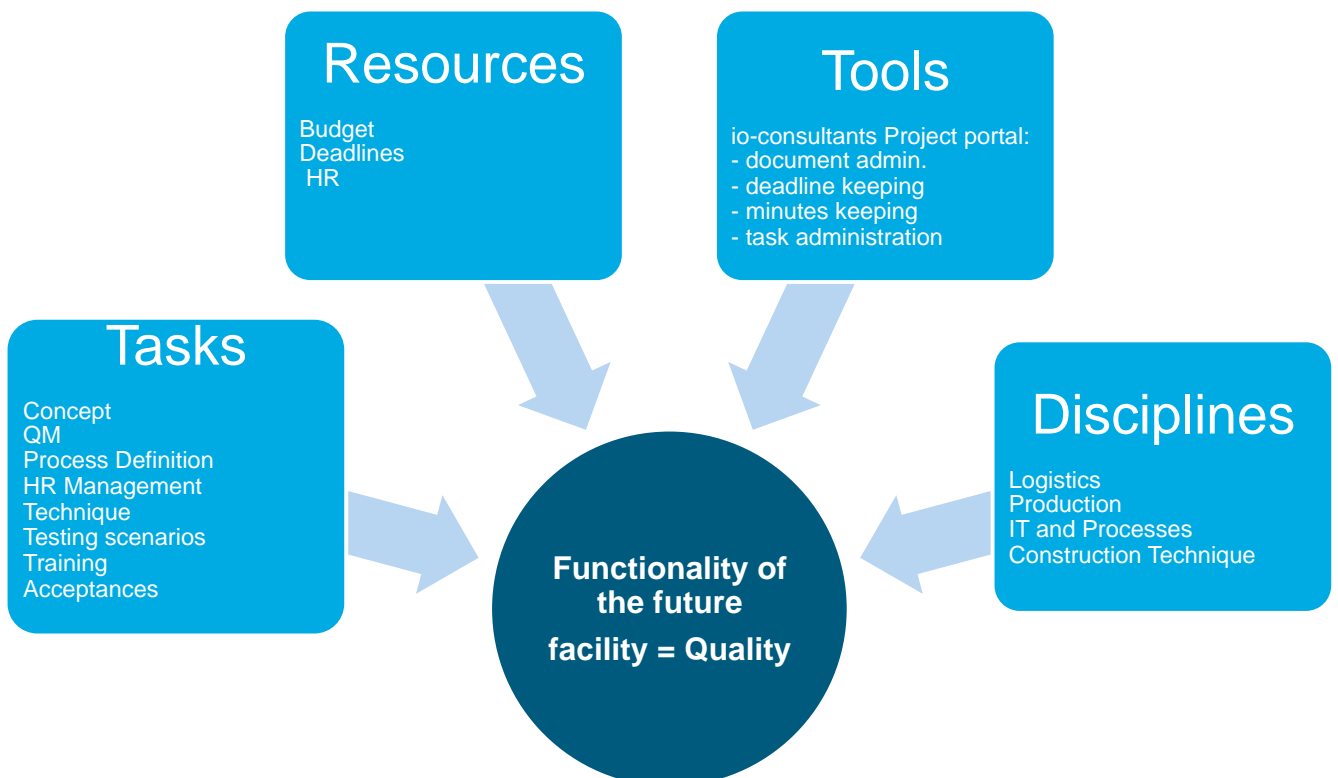
Project Organisation



Targets of io-consultants project management



Steering, Clarifying, Coordinating





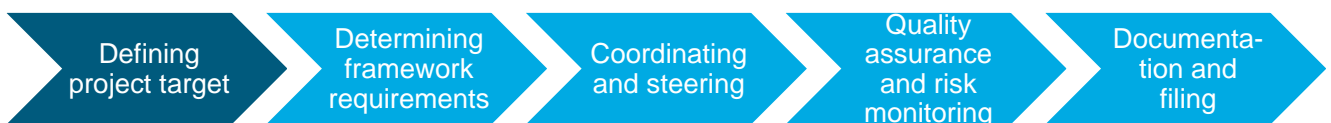
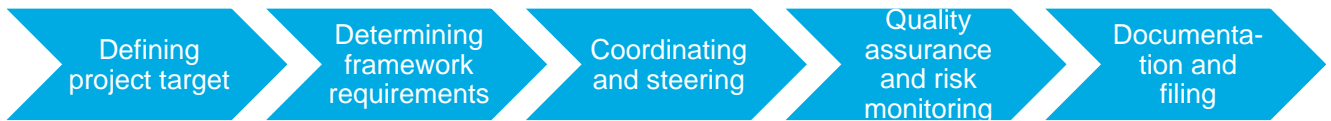
| Targets

- Highly profitable factory = minimizing running cost
- Staying on agreed budgets, time lines and human resources
- Minimizing risk factors

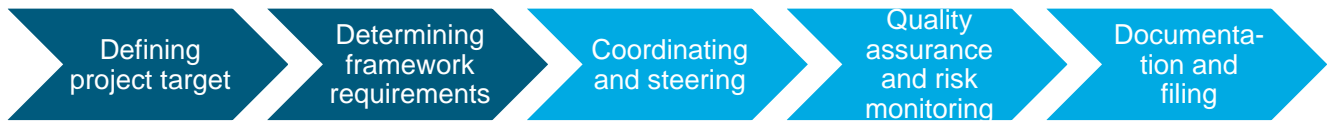
| Tasks

- Organisation of information exchange
- Creation of transparency by consistent, clear structures
- Consistent communication and information paths
- Consistent deadline coordination
- Consistent project documentation
- Comprehensive support of the customer and targeted steering of the projects

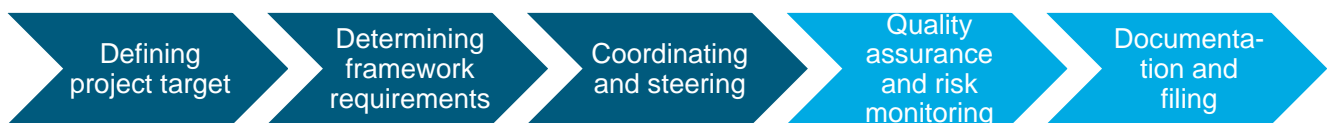
- The project management of io-consultants is basically separated into five elements.



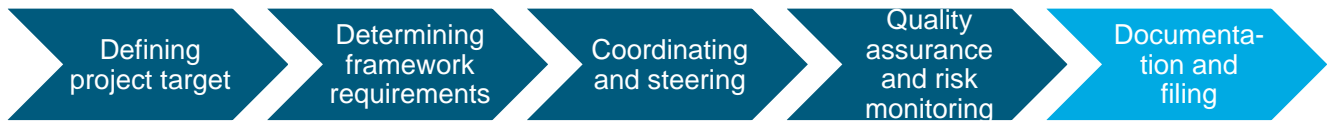
- Determination of project targets and frame of action
 - Individuality of the customer
 - Project definition and planned actions
 - Basis and background information
 - Resource planning and organizational formation (customer side, external planner)
- Budgeting of overall project and subprojects
- Creation of an overall project schedule (MS Project)



- Clear task definition using project organization charts
- Determination of project standards and glossary with document filing
- Definition of meeting types and cycles
- Preparing and updating of a project member list
- Documentation of project guidelines in project manual



- Deadline tracing and appointment coordination
- Securing of handling quality and keeping of standards
- Moderation of meetings
- Sticking to communication and information paths
- Tool based project steering
- Follow-up of tasks



- Regular reports to steering committees
- Securing of budget keeping
- Management summaries after important project steps
(content: project progress, results, documentation, deadlines, budget)
- Keeping of mile stones by means of project status reports
- In time activation of crisis managements



- Structured and transparent data filing
- Clarity and simple handling
- Auditing acceptability
- Final documentation

io-consultants Project portal

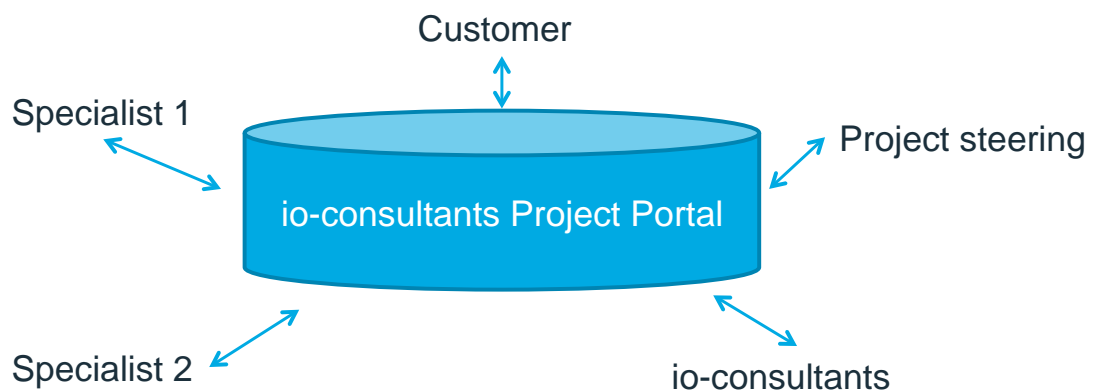
io-consultants Project portal

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- io-consultants developed this web-based and customised project management tool. It enables:
- Simple information exchange
 - Standardised communication and information channels
 - Resource allocation and control
 - Permanent process tracking and documentation of all activities
 - Keeping open issue lists
 - Budget management and control
 - Risk management
 - Early warning system
 - Individual access for all involved project members

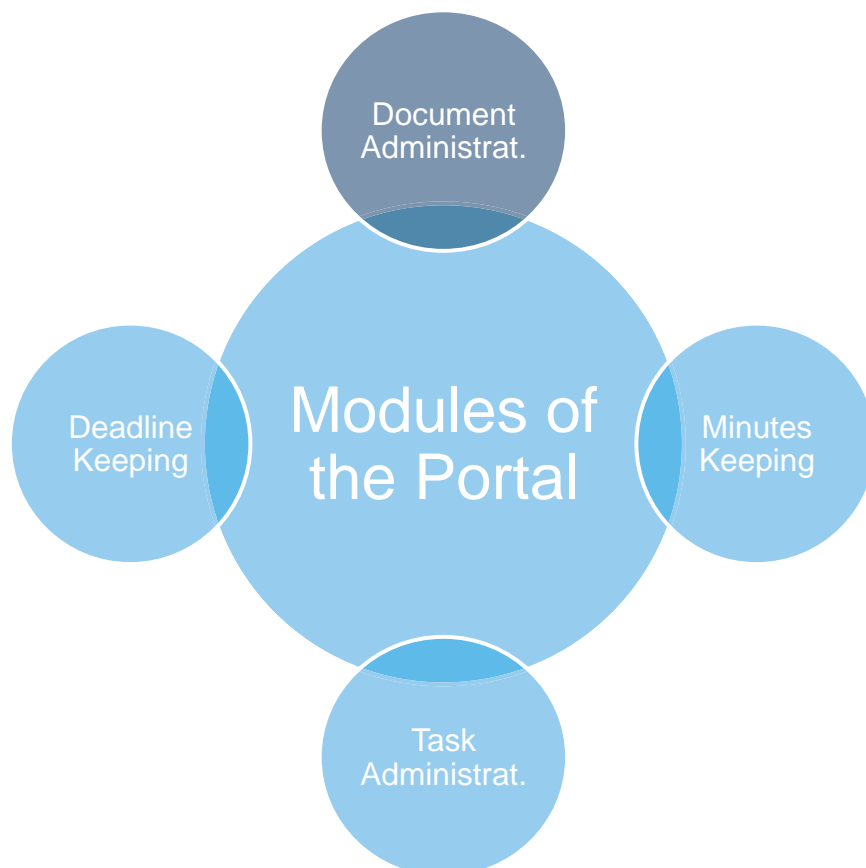
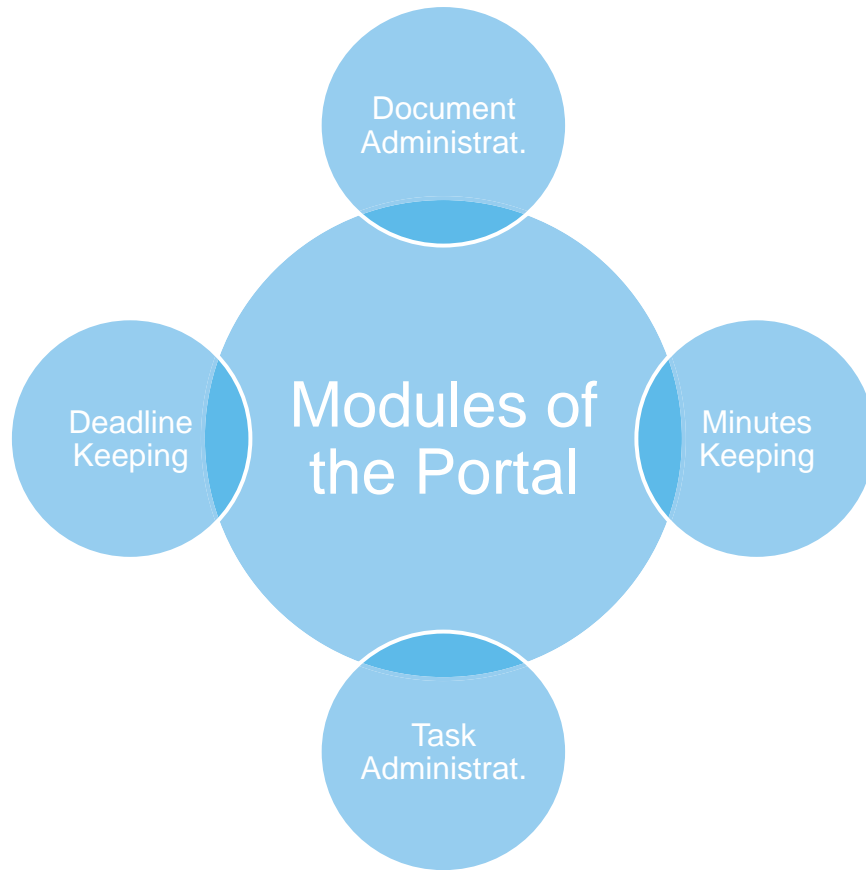
Using the io-consultants Project Portal, the following can be secured:

- Availability of latest data
- Smooth cooperation of all project members
- Creation of clarity and transparency
- Structured project steering
- User friendly thanks to office integration



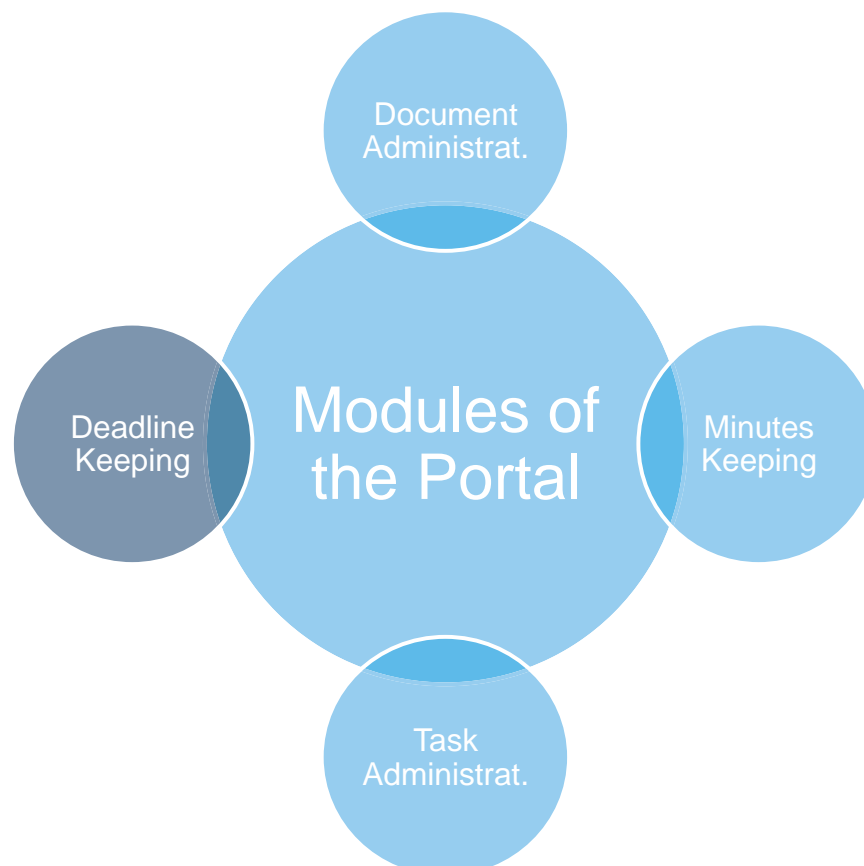
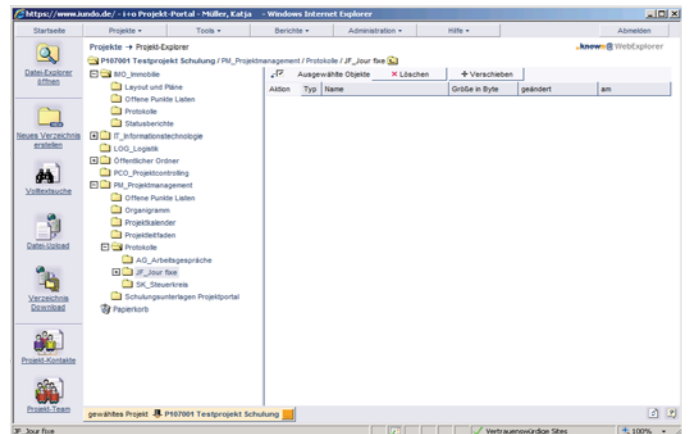
Every project member is able to do the following password protected from every part of the world:

- Inspecting, controlling and spreading of important documents
- Inspecting appointments and their status
- Inspecting and executing tasks, supervising und communicating status
- Resource planning
- Tracing project costs
- Creation of numerous reports



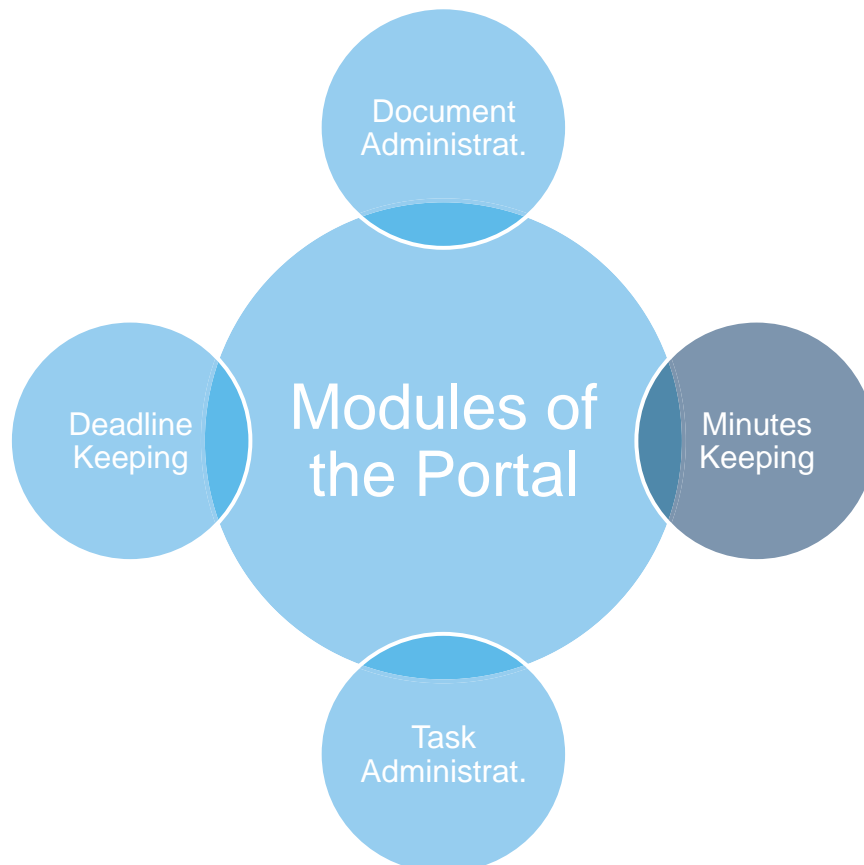
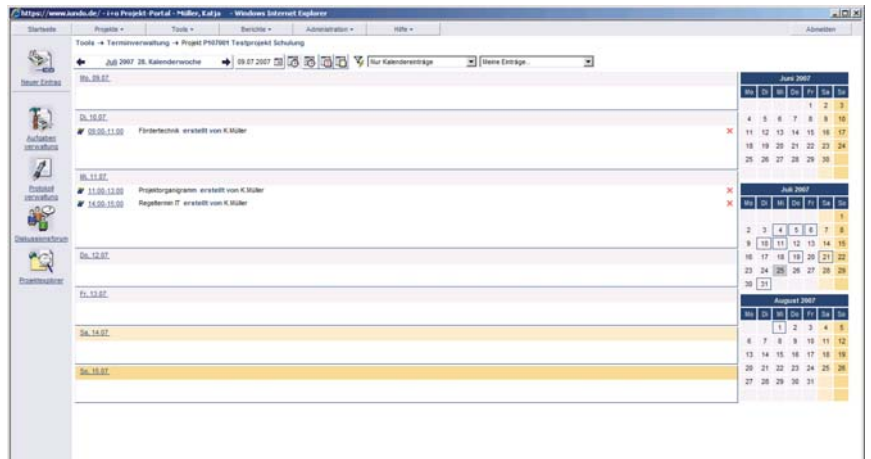
Document Administration

- Explorer functions for data and indexes (creating / renaming / cancelling)
- Downloading of complete indexes and index structures
- Differentiated assignment of rights on the different index levels
- Working with Word, Excel and PowerPoint documents directly in the portal
- Sending of e-mail links to documents
- Comprehensive search function for documents and contents



Deadline keeping

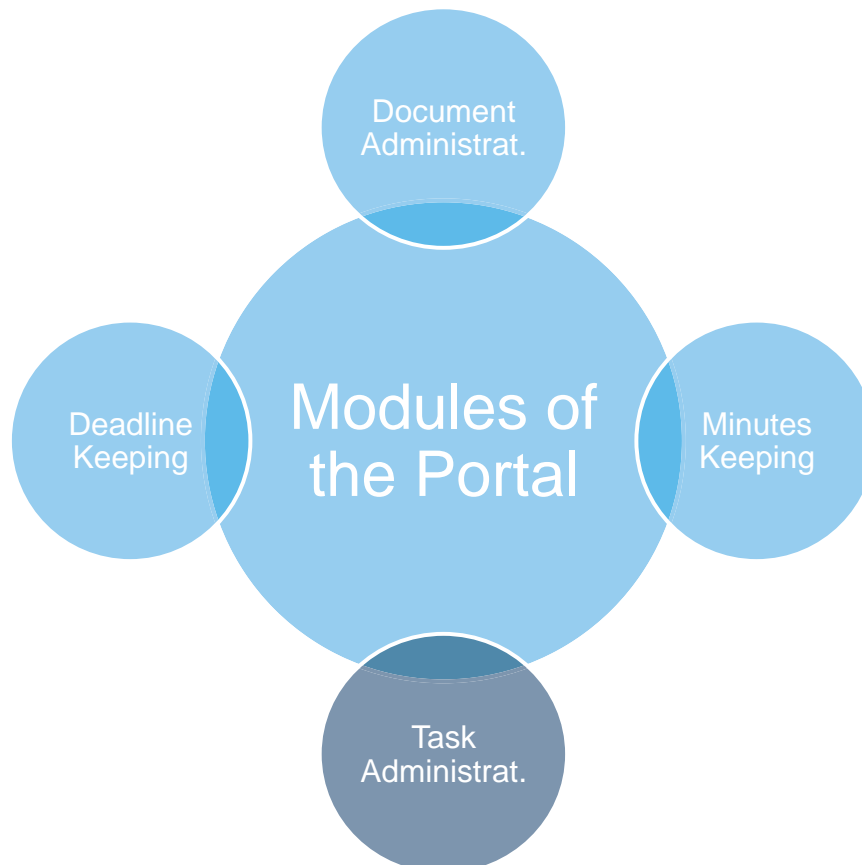
- Administration of all project related appointments
- Creation and sending of invitations
- Transferring of appointments into MS Outlook calendar
- Confirmations of participants
- Booking overview
- Project calendar



Minutes Keeping

- Creation of minutes related to the appointments
- Importing of minutes (Import)
- Showing of minutes to the relevant appointments
- Overview of all open, processed and adopted minutes
- Central filing of minutes
- Automated versioning of minutes

Projekt	Besprechungsart	Status	Koordinator	Geändert am	Thema
BAU (Bau)	AG (Arbeitsgespräch)				
IF (Jour fixe)	BAU-IF-006.07.2007 10.00	Kein Rücklauf		06.07.2007 08:25	06.07.2007 Jour fixe Bau
	BAU-IF-001	Eingesehen	Müller, Katja	06.07.2007 08:25	04.07.2007 Jour fixe Bau
	BAU-IF-001-V01.pdf			06.07.2007 08:25	
	Verhänge Versen(en)				
	BAU-IF-001-V01.doc			06.07.2007 08:25	
	BAU-IF-002	Eingesehen	Müller, Katja	06.07.2007 13:55	05.07.2007 Jour fixe Bau
	BAU-IF-002-V01.pdf			06.07.2007 13:55	
	Verhänge Versen(en)				
GP (general project)	M (meeting)				
	GM-001	Eingesehen	Müller, Katja	20.07.2007 13:54	31.07.2007 Kick-off
IT (Teilprojekt IT)	AG (Arbeitsgespräch)				
IF (Jour fixe)	IT-IF-05.04.2007 10.00	Kein Rücklauf			05.04.2007 Jour fixe
	IT-IF-11.07.2007 14.00	Kein Rücklauf			11.07.2007 Regeltermin IT
LOG (Logistik)	AG (Arbeitsgespräch)				
	LOG-AG-10.07.2007 09.00	Kein Rücklauf			10.07.2007 Förderetechnik
PK (Projektkoordination)	AG (Arbeitsgespräch)				



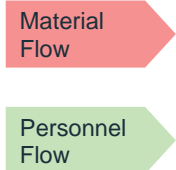
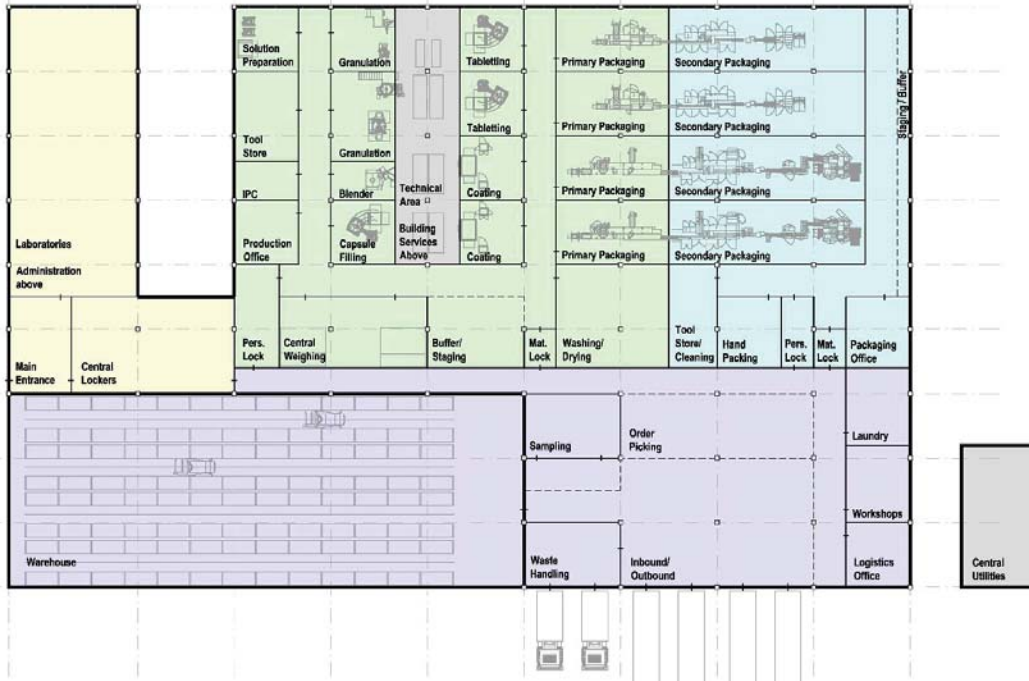
Tasks Administration

- Tasks, Decisions etc. transferring from minutes
- Adding tasks manually
- Journal function manually as well as via minute
- Journal administration via claim
- Filtering tasks according to any criteria (subproject, status, responsibilities, maturities, etc.)
- PDF evaluation of tasks
- Decision lists

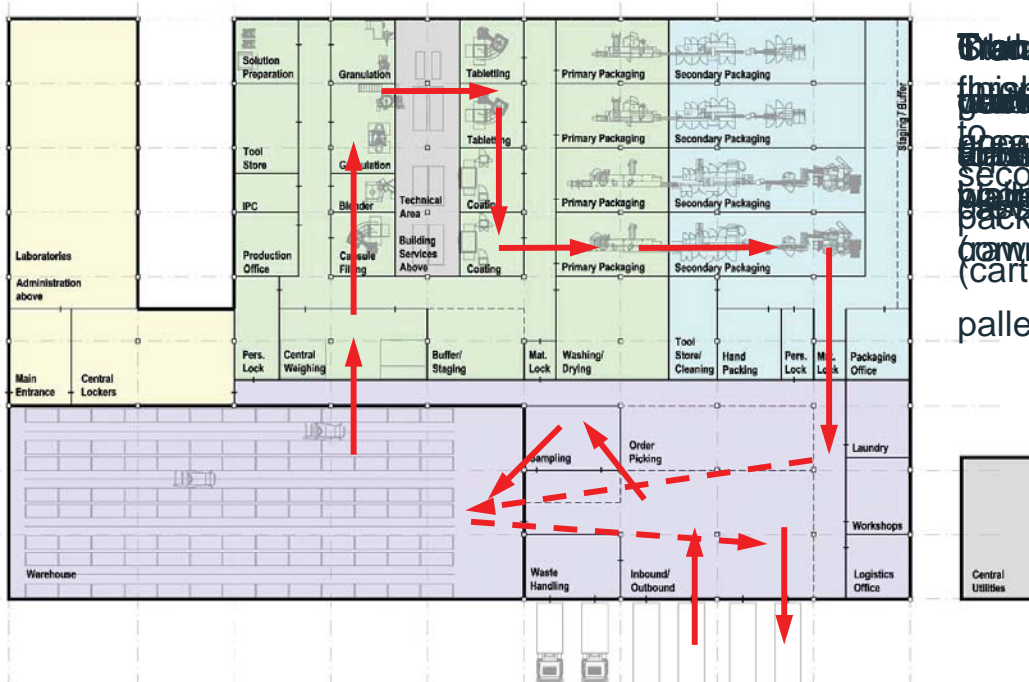
ID	Beschreibung	Status	Priorität	Zuständigkeitsbereich
PA-AG-002-002	23.07.2007 In Zusammenarbeit mit dem Kunden wird ein Organigramm erstellt.	In Bearbeitung	Normal	Frederic, Targa (V)
PA-AG-002-003	24.07.2007 Die Verantwortlichen für das Teilprojekt Bau müssen noch geteilt werden.	Offen	Hoch	Müller, Katja (V)
PA-AG-002-004	23.07.2007 Alle Konzepte der Projektarbeiten werden in einer Projektarbeitsweise erstellt.	Offen	Normal	Müller, Katja (V)
PA-AG-002-005	23.07.2007 Die Projektarbeiten werden für das Portal freigegeben und die Berechtigungen entsprechend verteilt.	Offen	Hoch	Müller, Katja (V)
PA-AG-002-006	23.07.2007 Es wird Schulungstermine für die Nutzer des Portals zu vereinbaren.	In Bearbeitung	Normal	Ottobauer, Cornelia (V)
PA-AG-002-007	24.07.2007 Der erste Schulungstermin wird am 10.08.07, der zweite am 24.08.07 stattfinden.	Offen	Hoch	Müller, Katja (V)
PA-AG-002-008	23.07.2007 Alle Vorlagen erhalten ein Kundenlogo. Das Logo wird in der entsprechenden Auffassung von Kunden zur Verfügung gestellt und von der io in Portal eingestellt.	Offen	Hoch	Müller, Katja (V)



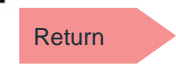
Standard Layout – Solid Dosages

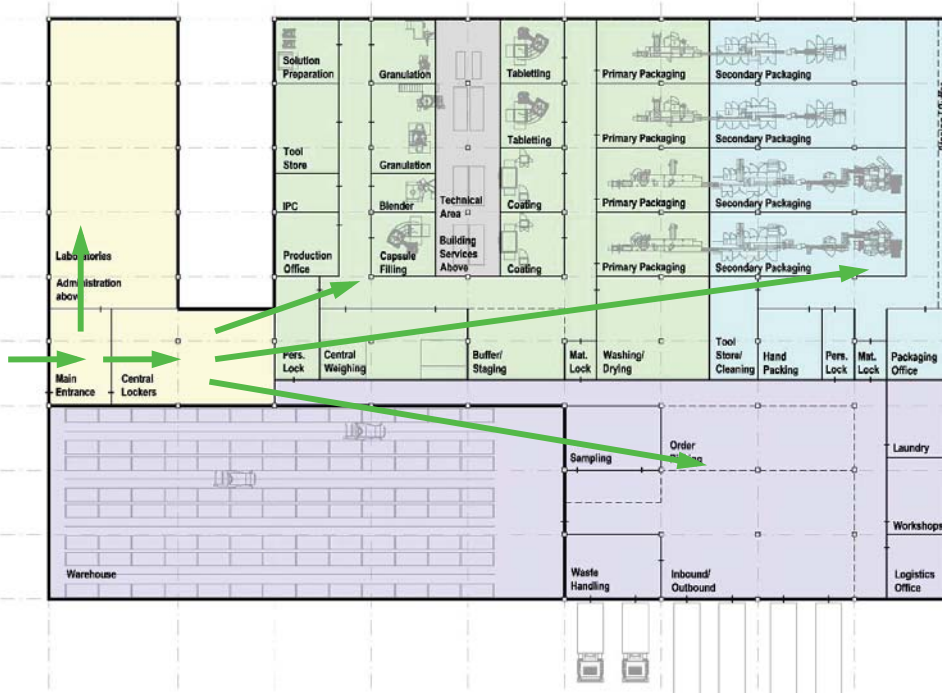


Standard Layout – Material Flow

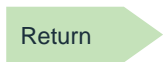


Blatage de la
finished the wall
to be installed
to the lock
secondary
packing
(cartons, cases,
pallets)





Areas with central
 production
 packaging (grey)
 production and
 packaging with
 additional
 area (white)
 via additional air
 locks with
 changing
 procedure



Success factors for a good project management



Success factors for a good project management

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- Clear communication
- Target orientated project work
- Structure and project transparency
- Fast recognition of project risks
- Usage of modern communication means to increase project efficiency
- Permanent supervision of all parties involved