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Managing equipment validation using ASTM approach for optimum cost and aggressive schedule

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What is ASTM E2500 approach - definition

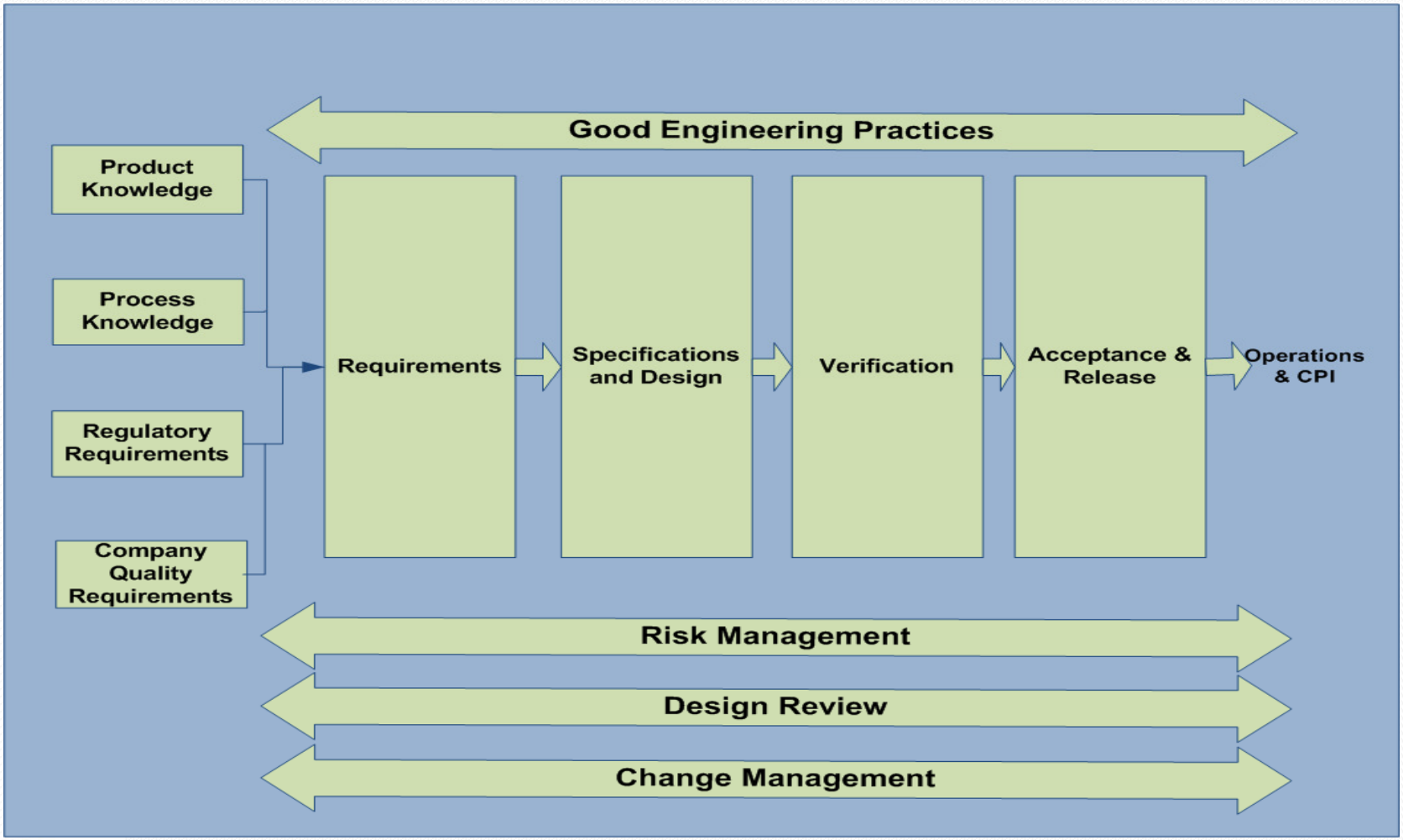
- A ***risk-based*** and ***science-based*** approach to the specification, design, and verification of equipment that have the potential to affect ***product quality*** and ***patient safety***.
- The ***level of effort***, formality and documentation should be ***commensurate with the level of risk***.

The ASTM standard focuses on lifecycle approach based on:

- Product Knowledge
- Process Knowledge
- Regulatory and Quality requirements
- Patient safety through risk assessment

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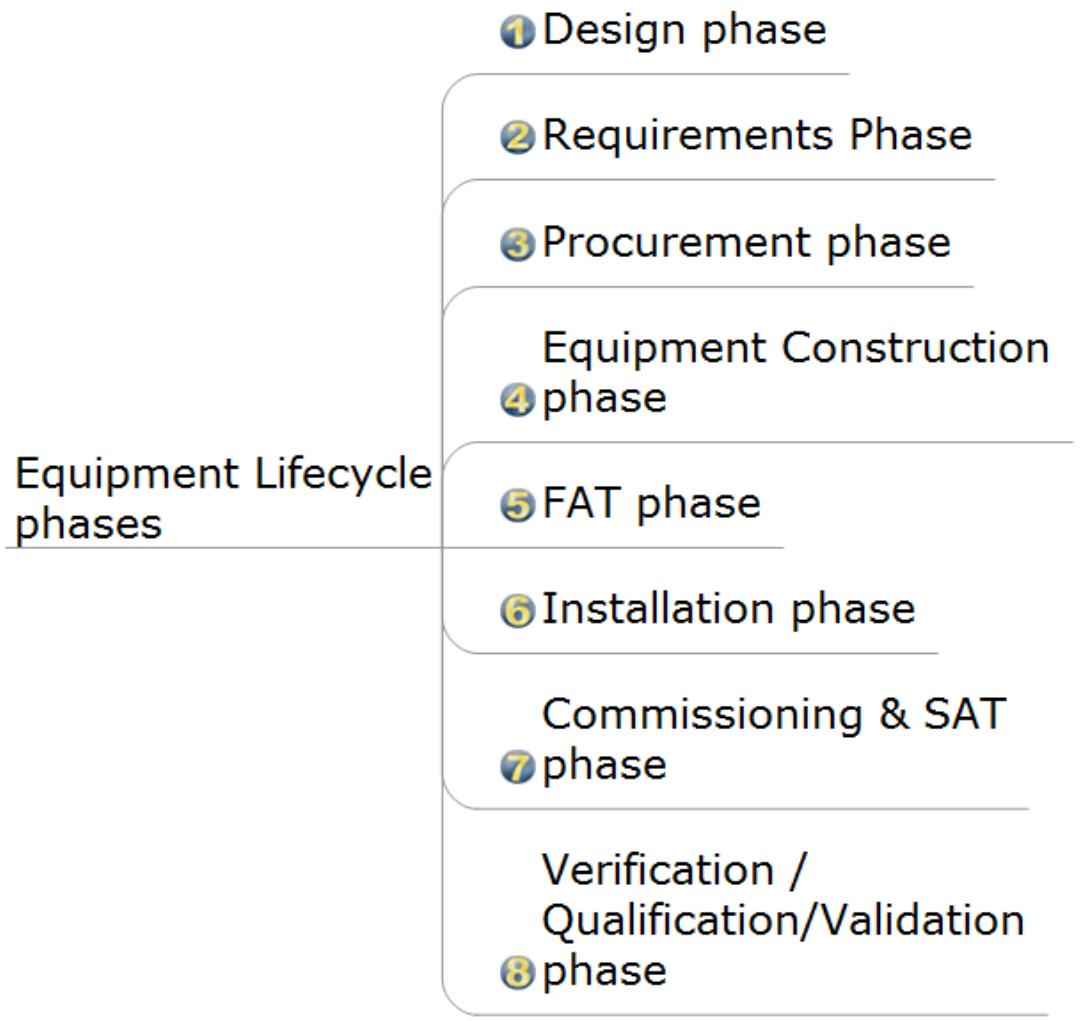
ASTM Model – approach to equipment qualification



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Equipment Lifecycle

The primary phases of Equipment Lifecycle is as follows



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Design Phase

Design team to provide the following information to prepare the specification of equipment

- Type of equipment
- Capacity
- Utilities availability and their specifications
- Standards, codes and specification
- Schedule
- CQAs
- CPPs
- CCPs

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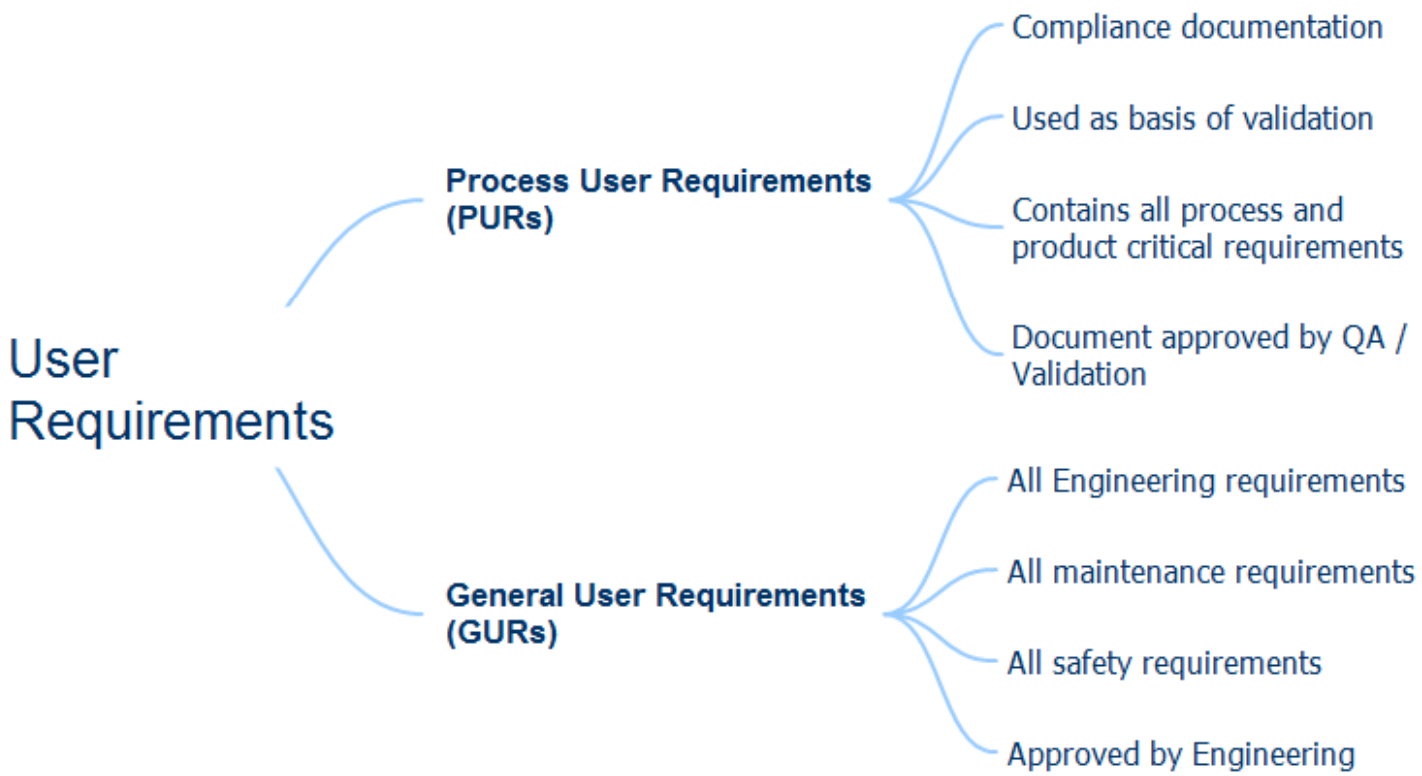
Definitions of CQA, CPP and CCP

- **CQAs**
  - Critical to patient safety
    - Defined impurity level
- **CPPs**
  - Related to CQA
    - CPP drives the impurity level, either indirect or direct
    - For example – Indirect – Temp measurement and direct is online conductivity measurement
- **CCPs**
  - Critical Control Points (or Process Parameter)
  - Critical point, step or procedure which controls the process

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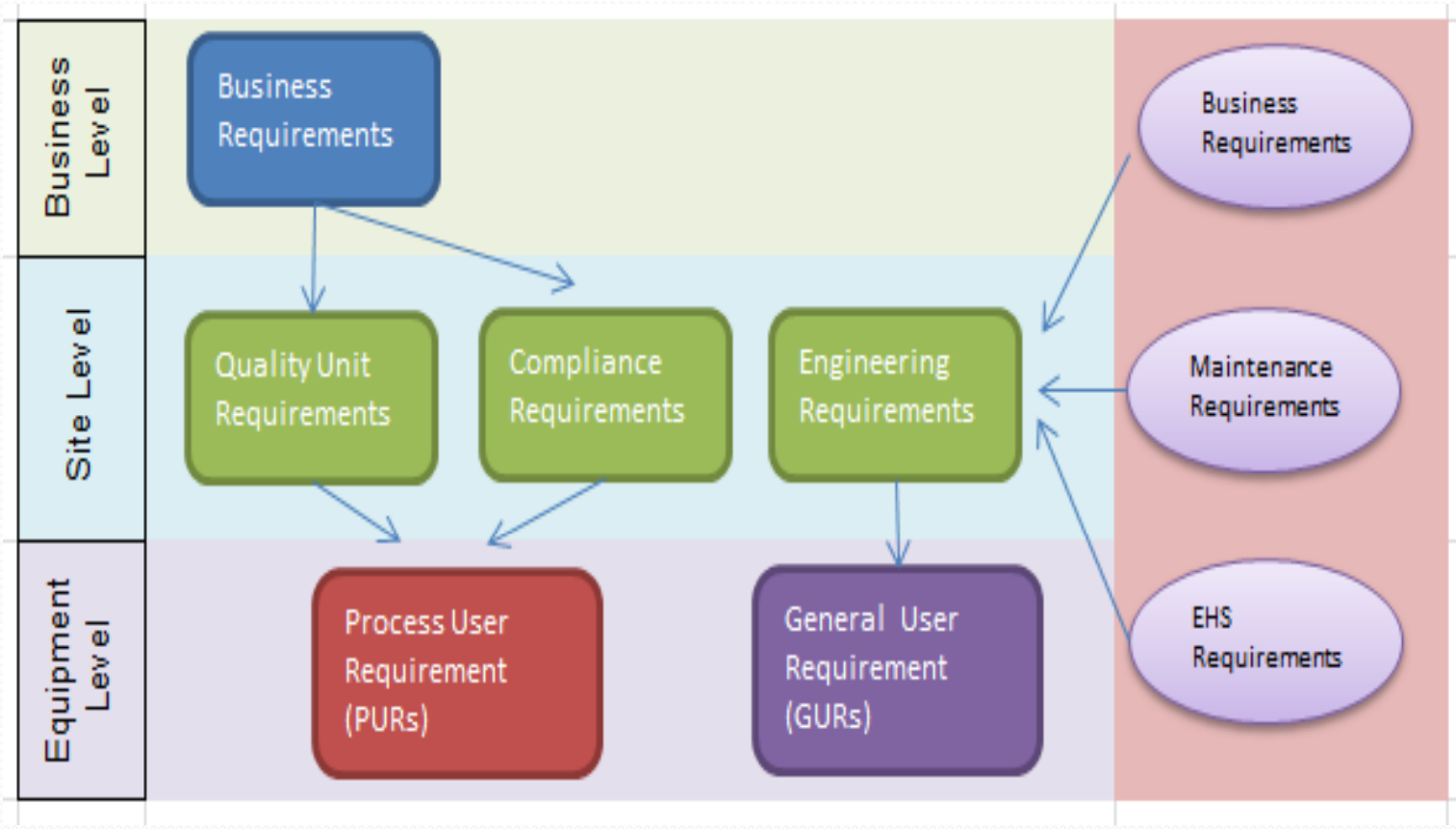
Requirements Phase – Creating User Requirements Specification (URS)

Create two URS documentation: PURs & GURs



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Requirements Phase



All requirements specified on PURs document will be Commissioned, Verified and Validated.

All requirements specified on GURs will be commissioned only according to Good Engineering Practice (GEP).

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Documenting requirements

Confirm each of the requirement satisfy every condition as per the table below

Requiments Characteristic	Description
Clear	No ambiguity about the requirement. Not open to multiple interpretations. No qualitative requirement and using units of measure to be used
Concise	Brief and to the point and well organised
Consistent	Consistent format and does not conflict between other requirements
Confirmed	Approved by appropriate stakeholders and aligned with business need. Describes what is needed to satisfy the requirement
Complete	Not ambiguous and gives all required information
Traceable	Each of the specification must link back to one of the appropriate requirements.
Testable	Ability to provide documented evidence to satisfy the requirement

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Procurement Phase - Vendor Selection and requirements

- The vendor must be an 'Approved Vendor' for the site, audited and approved by the site QA team.
- Vendor capable of providing all design and documentation requirements (DDR) identified for the equipment.
- The vendor must have the capability to act as Subject Matter Expert (SME) for the equipment and contribute to 'Quality Risk Assessment (QRA)' process.
- Vendor follows standard quality procedures to provide all certification and documentation leveraged into C&Q testing.
- For equipment requiring automation, the vendor capable of being compliant to GAMP or site Automation requirements.
- The preferable priority sequence for choosing the vendor must be 1) Quality, 2) Schedule and 3) Cost.

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Procurement Phase - Vendor Design Phase

- Vendor requested to provide the following information in the concept design phase of the equipment prior to detailed design phase of the equipment in view of conducting QRA.
  - High level concept design for the equipment.
  - Design documentation in draft format for review.
  - Equipment automation systems identified and concept design completed.
  - Utilities design completed.

Conduct ‘Quality Risk Assessment, as per ICH Q9, using a multidisciplinary team to confirm.’

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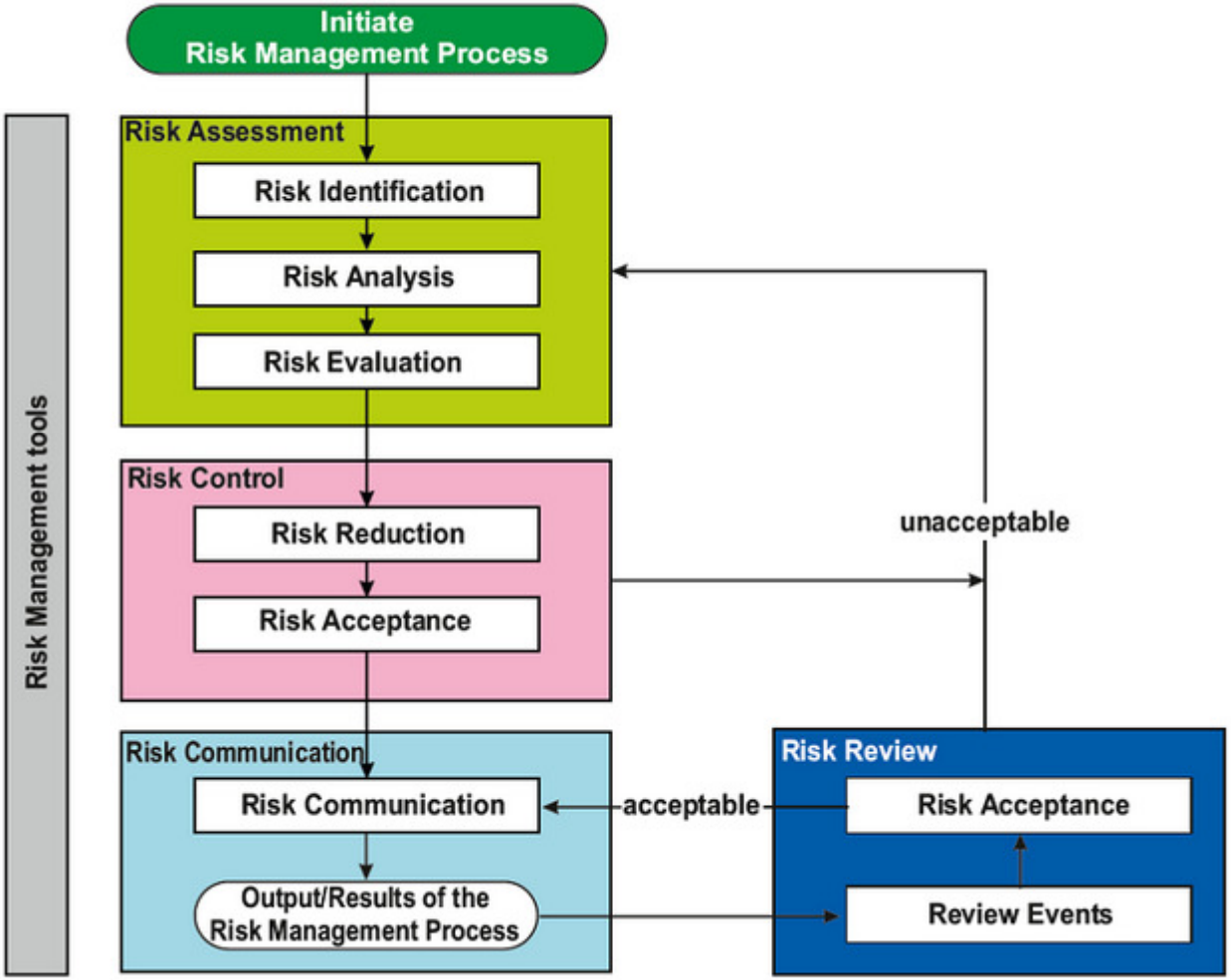
Quality Risk Assessment - Advantages

By conducting a proper Quality Risk Assessment using a multi-disciplinary team (SME, QA, Vendor, PM, CQV, etc.) including the vendor brings in the following advantage

- Deeper understanding of the process and equipment
- Reduced project cost and timelines as only critical areas will require increased level of effort (verification) and documentation
- Confirmation of meeting all CQAs, CPPs and CCPs.
- Confirmation that all risks have been reduced to acceptable / manageable limit through proper equipment design.

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Standard Quality Risk Assessment process as per ICH Q9



ICH Q9: Quality Risk Management

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Validation approach using Quality Risk Management (QRM)

- FOUR primary principles of QRM is as follows.
  - **EVALUATION** of risk to quality based on scientific knowledge.
  - **QRM PROCESS** should be dynamic, iterative and responsive to change.
  - **LEVEL OF RISK determines the level of effort, formality and documentation in C&Q.**
  - **CAPABILITY** for continual process improvement and enhancement should be embedded.

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Validation/Verification approach using QRM

Using QRM system approach for equipment validation will ensure that the

- Evaluation of the risk to quality is based on scientific knowledge.
- Provides in-depth knowledge and experience with the process.
- All risks ultimately links to the protection of the patient.
- The level of effort for verification / validation is linked to level of risk and complexity.

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Generate Validation Test Matrix

The Validation Test Matrix will identify where the verification or testing will be performed from the vendor premises to site premises.

- This test matrix will form the testing strategy for the equipment and must be approved by the QA unit.
- Identify the type of document for each testing phase.
- Validation Test Matrix must be prepared by C&Q team prior to FAT.
- The test matrix must be based on PURs, QRA, Traceability/ DQ matrix and other compliance documentation, as applicable.

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Test Matrix – typical example.

Item	Requirement N°	Quality Impact	Verification / Activity	Acceptance Criteria	Comments	FAT	Installation	SAT	Verification
Installation Testing									
1.1	**MDR-URS-015**: DOC-01	Y	P&ID Walkdown for HVAC & Cleanroom as per P&ID D2012032/MD01, D2012032/MD02, D2012032/MD03, D2012032/MD04	Master drawings reflect the actual system, or drawings have been redlined per procedure. Redlines are agreed to by the stakeholders & addressed according to ECM procedure.	1. Component presence, sequence, tagging, labeling and orientation. 2. P&ID Walkdown completed during SAT's will be leveraged towards IQ. 3. Final Official P&ID Walkdown is documented in the IQ.	X	L		

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Design Review and Design Qualification

- Conduct Design reviews during the design phase of the project to evaluate the design deliverables against the requirements and specifications.
- If issues or gaps are identified in the design, corrective actions must be taken by appropriate Subject Matter Experts (SME).
- Design Qualification or RTM may also be conducted during the design phase to ‘identify and document’ that the design meets all the requirements from the PURs.

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Requirements Traceability Matrix – Typical format

ID	Assoc ID	PURs Requirement	Functional Requirement	QRA Reference, if applicable	System Component(s)	Software Module(s)	Tested In	Verification	Additional Comments
001	1.1.1								
002	2.2.2								
003	3.3.3								
004	4.4.4								
005	5.5.5								
006									
007									
008									
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011									
012									

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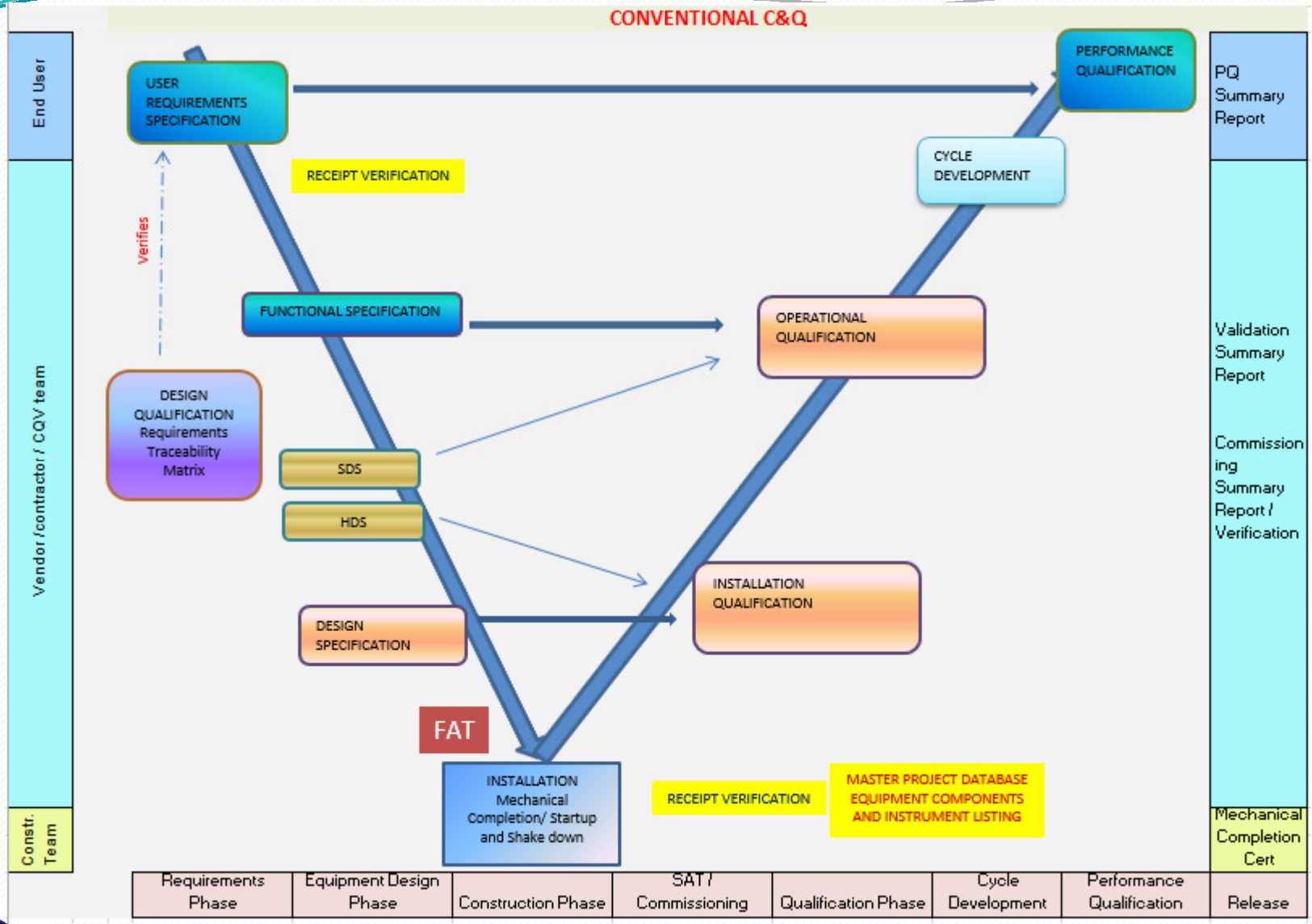
Change Management

It is important to follow proper 'Change Management Process' to make any change to Equipment once URS is approved.

- All changes must be assessed for impact not only on the equipment level but also on system level and business level.
- All proposed changes impact the PURs document must be evaluated and approved inclusive of QA unit.
- All proposed changes on GURs may be managed as an Engineering change.

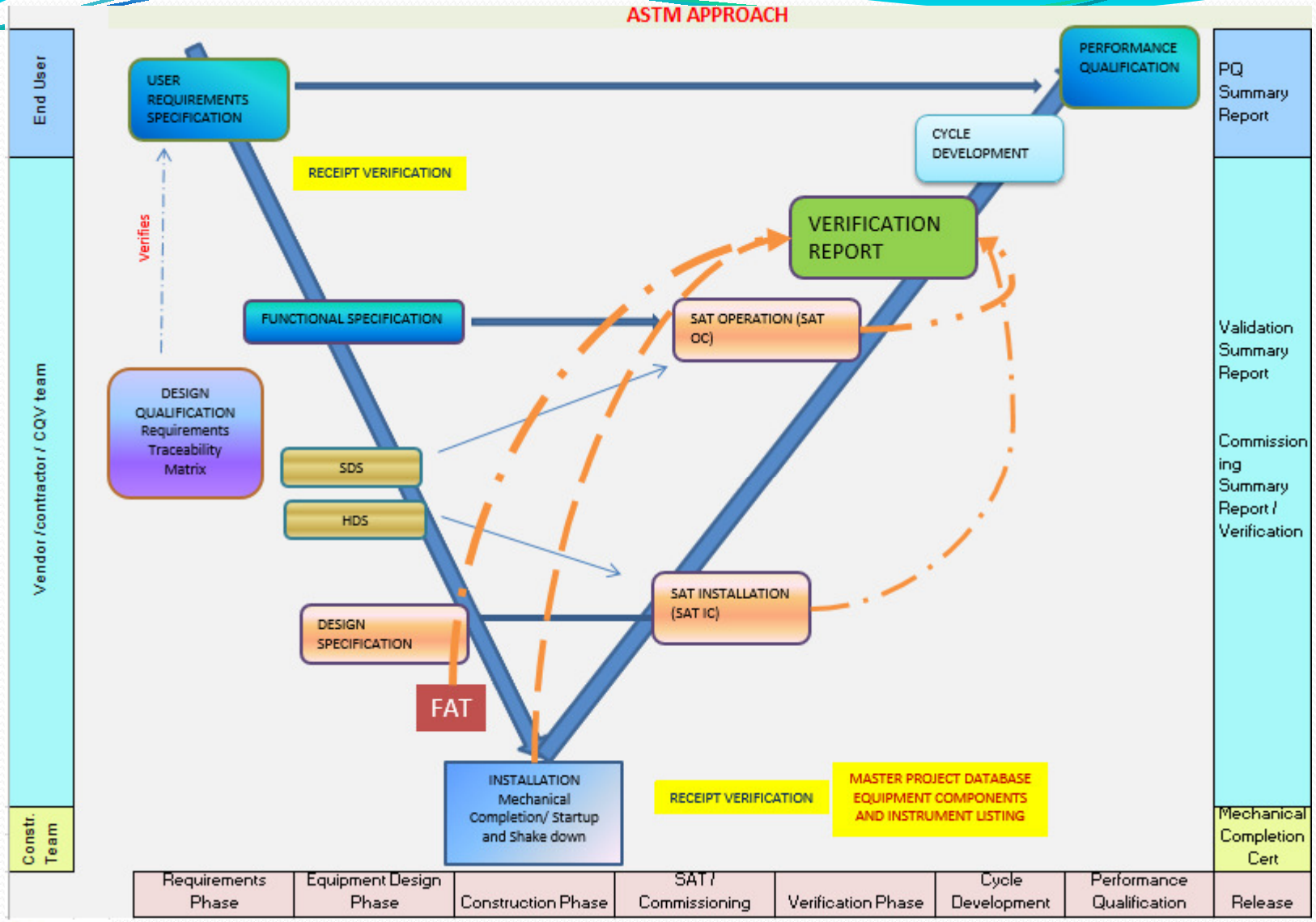
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Standard V-Model – CONVENTIONAL C&Q



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Standard V-Model – ASTM APPROACH



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Equipment Validation – Comparison for cost saving

Conventional C&Q	ASTM C&V
Significant duplication of effort in testing.	Testing is performed only once over the lifecycle
Extensive usage of dedicated resources for commissioning and validation from protocol generation to protocol closeout	Verification team consists of personnel from vendor, construction and C&V helps in Validation cost and timelines reduction
Excessive reviews and approval	Only quality critical aspects have critical review
Risk to process and patient safety **unknown** and scope of validation is based on equipment functionality.	Scope of validation is limited to critical aspects to product quality and patient safety
No specific input to engineering maintenance and calibrations.	Using QRA leads to effective calibrations and maintenance management.
Lack of product / process information lead to extensive compliance.	Pragmatic interpretation of compliance and regulation.

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Conclusion

Using the ASTM 2500-07 standard model as the basis for validation of the equipment will achieve

- Deeper understanding and knowledge of equipment
- Validation works completed in shortest path and time.
- Effective utilisation of multiple teams and hence reduced cost.

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Thank You

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