

Management de la Revue du statut BPF des installations, des équipements et des Utilités



Annexe 2 : Vue d'ensemble des réglementations et GSOP définissant l'ensemble des aspect GMP liés au Projets

Le tableau suivant donne un aperçu des réglementations et GSOP qui définissent et décrivent le contenu des différents types de documents mentionnés au chapitre 5.

Document	Regulation
<ul style="list-style-type: none"> - Product Information e.g. CQA, OEL, Product Attributes, Markets, Process Description, Development Report - Process Information e.g. CPP, Process Flow Diagram - Risk Assessment 	GSOP 142 "Perform Product Design and Development"
<ul style="list-style-type: none"> - Basic Material, Product, Waste and Personal Flow (Block Diagram) - Conceptual Facility Layout, Zone Concept - Pressure Cascade Concept 	GSOP 268 "Cleanliness Classes, Airlocks, and Monitoring of Controlled Environment"
Calibration <ul style="list-style-type: none"> - Calibration Master List 	GSOP 533 "Manage Calibration"
Maintenance <ul style="list-style-type: none"> - Room Book - Maintenance Master Plan 	GSOP 428 "Manage Maintenance"
Change Request	GSOP 503 "Manage Change" and associated documents
<ul style="list-style-type: none"> - User Requirement Specification (URS) System Level - Quality Impact Assessment(s) - Detailed Risk Assessment (Technical System related) - DQ Report - IQ-, OQ and PQ Protocol and Report 	GSOP 125 "General Procedures for Commissioning and Qualification of Technical Systems" GSOP 1413 "Qualify GxP relevant Technical Systems with Computerized Controls"
Risk Assessment	GSOP 105 "Manage Quality Risk" GOI 1450 "Perform Failure Mode and Effect Analysis (FMEA)" BP 1625 "Training Manual: Risk Assessments executed during CAPEX-Projects"
Site Master File	GSOP 257 "GMP Documentation and Retention of Related Records"
Technology Transfer Plan	GSOP 144 "Perform Technology Transfer"
Validation Master Plan	GSOP 206 "Manage Validation Master Plan"
-	Corporate Directive 11 "Management of CapEx Projects/ Programs"