



M+W Zander Present: Total Solutions for Biopharmaceutical Projects in China

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Total Solutions for Biopharmaceutical Projects in China

Investing in China? Yes, it is a great idea....but

- What should I know as investor about China specifics?
- How to approach complex life science projects?
- How to get entire project from one single partner?
- What is critical in project execution?

We, M+W Zander are pleased to provide answers to the above questions and indicate key aspects of the project execution in China, share our experience and expertise with you.

The following presentation will not only reflect turn key solutions but also the overall project approach and critical issues during project life cycle base on our experience in China.

Advantages of Investments in China

- China is one of the largest economies with annual growth at 10% in the last years and 6% during global recession in 2009
- China population exceeding 1.3 billion represents huge consumer basis
- Attractive incentive programs for new facility establishments
- Lower construction and manufacturing cost
- Existing large number of local, JV and foreign owned biopharmaceutical facilities in China
- Lower new biopharmaceutical drug development costs
- Education system at reasonable level allowing manufacturing and R&D staff recruitment
- Well established infrastructure in major cities is creating good basis for the new facilities

Investment Concerns in China

- Intellectual Property Risk despite official governmental policy
- Ongoing changes in law, regulations and their interpretation
- Extensive project approval process
- Material and service cost fluctuations
- Necessity of good relationship with local authorities
- Local material and component quality challenges
- Average low safety level by local subcontractors
- Importance of the project location – region, city, industrial parks
- Involvement of Local Design Institutes, General Contractors and other third parties (Accredited Checker, Jianli, etc.)

How to Minimize Investment Risk

- Conclusion: China is attractive market but with risks and traps for newcomers but also for previously established investors.
- In order to minimize investment risk there is a need to have reliable partner that will lead you through the whole project life cycle.
- Such partner is M+W Zander (Shanghai) Co., Ltd.
- Well planned project approach under consideration of all legal, market specific, resource and technical aspects will minimize project risks.



- Established in China since 1994
- Current headcount in China 530
- Head office in Shanghai and project offices across the nation
- More than 250 executed projects in China

Step by Step through the Project...

- I like to bring you step by step through various investment aspects and project phases.....

Site Selection

- It is essential during early project stage to obtain correct and objective investment status overview and define the project objectives. Project location is one of the major decisions at early stage.
- Site Selection Study provides data supporting decision on project location.
- MWZ have the knowledge and experience to lead you through site selection process.
- As result, optimized solution will be proposed that considers all specific project requirements and constrains.



Site Selection, Cont.

- Site selection criteria depend on project nature. For example a R&D facility will consider different criteria comparing with a packaging facility.
- In general, the following site selection criteria should be considered:
 - Land Availability
 - Park History and Development Plans, including previous use of the land, the development objectives, the time lines for development and specific industries being targeted for the “industrial zone”
 - Companies and industries surrounding and close to the available lots
 - Parks attributes for defined technology, the financial incentives/ advantages
 - Describe the park governance structure, defining the permitting and taxation authorities, local, provincial and national
 - Land use limitations. What are the limits on plot ratio, building lot coverage, building height, building floor area, number of floors and type of use
 - Utility Requirements and Capacity Availability

Site Selection, Cont.

- General industrial waste removal facilities
- Residential, education or other resource around the park
- Logistic and transportation of the park
- Tax Incentive, other incentives
- Land, utilities, service costs

Early Consulting

- Early Consulting helps investors to understand and define complex project establishment requirements, outline project strategy, understand authority approval process and other legal project aspects.
- Consulting stage provides overview about the local Chinese GMP (SFDA) specific requirements in comparison with US and European GMP guidelines.
- Initial facility concepts and high level site master plan are developed to allow first contacts to the industrial parks that will initiate further site transfer negotiations.
- First budget estimate will be provided for overall investment cost definition. Local versus imported material purchasing will be evaluated.
- Milestone schedule will be generated.



Authority Management

- One of the most critical and challenging aspects for the investments in China is the understanding of complex authority submission and approval processes.
- The authority project involvement starts at the early project stage and continue till the final acceptance of constructed facility.
- There are differences in regulations and their interpretations in provinces, cities, parks and even different officers may have different opinion.
- Incorrect authority requirement interpretation may cause significant project delays.
- Example: for investments exceeding local approval level, central authority approval in Beijing is required. Such approval process may last several months longer comparing with local one.
- Our experience is that the approval process takes always longer as indicated by the local authorities during site selection process.

Authority Management, Cont.

- How to minimize risks and unexpected project impact from the approval process:
 - There may be decisions and approvals required on the state, municipal and park level. Early evaluation process and communication with the authorities is essential.
 - It is important to identify the authorities that are of relevance for the project.
 - Contact authorities at early stage and follow up regularly with project data and status communication.
 - It is important to ask correct questions and evaluate the answers carefully.
 - In case of deviation from the applicable regulations provide sophisticated documentation explaining clearly the reasons for the proposed solutions and approach to be as close as practicable to the requirements.
 - Consider all site inspections with timely information to the authorities
 - Follow up the proper documentation from the construction, commissioning and validation stages.
 - Consider required and certified third parties in the project work.

Project Contractual Strategy

- It is important for each investor to have good understanding about project contractual strategy at the early stage.
- There are various options possible that should be evaluated by the investor based on various aspects:
 - Local market knowledge and team experience by the investor
 - Available own resources
 - Schedule
 - Budget
 - Anticipated quality level
 - Targeted compliance level (local, international, GMP, LEED, etc.)
 - Targeted client's and their expectations level
 - Project image

Project Contractual Strategy, Cont.

- EPCM service agreement based on the agreed lump sum.
- EPCM service agreement, reimbursable based on the agreed hourly rates plus expenses.
- Service agreements may have GMP cap (Guaranteed Maximum Price), incentive program for budget, schedule and safety.
- Service agreement can be negotiated phase by phase (Concept, Basic, Detail Design, Procurement, Construction Management, Commissioning, Validation) or agreed for several phases or entire project duration.
- Engineering agreement with follow up Design/Builder (EPC) lump sum agreement for the execution of entire project. Engineering company hold subcontractor's contracts. Client may keep contracts for process and laboratory equipment, office furniture, etc.
- Turn key approach agreed after engineering progress allows clear and safe definition.

General Contractor Selection

- There is legal requirement for construction license obtaining that a General Contractor will be appointed for the project.
- Selection of the GC for the project is one of the critical decision that the investor has to made.
- M+W Zander (Shanghai) has the required licenses allowing us to be registered as General Contractor.
- Such solution is accelerating the project schedule since agreement can be achieved before entire project will go into tendering phase for construction.
- Selection of MWZ is providing higher level of confidence for our clients in comparison with local construction companies.



Local versus Imported Material Selection

- There is fast development of production capabilities in China based on local, JV and foreign manufacturers.
- The relation between imported versus locally produced components is shifting fast by increment of locally sourced materials.
- MWZ perform careful vendor evaluation, factory audits, raw material source evaluation, quality management system availability, manufacturing, installation and after sales service capabilities review.
- Since market development is dynamic, knowledge of the actual status and possible achievable quality level is one of the aspect for successful project execution.



Engineering

- It is essential that engineering company has available resources in all disciplines in China that are required for the project performance during all phases.
- Solid knowledge of local engineering codes, regulations and standards combined with internationally experienced experts provides unique basis to fulfill project requirements.
- Project Execution Strategy will be developed at early stage to define project objectives, standards and working methods.
- Regular meetings, reviews and workshops with involved in house and external specialists, client and other involved parties support proper design development.
- Careful documentation and document control provide proper basis for future project work.

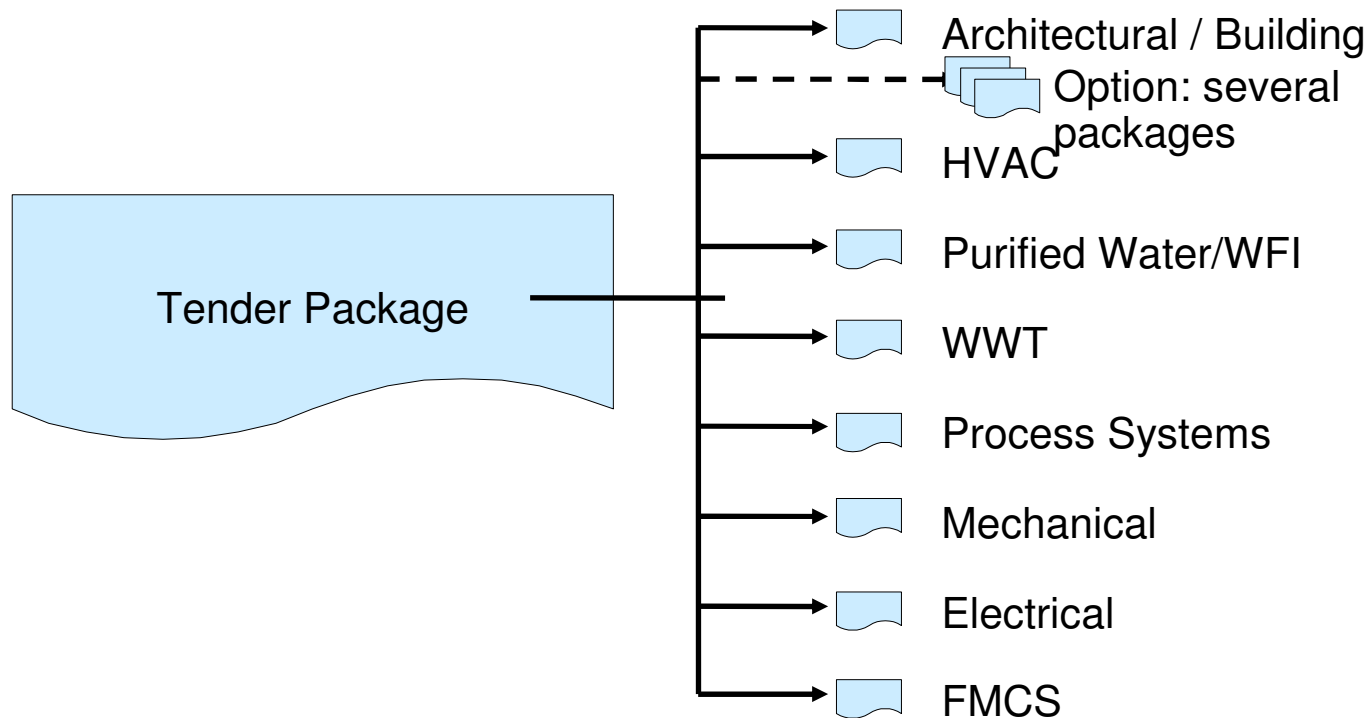


Procurement Services

- Develop Procurement Strategy including package break down and offshore versus onshore material purchase plan.
- Identify potential subcontractors and agree upon bidders list.
- Develop tender documents.
- Check subcontractor or vendor bids.
- Provide Bid Clarifications.
- Review/evaluate/recommend award.
- Prepare contract documentation for all bid packages.
- Budget control during project duration.
- Payment management.
- Change commercial management.
- Commercial project close out.

Tender Package Breakdown

Tender package structure should be followed during engineering stage to support tender document preparation and during budget estimate to provide clear structure for cost control.



Construction

- M+W Zander in China can execute projects in Turn Key, General Contracting, Open Book, GMP, EPC or EPCMV contractual scenario.
- We have solid knowledge about all specific construction aspects: Safety, Procurement, Contracting, Construction Management, Site Management, Commissioning and Qualification that can be utilized in the Client's projects.
- Unique construction methods, site office set ups, workers quarters site arrangements are well known aspects for our construction management team.



Safety

- M+W Zander in China is aiming highest safety targets in the projects – incident free project execution.
- Our safety targets are far above average safety behaviors of local subcontractors and vendors.
- Safety awareness and safe behavior must be understood and followed up by everybody.
- Therefore safety programs are in place and the implementation during design, pre-construction and construction is addressed to the project management and safety team on site.
- Training and daily supervision, preventive measures are in place to minimize the risk.
- Safety is everybody's responsibility.



Safety Challenges – Awards and Celebrations



Safety Challenges – Lifting activities



Safety Challenges – Proper PPE (?)



Safety Challenges – Signage and Inspections



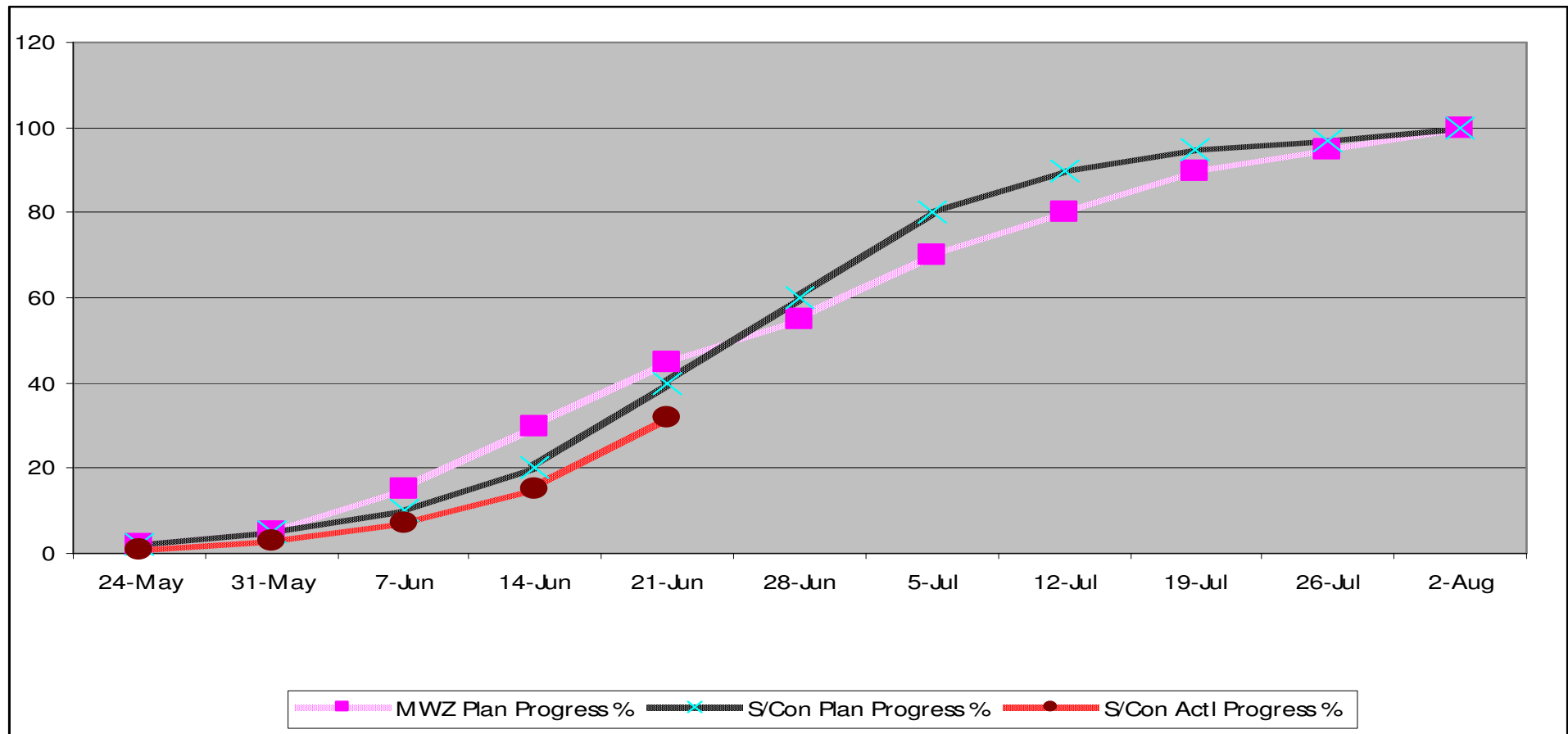
Scheduling

- Project schedule must consider all relevant authority submissions and approvals with sufficient buffer.
- Master schedule reflects all essential milestones and major project activities.
- Detailed schedules for design, procurement, installation, commissioning and validation activities.
- 90 days rolling schedule with major milestones.
- Two-week working co-ordination schedule.
- Check on efficient utilization of resources.
- Monitor construction progress against plan.

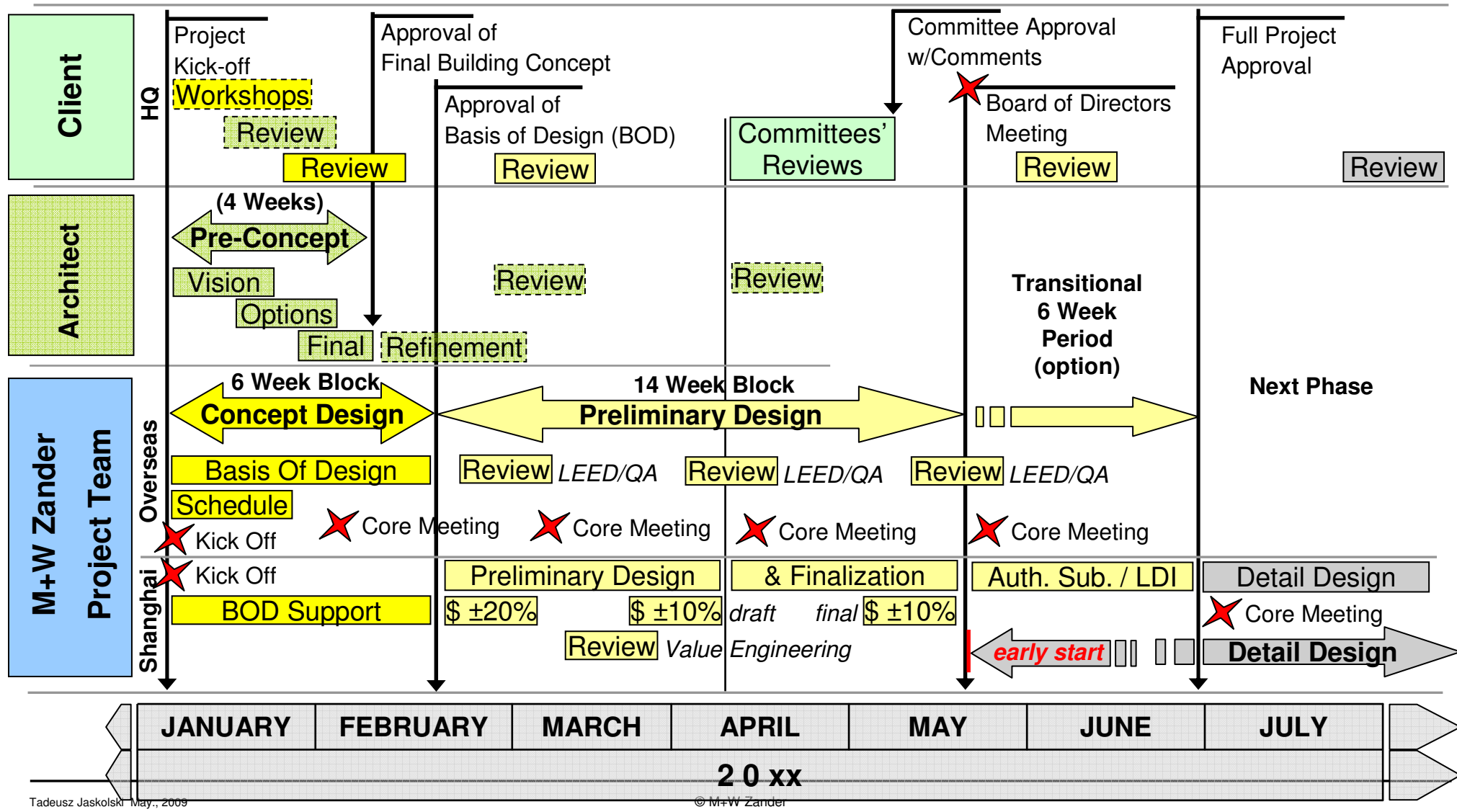


Detail schedules should be based on the material quantities, estimated duration per installation unit and manpower requirements.

Sample Schedule – Plan versus Actual Progress

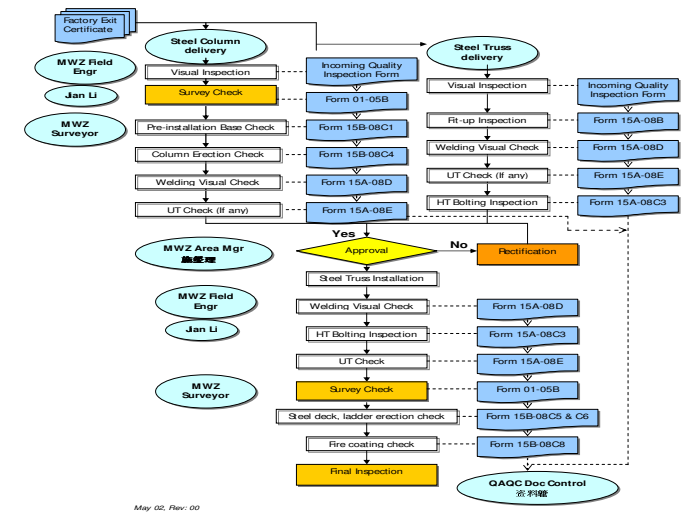


Project Schedule – Short Term Timeline



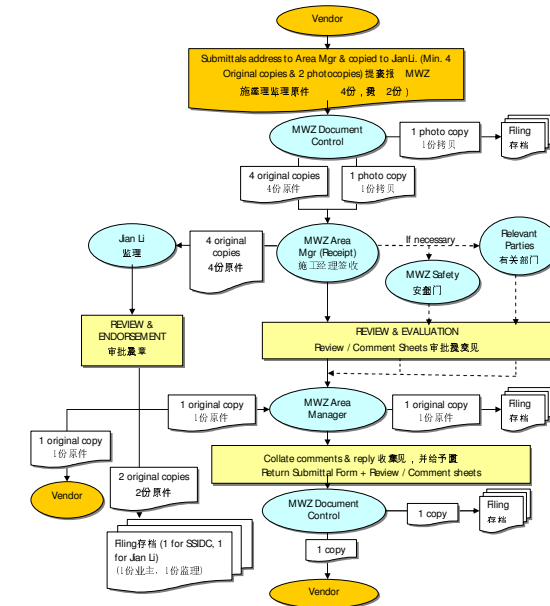
Quality Management

- Quality is one of M+W Zander's priority in the project execution.
- M+W Zander has established a corporate Quality Management manual which outlines the corporate approach so that the company objective of client satisfaction, economic efficiency and employee satisfaction can be realized in accordance with the International Quality Standard.
- Quality Implementation is progressing from design through construction, commissioning, qualification till final hand over.
- Quality programs, reviews, inspections, preventive and corrective actions are reinforcing team activates that are targeting quality objectives in the project.
- To achieve designed quality permanent and very close supervision during entire construction phase is required



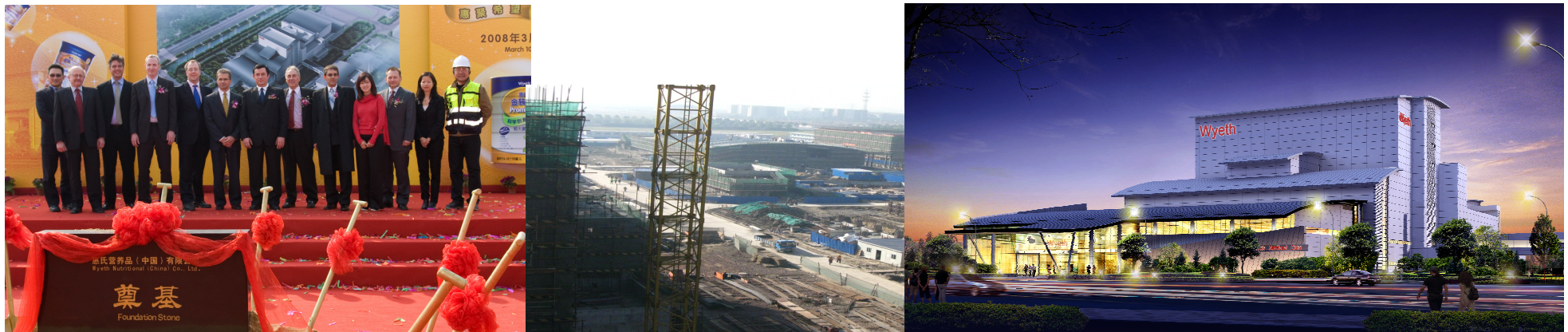
Qualification and Validation

- M+W Zander help clients to understand specific qualification and validation requirements that have to be followed in the projects.
- We support integrated approach with integrated commissioning and qualification process.
- Subcontractor and vendors are involved in the C&Q process under supervision of our team during protocol development and execution phase.
- Project approach and synergy usage are resulting in the schedule and cost savings.



Conclusion

- It is essential to identify all project critical aspects at early stage following by customized execution strategy.
- Successful project approach in China require solid partnering with engineering company experienced in China such as M+W Zander.
- Company that will guide you through all project life cycle in consulting, engineering, construction and qualification.



Contact in China

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Thank You!

