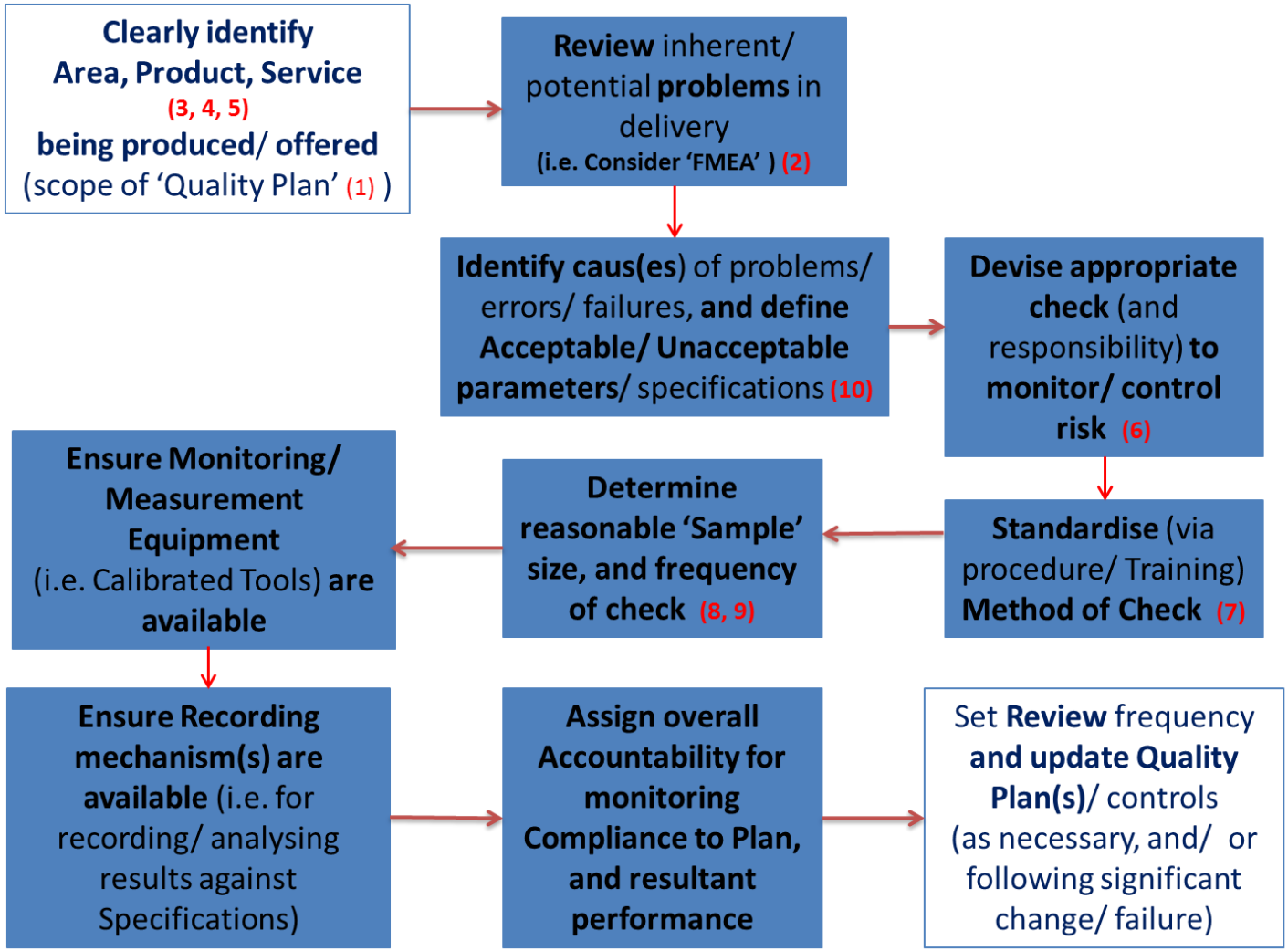
Quality Planning Process Flow-chart



Notes/ Application (to assist in developing these principles for your business):

(1) A 'QUALITY PLAN', is simply a document specifying checks, monitoring procedures, and associated resources to be applied to a specified process, product/ service delivery. This 'Plan' is normally a summary/ output from consideration of 'Quality Planning', and in some cases a FMEA(2), applied to either an Operational Area, specific product, or service).
(N.B. By developing an appropriate 'Quality Plan' organisations are able to satisfy various clauses/ principles of ISO 9001(12), whilst satisfying themselves that appropriate controls are established to mitigate risk of producing products/ services of poor/ unacceptable Quality).

(2) FMEA: Failure Mode and Effect Analysis; a technique for analysing failures, and classifying their severity/ likelihood ; this can assist in product development, enabling teams to design such failures out of the system (service delivery).

(3) The 'Quality Planning' principle may be applied to an OPERATIONAL AREA; outlining all Quality activities to be applied within the department/ area, to ensure consistent application of practices in line with overall company/ customer expectations, policy and objectives.

(4) The 'Quality Planning' principle may equally be applied to a specific PRODUCT; ensuring that any potential problem areas (i.e. where product specifications, characteristics may be at risk of not being met) are minimised/ mitigated. (i.e. based on previous complaints, failures, components).

(5) The 'Quality Planning' principle may similarly be applied to a specific SERVICE; ensuring that the service delivery process/ customer experience is too in line with company policy, objectives, and customers' needs/ wants are guaranteed. (i.e. development of service charter, eliminating customer waiting times, speaking to the wrong person, allowing phones to ring, etc).

(6) Checks/ Parameters that form part of the overall Product, Service, Operational Area, which need to be checked, monitored, measured in some way (i.e. reducing the potential for failures; example may be to check the concentration of an ingredient, or positioning of a metal component, etc)

(7) Formalised methodology to be used (Document reference) may be appropriate where there may be specific order within which checks must be done (i.e. pharmaceutical test methods, or specific order of mechanical fabrication inspections, etc).

(8) Sample Sizes are determined, based on historical risks, problem areas (as output from FMEA), and what is reasonable (i.e. it would not be feasible for an organisation to strip down and check every unit produced; however, perhaps a sample of 1 in every 1000 is acceptable).

(9) Similarly, when, and how often would it be reasonable to conduct such 'checks' and sampling, should be determined (i.e. every batch, once per week, or at start , middle and end of production runs/ shifts?).

(10) Within all such checking/ monitoring, it is important to define Acceptable/ non-acceptable (Pass/ No-Go) criteria/ 'Stage-gates' (i.e. if results are over, or below, a certain value; or if specification has not been met by +/- %).

(11) Results are normally recorded somewhere to support evidence of conformity, due diligence, traceability, etc ('Documented Information').

(12) Elements of ISO 9001 (2015), partially covered by successful development of a 'Quality Plan' (as described herein), may include (partially) clauses: 6.1, 7.1.4, 7.5.3, 8.1, 8.2.2, 8.3.1, 8.4.2, 8.5.1, 8.5.4, 8.5.5, 8.6, 9.1.1

QUALITY EYE Consultancy Services

Example of (Operational Area[3]/ Product[4]/ Service Related[5]) **'QUALITY PLAN'** [1]

Functional Area/ Department/ Process

Check/ Parameter [6]	Doc Ref(s) [7]	**Sample Size**[8]	**Frequency**[9]	**Check Performed by**	**Specification/ Allowable Tolerance** [10]	**Results Recorded**[11]
i.e. Check general condition of incoming material/ part?	Standard Operating/ Testing Procedure/ Work Instruction?	Select 1 from every 100 boxes/ items delivered?	Every Delivery?	Storeman?	No damage to packaging, no dampness, off-odours, etc?	Record on GRN stamp?
i.e. Check certificate of analysis, conformance, authenticity?	Specific test method?	1 C of A, or C of C per delivery?	Every Delivery?	QA Technician?	Declarations complete, Certificate of Analysis	Test results Data?
i.e. Information required to be supplied as part of service request?	Service Charter section?	5 Mandatory fields?	Every Call?	Operator?	No information missing from fields?	Electronic Form?
…	…	…	…	…	…	…