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

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Equipment Qualification / Validation can be made efficient with minimum time and cost if it can be adequately planned and managed from the requirements phase to validation phase. Using the ASTM 2500-07 standard model as guidance for managing the equipment lifecycle will achieve higher efficiency in a shortest path regardless of whether the given project follows ASTM or conventional C&Q model. The primary key to success is to capture all the installation and operational requirements of the equipment and document them appropriately on relevant user requirement documentation. All the regulatory, product / process requirements are documented under PURs (Process User Requirements) document while all the general and engineering requirements are documented under GURs (General User Requirements) document. Proper vendor selection is second key to success. Identifying the vendor based on technical capability, quality systems and quality of documentation must be the critical rather than selection of vendor driven by cost. Conducting Quality Risk Assessment with multi-disciplinary team (vendor included) based on the product / process requirements will add in a huge benefit to identify all the CQA'a and CPP's and will also provide the focus on required turn over documentation and validation testing. Training of relevant vendor personnel on client systems, using Change Management system for documenting changes, preparation of test matrix to identify the testing tiles and phases of testing, conducting design review on earlier phases of the project confirms that the equipment ordered will be fit for purpose. Equipment can be validated in shorter time and will meet all installation and operational requirements.

## Biography

Sundar Chellamani has completed Bachelor of Mechanical Engineering and Masters in Thermal Engineering from Bharadidasan University, India. He is the Technical Director of 'SysComm Project Management Limited', a cGMP and C&Q consultancy company based out in Ireland. Sundar is a highly capable Technical Engineer and Project Manager with hands-on experience for more than 26 years' practical experience out of which more than 14 years as a Process Mechanical Engineer primarily serving various roles in the field of C&Q with major 'Biotech/ Pharma/Medical devices' companies. He has presented technical papers in ISPE international conferences held in China and India. He has worked in India, Singapore, Ireland and China. He is also a Class II Certified Steam Engineer, accredited by the Ministry of Manpower, Singapore.

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