What Is A Control Plan? What Is An FDA Performance Qualification (P.Q.)?

Control Plan/ Performance Qualification (P.Q.) methodology is to aid the manufacturing and quality assurance functions.

Control Plans provide a written summary description in the systems used in reducing product and process variation.

ATL Control Plans are interchangeable with FDA cGMP Performance Qualifications (PQ's) (or FDA Equipment Qualifications, "EQ's").

Control Plans (PQ's) may be adapted to be a living document/ quality record. If this is the case, designated sign offs are required. Below are examples of a Control Plan or Performance Qualification.

ATL Performance Qualification/ Control Plan

Customer: (1) Date Initiated: (2)

Item Description: (3)

Process Qualification Team: Carolin Duncan, Don Dobert (6) Job #: (4) Notes: (5)

Operation Description (7)	(8) Press / Machine / Device for Manufacture	(9) Characteristics (10) Product	Process	(11) T-B-D	(12) Product / Process Specification Tolerance	Evaluation / Measurement Technique	(14) Sample Size	(15) Sample Freq.	(16) Control Method / Data Recording Method	(17) Reaction Plan
Incoming Material	None	Materials for job	Inspect		XX FM XXXX OP	Verify against ATL PO	Per QMS Sect. 8	ANSI Z1.4	CMTR: Verify quantities, mat. type, width, etc. check for damage	Quality NCCA
Press Set Up	Press checked for cleanliness	Cleaning	Inspect		Oil, Ink, and other contaminants cleaned and removed from press	Visual	N/A	Per Run	Visual check of press	Quality NCCA
Press Run	Delta 1	Seal	Inspect		Specifictions for XXX P/N XX-N-07-XXXX Rev. 2	Kestrel	32, start and	per CPK	Kestrel	Quality NCCA
Press Run	Delta 1	Seal	Inspect		Monitor and perform stability/capability analysis for all CTQ's	Kestrel/Cpk Software	Ongoing TBD	Ongoing TBD	Performance Qualification and or Quality Engineer Cpk	Quality NCCA
Preliminary Packaging	Quality Hold Area	Seal Packaging	Quality / bagging		Individually bag each roll upon roll approval	Visual	Per roll	Per roll	Visual	Quality NCCA
Final Inspection	Quality Dept.	Seal Packaging	Core Tags		Each individual roll identified in core	Visual Placement	100% ID	Each roll	Visual and final inspection report	Quality NCCA
Release of Product	Quality Dept./Shipping	Seal Final Packaging	QC checks before pkg		Qualities final check to assure all specs and packaging req. are met	Visual	Each unit	Each unit	Quality Dept. batch record release	Quality NCCA

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How does this work? Below are simulated Control Plan/ Performance Qualification Reference Numbers for the above sample.

1 List the customer name.

2 List the date initiated.

3 List item description, part number, revision (all that may be applicable).

4 List the Job Number.

5 List any special notes relevant to the job.

6 Enter the names of the individuals responsible for preparing or implementing the control plan/ performance qualification.

7 Operation/Description. All important/critical steps in the manufacturing of a system, subsystem, or component are described in this column.

8 Press/Machine/Device for Manufacture. Enter, for each operation that is described, the applicable processing equipment, process step, or other tools for manufacturing, as appropriate.

9 Characteristic – Product. A product characteristic is the feature or properties of a part, component, or assembly that is described on drawings or other primary engineering information. All special characteristics or critical to quality (CTQ) characteristics must be listed on the control plan. (Note: CTQ's are typically specified by the customer).

10 Characteristic – Process. Process characteristics are the process variables (input variables) that have a cause and effect relationship with the identified product characteristic. Note: There could be one or more process characteristics listed for each product characteristic. In some processes, one process characteristic may affect several product characteristics.

11 TBD (to be determined). This column is intentionally left "open". For example, the TBD column may be used to designate critical, major, or minor for various characteristics. In other applications, the TBD column may be used for personnel, initials, and date to signify completion of the form.

12 Product/Process/Specification Tolerance. List specifications or tolerances which may be obtained from various engineering documents, such as, but not limited to, drawings, customer design review, material standards, computer aided design data, manufacturing and/or assembly requirements.

13 Evaluation/Measurement Technique. This column identifies the measurement system being used. This could include gages, fixtures, tools, and/or test equipment required to measure the part/ process/ manufacturing equipment. Note: An analysis of the R&R, stability, and accuracy of the measurement system should be done prior to relying on a measurement system. R&R studies frequently accompany Cpk studies.

14 Sample Size. List the amount to be checked.

15 Sample Frequency. List the frequency of inspection for the sample size. Note: Sometimes it will be to your advantage to justify the frequency of inspection by determining the stability of a process and the capability of a process.

16 Control Method/Data Recording Method. This column contains a brief description of how the operation will be controlled, including procedure numbers were applicable. The control method utilized should be based on effective analysis of the process. Operations may be controlled by, but are not limited to, statistical process control, in-process inspection, attribute data, mistake proofing, and sampling plans. The method of control must be continually evaluated for effectiveness of process control (as part of the DMAIC discipline) (DMAIC = Six Sigma). For example, significant changes in the process or process capability must lead to an evaluation of the control method (for FDA cGMP requirements this may be governed by Change Control).

17 Reaction Plan. The reaction plan specifies the corrective actions necessary to avoid producing non-conforming products or operating out of control (a non-stable process). The actions are normally the responsibility of the people closest to the process (the operator, supervisor, etc.). In all cases, suspect and non-conforming products must be clearly identified and quarantined, and disposition made by the quality manager.

18 The authorized signature of the person responsible for the implementation of the control plan.

19 The date in which the authorized signature was affixed.

20 The page number or page numbers.

We hope this helps you to understand Control Plans and/ or Performance Qualifications.

If you have questions, please contact ATL. We will be glad to help.

Donald J. Dobert
President