ROLLOUT GUIDE | SOLABS QM

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1. Purpose of this Document

This guide contains information about the implementation of SOLABS QM from the client's perspective, and begins after the Kickoff Meeting, which is the official start of the implementation project.

The Guide is organized as follows:

- Overview of the key activities in the implementation project.
- Client's main responsibilities are described.
- Detailed discussion of each of the key activities.
- The administrative elements: people, meetings, etc.

If your implementation includes installation of any of our off-the-shelf (OTS) QM Apps, it is assumed at this point that you have already chosen their particular "flavor". See Section 5.4 for more details on flavors and naming conventions.

2. Overview of an Implementation Project

There are a number of activities in the implementation project – depending on the SOLABS QM options and add-ons that were selected by the client. No matter which features were selected, the implementation begins with the **Software Configuration, Workshops & Trainings** activities and ends with the **Hand Over to Operations** activity.

See Table 1 below for a complete list of these activities. They are further detailed in section 7.

Table 1: Complete List of Implementation Activities

Item	Activity Name	Standard (S) / Optional (O)
1	Software Configuration, Workshops & Trainings	S
2	Validation Activities SOLABS QM Essentials (Core Software, Document Control and Audit Process)	S
3	Software Installation and Initial Configurations	S
4	Add-On – Training Management (Configuration and Workshops)	O
5	Add-On – OTS QM APPs (Configuration, Workshops and Validation)	O
6	Data Migration	O
7	Formal Training for Super-Users	S
8	Handover of Environments and Transfer to SOLABS Support	S

2.1. Overview of the Sequence of Activities

From the client's perspective, the activities unfold roughly in the following sequence, with some activities occurring at nearly the same time as others:

Timeframe	Activities			
Earlier	1. Overview Training	2. Configuration Specification	3. Installation	4. Validation
	5. QM Apps (Optional)	6. Data Migration (Optional)		
Later	7. Handover of Environments	8. Formal Training for Super-Users		9. Support

Figure 1: Approximate Sequence of Main Activities

As shown in the table above, for instance, the first row of activities (1, 2, 3, 4) will all start about the same time, and continue in parallel.

Roughly 80% of the first-row activities will be completed before the beginning of the second row of activities. We say *roughly* because, for example, one of the elements of the Validation activity, the signing of the 21 CFR Part 11 document, can occur after the QM Apps and Data Migration activities have been largely completed.

3. Client Responsibilities

The most important responsibilities for clients are:

1. Delegate a person to act as PM on the project on client side, that is accountable for project advancement.
2. Participate in training workshops.
3. Review and sign validation documents.
4. Provide input for the configuration of the SOLABS QM (i.e., software configuration).
5. Author and approve client-specific deliverables.
6. Provide IT support for software installation and configuration.

3.1. Designate of a Project Manager

The role of PM (often referred to as Project Owner at SOLABS) ensures that all activities, deliverables and milestones are tracked and follow-up on. Those two roles, one in the SOLABS team and the other one in the client's team, are essential for a great collaboration and teamwork.

3.2. Participate in Training Workshops

These training workshops are designed to present various aspects of the SOLABS QM with sufficient detail. It is important for the client to designate the persons who will be responsible for that process and ensure that the assigned persons attend the workshop as well.

Tip: Start drawing up the list of these owners and their backups and determine their availabilities. Provide the list to SOLABS as soon as possible. See recommended [Client Team Members](.).

3.3. Review and Sign Validation Documents

Client signature on certain validation documents are important for two reasons:

1. **General:** They serve as proof that a specific aspect of the validation of the client's SOLABS QM software has been tested and passed.
2. **Project Specific:** They allow SOLABS to proceed from one part of the implementation project to the next.
   a) **Example:** When the client signs off on the *Client Installation & Operational Qualification for the Change Control Process P0052[1] (CPIOQ-CCR-SOL-0052 v1.1.1),* this gives SOLABS permission to validate that this process has been installed and operates correctly. When the client signs off on the *Client Installation & Operational Qualification Summary Report for the Change Control Process P0052 (CPIOQR-CCR_SOL-00052 v1.1.1)*, this means that the client agrees that the Change Control process has been installed correctly and it operates correctly.
   The client's signature on the summary report also means that SOLABS can now put this process in a production environment (PROD). Once the process is in PROD, SOLABS is ready to hand it over the client. This is formally done with a "Handover Memo", which is signed by the client.

3.4. Provide Input for Configuration

For SOLABS to properly configure SOLABS QM in a timely manner, it is important that the document templates containing configuration information are filled in correctly and as thoroughly as possible. Delay in the completion of these documents and/or errors in the documents can lead to the Handover Date being pushed to a later date.

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[1] Here, it is assumed that Change Control Process flavor P0052 is selected.

Tip: Get started gathering requirements to fill these documents as soon as possible. Much of the information required to complete the documents can be done before the workshops, e.g., usernames, permissions, etc.

4. Kick-Off Meeting

The scheduling of the Kick-off meeting marks the official start of the SOLABS QM implementation project. In the meeting, a high-level overview of the deliverables, timelines (including the expected Handover Date) and key risks is covered. The SOLABS team members for the project will also be introduced. The Kick-off meeting is also an opportunity for the client and SOLABS to clear up any outstanding questions/uncertainties before the project begins.

It is typically a 60–90-minute presentation with the following people expected to be present:

Table 2: List of Kick-off Meeting Attendees

Client	SOLABS
Reference: Client team members	Project Sponsor (Optional)
	Account Manager
	Project Manager
	Product Specialist
	PQM Specialist
	System Integrator

Each of the project activities is explained in more detail in the following section.

5. Implementation Project Activities

While collaborating with the SOLABS team for the implementation of your SOLABS QM10 environment, you will be guided through the following project activities.

1. Solabs Overview Training and Initial IntroductionSolabs Overview Training and Initial Introduction
2. Software Configuration Specifications
3. Installation and Validation of SOLABS QM Essentials
4. Installation and Validation Documentation of the SOLABS QM
5. QM APPS – OTS (Off the Shelf) or Unique to Client (Optional)
6. Data Migration (Optional)
7. Handover Preparedness
8. Formal Training
9. SOLABS Support
10. Go Live

5.1. Solabs Overview Training and Initial Introduction

Overview training is conducted using "walkthrough workshops". The purpose of the workshops is to familiarize the client with the SOLABS QM and to discuss how the client might want to configure, i.e., "customize", it. Document templates to help with the software configuration will also be presented.

The number and duration of the workshops is dependent on the number of users, which roles are assigned to them (e.g., System Administrator, Trainer, etc.) and their level of familiarity with the system.

Who gives it? Given by our Product Specialist. This person will also help you configure the system, i.e., personalize the system.

How long? It takes about 3 hours. This can be done in 2 or 3 sessions, depending on the client's preference.

Where? Given on-line. It is done using the client's SOLABS QM "Sandbox" – a fully functioning, but disconnected, "dummy" version of the SOLABS QM.

Walkthrough documents will be sent in advance so that the client has not only a better idea of what to expect at these workshops, but also to prepare questions, comments, etc.

Access to the Sandbox is usually not given before the first workshop. Once access is given, the client is encouraged to use the Sandbox as much as possible to get hands-on experience with SOLABS QM. This will make software configuration go more smoothly as well.

5.2. Software Configuration Specifications

This activity is to "customize" SOLABS QM according to the client's needs. This information is provided by the client in two documents:

1. *Environment Configurations for SOLABS QM 10 (EC-SOL-001)*
2. *Users and Roles Specification for SOLABS QM 10 Configuration (UR-SOL-001)*

There are two key parts:

- Users and Roles – The list of users, their roles and role assignments to determine what they will have permission to do in SOLABS QM
- Folder structure and document types – The tree view organization of the document folders and the list of document types, for example Standard Operating Procedures (SOPs), Certificates of Analysis (CoAs), Specifications, etc., along with their metadata and approval workflows.

There may also be other, additional configurations if requested, for example connection of SOLABS QM with Office 365 to allow for collaborative review of documents, and/or the connectivity to a training assessment system such as Questionmark.

5.2.1. Environment Configuration for SOLABS QM 10, EC-SOL-001

In EC-SOL-001, information in the following areas is typically documented by the client with the help of the Product Specialist:

Table 1: Areas covered in EC-SOL-001

Item	Area	Example
1	Roles	Roles related to job functions, document access.
2	Users and User Role Assignments	User names, e-mail addresses, employee ID.
3	System Custom Lists	Single-selection, multi-selection list fields for drop-down lists.
4	System Attributes	Document Metadata fields such as document owner, effective date, author.
5	Document Folders and Permissions	Hierarchy of folders, subfolders and folder permissions (view, modify, etc.).
6	Document Types	Standard Operating Procedures (SOPs), Specifications, Certificates of Analysis (CoAs).
7	Document Workflow Template	List of reviewers, approvers, approval cycles.
8	Document PDF Rendering Templates	Cover page data, header, status watermarks.

5.2.2. Users and Roles Specification for SOLABS QM 10 Configuration, UR-SOL-001

This is a spreadsheet for item 2 of the table above, Users and User Role Assignments. It is filled out by the client and contains the list of users and their roles, titles, etc.

Given that there may be employees who come and go, get different responsibilities, etc., it is understood that this document can change over the course of the implementation project. During the project implementation, however, software configuration based on two versions of UR-SOL-001 will be allowed.

5.2.3. Sequence of Configuration

The client should focus on getting a first version of EC-SOL-001 (v1) with desired backend configurations to the Product Specialist as soon as possible. This is used to configure the SOLABS environment and complete its validation. This part of the configuration is done by the Engineering Department (ENG) and checked by the Product Quality Management department (PQM) at SOLABS.

When this is completed, the SOLABS QM is then "released" by ENG to the Product Specialist. The remaining configuration (what is remaining in EC-SOL-001) can then be done either by the Product Specialist or the client, according to the agreement. It should be noted that this remaining part is done manually. The EC-SOL-001 document is expected to go through a few iterations.

5.3. **Installation and Validation of SOLABS QM Essentials**

A SOLABS QM implementation project has several installation and validation task done in parallel. The first installation and validation activities are about the SOLABS QM Essentials (Core Software, Document Control process and Audit process). The client will be introduced to the validation activities during the validation package presentation.

5.3.1. Validation Package Presentation

The purpose of the validation package presentation is to familiarize the client with the SOLABS Validation Package.

Who gives it?   Given by the Product and Quality Management Specialist.

How long?   About 1 hour.

Where?   Given online.

After the validation package presentation, the client can begin to review and approve the validation documents, in order of priority. This initiates the installation of the client's validated version of the SOLABS QM core software, Document Control process and Audit process.

5.3.2. Installation and Validation Documentation of the SOLABS QM Essentials

The objective of this activity is to install a validated version of the SOLABS QM application (as per regulatory requirements) that has been configured using the EC-SOL-001 and UR-SOL-001. The validation consists of an installation and an operational qualification (IQ and OQ)[2] to demonstrate the suitability of the computer software to perform assigned tasks.

Whether or not the client has chosen to include optional Add-Ons QM Apps such as CAPA, Change Control, Deviation, etc., in the SOLABS QM application, the installation of the complete SOLABS QM always begins with the core software ,Document Control process and Audit process installation. This is the foundation of the SOLABS QM. The validation documents that accompany this installation are:

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[2] Henceforth, validated will refer to IQ and OQ, unless otherwise specified.

Table 4: Core Software, Document Control Process and Audit Process Validation Documents

Number	Document Name	Document Reference	IQ or OQ
1	Validation Plan	CVMP-SOL-001	n/a
2	SOLABS QM Validation Documentation Index	INDEX-SOL-001	n/a
3	Software Installation Qualification (protocol)	IQ-SOL-001	IQ – Core
4	Core Software Installation Qualification Summary Report	IQR-SOL-001	IQ – Core
5	Core Software Operational Qualification Protocol	OQ-SOL-XXX	OQ – Core
6	Core Software Operational Qualification Summary Report	OQR-SOL-XXX	OQ – Core
7	Core Software Performance Qualification Protocol	CPQ-SOL-001	PQ – Core
7	Core Software Performance Qualification Summary Report	CPQR-SOL-001	PQ – Core
8	21 CFR Part 11 Assessment	CCFR-SOL-001	n/a
9	End User Configuration Verification Protocol	EUCVP-SOL-001	n/a
10	End User Configuration Verification Summary Report	EUCVPR-SOL-001	n/a
11	Installation and Operational Qualification Protocol for theDocument Control Process	PIOQ-DOC-SOL-0007	IQ and OQ – Document Control Process
12	Installation and Operational Qualification Summary Report for the Document Control Process	PIOQR-DOC-SOL-0007	IQ and OQ – Document Control Process

As shown in the table above, most of the documents are test protocols (henceforth referred to as "protocols") or summary reports.

5.3.3. IQ and OQ Protocols and Summary Reports

The client is expected to review and sign protocols and summary reports.[3]

- When the client signs the protocol, this allows SOLABS to execute the protocol and produce the summary report based on the results of the execution of the protocol.
  - o The protocol is the plan that indicates what will be done to ensure that a particular component of the SOLABS QM is installed and/or operates correctly. SOLABS has standard protocols for various SOLABS QM components such as the Core, Document Control process and Audit process. The protocol consists of a series of test scripts that

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[3] If the client has any questions about a test protocol or summary report, they will be addressed by SOLABS and if required, the document will be amended and reissued for client signature.

are executed to test the software. The result of the execution of the protocol is documented in the report.

- When the client signs the summary report, it indicates that the client agrees with the report content and conclusions. Any errors/deviations found along the way and their corrections will be noted in the summary report.
- For the Core, the client will sign four (4) installation and operational qualification documents – a protocol and a summary report for each qualification type.
- For the Document Control process and Audit Process, the client will sign two (2) installation and qualification documents, a protocol for both the IQ and OQ combined along with a summary report.
- The Users Roles Migration Qualification documents are explained in subsection 5.3.4.

5.3.4. End User Configuration Verification

As mentioned in section 5.2.1, the client will be called provide the desired environment configuration. This configuration will be manually done by the client alone or by SOLABS, depending on the agreement.

As mentioned in section 5.2.2, the client will be called to document the users and roles that are needed to be configured in their SOLABS QM environment. The users and roles chosen by the client will be created in SOLABS QM. The method of creation can be manual or automatic depending on the quantity.

As stated previously those activities will be done with the support of SOLABS Product Specialist. Few modification iterations will be allowed for those documents to respect the deadline of the established project plan.

Once the environment is configured, a verification of the information will be done in SOLABS QM. This verification is documented in the End User Configuration Verification (EUCVP-SOL-001). If errors are found, a new iteration will be done in order to correct the situation. The result of the execution of this protocol is documented in the report.

5.3.5. Additional Test Scripts

Some clients may request additional client-specific test scripts. SOLABS allows the client to include those as part of the Performance Qualification Protocol (CPQ-SOL-001).

5.3.6. Continuous Client Configuration After SOLABS QM Release

Once the Installation and Operational Qualification along with the End User Configuration Verification are completed, SOLABS will release the validated environment. The SOLABS QM URL address and credentials will be provided to the client.

It is understood that the configuration of SOLABS QM will likely continue to evolve on the client side during its use.

When interventions are required in the client's Validation and Production environment of SOLABS QM, SOLABS will communicate clearly with the client. Occasional downtimes will be required and planned in collaboration with the client.

5.4. QM APPS – OTS (Off the Shelf) or Unique to Client (Optional)

In addition to the SOLABS Essentials, optional QM App can be included in the implementation project. SOLABS has developpe an expertise to offer a variety of QM App. Some of the QM Apps are built as "Off The Shelf" which are ready to be implemented in a client environment, while others are considered Unique to Client Apps that can be built to suit client-specific needs.

Each "flavour" (version) of a QM App is identified by the App number in the format of Pxxxx, where P stands for "Process" and xxxx is a 4-digit number representing that unique App – eg., P0052 or P0045.

(Here it is assumed that the QM App selected is "off-the-shelf" (OTS). OTS QM Apps do not have any additional test scripts and no client changes/customizations are included

Examples of OTS SOLABS QM Apps are – Change Control, CAPA, Audit, Complaints, etc. Activities for the implementation QM Apps include training and, per regulatory requirements, validation (IQ and OQ) of the QM Apps.

They are incorporated one by one after the SOLABS Essentials has been validated.

QM Apps follow essentially the same procedure as the SOLABS Essentials.

1. The QM App is installed in the Sandbox and an overview of the QM App is given in a walkthrough workshop by the Product Specialist.
2. **Addition:** The *Client Process Configuration (CPC-SOL-001)* document is created and signed by the client. It lists the QM Apps that are installed in the SOLABS QM. It is updated and re-signed each time a new QM App is added.
3. IQ and OQ documents (protocol and summary report) are provided for client signature.
   a. As noted earlier, for processes, the IQ and OQ are done as a set so there are only 2 documents (a protocol and a summary report) to sign for each QM App.
4. Once the summary report has been signed, the QM App is considered validated for the client.

5.5. Data Migration (Optional)

This activity relates to the transfer of documents and other data.

Data Migration may be required if:

1. The client is migrating from specific previous versions of SOLABS QM.
2. The client has requested that data (e.g., user names, roles, documents, etc.) from another system be migrated into SOLABS QM in an automated process (e.g., not manually).

3. The client has requested that their final list of users be uploaded through a spreadsheet/table.

In all cases, the effort for the migration of data is estimated and agreed upon prior to rollout. During migration testing and final migration activities, the client will not be able to use the system.

5.6. Handover Preparedness

About one month before the Handover date, the SOLABS Project Owner will prepare a Handover Countdown Checklist (HCC) which will contain all the remaining activities/tasks to be completed by both SOLABS and the client before the handover takes place. This is to ensure that the Handover can go as smoothly as possible.

5.7. Formal Training

This activity is to provide hands-on training in preparation of the Go-Live. It presents the process flows and actions needed to maintain the system.

These are workshop(s) that are held close to, but before the Handover date. They are given to the Super Users and Trainers. Super Users include the owner of the SOLABS QM, the person responsible for technical support of the SOLABS QM, and the owners of the various QM Apps. The Trainers would be those who would provide the training to the end-users.

To facilitate the formal training, SOLABS will provide a list of use cases/scenarios that the client would like to see in Formal Training. Based on what was selected by the client, SOLABS will create a training plan for the Super Users and Trainers.

If the client believes that formal training is not required, the client will be asked to sign off on a form indicating that the client has declined formal training.

5.7.1. Client-side training responsibilities

The client should also ensure that a training plan has been developed for the rest of its end-users.

5.8. SOLABS Support

Around the same time or shortly after Formal Training, the client will be given a presentation by a Support Team Member. The presentation is used to explain how SOLABS support works, the levels of

support that are available, depending on the agreement. In addition, the client will be asked to fill in a point-of-contact form for support-related communications.

5.9. Go Live

The Go-Live Date is chosen by the client. This is the date that officially marks when the client should be using or beginning to use SOLABS QM in its day-to-day operations. At this point, the SOLABS QM has been successfully implemented.

It should be noted that some customers will select a Go-Live date, but will schedule a gradual rollout of either users, departments, processes or trainings to manage the change impact on the users and the organization. This can be an effective way to control the volume of effort required by the Super Users during rollout, especially if they perform other duties outside of SOLABS QM.

6. Administrative and Other Topics

This section discusses the staffing, communication and issues regarding changes in time, budget, or scope of the project.

6.1. Staffing the Project

The key members of the implementation project are listed below. Their level of involvement will depend on what activities are currently being completed within the implementation project.

Table 5: SOLABS Project Team

Role	Key Responsibilities
Project Owner	• Project progress (Time, Budget, Scope) • Scheduling of recurrent meetings • Scheduling of SOLABS resources
Product Specialist	• Walkthrough Workshops • Software Configuration • Formal Training
PQM Specialist	• Validation documents—execution, writing • Client follow-up for signatures
Systems Integrator	• Software Installation

Table 6: Client Project Team

Key roles and responsibilities in a SOLABS QM Implementation

6.2. Communication Tools

Several communication tools will be at your disposal at all steps of the process.

6.2.1. Project Plan

A project plan with timelines is agreed upon with the client's project manager prior to the kick-off meeting. A typical project timeline is 4-8 months depending on the scope. The project plan covers the project activities mentioned above and dependencies amongst them.

Client activities are highlighted in orange so it is easy to see the estimated effort that will be needed on the client end.

6.2.1.1. Handover Date

Every week the project plan is updated to reflect the progress of the most recent activities. Consequently, the Handover Date can be impacted positively or negatively, in the case of project delays.

6.2.2. Stakeholder Register

The stakeholder register is a document which keeps track of all the individuals involved in the project for SOLABS and the client. It includes their roles within each organization and within the project.

6.2.3. Validation Document Tracker

The Tracker can be viewed as the backbone of the validation activities. It is a spreadsheet that contains the list of documents that are required to complete the validation efforts. The tracker also includes a priority column which helps clients allocate resources efficiently.

It includes:

1) **Validation Documents:** Documents that indicate that one particular aspect of the validation of the system has been tested and passed, per regulatory requirements.
   a. Some of the documents do not require client signature. These are SOLABS' owned validation documents. However, they are still part of the set of validation documents that are given to the client as evidence that the client's SOLABS QM is validated. The reason for this is that some of the *client's* versions of documents reference the SOLABS-owned versions.
   b. Validation of the SOLABS QM is done using the IQ/OQ/PQ framework, i.e. Installation Qualification, Operational Qualification, Performance Qualification.
2) **Software configuration documents**: Documents that are used to tailor the system according to the client's needs.

6.2.4. SOLABS' eRoom

During the implementation project, all documents shared by SOLABS will be placed in our eRoom. This allows us to track exactly which documents have been shared and ensures that all the information in regards to the project can be found in a single spot.

The eRoom can be accessed through the following URL:
https://my.solabs.com/eroom/

SOLABS will set up your accounts and give accesses to appropriate personnel in your team when the project begins.

6.2.5. Regular Project Communications

Email

At any point in the project, emails can be used to communicate with the SOLABS team members.

Recurrent Project Meeting

Weekly or bi-weekly meeting will be setup for the duration of the project. SOLABS recommend those meetings for both project PMs to follow-up on the project activities and keep the project on track, with respect to budget and time. The frequency of those meeting will be agreed between SOLABS and client PM at the kick-off meeting. It can be adjusted at different times in the project.

Project monthly reports

Each month, SOLABS PM will issue a report that provides updates on the activity's completion, up-coming activities, risks, issues, and budget.

6.2.6. Project Change Request (PCR)

In the event of a project change (change in the scop or budget), a PCR will be issue and communicated with the client.

6.2.7. Project Closing Report

Once the project deliverables are completed, a report will be issued and communicated to the client. This report will reflect the entire project's scope and budget accomplishments.

6.3. Project Delays

There are a number of reasons why the Handover Date may be deferred over the course of the project:

1. Absences due to illness, vacations, etc.
2. Change in project team members (eg., project manager, process owner)
3. Responsiveness of the client
4. Errors and bugs
5. SOLABS scheduling
6. Project change request

The first two are obvious response and need no explanation. The last four are explained below.

6.3.1.1.   Responsiveness of the client

The Document Tracker includes dates by when the client should sign a particular document and provide the signed copy to SOLABS. The dates are based on the project plan which, as noted earlier, is updated each week. It is important therefore that the client allocate enough time and resources to ensure that documents are delivered in a timely manner so as not to negatively impact the Handover Date.

6.3.1.2.   Errors and Bugs

Because the SOLABS QM system must be validated per regulatory requirements, there is quality control at nearly every step of the implementation project. This makes errors particularly onerous since any change needs to be rechecked and formally documented by SOLABS Product Quality Management (PQM). It is not merely enough to have the error fixed by the software developer or system integrator and checked by the Head of Engineering (ENG).

For example:

- PQM experiences an error when executing the IOQ protocol
- Error is recorded in the issues log
- Investigation shows error needs ENG resources to resolve
- Error resolution is scheduled for ENG and completed
- ENG documents the error and the resolution, and hands it over to PQM
- PQM documents the error and resolution and retests
    o   If error recurs, start again
- If error is resolved PQM completes the IOQ protocol
- PQM prepares the IOQ Summary Report and includes the findings and actions taken for the error, and any changes to the system that occurred due to the error
- IOQ Summary Report is provided to client for signoff
- Client signs off on IOQ Summary Report

SOLABS tries to anticipate this and builds time into the project plan accordingly.

6.3.1.3.   SOLABS Scheduling

SOLABS works on a priority system in order to best handle multiple projects. The priorities are set so that the Handover Dates can be met, based on experience on similar projects. The scheduling of resources required to carry out particular activities is planned on the priorities and is set from week to

week. This should not normally have impact on the Handover Date unless there are changes to the dates within the project.

6.3.1.4.   Project Change Request (PCR)

After the start of the implementation project, there could be unforeseen issues or changes to prior decisions that impact timelines, scope or budget. If the unforeseen issue or decision change is major, a PCR may be required. (This is discussed in the contractual agreement between SOLABS and the client.) Depending on the nature of the outcome of the PCR it may or may not push back the Handover Date.

7. Glossary of Terms

TERM	DEFINITION
Agreement	Contractual obligations of SOLABS and the client with respect to the roles and responsibilities in the SOLABS QM implementation.
Go-Live Date	Date at which the client decides to use the SOLABS QM in production, ie., its day-to-day operations.
Handover Date	Date at which SOLABS deems that the SOLABS QM (or parts of it) is ready for the client to use in production.
IQ	Installation Qualification: Document and test scripts that describe the process for installing the Core Software or QM Apps. IQ is executed for each occurrence in order to verify that the Core Software and any QM Apps were installed as documented.
OQ	Operational Qualification: Document and test scripts that describe they way the Core System or QM Apps work. OQ is executed for installation of the Core System and each QM App to ensure that the system is functioning as designed.
PQ	Performance Qualification: Document and test scripts that describe the way the Core System and QM Apps work over a period of time. Tests the system in a live environment (production) to ensure it stands over time.
Sandbox	A full-functioning SOLABS QM that is disconnected … All overview training and QM Apps training sessions are done in the Sandbox. Formal training will be done in either the sandbox environment, or the validation environment, depending on the customer.
Super Users	The System Administrators, Training Administrators and Document Administrators are required to ensure the system remains set up as needed, and to administer the day to day changes in users, documents and training requirements. These Administrators have System access to all or most areas of the system.
Validation	The process of confirming the system works as designed and as configured. The result of the validation process is a set of approved and executed procedures and tests. Deviations may also be included, for tracking issues that arise during testing and the resolution of these issues.