Services Offer

Supplier:

PHARMACEUTICAL CONSULTANCY SERVICES (PCS),
The NETHERLANDS

With Respect to the provision of Project Support

Completion date (expected): MONTH, YEAR

Pharmaceutical Consultancy Services
Veluwemeer 112, 3446 JD Woerden, the Netherlands,
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Chamber of Commerce 30280650

Assignment:

ERECTING A GMP COMPLIANT FACILITY
&
IMPLEMENTING A PHARMACEUTICAL QMS

Supplier: Pharmaceutical Consultancy Services (PCS),
Veluwemeer 112
3446 JD Woerden
the Netherlands

Project Director: Jaap Koster

Assignment :

- Implementing a Pharmaceutical QMS
- Support start-up of commercial manufacturing and verification during manufacturing continuation
- Preparation of THE CLIENT for an international inspection

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GENERAL

a) THE CLIENT Pharmaceutical Industries, based in Country is projecting to supply pharmaceutical finished products into (in principle) national and international regulated markets.

b) THE CLIENT Pharmaceutical Industries has entered into a project with the intention to establish an international (Country NRA and EU GMP) compliant facility with a Pharmaceutical QMS (Quality Management System) and a supporting organization.

c) THE CLIENT will erect the GMP compliant factory in a number of phases. Each phase will have different documentation, organizational and validation requirements. However, the overall QMS structure and approach will remain equal.

d) It is intended that PCS (the Supplier) will support THE CLIENT Pharmaceutical Industries (the Client) to realize this facility, QMS and organization; in order to meet international regulatory (GMP) expectations.

e) The project is considered to have the following stages:

0. QMS development
1. Validation and Qualification
2. Start-up of the facility
3. Manufacturing of commercial batches (and stability batches)
4. Verification (approx.6 months after first commercial batches)
5. Closure of project

f) It is understood that this preliminary offer is based on limited insights concerning the status of the project and available competent support for the project by Client's team, which is to be addressed during a foreseen meeting with Client's team by PCS.

ABOUT PCS

PCS is an established, independent consulting group based in the Netherlands. The company provides specialised services to the pharmaceutical, medical devices and related health care industries to meet current regulatory requirements. It is the oldest pharmaceutical training institute in the Netherlands and organizes over 30 courses for each level of the industry annually.

PROPOSAL

a) PCS will provide a Project Director during the entire project for all stages as mentioned under section 1.d.

b) in coordination with Client, PCS will review at the start of the project:
- Product Range, Process Flow and description as being the basis for the project
- Concepts of the facility including (but not limited) materials- and personnel flows, against international standards and expectations.
- Project planning, including team-build-up, validation (principles and masterplanning) , risk assessments, QMS (documentation, records, reporting system, etc),

c) During the first stages of the project, PCS will direct and review the quality of and timelines for (not limited):

- Design, creation and implementation of the QMS, including the Quality Manual, Validation Master Plan (VMP) and Risk Management.
- Training and induction process of key-personnel for Manufacturing and Control of the anticipated product-range.
- Validation Protocols writing
- Batch-records and SOP's writing (to be discussed)
- Design Qualification of facility and utilities
- FAT/SAT (Factory/Site Acceptance testing)
- Stability Programme
- Vendor Qualification and management

Note 1: Equipment Software will be validated during the Qualification of the Equipment itself

Note 2: The level of Computerized Systems (IT systems) other than for Equipment and/or complex should be discussed in full, since validation of those systems might become very challenging (and cumbersome) for inexperienced/starting pharmaceutical companies.

d) During the commissioning phase of the facility, PCS will direct and review the quality of and timelines for (not limited):

- Pre-commissioning and commissioning of the facility, including utilities and critical cleanroom-areas.
- Validation Programme, including Computerized Systems, Analytical Methods, Cleaning, Process, Utilities, etc.
- Qualification Programme
- Training of personnel (process knowledge and SOPs)
- Implementation of (batch) records
- Engineering runs
- Vendor auditing programme for critical to quality raw materials
- Start-up of the facility, including Media Simulation runs

e) During the commercial manufacturing phase of the facility, PCS will direct and review the quality of and timelines for (not limited):

- Verification of process performance
- Effectivity of the implemented QMS
- Scientific rationale for divergences (Change Control, Deviations etc)
- Risk Management
- Product Quality Review
- On-going stability programme
- Management Quality Review programme
- Functioning of QA Department
- Behaviour of personnel (according GMP)

f) PCS will implement a programme to be prepared for an international inspection team and will train people on how to act and react during those inspections.

A separate project plan for training will be provided during the initiation of the project.

All training sessions will be given in English. In case required, THE CLIENT will arrange a translator.

3. SUPPORT BY PCS:

a) Support by PCS might be adjusted depending on (future) available support by Client, and the level of that support.
Hereunder a preliminary scenario is presented to obtain insight of possible support to be delivered by PCS. It should be noticed that the scenario might change during the course of the project.

b) *Proposed scenario*: employment is delivered by Client, as indicated with the separate sent plan for establishment, reference is made as well to the Annexes of this proposal.

- A Project Director of PCS will be working 2 to 4 days from the PCS-office and potentially 4 to 5 days on-site, depending on demand.
- 1 Technical Management Consultant of PCS-India will be working up to 9 days per month from the PCS-India-office and roughly 6 days on-site.
- 10 Supporting Consultants of PCS-India will be on site 5 to 15 days per month and 2 to 5 days working from the PCS-office
- 1 Supervisor of PCS-India will be on site 4 to 8 days per month and 3 to 6 days working from the PCS-office.
- 1 Project Manager of PCS will be ons-site 3 to 5 days per month and up to 5 days working from the PCS-office
- 1 QC Expert of PCS will be on-site up to 5 or 6 days per month and up to 10 days working from the PCS-office.

c) The above is subject to discussion between management of Client and PCS. The default principle position of PCS is that THE CLIENT should built-up the own employee-group and management-layer which will be trained, mentored and supported by the consultants of the PCS-core-team, in order to achieve the overall objectives.

4. DETAILED SUMMARY:

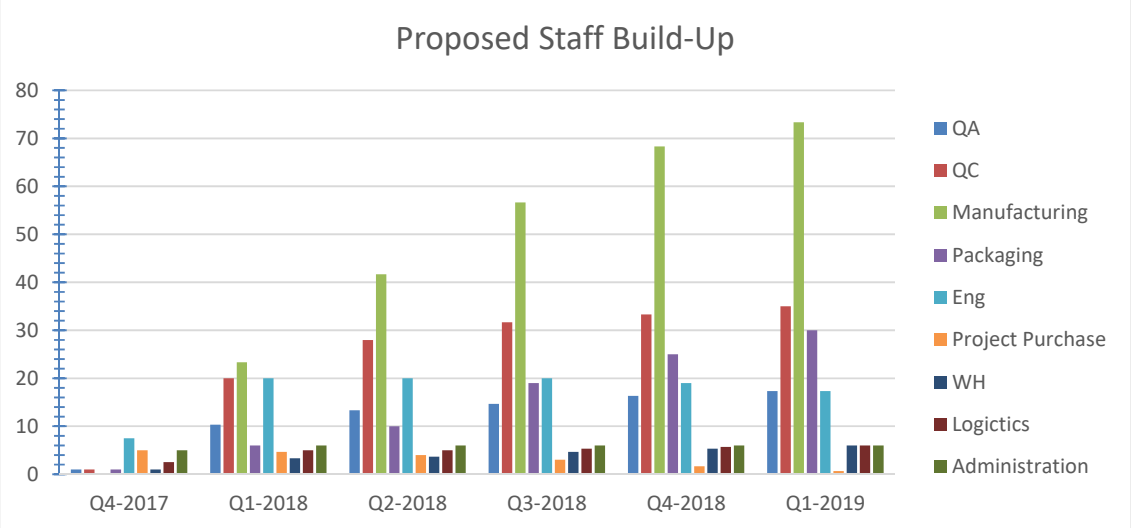
Timeline

For the purpose of having the factory completed and ready for production as quickly as possible all activities must commence in XXXX to be completed (estimated) in XXXX.

It is important to have staff of THE CLIENT start at the same time to support the aforementioned deadline. As well as hiring and selection of QA, manufacturing and packaging staff (amongst others) to support the activities of PCS.

To support the buildup of staff PCS can guide THE CLIENT with an expectation for the build-up of staff, staff profile creation and staff selection.

The chart below shows the proposed build-up of staff (averages per quarter).



In Appendix B of this proposal a project charter can be found which explores this

support and build-up of staff in more detail.

Assumptions and Limitations

For this offer a number of assumptions have been made and a number of factors have been left out purposefully. The actual amount of activities and their duration can only be determined after assessing the situation on the ground and the support delivered by the staff of THE CLIENT.

In addition the GMP compatability of selected machinery, building materials and lay-out will play a major role in the amount of actual hours spent on validation.

As an R&D facility will not be part of this section of the plant it has not been budgeted for.

If a QA manager is not on the payroll of THE CLIENT yet at project start up, one of the QA specialists nominated for this project will be assigned as Temporary Interim QA Manager.

QMS and Document Structure

As THE CLIENT currently has no documentation structure PCS will propose a QMS based on earlier projects whereby the focus lies on essential quality elements rather than exhaustive paper compliance which is no longer favoured by the international regulatory authorities.

As such PCS will propose the following documentation structure (QMS);

An exhaustive list of required documentation is provided in Appendix A of this document. Parts of the respective lists have been included. Full disclosure will be given after procurement of this project by PCS.

Validation of Equipment

All production, QC and related equipment will have to be validated. Risk assessments for equipment are mandatory as per the GMP regulations, these must also be conducted. It is foreseen that the validation will start simultaneously with the writing of (QMS) documentation. In itself the validation will produce an extensive amount of documentation which is included in the estimation of hours for the validation of equipment. Besides equipment validation processes, installations (such as HVAC, WFI etc.) will also require validation. The amount of

validation will depend largely on the equipment manufacturer, quality and suitability. As well as the choices made during initial design of the facility.

Three validation engineers will be sourced by PCS to perform these activities alongside THE CLIENT's own personnel. These activities will be overseen by supervisors, project managers and the project director whom all have performed -or have experience with- validation.

Before validation of important equipment and installations can commence risk assessments will have to be performed.

Validation of Others

Risk assessments for these systems are mandatory as per the GMP regulations, these must also be conducted. Supporting systems have been indicated in the URS as provided by THE CLIENT. The Building Management System (BMS) and Environmental Monitoring System (EMS) have thus been budgeted in this proposal. It will depend largely on the complexity, manufacturer and compatibility of these systems whether or not the validation activities will exceed the amount of time budgeted.

QC Equipment Assembly, Installation and Calibration

The QC equipment to be procured (or already procured) by THE CLIENT have been requested to be assembled, installed and calibrated. PCS will rely on local expertise to aid in these activities. Also, the validation engineers sourced by PCS will provide input to this process. One person with specialized QC knowledge will be on-site for 15 days per quarter to provide relevant knowledge and input. As such, lump sums have been provided for these activities rather than more exact estimations.

More accurate estimations can be made after the first visit and when the exact list of equipment (model numbers), their manufacturer and manuals/technical documentation have been made available.

6. OVERVIEW OF ACTIVITIES AND COSTING

6.1 Overview

For each phase a separate overview will be given of the approximate costing. Please note that this is not a fixed costing but will depend on a number of variables such as staff availability, equipment, basic design of facilities and so forth.

The erection phases for which a costing overview will be provided are;

1. Oral Solid Dosage Forms & Soft Gelatin Capsules (first),
2. Oral Liquid Line (second),
3. Sterile Production Lines (third).

6.2 Oral Solid Dosage Forms & Soft Gelatin Capsules Facility

The cost estimation for this part of the factory is divided into five categories; Creation of Documentation, Validation of Equipment, Validation of Utilities, Validation of Overall Activities and Validation of Supporting Systems. All estimations of the required amount of time are based on experience and/or logical calculations.

Creation of Documentation

The amount of documents below and their respective categories are a best-case-estimate. The final number of documents will become apparent as the project progresses. Each document will require creation, an X number of reviews by Quality Assurance as well as approval by Quality Assurance and key personnel. The writing of documents will be performed by four persons.

Validation of Equipment

The validation of equipment will need to be performed for each piece of equipment utilized by THE CLIENT. The list of equipment below is based on the equipment list provided by THE CLIENT for both Quality Control and production and an estimate for Warehousing. Any equipment not on that list has not been planned/budgeted for and will become apparent after an initial visit. Ten (10) pieces of equipment have been accounted for as a contingency, however these pertain to QC, Warehousing and Production.

Validation of Utilities

The validation of utilities will be performed by Subject Matter Experts (SME's) of PCS in conjunction with staff of THE CLIENT. Risk assessments will need to be performed by these SME's before validation activities may commence. If utilities such as electricity and/or water supply prove to be unreliable due to environmental circumstances the level of validation may increase and may include backup-facilities which have not yet been designed, procured or budgeted for by THE CLIENT. This is to be determined after the initial visit.

Validation of Overall Activities

Overall activities include plant-wide activities such as cleaning, IT infrastructure, temperature control and so forth. The high-risk/high-level activities such as the process require risk assessment before validation can commence.

The risk assessment and validation execution will be performed by SME's and validation engineers with experience in these systems. Lower level activities such as transportation of capsules (at room temperature) require a less extensive validation effort but require risk assessment nonetheless.

Additionally, for Process Validation, Process-Flow-Diagrams (PDF's), Critical to Quality Parameters and Critical to Quality Attributes have to be defined.

The amount of computerized system validation depends highly on the amount and complexity of the systems at THE CLIENT.

Validation of the Supporting Systems

The supporting systems include the Building Management System (BMS) and Environmental Monitoring System (EMS). As stated before, the level of validation depends highly on the vendor, complexity and GMP-compatability of these systems. The number of hours detailed below are an estimation. The actual amount of validation will be established after the initial visit.

APPENDIX A

Bill of Documents

Quality Assurance Documentation (Part of Total List)

SOP NUMBER	SOP
QMS-SOP-001	SOP FOR SOP
QMS-SOP-002	CHANGE CONTROL
QMS-SOP-003	OUT OF SPECIFICATION
QMS-SOP-004	TRAINING
QMS-SOP-005	VENDOR DEVELOPMENT
QMS-SOP-006	BATCH RELEASE
QMS-SOP-007	STATUS LABELING
QMS-SOP-008	STABILITY STUDY OF STERILE WATER FOR INJECTION
QMS-SOP-009	DEVIATION
QMS-SOP-010	CONTROL OF DOCUMENTS
QMS-SOP-011	COMPLAINT HANDLING
QMS-SOP-012	PRODUCT RECALL
QMS-SOP-013	INTERNAL AUDIT
QMS-SOP-014	CORRECTIVE AND PREVENTIVE ACTION
QMS-SOP-015	PEST AND RODENT CONTROL
QMS-SOP-016	ISSUING BATCH RECORDS
QMS-SOP-017	PREPARATION OF BATCH RECORDS [MASTER BMR-BPR]
QMS-SOP-018	RECEIPT AND REVIEW OF BATCH RECORDS
QMS-SOP-019	USAGE OF BATCH RECORDS
QMS-SOP-020	STORAGE, RETRIEVAL & DESTRUCTION OF BATCH RECORDS
QMS-SOP-021	REJECTED MATERIAL
QMS-SOP-022	HANDLING OF EXPIRED PRODUCTS
QMS-SOP-023	RELEASE OF PRODUCT
QMS-SOP-024	HANDLING OF REJECTS-SCRAP
QMS-SOP-025	NUMBERING SYSTEM OF RAW MATERIAL,PACKING MATERIAL,FINISHED PRODUCT
QMS-SOP-026	ARTICLE NUMBERING SYSTEM
QMS-SOP-027	MEDICAL EXAMINATION
QMS-SOP-028	ART WORK PREPARATION & CHECKING OF PRINTED PACKING MATERIALS
QMS-SOP-029	AUTHORISED SIGNATORY
QMS-SOP-030	BATCH NUMBERING SYSTEM
QMS-SOP-031	PRODUCT CODE NUMBERING SYSTEM
QMS-SOP-032	INDUCTION PROGRAM
QMS-SOP-033	INPROCESS QUALITY ASSURANCE-QUALITY CONTROL
QMS-SOP-034	GOOD HOUSE KEEPING

Manufacturing Documentation (Part of Total List)

SOP NUMBER	SOP
EQP-SOP-001	OVERALL CLEANING & SANITATION SOP
EQP-SOP-002	CLEANING & SANITATION OF TABLET COATER X
EQP-SOP-003	CLEANING & SANITATION OF COLLOID-MILL X
EQP-SOP-004	CLEANING & SANITATION OF VACUUM TRANSFER SYSTEM X
EQP-SOP-005	CLEANING & SANITATION OF IPC LIFTER (FOR RMG) X
EQP-SOP-006	CLEANING & SANITATION OF VIBRO SIFTER X
EQP-SOP-007	CLEANING & SANITATION OF RAPID MIXER GRANULATOR (RMG) X
EQP-SOP-008	CLEANING & SANITATION OF GRINDING GRANULATOR (WET AND DRY) X
EQP-SOP-009	CLEANING & SANITATION OF BIN BLENDER X
EQP-SOP-010	CLEANING & SANITATION OF FBD X
EQP-SOP-011	CLEANING & SANITATION OF CIP X
EQP-SOP-012	CLEANING & SANITATION OF CAPSULE FILLING MACHINE X
EQP-SOP-013	CLEANING & SANITATION OF TABLET COUNTING MACHINE X
EQP-SOP-014	CLEANING & SANITATION OF PASTE KETTLE X
EQP-SOP-015	CLEANING & SANITATION OF TABLET PRESS X
EQP-SOP-016	CLEANING & SANITATION OF WATER CHILLER X
EQP-SOP-017	CLEANING & SANITATION OF BLENDER (FOR EFFERVESCENT) X
EQP-SOP-018	CLEANING & SANITATION OF TABLET PRESS (FOR EFFERVESCENT) X
EQP-SOP-019	CLEANING & SANITATION OF TUBE FILLING X
EQP-SOP-020	CLEANING & SANITATION OF BOTTLE WASHING & DRYING MACHINE X
EQP-SOP-021	CLEANING & SANITATION OF SUGER VACCUME MACHINE X
EQP-SOP-022	CLEANING & SANITATION OF SUGAR SIEVING VESSEL X
EQP-SOP-023	CLEANING & SANITATION OF SUGAR SOLUBLE & FILTERING VESSEL X
EQP-SOP-024	CLEANING & SANITATION OF LIQUID SYRUP MANUFACTURING VESSEL X
EQP-SOP-025	CLEANING & SANITATION OF FILLING & CAPPING MACHINE X
EQP-SOP-026	CLEANING & SANITATION OF PRINTER & SHIRINK X
EQP-SOP-027	CLEANING & SANITATION OF GELATIN PREPARATION MACHINE X
EQP-SOP-028	CLEANING & SANITATION OF MEDICINE COMPOUNDING VESSEL X
EQP-SOP-029	CLEANING & SANITATION OF ENCAPSULATION MACHINE X
EQP-SOP-030	CLEANING & SANITATION OF SOFT GEL PRINTING MACHINE X
EQP-SOP-031	CLEANING & SANITATION OF SOFT GEL COUNTER X
EQP-SOP-032	CLEANING & SANITATION OF SOFT GEL POLISHER X
EQP-SOP-033	CLEANING & SANITATION OF TABLET/ CAPSULE PRINTER X
EQP-SOP-034	CLEANING & SANITATION OF BLISTER X
EQP-SOP-035	CLEANING & SANITATION OF CARTONER X
EQP-SOP-036	OPERATION OF TABLET COATER X
EQP-SOP-037	OPERATION OF COLLOID-MILL X
EQP-SOP-038	OPERATION OF VACUUM TRANSFER SYSTEM X
EQP-SOP-039	OPERATION OF IPC LIFTER (FOR RMG) X
EQP-SOP-040	OPERATION OF VIBRO SIFTER X

Quality Control Documentation (Part of Total List)

SOP NUMBER	SOP
EQP-SOP-070	OPERATION, CLEANING & SANITATION OF GAS CHROMATOGRAPH X
EQP-SOP-071	OPERATION, CLEANING & SANITATION OF HPLC X
EQP-SOP-072	OPERATION, CLEANING & SANITATION OF UV-VIS SPECTROPHOTOMETER X
EQP-SOP-073	OPERATION, CLEANING & SANITATION OF GAS PURIFICATION SYSTEM X
EQP-SOP-074	OPERATION, CLEANING & SANITATION OF KF TITRATOR X
EQP-SOP-075	OPERATION, CLEANING & SANITATION OF PH METER X
EQP-SOP-076	OPERATION, CLEANING & SANITATION OF POTENTIOMETRIC TITRATOR X
EQP-SOP-077	OPERATION, CLEANING & SANITATION OF ANALYTICAL BALANCES WITH PRINTERS (FOR EACH DISTINCT BALANCE & PRINTER) X
EQP-SOP-078	OPERATION, CLEANING & SANITATION OF MICRO BALANCE WITH PRINTER X
EQP-SOP-079	OPERATION, CLEANING & SANITATION OF LARGE WEIGHT BALANCE X
EQP-SOP-080	OPERATION, CLEANING & SANITATION OF STANDARD WEIGHT BOX X
EQP-SOP-081	OPERATION, CLEANING & SANITATION OF TLC PHOTODOCUMENTATION SYSTEM X
EQP-SOP-082	OPERATION, CLEANING & SANITATION OF TLC SPOTTER X
EQP-SOP-083	OPERATION, CLEANING & SANITATION OF TLC UV CABINET X
EQP-SOP-084	OPERATION, CLEANING & SANITATION OF LABORATORY OVEN X
EQP-SOP-085	OPERATION, CLEANING & SANITATION OF VACUUM OVEN X
EQP-SOP-086	OPERATION, CLEANING & SANITATION OF GLASSWARE DRYER X
EQP-SOP-087	OPERATION, CLEANING & SANITATION OF MUFFLE FURNACE X
EQP-SOP-088	OPERATION, CLEANING & SANITATION OF FUME HOOD X
EQP-SOP-089	OPERATION, CLEANING & SANITATION OF GLASSWARE WASHING MAHINE X
EQP-SOP-090	OPERATION, CLEANING & SANITATION OF REFRIGERATOR X
EQP-SOP-091	OPERATION, CLEANING & SANITATION OF MAGNETIC STIRRERS X
EQP-SOP-092	OPERATION, CLEANING & SANITATION OF INCUBATOR X
EQP-SOP-093	OPERATION, CLEANING & SANITATION OF AUTOCLAVE (SMALL) X
EQP-SOP-094	OPERATION, CLEANING & SANITATION OF HORIZONTAL LF UNIT X
EQP-SOP-095	OPERATION, CLEANING & SANITATION OF CONSTANT TEMPERATURE BATH X
EQP-SOP-096	OPERATION, CLEANING & SANITATION OF WATER BATH X
EQP-SOP-097	OPERATION, CLEANING & SANITATION OF ULTRASONIC BATH X
EQP-SOP-098	OPERATION, CLEANING & SANITATION OF KNORR PUMP FOR HPLC COLUMN WASHING
EQP-SOP-099	OPERATION, CLEANING & SANITATION OF VERNIER CALIPER
EQP-SOP-100	OPERATION, CLEANING & SANITATION OF AIR SAMPLER X
EQP-SOP-101	OPERATION, CLEANING & SANITATION OF MELTING POINT APPARATUS X
EQP-SOP-102	OPERATION, CLEANING & SANITATION OF MICRO OVEN X
EQP-SOP-103	OPERATION, CLEANING & SANITATION OF TOC ANALYSER X
EQP-SOP-104	OPERATION, CLEANING & SANITATION OF PRINTERS FOR INSTRUMENTS (FOR EACH PRINTER FOR EACH INSTRUMENT) X
EQP-SOP-105	OPERATION, CLEANING & SANITATION OF TORQUE TESTER X
EQP-SOP-106	OPERATION, CLEANING & SANITATION OF PHOTOSTABILITY CHAMBER X
EQP-SOP-107	OPERATION, CLEANING & SANITATION OF STABILITY CHAMBERS X
EQP-SOP-108	OPERATION, CLEANING & SANITATION OF STABILITY CHAMBERS RACKS X
EQP-SOP-109	OPERATION, CLEANING & SANITATION OF VACCUM CLEANERS X

Warehousing Documentation (Part of Total List)

SOP NUMBER	SOP
WAH-SOP-001	HANDLING OF INCOMING GOODS
WAH-SOP-002	DISPENSING OF RAW MATERIALS
WAH-SOP-003	ISSUANCE OF PACKAGING MATERIALS
WAH-SOP-004	HANDLING OF RETEST MATERIALS
WAH-SOP-005	HANDLING OF REJECTED MATERIALS
WAH-SOP-006	HANDLING OF RETURNED GOODS
WAH-SOP-007	WAREHOUSE CLEANING
WAH-SOP-008	MATERIAL RECONCILLIATION
WAH-SOP-009	RECEIPT OF MISCEALLANEOUS ITEMS
WAH-SOP-010	WASTE DISPOSAL
WAH-SOP-011	GENERAL WAREHOUSING PROCEDURE
WAH-SOP-012	HANDLING OF DAMAGED GOODS
WAH-SOP-013	USE OF SCALES/BALANCES
WAH-SOP-014	ENVIRONMENTAL CONTROL AND/OR MONITORING
WAH-SOP-015	PART NUMBERING SYSTEM
WAH-SOP-016	INVENTORY CONTROL
WAH-SOP-017	QUARANTINE PROCEDURE
WAH-SOP-018	TESTING OF INCOMING GOODS
WAH-SOP-019	RELEASE OF INCOMING GOODS
WAH-SOP-020	MATERIAL SPECIFICATIONS

Maintenance Documentation (Part of Total List)

SOP NUMBER	SOP
ENG-SOP-001	EQUIPMENTS-INSTRUMENTS NUMBERING SYSTEM
ENG-SOP-002	WASTE DISPOSAL
ENG-SOP-003	MAINTENANCE OF GAS CHROMATOGRAPH X
ENG-SOP-004	MAINTENANCE OF HPLC X
ENG-SOP-005	MAINTENANCE OF UV-VIS SPECTROPHOTOMETER X
ENG-SOP-006	MAINTENANCE OF GAS PURIFICATION SYSTEM X
ENG-SOP-007	MAINTENANCE OF KF TITRATOR X
ENG-SOP-008	MAINTENANCE OF PH METER X
ENG-SOP-009	MAINTENANCE OF POTENTIOMETRIC TITRATOR X
ENG-SOP-010	MAINTENANCE OF ANALYTICAL BALANCES WITH PRINTERS (FOR EACH DISTINCT BALANCE & PRINTER) X
ENG-SOP-011	MAINTENANCE OF MICRO BALANCE WITH PRINTER X
ENG-SOP-012	MAINTENANCE OF LARGE WEIGHT BALANCE X
ENG-SOP-013	MAINTENANCE OF STANDARD WEIGHT BOX X
ENG-SOP-014	MAINTENANCE OF TLC PHOTODOCUMENTATION SYSTEM X
ENG-SOP-015	MAINTENANCE OF TLC SPOTTER X
ENG-SOP-016	MAINTENANCE OF TLC UV CABINET X
ENG-SOP-017	MAINTENANCE OF LABORATORY OVEN X
ENG-SOP-018	MAINTENANCE OF VACUUM OVEN X
ENG-SOP-019	MAINTENANCE OF GLASSWARE DRYER X
ENG-SOP-020	MAINTENANCE OF MUFFLE FURNACE X
ENG-SOP-021	MAINTENANCE OF FUME HOOD X
ENG-SOP-022	MAINTENANCE OF GLASSWARE WASHING MAHINE X
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ENG-SOP-036	MAINTENANCE OF TOC ANALYSER X
ENG-SOP-037	MAINTENANCE OF PRINTERS FOR INSTRUMENTS (FOR EACH PRINTER FOR EACH INSTRUMENT) X
ENG-SOP-038	MAINTENANCE OF TORQUE TESTER X
ENG-SOP-039	MAINTENANCE OF PHOTOSTABILITY CHAMBER X

Site Documentation (Part of Total List)

SOP NUMBER	SOP
STE-SOP-001	MAINTAINANCE, CLEANING & SANITATION OF BUILDING SURROUNDING
STE-SOP-002	PROCEDURE TO BE FOLLOWED IN CASE OF POWER FAILLURE
STE-SOP-003	GENERAL PROCESS FLOW CHART
STE-SOP-004	DESIGN OF THE FACILITIES
STE-SOP-005	ROUTING OF PERSONNELL AND MATERIALS
STE-SOP-006	AIR CLASSIFICATION DOCUMENT
STE-SOP-007	HVAC SYSTEM DESIGN
STE-SOP-008	WATER/SEWAGE SYSTEMS OVERVIEW
STE-SOP-009	MATERIALS USED FOR SURFACES
STE-SOP-010	PLANT MASTER FILE
STE-SOP-011	SOP ON CONTROL OF PLANT MASTER FILE
STE-SOP-012	PROCEDURE FOR SPARE KEYS
STE-SOP-013	SOP ON RECEIVAL OF VISITORS AND INSPECTORS
STE-SOP-014	SOP ON OPERATION OF CENTRAL ALARM SYSTEM, PERIODIC CONTROL, DAILY REVIEW OF ALL ALARMS, CONTACT PERSONS FOR ALARMS
STE-SOP-015	OVERVIEW OF ALL TECHNICAL DRAWINGS
STE-SOP-016	EMERGENCY EXIT PLAN FOR ALL PERSONNELL
STE-SOP-017	EMERGENCY PLAN FOR FIRE DEPARTMENT AND PERSONNELL
STE-SOP-018	INVENTORY OF HAZARDOUS MATERIALS AND THEIR STORAGE PLACE
STE-SOP-019	LIST OF PERSONS IN CHARGE AND THEIR PHONE NUMBERS
STE-SOP-020	PLANNING FOR EMERGENCY TRAININGS

Computerized Systems Documentation (Part of Total List)

SOP NUMBER	SOP
CSV-SOP-001	SOP ON COMPUTERIZED SYSTEMS VALIDATION
CSV-SOP-002	SOP ON CHANGE MANAGEMENT
CSV-SOP-003	SOP ON COMPUTERIZED SYSTEMS BACKUP AND RECOVERY
CSV-SOP-004	SOP ON COMPUTERIZED SYSTEMS CATEGORIZATION
CSV-SOP-005	SOP ON VENDOR ASSESSMENT
CSV-SOP-006	SOP ON SYSTEM RETIREMENT
CSV-SOP-007	SOP ON LEGACY COMPUTERIZED SYSTEMS