Project Efficiency
Response to Increasing Cost Pressure in the Biopharmaceutical Industry

18. April 2013, Dr. Michael Atzor

Bayer Technology Services
LEGO Starts New Series of Construction Kits “Failed German Megaprojects”

Berliner Großflughafen
BER

Elbphilharmonie
Hamburg

Bahnhof Stuttgart 21
Erweiterung
“Der Geißler”

(announcement in “Der Postillon” dated 18 Feb 2013)
Magical Triangle of Project World for Investments

Costs

Business Case & Project Scope

Quality

Deadlines
COGS Effect on Costs

Our Target: Minimized COGS
Time to Market for Biopharmaceutical Products

DISCOVERY 2-10 years

PRECLINICAL TESTING  Laboratory and animal testing, IND

PHASE I 20-80 healthy volunteers used to determine safety and dosage

PHASE II 100-300 patient volunteers used to monitor for efficacy and side effects

PHASE III 1000-5000 patient volunteers used to monitor for adverse reactions to long-term use

LICENSING  FDA Review, Approval

PHASE IV  Additional Postmarking Testing

Development of Biotech Capacity

Concept and Design Engineering
Construction
Commissioning, Qualification, Validation

Development of Manufacturing Capacity

permits
approval of funds
The Capacity Decision Goal is simple

Commit to capacity as late as possible and at the lowest overall cost …

… without EVER having Supply Constraints
Key Basics to Ensure Efficient Design and Execution of Healthcare Investment Projects

- Stakeholder Engagement and Communication
- Structured Workflows
- Clear Project Organization with Defined Roles & Responsibilities
- Resource Management and Healthcare Expertise
- Build in Flexibility
- Adequate Tools
- Consistent Project Controlling
- Clear Contract and Procurement Management
Phase Model for Healthcare Projects

Phase Structure

- Activity Knowledge Sheets
- Gates
- Milestone

How to Guide
Performance Metrics (KPI's)

Long term opportunity to standardise SOP’s

Web enabled with a search engine

Policies, Directives, SOP’s

Simplified Standardised and Linked

Standard formats (Tools, External Literature, Examples)

Resource Estimating

Generic Scheduler

Proven and refined

Management and Support Processes

Phase Structure

- Establishment of Fundamentals and Preliminary Planning
  - Phase 1: Technical feasibility
  - Phase 2: Technical design

- Basic Engineering
  - Phase 3: Detailed design
  - Phase 4: Detailed design

- Engineering Procurement & Construction
  - Phase 5: Construction

- Start up

- Organic completion

- Ready for production

- Completion of project

- Management and Support Processes
Build in Flexibility
(Time to Market as Top Priority)

Solution:
- Concurrent Engineering (Parallelism of Process Development & Engineering)
- Build in Response Time
- Possibility for Future Innovation
- Fast Iterations & Continuous Feedback
- Modular / Matrix Approach
Impact of Changes & Value Improving Practices

- Technology Selection
- Process Design & Simulation
- Constructability Review 1
- Facility Quality
- Barebone Review
- Procurement Services
- Predictive Maintenance
- Constructability Review 2
- Constructability Review 3
- Authorization

Potential to impact COGS
Project Controlling

- Steering
- Navigating
- Adjusting
Importance of Controlling System

- Preparation (make controllable) “Theoretical Values”
  - Monitor: Forecast and Actual Values
  - Steer: Decide and Act on Deviations
  - Reporting

- Project Scope (Contract Elements)
- Costs
- Deadlines & Work Progress
- Quality

- Organization Structure
- Workflow Organization
- Execution Strategy
- Purchasing and Contracts
Selection of adequate contract type and procurement strategy early on is bases for success and will vary according to project phases and/or business/project model.
Summary of main Drivers of Capital Effectiveness (KPI’s)

Key Leading Indicators

- Business Strategy
- Technology Strategy
- Alignment of Functions
- Front-End Loading
- Use of Value Improving Practices
- Leading Technology

Optimal Scope for Business Needs

- Project Controls
- Team Continuity

Executed With Minimum Change

- Timely Involvement of Contractors/Vendors

SAFETY
- Low Cost
- Fast Cycle Time

BETTER VALUE
- Facility Quality
Key Success/Risk Factors for Efficient Project Design & Execution

TOP 5 Do’s

- Ensure required and experienced resources are fully dedicated (sufficient, knowledgeable, empowered)
- Establish well defined Roles & Responsibilities (e.g. RACI)
- Live/apply the established procedures, workflows and best practices
- Define clear escalation process to drive decisions
- Build trustful relationships inside team and stakeholders
Key Success/Risk Factors for Efficient Project Design & Execution

TOP 5 Don’ts

- Avoid changes/turnover in project leadership and core team members
- Avoid unneeded interfaces to reduce complexity and streamline communication
- Don’t commit to unrealistic cost & timelines
  (quote Ed Merrow IPA Inc.: “There are too many business cowboys with weak accountability for results driving the projects too fast”)
- Avoid unnecessary strain on team members to prevent burn outs and demotivation
- Avoid ambiguity in assigning responsibilities and in defining scope
Thank you for your Attention!