



工程与品质管理理论分享

PDCA (Plan, Do, Check, Act)

(Process Feasibility)

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源头来自对客户需求的精准了解 (Customer Focus), 并将其转化为产品规格 (Product Specification) – 诸如产品环

/ (Design - Plan, Prototype - Do, Validation - Check, Release - Act)
(DCR/DCO/DCN)

/ (ECR/ECO/ECN)



+DOE

DOE



Capability of a Process: Ability of a process to produce a product that will fulfill the requirements of that product. The concept of process capability can also be defined in statistical terms.

Commercial Manufacturing Process: The manufacturing process resulting in commercial product.

Continued Process Verification: Assuring that during routine production the process remains in a state of control.

Performance Indicators: Measurable values used to quantify quality objectives to reflect the performance of an organization, process or system.

Process Definition: Defining the commercial manufacturing process based on knowledge gained through development and scale-up activities.

Process Qualification: Confirming that the manufacturing process as defined is capable of reproducible commercial manufacturing.

Process Validation: The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products.

Quality: The degree to which a set of inherent properties of a product, system, or process fulfills requirements.

