Project Management in the Pharma Industry based on PM@SBT
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The pharmaceutical industry is one of the most regulated industries in the world. The main purpose of this regulation is to protect the public health. There are special procedures (GMP or GxP) for all processes, which could have an impact on the drug quality. Often the building infrastructure also has an impact on the drug quality, e.g., the air treated in a HVAC system, the flow of people controlled by an access control system, or through an environmental monitoring system, which provides the information if a drug can be released or not. The plants in the pharmaceutical industry usually are running 7/24. So each shut down e.g., from a HVAC system not only causes a business harm worth up to millions, it can also result in a down time of a week or more. Due to these reasons, the pharmaceutical industry requires a special way of project execution and operation of the sites.

Siemens has established an excellent project management procedure with PM@Siemens and the application PM@SBT. This document provides you with an overview, how to apply PM@SBT for Pharma projects, where the special issues are and where should be taken care during the execution of projects in the Pharma Industry.

Successful project management relies on adherence to certain basic principles. Clearly defined project workflows ("phase model" and "milestones") as well as the specification of clear and unambiguous responsibilities for the various project phases and tasks ("roles") of the project together with comprehensible targets for all of those involved are the key factors for success. Project management thus involves leadership tasks, organization, techniques and means for performing the project flow in such a way that the cost, deadline, and functionality targets can all be met satisfactorily.

These PM guidelines aim to define and implement a consistent, high standard of project management and qualification in all sections (national and regional companies). This process is supported significantly with the electronic validation tool EVT, provided from the Center of Competence Pharma. It applies equally to large and complex projects as well as for small and straightforward projects.

To reduce the project risks for our customers and for us, the Center of Competence Pharma has established a certification process for the local GxP project execution. Based on a comprehensive assessment, we support the local organizations to establish the proper processes, to acquire the required knowledge and to pass the audit successfully.

By applying PM@SBT for Pharma, consistent processes can be optimized and risks minimized; efficiency, quality, and planning security are all increased simultaneously.
**Bid Preparation**

**User Requirement Specification (URS)**
This describes what the equipment or system is supposed to do, and as such is normally written by the pharmaceutical manufacturer. This links to performance qualification, which tests these user requirements.

Any project within the pharmaceutical industry that requires Validation, should have an available URS, User Requirement Specification. The URS is a prerequisite for Validation, and must include details of the scope of the Validation and is required to qualify the project and provide an accurate quotation. In the event that the customer does not have the capacity or skills to produce a URS, Siemens can assist in the production of a URS, or even produce a URS on behalf of the customer.

**Impact Analysis**
The scope of the impact assessment is to evaluate the impact of a system on product quality. Those systems having a direct impact on product quality are subject to qualification practices in addition to Good Engineering Practice (GEP). Indirect impact or no impact systems are designed, installed and commissioned according to GEP only. This allows appropriate effort and focus to be concentrated on the quality impact systems. Siemens provides a service to support the impact analysis for the customer.

**Risk Assessment**
The Risk Assessment will be used to assess systems (these can be a building management system, a HVAC, a project risk, etc.) which due to a failure can lead to a risk that can have an impact on product quality or data integrity. It will provide a base for decision that determines the amount of measures and tests during the validation process to beware or minimize potential risks. Siemens provides a service to support the risk assessment for the customer.
PM@SBT Pharma – Execution

**Execution Phase**

- **Project Opening**
  - PM100

- **Detail Planning**
  - PM200

- **Purchasing Manufacture**
  - PM300

- **Dispatch**
  - PM400

**Installation**

- PM550

**Commissioning**

- PM580

**Acceptance**

- PM590

**Operating Phase**

- PM600

**Warranty**

- PM650

**Process**

1. **Enter Order/Establish PM Goals**
   - Finance
2. **Initiate / Set up Project**
   - Monitoring & Controlling
3. **Obtain Deliverables from Enabling Processes**
   - Project Manager
4. **Audit Suppliers & Audit of customer**
   - Logistics
5. **Daily Material Requirements**
   - Material Requirements Resourcing Planning Engineering Subcontract Procurement
6. **Defining Deliverables from Enabling Processes**
   - Project Change Management
7. **Kick-off meeting with the customer**
   - Project Manager
8. **Review Defining the Project**
   - Project Manager
9. **Define URS**
   - Revision
10. **Risk Assessment**
    - Project Manager
11. **Defining Project Organization & Responsibility Matrix**
    - Pharma Specialist

**Reporting Output**

- **Target agreement PM700-1**
- **Project Schedule PM700-2**
- **Issue list PM700-3**
- **Master Validation Plan (customer) VA100-1**
- **Audit Report Suppliers VA100-2**
- **Audit Report Siemens VA100-3**
- **Project Validation Manager CoC Pharma**

**Performing Function**

- **Contracting Execution Manager**
- **Project Manager Project Controller**
- **Project Manager**
- **Project Manager**
- **Project Manager**
- **Project Manager**
- **Pharma Specialist**
- **Local Pharma/Validation Manager**
- **Customer**
- **Local Pharma / Validation Manager**
- **Local Pharma/Validation Manager**
- **Local Pharma / Validation Manager**
- **Local Pharma / Validation Manager**
- **Local Pharma / Validation Manager**

**Review**

- **Local Pharma Manager**
- **Local Pharma Manager**
- **CoC Pharma**
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**Project/Validation Manager**

- **PM850**
- **PM800**
- **PM590**
- **PM550**
- **PM700**
- **PM670**
- **PM@SBT Pharma – Execution**

**Sales**

- **Service**

**Execution**

- **Version 2.9**

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Project Opening

Audit
An activity to determine through investigation the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards or other applicable contractual and licensing requirements, and the effectiveness of implementation of a vendor.

As an offer to our customers, Siemens can provide the customer access to an audit report of our development in Zug made by external auditors.

Project Specific Quality Plan (PSQP)
Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract. This Project Specific Quality Plan (PSQP) defines how Siemens Building Technologies will fulfill both Siemens and customer quality requirements of the project as they relate to the design, supply, installation, and commissioning of the Building Management System (BMS) for the customer plant. The PSQP defines the activities to be performed, their timing, which will perform them, the control mechanisms to be used, and the deliverable items.
Detail Planning

Hardware Design Specification (HDS)
The Hardware Design Specification is to specify and document the choice of control and electric components. The Hardware Design Specification concerns design and construction which requires particular attention, including the choice of:
- Servers and hardware configuration of these
- Clients and hardware configuration of these
- Network components
- Printers and monitors
- External storage medias
- Controllers, I/Os, and sensors
- Uninterruptible power supply

The HDS, Hardware Design Specification, should be completed and signed off by the customer during this step.

Hardware Configuration List (HWCL)
The purpose of the Hardware Configuration List is to have a detailed document of: The firmware versions, internal hardware settings through jumpers and switches, used network IP addresses, serial numbers and computer hardware configurations; i.e. for the components that are assigned with a configuration item index number (CI) in the main configuration drawing in the document.

Software Design Specification (SDS)
The SDS describes how the software will be configured to achieve what the BMS is designed to do and provides a list of design objectives, as well as identifying system limitations, as detailed in the URS document and in sufficient detail to avoid any ambiguities.

Software List (SWL)
This SWL will list the software for Siemens BMS Pharma system. This software list is an appendix to the software design specification.

Test Plan / Protocol
A document describing the scope, approach, resources, and schedule of intended test activities. It identifies test items, features to be tested, testing tasks, who will do each task, and any risks requiring contingency planning.

Test Protocol
Detailed instructions for the set-up, execution, and evaluation of results for a given test case. After execution of the tests the test plan will be our protocol.

Design Qualification (DQ)
Design Qualification, formal and systematic verification that the requirements defined during specification are completely covered by subsequent specification or implementation.
Purchasing Manufacture

Factory Acceptance Test (FAT)
The Factory Acceptance Test (FAT) is executed after completion of system implementation at the system supplier’s site. At the end of the FAT the client should agree to the delivery of the system. An additional advantage of an extensive FAT is to detect possible faults in software programming early and to be able to correct them prior to the installation of the system at the client’s site, so that the commissioning can be executed quickly. As far as possible the FAT should be executed with the original system equipment and can be supported with the help of simulated processes and test programs.

Qualification

Installation Qualification (IQ)
This is a documented verification that all key aspects of hardware installation adhere to appropriate codes and approved design intentions and that the recommendations of the manufacturer have been suitably considered.

IQ Protocols should include
- Documentation – introduction, objective, signature record, abbreviation and definitions, documentation checks, conclusions and approvals.
- Hardware – drawing information, major hardware components, locations, pre-start hardware checks.
- Software – software version numbers, service pack number. Pre-start application software checks.
- Installation procedures – installing the software on the target hardware platform.
- Calibration – schedules, certificates.

Operational Qualification (OQ)
This is a documented verification that the equipment-related system or sub-system performs as intended throughout representative or anticipated operating ranges.

OQ Protocols should include
- Documentation – introduction, objective, signature record, abbreviation and definitions, documentation checks, conclusions and approvals.
- Hardware – digital input/output tests, analogue input/output tests.
- Software – system security tests, computer functionality tests, operator control tests, invalid input tests.
- Systems – control system sequence tests, control system alarm tests.
- General – stress/recovery tests, source code audit, software version tests.
- Flow measurement devices
- Temperature/humidity devices
- Alarms and alarm messages
- etc.

Note:
Siemens Building Automation is normally not directly involved in PQ.

IQ/OQ Report:
After the tests of all test phases are executed according to their specification and the single test results are evaluated and no major deviations are left, the end of the qualification phases has to be documented. The Qualification Report is created by the client/system supplier. It summarizes the test results of all test phases, e.g. FAT, SAT, IQ, OQ.

Deviation List:
To each test phase one Deviation List has to be included. It contains test points that were not evaluated as successful, i.e. the specified acceptance criteria were not fulfilled. The Deviation List is appended to the xQ-Report. Further on in the master exemplar (not in any copy!) of the Deviation List the correction of the defects has to be signed by the respective person and to be approved by the client.

Acceptance

Validation Report
Whatever the scale or scope of the project, there is always a requirement to issue a final Validation Report which summarizes the entire project, measures its ultimate success, and clearly signifies acceptance of a final solution by the user and quality assurance. This report should document the outcome of activities defined in the validation plan.
PM@SBT Pharma – Service

Service

**Service-Phase**

**Lead-Generation**

- Assign Service Sales Resource
- Include Lead in Service Sales Funnel (Prospect List)
- Check Handover Checklist for Prospect / Customer
- Identify Key Customer Prospect Contacts

**Qualifying & Verification**

- Obtain approval
- Arrange Customer / Prospect Contractor Visit
- Prepare customer / prospect contact in line with segment and opportunity
- Analyze business opportunity & integration of SBT capabilities (linked with SBT modules)
- Complete Customer Mapping
- Generate Qualification Profile

**Proposal Generation**

- Negotiation
- Subcontract Procurement
- Scope confirmed Software Data

**Service Negotiation**

- Complete Qualification Profile
- BT 410 Qualified profile reviewed & verified
- Customer Offering
- BT 410 Target Leads Identified
- Analyze business opportunity & integration of SBT capabilities (linked with SBT modules)
- Complete Customer Mapping
- Qualification Profile

**Service-Phase**

**Handover & Execution**

- Complete Qualification Profile

**Service Execution**

- BT 410
- BT 420
- BT 430
- BT 440

**Service Settlement**

- BT 410

**Process**

- Assign Service Sales Resource
- Include Lead in Service Sales Funnel (Prospect List)
- Check Handover Checklist for Prospect / Customer
- Identify Key Customer Prospect Contacts

**Review**

- Service Manager
- Local Pharma Manager
- Service Support
- Local Pharma Manager
- Service Supervisor Sales Rep.
- Local Pharma Manager
- Service Sales Rep.
- Local Pharma Manager
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- Service Sales Rep.
- Local Pharma Manager

**Reporting Output**

- BT 410
- BT 420
- BT 430
- BT 440
<table>
<thead>
<tr>
<th>Process</th>
<th>Reporting Output</th>
<th>Performing Function</th>
<th>Review</th>
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<td>Prepare Service Proposal incl. Duration</td>
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<td>Service Sales Rep.</td>
<td>Pharma / Validation Manager</td>
</tr>
<tr>
<td>Review Service Proposal</td>
<td></td>
<td>Service Sales Rep.</td>
<td>Local Pharma Manager</td>
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<tr>
<td>Service Proposal Complete</td>
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<td>Service Sales Rep.</td>
<td>Pharma Manager / Project Controller</td>
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<td>Submit Request Service Proposal</td>
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<td>Service Support Sales Rep.</td>
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<td></td>
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<td>Service Support Sales Rep.</td>
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<tr>
<td>Negotiation Service Proposal Pharma</td>
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<td>Service Sales Rep.</td>
<td>Local Pharma Manager</td>
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<td>Adjustments Required</td>
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<td>Send Confirmation and Copy of Contract to customer</td>
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<td>Service Support Sales Rep.</td>
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<td>Verify Handover Documents &amp; Address Changes out of Negotiation</td>
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<td>Service Sales Rep.</td>
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<td>Conduct Handover Meeting / Submit Handover Checklist</td>
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<td>On-Call</td>
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<td>Service Planning</td>
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<td>Service Settlement (in case of existing customer)</td>
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<td>Service Sales Rep.</td>
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<td>Request for Proposal from existing customer only</td>
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<td>Service Sales Rep.</td>
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<td>Qualifying &amp; Verification</td>
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<td>US Service Sales Funnel Tool BAU (PM440-1)</td>
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<td>Analysis Win/Loss &amp; Win/Loss Reporting</td>
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<td>PART11 Audit Consulancy</td>
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<td>Risk Assessment UK-450-2</td>
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**Process Steps:**
- PM@SBT
- Pharma specific step
- Pharma specific Documents
- Original Document of PM@SBT
- Pharma Sales Rep.

**Original Document:**
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Service Lead Generation

The Lead Generation step in the service sales process includes activities that lead to prospecting for customers and covering their potential needs. A strategy is planned based on these needs and questions and implications are prepared for use during this phase.

Qualifying & Verification

The QUALIFYING step of the service process identifies the customer’s service needs and links them to Pharma service modules. The service salesperson relies on knowledge of our service capabilities, knowledge of the customer’s market drivers and specific goals, and on sales skills and techniques to determine the needs of the customer.

Once needs are acknowledged in consultation with the customer, the Customer Requirement Solutions Matrix is used to quickly highlight applicable solutions to address those needs.

The VERIFICATION step confirms the importance of the customer’s needs or requirements. Potential services are positioned as solutions to meet their needs or satisfy their requirements.

Proposal Generation

In this step a proposal or a site specific contractual agreement (Service Level Agreement) is created to document the scope of recommended services. The customer-specific service concept not only covers the services from the Pharma Service Program but also includes "traditional" Advantage Services™ specially adapted to Pharma.

Pharma Service Concept

The Pharma Service Concept for maintaining a validated state is divided into three main groups:

- Compliance consultancy (URS Consultancy, Impact Analysis, Risk Assessment)
- Business continuity (Backup Integrity, System Integrity, Archive Test)
- Validation review (Part 11 Audit, Calibration, Baselining)

The program’s modular structure allows us to offer an individual service program tailored to the customer’s needs:

Each module specifically offers:
- Standard operating procedure (SOP) for executing the service
- Required tools and processes
- Required checklists to support our experts on-site
- Expert training

Service Negotiation

The NEGOTIATION step involves obtaining the approval of the customer and conforming acceptance of the terms and conditions identified within the service contract. The salesperson addresses the entire contract, including scope, price, terms and conditions and service dates.

Service Handover Execution

During the HANDOVER phase, the service team clearly understands and delivers the individual, customer specific service concept or standard service package identified in the service agreement.

When executing services in a critical environment, the service staff must be trained on how to operate in this environment and be fully aware of the customer’s change management procedures.

A formal analysis of the possible impact of any planned changes to a validated system, combined with a risk assessment, is required.

All changes to existing systems must be formally approved from the customer prior to execution.

Compliance Consultancy

Validation Review

Business Continuity

Your individual Service program
The information in this document contains general descriptions of technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.

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