

GAP ANALYSIS AND SET-UP OF A FUNCTIONAL SAFETY MANAGEMENT SYSTEM

PROJECT OWNER: Turnkey Contractor (chemical / pharmaceutical plant), Germany

TIMEFRAME: 2019/2020

KEY PROJECT DATA: A medium-sized Turnkey Contractor (annual turnover 25 Mio. EUR) requested assistance to set up a Functional Safety Management System in accordance with IEC 61511-1

SCOPE OF SERVICES: PSC provided consultancy services to set-up a FSMS that was tailor-made to the engineering, fabrication and installation activities of the Turnkey Contractor.

The project comprised three stages:

1. Gap Analysis acc. IEC 61508/61511 Checklists

- Desk-top-Review of existing FSM-, QM-Procedures
- Compliance-Review and Interviews acc. to Checklist at Contractor premises
- Management Report, Presentation/Discussion of Recommendations

2. Preparation of the FSMP

- FSM-Plan: Table of Contents, Scope
- Preparation of SLC Responsibility Matrix and Activities
- Pragmatic way forward, cross-reference / integration of existing QM-Procedures
- Define Priorities for the next steps: training requirements, preparation of missing documentation/procedures
- Road-Map“ for phased Compliance

3. Preparation of FSM-Templates

- Preparation of 24 templates
- Intensive comment / review sessions to adapt templates to Turnkey Contractor scope and responsibilities as per IEC 61511



Compliance Target # / Description	Procedures and Controls Required to Comply	IEC 61511 Refs. (Clause, Para)
1 General	FSM System	5.1
2 Requirements	FS Policy Statement	5.2.1
3 Organization & Responsibilities	Applied FS Lifecycle Phases – Procedures Competency Assessment Policy Personnel Competency Procedure Competency Assessment Report	5.2.2.1 5.2.2.2, 5.2.2.3
5	Training and Development Policy Training & Education Records Performance Appraisal Form	5.2.2.2
6 Risk evaluation and Risk management	HRA procedure including the requirement to identify the overall safety requirements and allocation of safety requirements Procedures for maintaining information on hazards with respect to all safety related systems (Assessment & Auditing) Post Incident / Accident activities	5.2.3 & 8.2
7 Planning	Functional Safety Planning (PFSP) Verification Planning	5.2.4 & 5.2.3 5.2.5
8 Implementation	SRS - Procedure / Checklist	5.2.5, 10
9 and Monitoring	Validation & Verification Planning	5.2.5, 15
10	Supplier Auditing & Assessment process	5.2.5.2
11	SIS Verification Procedure	5.2.5
12	SIL Conformance Assessment	5.2.5.3
13	Production Control & Issue of SIS Data	5.2.5, 5.2.6
14	SIS Project Checklists Procedure	5.2.5, 5.2.6
15	SIS Change Control Procedure for modification process of SIS	5.2.5, 5.2.6
16	Operation & Maintenance Procedures including: Proof testing regime Proof Test Procedures SIS Fault & Review (Assessing dangerous failures)	5.2.5.3, 5.2.6
17 FS Assessment	Functional Safety Assessment Procedure and plan for functional safety management system formal review	5.2.6.1.1 to 5.2.6.1.10
18 FS Audit Process	FS Audit Procedure and Schedule	5.2.6.2, 5.2.6.3
19 Management of Change	Management of Change	5.2.6.1.9, 5.2.6.2.4, 5.2.6.2.5, 17.2.1 to 17.2.8