



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

CONTENTS

1.0	BACKGROUND AND SCOPE	2
2.0	CRITICAL UTILITIES REVIEW	3
2.1	PW Generation System	4
2.2	PW Storage and Distribution System	10
2.3	WFI Generation System	17
2.4	WFI Storage and Distribution System	21
2.5	Pure Steam Generation	28
2.6	Pure Steam Distribution	33
2.7	Process Gases; Bulk Delivery and Storage	38
2.8	Process Gases Distribution	42
2.9	Compressed Air Generation	48
2.10	Compressed Air Distribution	55
2.11	HVAC Intake and Air Handling Units	60
2.12	HVAC Ductwork and Filtration	68
2.13	Engineering Maintenance and Support	71
	SCHEDULE OF ATTACHMENTS	75

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 1 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

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

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 2 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

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		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 3 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.1 PW GENERATION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Raw water input to the system meeting potable water standards, monitored and demonstrated control	<p>Feed Water Quality to the PW Gen plant shall meet drinking water standards.</p> <p>How is this monitored?</p> <p>How is control demonstrated?</p>		
Schematic and Description of the Generation plant components.	<p>Accurate Schematic and P&ID of the Generation Plant.</p> <p>Function of each item in the Generation Plant understood and described?</p> <p>How is the performance of each item monitored?</p> <p>What PM's are in place for each item and how does condition monitoring impact on this?</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 4 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 5 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Generation Plant.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Generation Plant Functionality.	<p>Continuous operation. Recirculation flow constantly.</p> <p>Softener regen functionality.</p> <p>RO Reject recirculation at high and low flow.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 6 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 7 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		
Consumables Control	QC Control on consumables. Resins Filters RO Membranes Expiry Dates Manufacturers recommendations		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 8 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 9 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.2 PW STORAGE AND DISTRIBUTION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Storage and Distribution System Design.	<p>Design Principal (Flow control, Pressure Control, Pump control etc)</p> <p>How does the design achieve reliable turbulent flow throughout the loop.</p> <p>How is flow monitored?</p> <p>What action is taken in the event of low flow / low pressure.</p>		
Schematic and Description of the Generation plant components.	<p>Accurate Schematic and P&ID of the Storage and Distribution System.</p> <p>Function of each item in the Generation Plant understood and described?</p> <p>How is the performance of each item monitored?</p> <p>What PM's are in place for each item and how does condition monitoring impact on this?</p>		
User point schedule	<p>User point schedule detailing the flow, pressure and temperature requirements at each defined user point on the distribution system</p> <p>Link to sample point schedule.</p> <p>Are any user points redundant, if so how managed.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 10 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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?		
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)		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 11 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	<p>Frequency of Validation Review Reports.</p> <p>Validation Review Reports include: -</p> <p>Change Controls</p> <p>Incident Reports</p> <p>CAPA's</p> <p>PM's history</p> <p>Control System Maintenance</p> <p>GAMP Classifications</p> <p>Data Trends and analysis</p> <p>Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.</p>		
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 12 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the distribution loop.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Loop Components Design and Operation	<p>Heat Exchanger performance against design calculations.</p> <p>Heat Exchanger hygienic design to ensure no leak between dirty and clean side.</p> <p>Evidence of temperature control performance throughout the year.</p> <p>UV Lamp design, lamp intensity monitoring, PM change frequency.</p> <p>Pump calculations and control.</p> <p>Ozone generation and detection systems</p> <p>Other loop components, orifices, constaflows, regulating valves? Hygienic design, operation and maintenance</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 13 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Storage Tank	<p>Materials of construction, surface finish and design.</p> <p>Loop recirculation design for tank wetting. Sprayball effectiveness.</p> <p>Ozone headspace sanitisation.</p> <p>Tank connections hygienic and compliant dead legs.</p> <p>Vent filter installation.</p> <p>Vent filter change, inspection, integrity testing.</p> <p>Bursting disc installation and burst indicator.</p> <p>Storage Tank Bottom outlet to loop pumps, ensure no deadlegs to pumps, changeover pumps etc.</p>		
Loop Pumps	<p>Duty and Standby or changeover system.</p> <p>Pump seal material, change frequency and inspection frequency.</p> <p>Maintenance procedure for any loop break in. e.g. pump repair or change.</p>		
System Rouge Monitoring and Control	<p>How and where is Rouge monitored.</p> <p>How is rouge recorded.</p> <p>Rouge removal and re passivation frequency? Condition based? Rationale.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 14 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 15 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Loop Sanitisation.	<p>Method of Sanitisation.</p> <p>Review Procedure.</p> <p>Frequency and Control.</p> <p>Heat sanitisation data on overall lethality, efficacy.</p> <p>Ozone sanitisation data on residual ozone.</p> <p>User point sanitisation.</p> <p>Dead areas sanitisation, valve movements etc.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 16 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.3 WFI GENERATION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ 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?		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 17 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 18 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Generation Plant.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Generation Plant Functionality.	<p>Functional description. Operational parameters.</p> <p>Plant Steam supply requirements and controls.</p> <p>System Pressure controls and monitoring.</p> <p>Output Temperature Control and monitoring.</p> <p>Blowdown function.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 19 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Generation Plant Installation Following Hygienic design guidelines.	<p>Materials of construction. Internal columns, external and pipework.</p> <p>Detailed review of pipework specification and weld data.</p> <p>Soft Parts schedule and change frequency.</p> <p>Drain ability. (Line slopes >1:100)</p> <p>Dead legs. (< 2D)</p> <p>Connections.</p>		
Generation Plant output to the Storage vessel.	<p>Stop / Start design and drainability from wfi still output to the wfi storage vessel.</p> <p>Zero dead leg diaphragm valve at Storage vessel.</p> <p>Storage Vessel connection draining and zero dead leg.</p> <p>Sanitisation of feed line from Generation to Storage Vessel.</p>		
Wfi still start up procedure.	<p>Functionality of start up.</p> <p>Purge requirements prior to feed forward.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 20 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.4 WFI STORAGE AND DISTRIBUTION SYSTEM

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

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 21 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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?		
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)		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 22 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	<p>Frequency of Validation Review Reports.</p> <p>Validation Review Reports include: -</p> <p>Change Controls</p> <p>Incident Reports</p> <p>CAPA's</p> <p>PM's history</p> <p>Control System Maintenance</p> <p>GAMP Classifications</p> <p>Data Trends and analysis</p> <p>Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.</p>		
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 23 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the distribution loop.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Loop Components Design and Operation	<p>Heat Exchanger performance against design calculations.</p> <p>Heat Exchanger hygienic design to ensure no leak between dirty and clean side.</p> <p>Evidence of temperature control performance throughout the year.</p> <p>Pump calculations and control.</p> <p>Other loop components, orifices, constafloes, regulating valves? Hygienic design, operation and maintenance</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 24 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Storage Tank	<p>Materials of construction, surface finish and design.</p> <p>Loop recirculation design for tank wetting. Sprayball effectiveness.</p> <p>Tank connections hygienic and compliant dead legs.</p> <p>Vent filter installation.</p> <p>Vent filter change, inspection, integrity testing.</p> <p>Bursting disc installation and burst indicator.</p> <p>Storage Tank Bottom outlet to loop pumps, ensure no deadlegs to pumps, changeover pumps etc.</p>		
Loop Pumps	<p>Duty and Standby or changeover system.</p> <p>Pump seal material, change frequency and inspection frequency.</p> <p>Maintenance procedure for any loop break in. e.g. pump repair or change.</p>		
System Rouge Monitoring and Control	<p>How and where is Rouge monitored.</p> <p>How is rouge recorded.</p> <p>Rouge removal and re passivation frequency? Condition based? Rationale.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 25 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review. Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 26 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

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

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 27 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.5 PURE STEAM GENERATION

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Steam Quality Uses and Requirements analysis.	<p>Product / Equipment Contact.</p> <p>Highest quality impact requirements for Clean steam.</p> <p>Defined site specification for steam quality.</p> <p>Link to EP, USP, EN285 requirements.</p>		
Water Quality feeding CSG / PSG, monitored and demonstrated control	<p>Feed Water Quality to the Steam Generator meets design requirements for the Generator.</p> <p>How is this monitored?</p> <p>How is control demonstrated?</p>		
Schematic and Description of the Steam Generator.	<p>Accurate Schematic and P&ID of the Generation Plant.</p> <p>Function of each item in the Generation Plant understood and described?</p> <p>How is the performance of each item monitored?</p> <p>What PM's are in place for each item and how does condition monitoring impact on this?</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 28 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 29 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Steam Generator.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Steam Generator Functionality.	<p>Functional description. Operational parameters.</p> <p>Plant Steam supply requirements and controls.</p> <p>System Pressure controls and monitoring.</p> <p>Output Temperature Control and monitoring.</p> <p>Blowdown function.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 30 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Steam Generator Installation Following Hygienic design guidelines.	<p>Materials of construction. Internal columns, external and pipework.</p> <p>Detailed review of pipework specification and weld data.</p> <p>Soft Parts schedule and change frequency.</p> <p>Drain ability. (Line slopes >1:100)</p> <p>Dead legs. (< 2D)</p> <p>Connections.</p> <p>Steam Trap installations to minimise condensate.</p>		
Steam Quality Measurements	<p>Steam Quality Test Points at Generator output for EN285 Testing (NCG, Dryness and Superheat)</p> <p>SQT Data trends.</p> <p>Condensate sample device.</p> <p>Condensate data trends.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 31 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Steam Start up procedure	<p>Functionality of start up.</p> <p>Purge requirements prior to use of Steam.</p> <p>Condensate and EN285 SQT data to qualify steam start up procedure.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 32 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.6 PURE STEAM DISTRIBUTION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Distribution System Design.	<p>Design Principal (Loop or single flow).</p> <p>Multiple Steam Generators, control logic and performance.</p> <p>How is pressure monitored?</p> <p>Pressure Control and reduction throughout the loop.</p> <p>What action is taken in the event of low pressure.</p>		
Schematic and Description of the distribution system components.	<p>Accurate Schematic and P&ID of the Distribution System.</p> <p>What PM's are in place for each item and how does condition monitoring impact on this?</p>		
User point schedule	<p>User point schedule detailing the pressure control requirements at each defined user point on the steam distribution system</p> <p>How are pressure limits linked to the user point equipment validation.</p> <p>Are any user points redundant, if so how managed.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 33 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Steam Trap schedule.	<p>Check accuracy of steam trap schedule.</p> <p>Steam Trap installation at least every 30m on the distribution loop.</p> <p>Steam trap installation where ever the steam distribution pipework rises or falls.</p> <p>Steam Trap installation onto equal T's</p> <p>Steam trap discharge onto a 'non back pressure' system to allow free flow of condensate.</p> <p>Steam Trap inspection and maintenance.</p>		
User point connections.	<p>User points taken off the top of the distribution pipework.</p> <p>Additional steam traps at the user take off points.</p>		
User point steam quality requirements	<p>Steam Quality requirements defined at each user point.</p> <p>Steam Quality testing data and frequency of testing at each user point</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 34 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 35 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the distribution loop.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
System Rouge Monitoring and Control	<p>How and where is Rouge monitored.</p> <p>How is rouge recorded.</p> <p>Rouge removal and re passivation frequency? Condition based? Rationale.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 36 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 37 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.7 BULK DELIVERY AND STORAGE OF PROCESS GASES

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Define Process Gases	<p>List all Process Gases used in Quality Critical applications.</p> <p>Define quality Standard of the Process Gas</p> <p>NOTE Purity Classification (e.g. 4.7 =99.997%)</p> <p>NOTE Water Content (e.g. N₂ <5ppm v/v, -65°C Dew point)</p> <p>NOTE Oxygen content (e.g. N₂ <5ppm v/v)</p> <p>NOTE Hydrocarbons (e.g. N₂ <5ppm as Methane)</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 38 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review. Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the
beginning of the reviews.

Date Issued:

24th April 2017

Page 39 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 40 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Bulk Process Gas storage facility.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 41 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.8 PROCESS GASES DISTRIBUTION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Process Gas User point schedules	<p>P&ID for distribution system.</p> <p>User point schedule.</p> <p>User point risk assessment / criticality assessment.</p> <p>User point area classification assessment</p>		
Non Critical Processes Gases and Compressed air entering clean rooms.	<p>Assessment of all other Process Gases and Compressed air entering the production environment.</p> <p>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.</p> <p>Documented assessment of all other gases and air.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 42 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Distribution System Quality Improvement specifications	<p>Define any aspects of quality / specification of the process gases that are intended to be improved by the site system and distribution system;</p> <p>Microbial Quality</p> <p>Particulate Quality</p>		
Filtration in the Distribution system.	<p>Filter Schedule from Storage to user point filtration.</p> <p>Filter Specifications</p> <p>Change out frequency. Condition or time.</p> <p>Filter Integrity testing</p> <p>Filter Sterilisation requirements.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 43 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
User Point Connections and Identification.	<p>Connection hoses and connection equipment.</p> <p>Storage, sanitisation.</p> <p>Change frequency and inspection of connection hoses.</p> <p>Identification of user points and link to critical operations.</p>		
Validation	<p>Review Validation Lifecycle</p> <p>URS</p> <p>FDS/DDS/ Specifications</p> <p>Risk assessments/ FMEA/ RTM's?</p> <p>DQ</p> <p>IQ</p> <p>OQ</p> <p>PQ</p> <p>Validation Review linked to site Validation Master Plan (Check Critical system status on VMP)</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 44 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review	<p>Frequency of Validation Review Reports.</p> <p>Validation Review Reports include:-</p> <p>Change Controls</p> <p>Incident Reports</p> <p>CAPA's</p> <p>PM's history</p> <p>Control System Maintenance</p> <p>GAMP Classifications</p> <p>Data Trends and analysis</p> <p>Review against cGMP, Standards, Guidance Documents and pharmacopeia updates.</p>		
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 45 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Distribution system.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Distribution System Pressure Control	<p>Identify supply pressure control and pressure reducing stations.</p> <p>Low pressure alarms and actions.</p> <p>Pressure trends, control.</p>		
Distribution System Following Hygienic design guidelines.	<p>Materials of construction.</p> <p>Detailed review of pipework specification and weld data.</p> <p>Soft Parts schedule and change frequency.</p> <p>Drain ability. (Line slopes >1:100)</p> <p>Tubing and connector assessment for moisture ingress.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 46 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 47 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.9 COMPRESSED AIR GENERATION

PARAMETER	REQUIREMENTS	SITE XYZ 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).		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 48 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Air Output conditioning equipment Specification.	Filters		
	Wet Receiver		
	Dryer.		
	Dry Receiver		
	Pressure Control		
	Control System		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 49 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Dryer	<p>Define the dryer design (Refrigerant Dryer, Regenerative desiccant dryer, heat of compression dryer).</p> <p>Assess System contamination risks from the dryer design and operation.</p> <ul style="list-style-type: none"> a) Refrigerant leaks b) Desiccant particles <p>Maintenance schedule, inspection and performance monitoring of the dryer.</p> <p>Moisture removal system (Drain, blowdown)</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 50 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Filter Schedule	<p>Schedule of all filters from Compressor to the output from the Generation Plant.</p> <p>Oil removal Filters:-</p> <ul style="list-style-type: none"> a) Coalescing filters to remove oil droplets b) Adsorbent filters to remove oil vapour <p>Particulate Filters</p> <p>Final Sterile Filter (0.2um liquid rated filter 0.003um gas rated)</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 51 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 52 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Air Compressor.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 53 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Compressor output pressure control.	Pressure Control Calibration Trends and Alarms		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 54 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.10 COMPRESSED AIR DISTRIBUTION SYSTEM

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Compressed Air User point schedules	<p>P&ID for distribution system.</p> <p>User point schedule.</p> <p>User point risk assessment / criticality assessment.</p> <p>User point area classification assessment</p>		
Distribution System Quality Improvement specifications	<p>Define any aspects of quality / specification of the compressed air that are intended to be improved by the site system and distribution system;</p> <p>Microbial Quality</p> <p>Particulate Quality</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 55 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 56 of 75



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 57 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the Distribution system.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
Distribution System Pressure Control	<p>Identify supply pressure control and pressure reducing stations.</p> <p>Low pressure alarms and actions.</p> <p>Pressure trends, control.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 58 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Distribution System Following Hygienic design guidelines.	<p>Materials of construction.</p> <p>Detailed review of pipework specification and weld data.</p> <p>Soft Parts schedule and change frequency.</p> <p>Drain ability. (Line slopes >1:100)</p> <p>Tubing and connector assessment for moisture ingress.</p>		
User Point Testing schedule	<p>User point Testing schedule:-</p> <p>Viabile</p> <p>Non Viabile</p> <p>Moisture Level</p> <p>Other critical parameters based upon risk assessment from supplied compressed air quality.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 59 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.11 HVAC: INTAKE AND AIR HANDLING UNITS

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
HVAC Plant AHU Schedule and location	<p>Defined schedule of AHU's</p> <p>Air intake locations defined</p> <p>Common air intake locations defined</p> <p>HVAC Ductwork / supply areas defined</p> <p>Recirculation air ductwork routes</p>		
HVAC Cross Contamination and Contamination Control Risk assessment	<p>High risk products and processes identified.</p> <p>Cross Contamination / Contamination Control Risk assessment available and current.</p> <p>CC RA maintained as a live document.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 60 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
HVAC Air Intake	Any specific risks or challenges identified due to the location of AHU inlet locations.		
HVAC Heat Exchangers Risk assessment	<p>Heating and Cooling Coils Schedule.</p> <p>Maintenance, Inspection and Testing schedule for heat exchangers and cooling coils in the AHU.</p> <p>Failure mode impact assessments and risk assessments.</p>		
HVAC Humidification Risk assessments	<p>Humidification systems?</p> <p>Steam Quality used for humidification?</p> <p>Inspection and maintenance of the humidification system and areas of AHU.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 61 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 62 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Validation Review / Aged Plant analysis	<p>Assessment of plant age and supportability included in VRR?</p> <p>Age related performance issues.</p> <p>Material impact of age / use / sanitisation frequency.</p> <p>Equipment Supportability by Technical expertise and experience.</p> <p>Spare parts availability.</p> <p>Obsolete components</p> <p>Control System supportability.</p>		
In Process Measurements, Limits and trends.	<p>On line and In line instrumentation on the AHU.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits.</p> <p>Off line, sampling frequency and testing.</p> <p>View trends, alert and action limits.</p> <p>Defined actions for the action limits</p>		
AHU Functionality and Control.	<p>Functional description. Operational parameters.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 63 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
AHU Balancing and Damper settings.	<p>Schedule of manual settings.</p> <p>Recorded settings.</p> <p>Dampers locked / secured / marked on site.</p>		
AHU Installation, ductwork	<p>Materials of construction.</p> <p>Detailed review of ductwork specification and installation quality.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 64 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Filter Test points	<p>DOP test points installed correctly.</p> <p>DOP test points identified correctly.</p> <p>Velocity measurement locations identified.</p> <p>Review 6 monthly Testing of Filters, Velocities, pressures etc. Review report and data.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 65 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Filter change schedule.	<p>Filter schedule and justification for change out frequency.</p> <p>Manufacturers recommendations for filter life.</p> <p>Potential for filter event / disruption to increase particulate levels</p> <p>Filter Specifications consistent and 'as designed' / 'as validated'</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 66 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Ductwork and AHU internal inspection	<p>Inspection Frequency</p> <p>Scope of inspection</p> <p>When is cleaning performed, required? How is this assessment made.</p> <p>Microbiology control within the AHU and Ductwork.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 67 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.12 HVAC DUCTWORK AND FILTRATION

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Terminal ductwork and Filtration	<p>Terminal Filter Specifications.</p> <p>Terminal Filter Test frequency.</p> <p>Review filter test methods and data.</p>		
Filter change Procedure	<p>Review terminal filter change procedure for impact on clean room.</p> <p>Cleaning ductwork around filter change.</p> <p>Inspection of ductwork.</p> <p>Micro biological assessment.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 68 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Filter Installation compliance with manufacturers recommendations	<p>Installation.</p> <p>Flow rate and Differential Pressure performance.</p> <p>Filter performance rating linked to installed flow rate and differential pressure.</p> <p>Filter manufacturers recommended life compliance.</p>		
Terminal Filter Plant room protection	Access and inadvertent impact with terminal filters in plant room areas.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 69 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Local / Final damper settings recorded 'as validated'	<p>Schedule of local and final damper settings.</p> <p>Dampers locked or secured in place.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 70 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

2.13 ENGINEERING MAINTENANCE AND SUPPORT

PARAMETER	REQUIREMENTS	SITE XYZ 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.		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 71 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Technical Access Controls	<p>Engineering access controlled physically.</p> <ul style="list-style-type: none"> a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems. <p>Engineering Control Systems access controlled.</p> <ul style="list-style-type: none"> a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems 		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 72 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Approved Contract Resource	<p>List all suppliers engineering companies and contract engineering/test companies.</p> <ul style="list-style-type: none"> a) High Purity Water Systems b) Clean / Pure Steam Systems. c) Compressed air and process gases d) HVAC AHU's and systems <p>Check Technical Agreements.</p> <p>Check Named engineers.</p> <p>Check Training</p>		
Site Engineering Training and Competency Assessment	<p>Named / Approved Engineers.</p> <p>Check Training and competency assessments for different systems.</p> <p>Engineering GEP Training.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 73 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

PARAMETER	REQUIREMENTS	SITE XYZ REVIEW	GAP ANALYSIS AND ACTIONS
Technical Knowledge	<p>Where does the required technical expertise rest.</p> <p>Is this required technical expertise sustainable.</p>		
Maintenance Procedures	<p>Responsibility for Review and Control of Maintenance procedures.</p> <p>Do maintenance procedures reflect the age and condition of the equipment.</p> <p>How are maintenance procedures, schedules and frequencies reviewed.</p>		

Issued : Template 1 for information collection at the beginning of the reviews.

Date Issued:

24th April 2017

Page 74 of 75



Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1

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		



MARK THOMPSON
L I F E S C I E N C E S

Quality Critical Utilities Review.
Example Audit Template.

Document:
CUA.T.0417

Template 1