



Outsourcing, Technology Transfer & CMO-Client Relationships

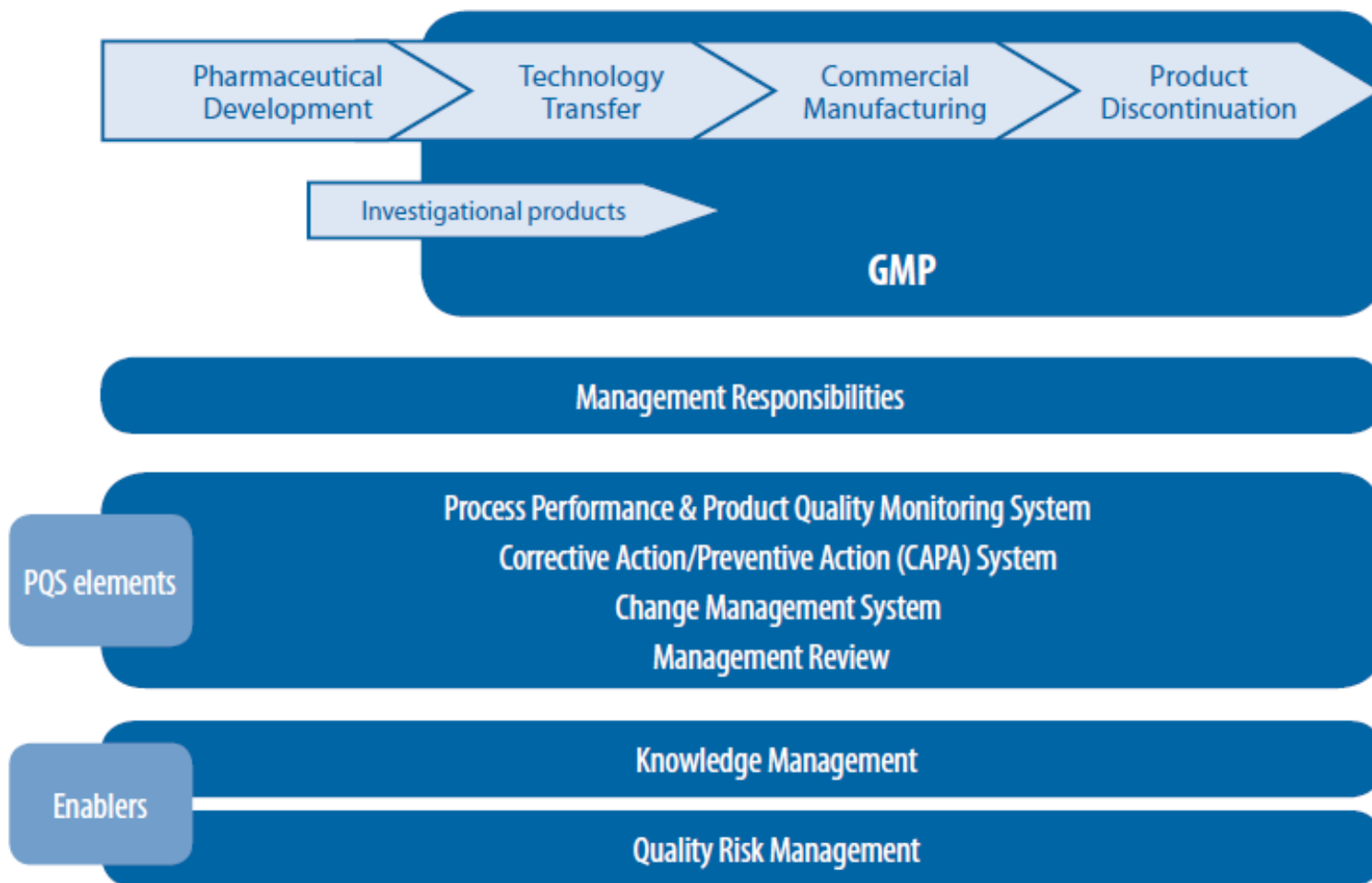
Project Execution and Management

*Contract Manufacturing / Outsourcing
Munich, 23-24 November 2017*

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NNE*



- Align expectations
- Appreciate different cultures and success criteria
- Go in detail – stage by stage
- Nothing is obvious – define/discuss assumptions
- Timeline
- Organization
- Build platform for communication between sponsor and CMO
- F2F meeting – especially in the initial phases
- Responsibility matrix - RACI
- Project Management
- Document decisions and include a communication strategy for all decisions



PQS: Pharmaceutical Quality System

Modular – Copy / Paste

On-site construction, where same type of rooms are build as copies – same size and configuration

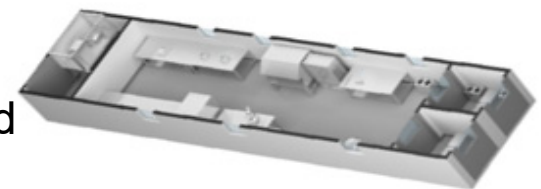
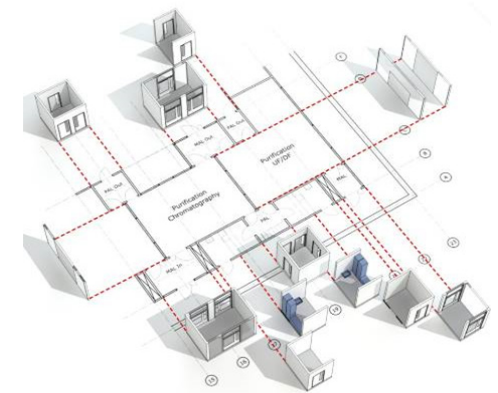
Modular – Off-site construction of building elements – LEGO concept

A method of construction that utilizes off-site pre-engineered, pre-fabricated structures which are reassembled on-site.

Up to 100% of the building and the equipment are already completed and pre-tested at the factory prior to shipping.

Modular – PODular

Full clean-room facilities built in a POD, including HVAC, air locks etc., which is build and qualified off-site. The POD's are then shipped to the site for the pharmaceutical production and connected to the stick built part of the facility.



Legal + technical + quality objectives

For each stage:

1. Objective
2. Assumptions
3. Prerequisites
4. Scope of work
5. Resources
6. Deliveries
7. Documentation
8. Duration
9. Price
10. Predecessor(s)
11. Risk assessment

NETWORK

Partners
Stakeholders

TOOLS

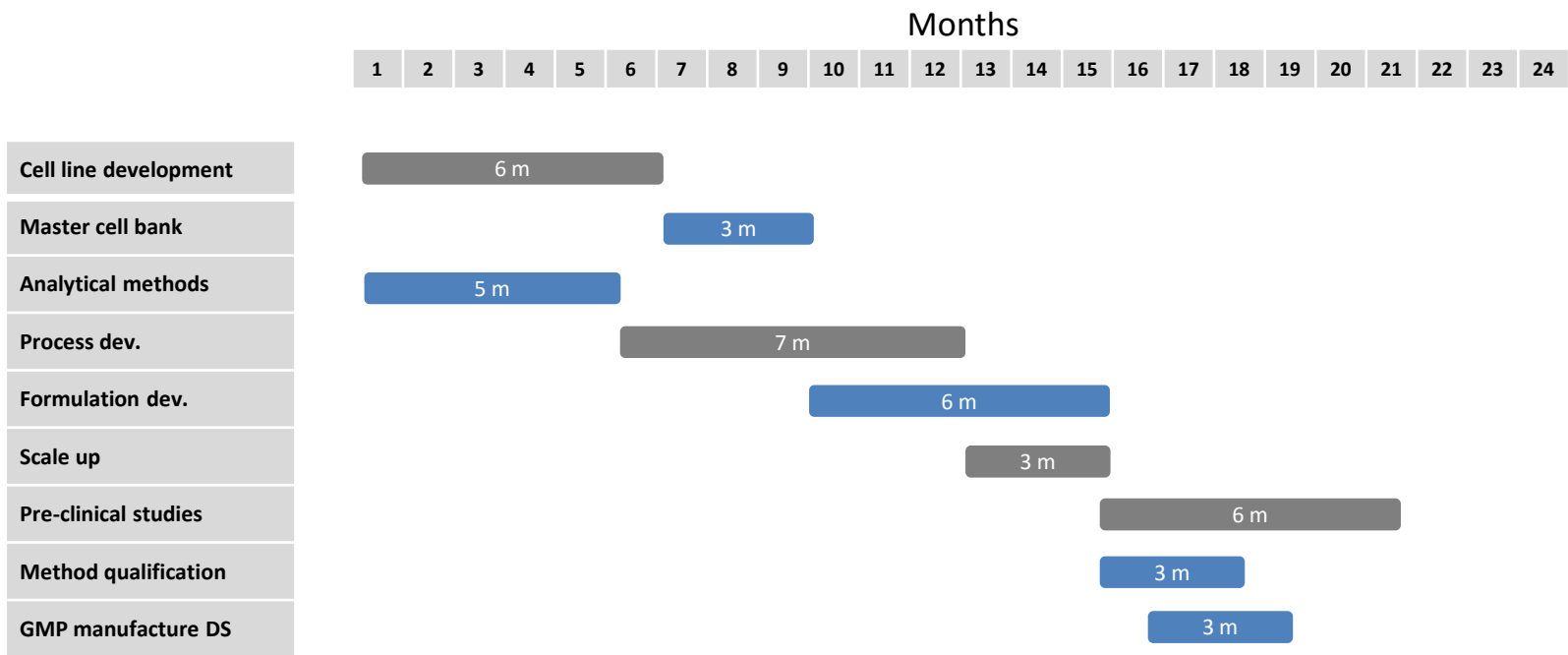
Project plan
Validation plan
Timelines
Budget
Cash flow

DOCUMENTATION

Project index

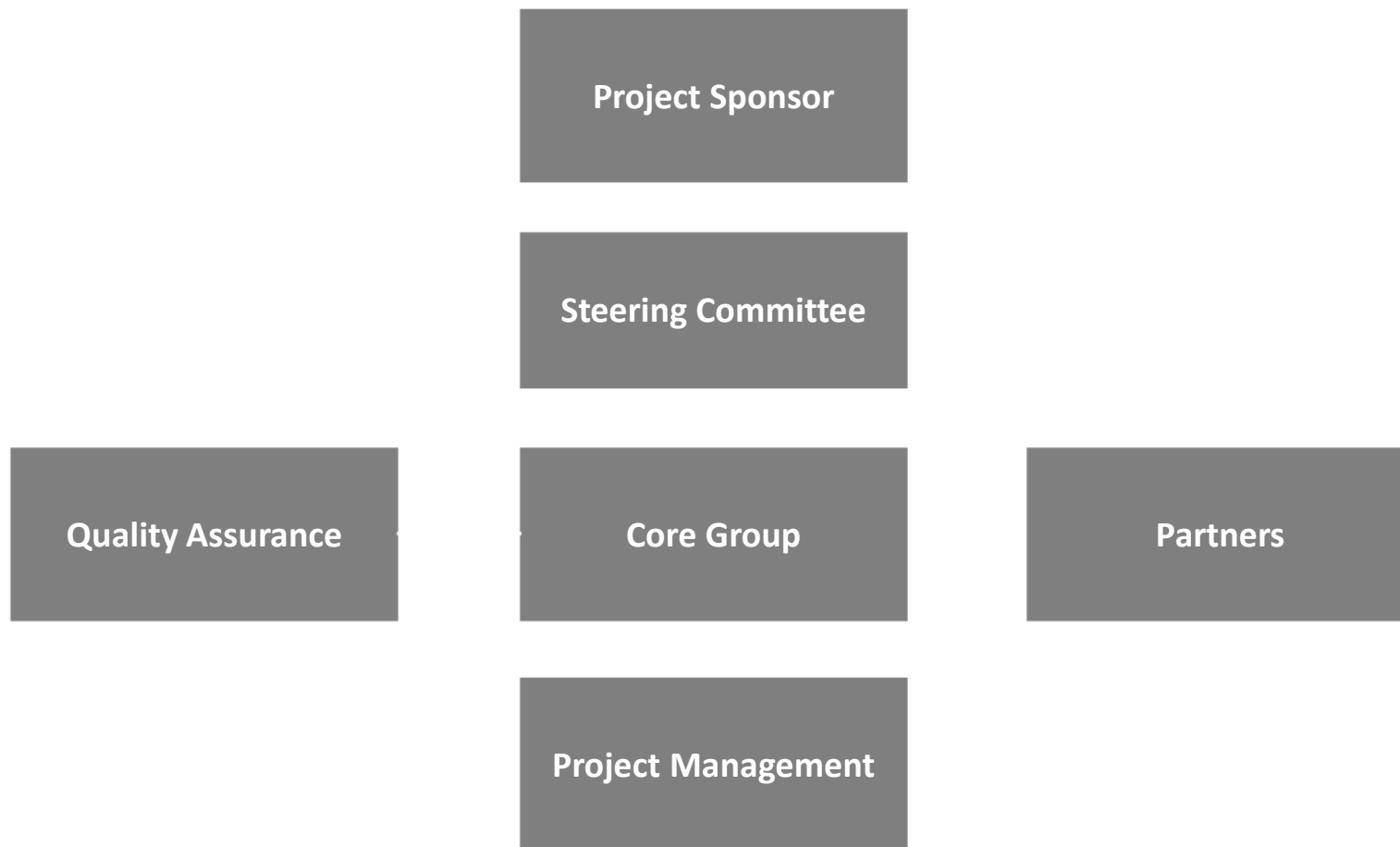


Time Line





Organization





Project Management Structure

Core Team

- The technical decision forum
- Focus on best technical solution, within the limits of the agreed contract
- Frequent meetings, involving all relevant technical parties
- Direct contact scientist to scientist

Steering Committee

- Strategic decision forum
- Members have authorized decision power
- Financial, timeline and issues escalated from Core team
- Long-term strategic project management

Steering Committee

Client & CMO Management

Core Team

Client

Project Manager
Upstream,
Downstream &
Analytical
Development
Quality Control
Manufacturing
Quality
Assurance

CMO

Project Manager
Upstream,
Downstream &
Analytical
Development
Quality Control
Manufacturing
Quality
Assurance



RACI Chart – Decisions and Communication

Responsible for performing the task (can be multiple people)

Accountable for the task being completed/results (only one person)

Consulted with prior to the task being performed (can be multiple people)

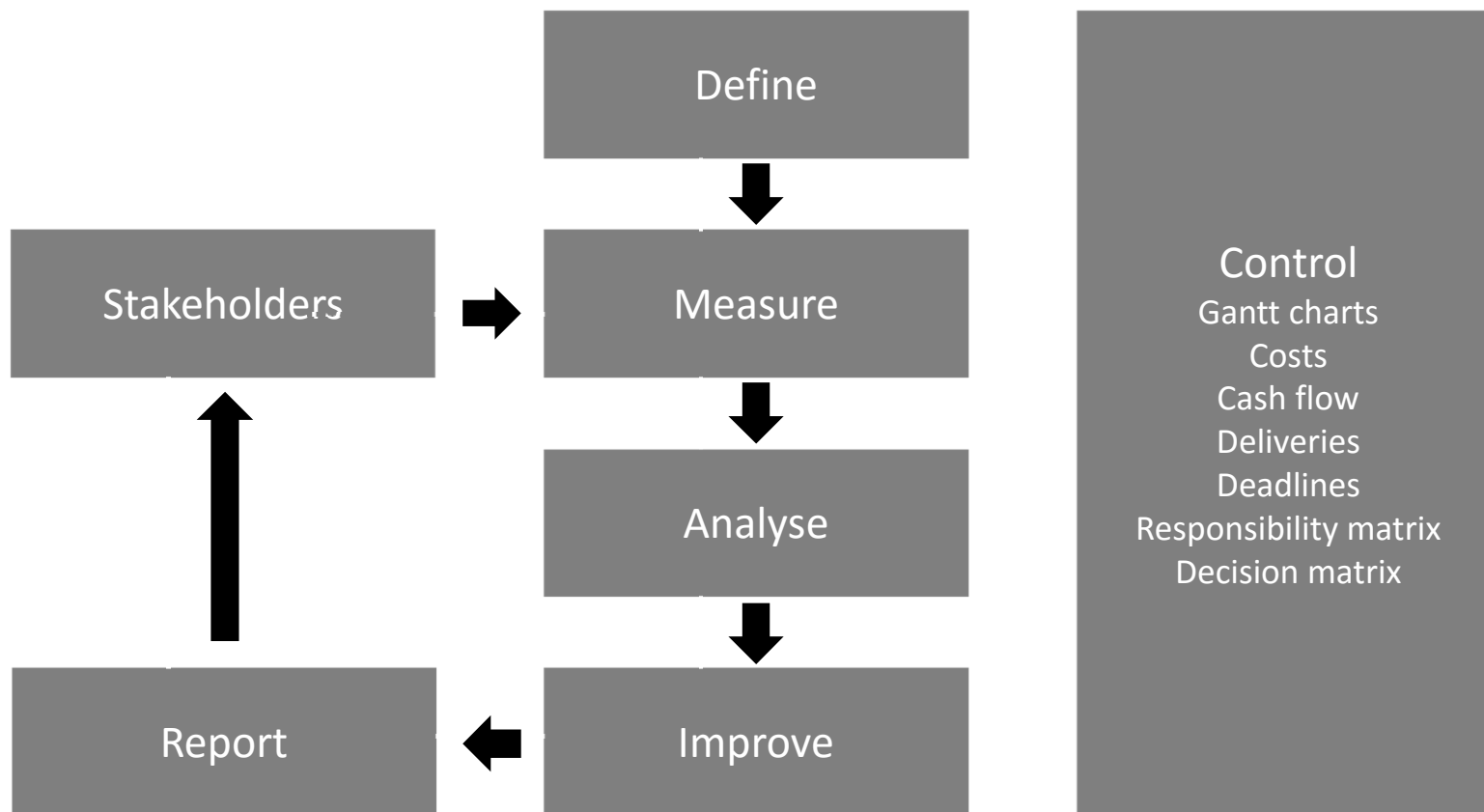
Kept In the loop about the task (can be multiple people)

Activity / Stakeholder	Sponsor Owner	Sponsor PM	CMO BD rep	CMO PM	Steering group	Core Team	Development/ Finance/ Manufacturing /Analytical /etc.
Contract							
Work scope	C	R	A,R	C	R	C	I
Quality agreement	C	R	A,R	C	R	C	I
Price	R	R	A,R	I	R	NA	I / NA
Process							
Specification	I	C	I	A,R	I	R	C
Batch record	I	C	I	A,R	I	R	C
Tech transfer	I	C	I	A,R	I	R	C



Project Manager Challenges

- The project manager is never given enough money, time, and resources
- The PM has little power – most team members report to other departments of the organization
- The PM should be an expert in crisis handling
- Company cultures are different
- Communication skills
- Be prepared for changes
- Consider that people might have different agendas. Balancing the interest of the project and of the respective companies (and maybe of the personal career)



Technical batches

- Risk assessment (reducing the number of technical batches increases risk for Tox and GMP batch failure)
- How many are required?

Tox batches

- No late changes
- Is process design complete?
- Allow one month for finalizing master production records and bill of materials (and even more time if translations are needed)
- Minimize reasons for conflicts

GMP batches

- Preferably no process changes compared to Tox batch

- Lack of communication
- Nothing is obvious
- Define assumptions
- Insufficient process development
- Warnings from small scale and technical batches ignored
- Lack of trust
- Decision-making not clearly defined
- Late or not well-controlled process changes
- Insufficient decision making
- Lack of commitment
- Lack of win – win approach

Failed to
ALIGN EXPECTATIONS