AUDIT TEMPLATE

Quality critical utilities review

Example audit template for gathering and assessing data on quality critical utilities against cGMP expectations.

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Ensuring the best quality and safety, everywhere

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1.0 Background and scope

The scope of this review is the Quality Critical Utilities at XYZ manufacturing site.

The Quality Critical Utilities are the utilities that have a direct impact on product quality (also referred to as Process Utility Systems). These Quality Critical Utilities will be determined as quality critical for one of the following reasons:

- Utility that Contacts the Product
- Utility that contacts material or surfaces that ultimately will become part of the product.
- Utility that controls contamination of surfaces that contact the product
- Utility that could directly affect product quality as determined in Process Risk Assessment.

The Quality Critical Utilities defined for the manufacturing processes at the SITE XYZ site are as follows:

» Need a full schedule of the Utilities

» Is there a Process Risk Assessment for the manufacturing processes we can refer to

» Example of the data we need to be compiling….

UTILITY GENERATION PLANT	UTILITY DISTRIBUTION SYSTEM	UTILITY USER POINT SCHEDULE	DOCUMENTS AND PROCEDURES ASSOCIATED
PW Generation PW4 in Building 22	PW4 Loop 1. Hot loop in B22.	13 User Points described on User point schedule ######.	List all documents and procedures that apply.
	PW4 Loop 2. Cold loop in B22	19 User Points described on User point schedule ######.	

The tables included in section 2 detail the areas of investigation and review. The defined critical utilities shall be assessed in these defined areas against cGMP expectations for Critical Utilities. During the review these tables shall be used as prompt, data shall be referenced and attached as required.

Any gaps against cGMP or identified further investigation required shall be defined in the final column. Following completion of this review a separate review report shall be issued for Critical Utilities Review which shall reference these tables and all of the attached data.

2.0 Critical utilities review

The following templates will act as prompts for data gathering and analysis.

Many of the sections will require support documentation which will be attached as Appendices and referenced in the table below.

Critical Utilities Management and expertise to be defined:

CRITICAL UTILITY	SUBJECT MATTER EXPERT	MECHANISM FOR MAINTAINING CGMP UNDERSTANDING AND COMPLIANCE
PW and WFI System		
Compressed Air and Process Gases		
Pure Steam		
HVAC		

2.1 PW generation system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Raw water input to the system meeting potable water standards, monitored and demonstrated control	Feed Water Quality to the PW Gen plant shall meet drinking water standards. How is this monitored? How is control demonstrated?		
Schematic and Description of the Generation plant components.	Accurate Schematic and P&ID of the Generation Plant. Function of each item in the Generation Plant understood and described? How is the performance of each item monitored? What PM's are in place for each item and how does condition monitoring impact on this?		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Generation Plant. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Generation Plant Functionality.	Continuous operation. Recirculation flow constantly. Softener regen functionality. RO Reject recirculation at high and low flow.		
Generation Plant Installation Following Hygienic design guidelines.	Materials of construction pre RO. Materials of construction post RO. Detailed review of pipework specification and weld data from RO onwards. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections. Review from Chlorine removal stage to the Storage Vessel feed.		
Generation Plant Sanitisation.	Method of Sanitisation. Review Procedure. Frequency or condition / data based sanitisation.		
Generation Plant output to the Storage vessel.	Loop return design with turbulent flow. How is loop velocity controlled. Zero dead leg diaphragm valve at Storage vessel. Storage Vessel connection draining and zero dead leg. Sanitisation of feed line from Generation to Storage Vessel.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Consumables Control	QC Control on consumables. Resins Filters RO Membranes Expiry Dates Manufacturers recommendations		
Buffer Tanks on Generation System.	Materials of Construction. Sealing and Venting. Vent Filter specification. Vessel turnover rate. Internal flow rates and wetting of the internals. Hygienic connections and equipment.		

2.2 PW storage and distribution system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Storage and Distribution System Design.	Design Principal (Flow control, Pressure Control, Pump control etc) How does the design achieve reliable turbulent flow throughout the loop. How is flow monitored? What action is taken in the event of low flow / low pressure.		
Schematic and Description of the Generation plant components.	Accurate Schematic and P&ID of the Storage and Distribution System. Function of each item in the Generation Plant understood and described? How is the performance of each item monitored? What PM's are in place for each item and how does condition monitoring impact on this?		
User point schedule	User point schedule detailing the flow, pressure and temperature requirements at each defined user point on the distribution system Link to sample point schedule. Are any user points redundant, if so how managed.		
User point Control	Auto, Manual or semi automatic control of each user point valve? Limit switch sensing of valve positions. (logic)		
User point connections.	Review user connections, hoses, fixed connections etc for hygienic design and operation compliance. Drain ability, storage of components. Any links to pressurised systems. Any direct CIP connections, pressure control requirements.		
User point diversity requirements and control.	Link to user point schedule. Interlocking of user points?		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the distribution loop. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Loop Components Design and Operation	Heat Exchanger performance against design calculations. Heat Exchanger hygienic design to ensure no leak between dirty and clean side. Evidence of temperature control performance throughout the year. UV Lamp design, lamp intensity monitoring, PM change frequency. Pump calculations and control. Ozone generation and detection systems Other loop components, orifices, constaflows, regulating valves? Hygienic design, operation and maintenance		
Storage Tank	Materials of construction, surface finish and design. Loop recirculation design for tank wetting. Sprayball effectiveness. Ozone headspace sanitisation. Tank connections hygienic and compliant dead legs. Vent filter installation. Vent filter change, inspection, integrity testing. Bursting disc installation and burst indicator. Storage Tank Bottom outlet to loop pumps, ensure no deadlegs to pumps, changeover pumps etc.		
Loop Pumps	Duty and Standby or changeover system. Pump seal material, change frequency and inspection frequency. Maintenance procedure for any loop break in. e.g. pump repair or change.		
System Rouge Monitoring and Control	How and where is Rouge monitored. How is rouge recorded. Rouge removal and re passivation frequency? Condition based? Rationale.		
Storage and Distribution system; Biofilm monitoring and control.	Evidence, inspection or sampling for biofilm. Biofilm removal actions. Trend and monitoring data.		
Loop and components hygienic design.	Materials of construction. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Lagging	Lagging requirements for hot loops or cold loops. Hygienic design in clean areas. Impact on user point and sample valves.		
Loop Sanitisation.	Method of Sanitisation. Review Procedure. Frequency and Control. Heat sanitisation data on overall lethality, efficacy. Ozone sanitisation data on residual ozone. User point sanitisation. Dead areas sanitisation, valve movements etc.		

2.3 WFI generation system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
WFI Quality Uses and Requirements analysis.	Product / Equipment Contact. Highest quality impact requirements for wfi. Defined site specification for wfi quality. Link to EP, USP requirements. Analyse all wfi quality trend data and history. Wfi alert and action levels.		
Water Quality feeding WFI still, monitored and demonstrated control	Feed Water Quality to the Still meets design requirements for the still. How is this monitored? How is control demonstrated?		
Schematic and Description of the wfi generation plant.	Accurate Schematic and P&ID of the Generation Plant. Function of each item in the Generation Plant understood and described? How is the performance of each item monitored? What PM's are in place for each item and how does condition monitoring impact on this?		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Generation Plant. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Generation Plant Functionality.	Functional description. Operational parameters. Plant Steam supply requirements and controls. System Pressure controls and monitoring. Output Temperature Control and monitoring. Blowdown function.		
Generation Plant Installation Following Hygienic design guidelines.	Materials of construction. Internal columns, external and pipework. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections.		
Generation Plant output to the Storage vessel.	Stop / Start design and drainability from wfi still output to the wfi storage vessel. Zero dead leg diaphragm valve at Storage vessel. Storage Vessel connection draining and zero dead leg. Sanitisation of feed line from Generation to Storage Vessel.		
Wfi still start up procedure.	Functionality of start up. Purge requirements prior to feed forward.		

2.4 WFI storage and distribution system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Storage and Distribution System Design.	Design Principal (Flow control, Pressure Control, Pump control etc) How does the design achieve reliable turbulent flow throughout the loop. How is flow monitored? What action is taken in the event of low flow / low pressure.		
Schematic and Description of the Generation plant components.	Accurate Schematic and P&ID of the Storage and Distribution System. Function of each item in the Generation Plant understood and described? How is the performance of each item monitored? What PM's are in place for each item and how does condition monitoring impact on this?		
User point schedule	User point schedule detailing the flow, pressure and temperature requirements at each defined user point on the distribution system Link to sample point schedule. Are any user points redundant, if so how managed.		
User point Control	Auto, Manual or semi automatic control of each user point valve? Limit switch sensing of valve positions. (logic)		
User point connections.	Review user connections, hoses, fixed connections etc for hygienic design and operation compliance. Drain ability, storage of components. Any links to pressurised systems. Any direct CIP connections, pressure control requirements.		
User point diversity requirements and control.	Link to user point schedule. Interlocking of user points?		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the distribution loop. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Loop Components Design and Operation	Heat Exchanger performance against design calculations. Heat Exchanger hygienic design to ensure no leak between dirty and clean side. Evidence of temperature control performance throughout the year. Pump calculations and control. Other loop components, orifices, constaflows, regulating valves? Hygienic design, operation and maintenance		
Storage Tank	Materials of construction, surface finish and design. Loop recirculation design for tank wetting. Sprayball effectiveness. Tank connections hygienic and compliant dead legs. Vent filter installation. Vent filter change, inspection, integrity testing. Bursting disc installation and burst indicator. Storage Tank Bottom outlet to loop pumps, ensure no deadlegs to pumps, changeover pumps etc.		
Loop Pumps	Duty and Standby or changeover system. Pump seal material, change frequency and inspection frequency. Maintenance procedure for any loop break in. e.g. pump repair or change.		
System Rouge Monitoring and Control	How and where is Rouge monitored. How is rouge recorded. Rouge removal and re passivation frequency? Condition based? Rationale.		
Storage and Distribution system; Biofilm monitoring and control.	Evidence, inspection or sampling for biofilm. Biofilm removal actions. Trend and monitoring data.		
Loop and components hygienic design.	Materials of construction. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections.		
Lagging	Lagging requirements for hot loops or cold loops. Hygienic design in clean areas. Impact on user point and sample valves.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Loop Sanitisation.	Method of Sanitisation. Review Procedure. Frequency and Control. User point sanitisation. Dead areas sanitisation, valve movements etc.		

2.5 Pure steam generation

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Steam Quality Uses and Requirements analysis.	Product / Equipment Contact. Highest quality impact requirements for Clean steam. Defined site specification for steam quality. Link to EP, USP, EN285 requirements.		
Water Quality feeding CSG / PSG, monitored and demonstrated control	Feed Water Quality to the Steam Generator meets design requirements for the Generator. How is this monitored? How is control demonstrated?		
Schematic and Description of the Steam Generator.	Accurate Schematic and P&ID of the Generation Plant. Function of each item in the Generation Plant understood and described? How is the performance of each item monitored? What PM's are in place for each item and how does condition monitoring impact on this?		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Steam Generator. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Steam Generator Functionality.	Functional description. Operational parameters. Plant Steam supply requirements and controls. System Pressure controls and monitoring. Output Temperature Control and monitoring. Blowdown function.		
Steam Generator Installation Following Hygienic design guidelines.	Materials of construction. Internal columns, external and pipework. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections. Steam Trap installations to minimise condensate.		
Steam Quality Measurements	Steam Quality Test Points at Generator output for EN285 Testing (NCG, Dryness and Superheat) SQT Data trends. Condensate sample device. Condensate data trends.		
Steam Start up procedure	Functionality of start up. Purge requirements prior to use of Steam. Condensate and EN285 SQT data to qualify steam start up procedure.		

2.6 Pure steam distribution system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Distribution System Design.	Design Principal (Loop or single flow). Multiple Steam Generators, control logic and performance. How is pressure monitored? Pressure Control and reduction throughout the loop. What action is taken in the event of low pressure.		
Schematic and Description of the distribution system components.	Accurate Schematic and P&ID of the Distribution System. What PM's are in place for each item and how does condition monitoring impact on this?		
User point schedule	User point schedule detailing the pressure control requirements at each defined user point on the steam distribution system How are pressure limits linked to the user point equipment validation. Are any user points redundant, if so how managed.		
Steam Trap schedule.	Check accuracy of steam trap schedule. Steam Trap installation at least every 30m on the distribution loop. Steam trap installation where ever the steam distribution pipework rises or falls. Steam Trap installation onto equal T's Steam trap discharge onto a 'non back pressure' system to allow free flow of condensate. Steam Trap inspection and maintenance.		
User point connections.	User points taken off the top of the distribution pipework. Additional steam traps at the user take off points.		
User point steam quality requirements	Steam Quality requirements defined at each user point. Steam Quality testing data and frequency of testing at each user point		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the distribution loop. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
System Rouge Monitoring and Control	How and where is Rouge monitored. How is rouge recorded. Rouge removal and re passivation frequency? Condition based? Rationale.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Loop and components hygienic design.	Materials of construction. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Dead legs. (< 2D) Connections.		
Steam System Start up Procedure	Qualification of a procedure to ensure the correct quality of steam at critical user points.		

2.7 Bulk delivery and storage of process gases

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Define Process Gases	List all Process Gases used in Quality Critical applications. Define quality Standard of the Process Gas NOTE Purity Classification (e.g. 4.7 =99.997%) NOTE Water Content (e.g. N_2 <5ppm v/v, -65°C Dew point) NOTE Oxygen content (e.g. N_2 <5ppm v/v) NOTE Hydrocarbons (e.g. N_2 <5ppm as Methane .		
Supplier Details	Supplier Details Technical Agreement with supplier (Check QC testing responsibilities and audit of QC testing) Supplied Gas Traceability details. Check Supplier / User responsibility at Storage Vessel, Vaporiser, Downstream etc		
Delivery Methods	Review Delivery Methods and connection procedures for bulk gases.		
Storage Vessel	Inner vessel Material of construction. Check IQ Data for Inner Vessel.		
Vaporising System	Vaporising System Material of Construction. Check IQ Data for Wetted parts.		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Bulk Process Gas storage facility. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		

2.8 Process gases distribution system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Process Gas User point schedules	P&ID for distribution system. User point schedule. User point risk assessment / criticality assessment. User point area classification assessment		
Non Critical Processes Gases and Compressed air entering clean rooms.	Assessment of all other Process Gases and Compressed air entering the production environment. Viable and non viable specification of the process gas or air entering the clean room should meet the clean room viable and non viable specification. Documented assessment of all other gases and air.		
Distribution System Quality Improvement specifications	Define any aspects of quality / specification of the process gases that are intended to be improved by the site system and distribution system; Microbial Quality Particulate Quality		
Filtration in the Distribution system.	Filter Schedule from Storage to user point filtration. Filter Specifications Change out frequency. Condition or time. Filter Integrity testing Filter Sterilisation requirements.		
User Point Connections and Identification.	Connection hoses and connection equipment. Storage, sanitisation. Change frequency and inspection of connection hoses. Identification of user points and link to critical operations.		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Distribution system. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Distribution System Pressure Control	Identify supply pressure control and pressure reducing stations. Low pressure alarms and actions. Pressure trends, control.		
Distribution System Following Hygienic design guidelines.	Materials of construction. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Tubing and connector assessment for moisture ingress.		
User Point Testing schedule	User point Testing schedule:- Viable Non Viable Moisture Level Other critical parameters based upon risk assessment from supplied process gas quality.		

2.9 Compressed air generation

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Air Compressor Design	Compressed air generation system design; number of compressors, duty standby control etc. Oil Free Compressor Compressor quality specification		
Air Compressor input.	Risk assessment of compressed air inlet contaminants.		
Compressor After cooler design and hygienic operation.	Check intercooler and after cooler design. Failure modes. Moisture separators (Sanitisation of moisture separators).		
Air Output conditioning equipment Specification.	Filters Wet Receiver Dryer. Dry Receiver Pressure Control Control System		
Dryer	Define the dryer design (Refrigerant Dryer, Regenerative desiccant dryer, heat of compression dryer). Assess System contamination risks from the dryer design and operation. a) Refrigerant leaks b) Desiccant particles Maintenance schedule, inspection and performance monitoring of the dryer. Moisture removal system (Drain, blowdown)		
Filter Schedule	Schedule of all filters from Compressor to the output from the Generation Plant. Oil removal Filters:- a) Coalescing filters to remove oil droplets b) Adsorbent filters to remove oil vapour Particulate Filters Final Sterile Filter (0.2um liquid rated filter 0.003um gas rated)		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Air Compressor. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Compressor output pressure control.	Pressure Control Calibration Trends and Alarms		

2.10 Compressed air distribution system

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Compressed Air User point schedules	P&ID for distribution system. User point schedule. User point risk assessment / criticality assessment. User point area classification assessment		
Distribution System Quality Improvement specifications	Define any aspects of quality / specification of the compressed air that are intended to be improved by the site system and distribution system; Microbial Quality Particulate Quality		
Filtration in the Distribution system.	Filter Schedule from Storage to user point filtration. Filter Specifications Change out frequency. Condition or time. Filter Integrity testing Filter Sterilisation requirements.		
User Point Connections and Identification.	Connection hoses and connection equipment. Storage, sanitisation. Change frequency and inspection of connection hoses. Identification of user points and link to critical operations.		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the Distribution system. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
Distribution System Pressure Control	Identify supply pressure control and pressure reducing stations. Low pressure alarms and actions. Pressure trends, control.		
Distribution System Following Hygienic design guidelines.	Materials of construction. Detailed review of pipework specification and weld data. Soft Parts schedule and change frequency. Drain ability. (Line slopes >1:100) Tubing and connector assessment for moisture ingress.		
User Point Testing schedule	User point Testing schedule:- Viable Non Viable Moisture Level Other critical parameters based upon risk assessment from supplied compressed air quality.		

2.11 HVAC: intake and air handling units

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
HVAC Plant AHU Schedule and location	Defined schedule of AHU's Air intake locations defined Common air intake locations defined HVAC Ductwork / supply areas defined Recirculation air ductwork routes		
HVAC Cross Contamination and Contamination Control Risk assessment	High risk products and processes identified. Cross Contamination / Contamination Control Risk assessment available and current. CC RA maintained as a live document.		
HVAC Air Intake	Any specific risks or challenges identified due to the location of AHU inlet locations.		
HVAC Heat Exchangers Risk assessment	Heating and Cooling Coils Schedule. Maintenance, Inspection and Testing schedule for heat exchangers and cooling coils in the AHU. Failure mode impact assessments and risk assessments.		
HVAC Humidification Risk assessments	Humidification systems? Steam Quality used for humidification? Inspection and maintenance of the humidification system and areas of AHU.		
Validation	Review Validation Lifecycle URS FDS/DDS/ Specifications Risk assessments/ FMEA/ RTM's? DQ IQ OQ PQ Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	Frequency of Validation Review Reports. Validation Review Reports include:- Change Controls Incident Reports CAPA's PM's history Control System Maintenance GAMP Classifications Data Trends and analysis Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.		
Validation Review / Aged Plant analysis	Assessment of plant age and supportability included in VRR? Age related performance issues. Material impact of age / use / sanitisation frequency. Equipment Supportability by Technical expertise and experience. Spare parts availability. Obsolete components Control System supportability.		
In Process Measurements, Limits and trends.	On line and In line instrumentation on the AHU. View trends, alert and action limits. Defined actions for the action limits. Off line, sampling frequency and testing. View trends, alert and action limits. Defined actions for the action limits		
AHU Functionality and Control.	Functional description. Operational parameters.		
AHU Balancing and Damper settings.	Schedule of manual settings. Recorded settings. Dampers locked / secured / marked on site.		
AHU Installation, ductwork	Materials of construction. Detailed review of ductwork specification and installation quality.		
Filter Test points	DOP test points installed correctly. DOP test points identified correctly. Velocity measurement locations identified. Review 6 monthly Testing of Filters, Velocities, pressures etc. Review report and data.		

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Filter change schedule.	Filter schedule and justification for change out frequency. Manufacturers recommendations for filter life. Potential for filter event / disruption to increase particulate levels Filter Specifications consistent and 'as designed' / 'as validated'		
Ductwork and AHU internal inspection	Inspection Frequency Scope of inspection When is cleaning performed, required? How is this assessment made. Microbiology control within the AHU and Ductwork.		

2.12 HVAC ductwork and filtration

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Terminal ductwork and Filtration	Terminal Filter Specifications. Terminal Filter Test frequency. Review filter test methods and data.		
Filter change Procedure	Review terminal filter change procedure for impact on clean room. Cleaning ductwork around filter change. Inspection of ductwork. Micro biological assessment.		
Filter Installation compliance with manufacturers recommendations	Installation. Flow rate and Differential Pressure performance. Filter performance rating linked to installed flow rate and differential pressure. Filter manufacturers recommended life compliance.		
Terminal Filter Plant room protection	Access and inadvertent impact with terminal filters in plant room areas.		
Local / Final damper settings recorded 'as validated'	Schedule of local and final damper settings. Dampers locked or secured in place.		

2.13 Engineering maintenance and support

PARAMETER	REQUIREMENTS	SITE REVIEW	GAP ANALYSIS AND ACTIONS
Utility Ownership clearly defined.	High Purity Water Systems Clean / Pure Steam Systems. Compressed air and process gases HVAC AHU's and systems.		
Technical Access Controls	Engineering access controlled physically. a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems. Engineering Control Systems access controlled. a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems		
Approved Contract Resource	List all suppliers engineering companies and contract engineering/test companies. a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems Check Technical Agreements. Check Named engineers. Check Training		
Site Engineering Training and Competency Assessment	Named / Approved Engineers. Check Training and competency assessments for different systems. Engineering GEP Training.		
Technical Knowledge	Where does the required technical expertise rest. Is this required technical expertise sustainable.		
Maintenance Procedures	Responsibility for Review and Control of Maintenance procedures. Do maintenance procedures reflect the age and condition of the equipment. How are maintenance procedures, schedules and frequencies reviewed.		

3.0 Schedule of attachments

Support Data should be referenced in the sections identified above with site documentation references and version numbers. Copies of this documentation does not require to be attached to this document.

Any additional documents used or referenced in this review that do not form part of the documentation system and do not have a document reference shall be listed here and attached. Attachments shall be referenced A1, A2 etc.

ATTACHMENT REFERENCE	DOCUMENT TITLE	SECTION REFERENCE
A1		
A2		
A3		
A4		
A5		
A6		
A7		
A8		
A9		
A10		
A11		
A12		