Kursusprogram
Statistik for procesvalidering

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Dag 1: 09.00 – 16.30

Welcome and expectations

Measurement systems analysis

- GageRR undestructive testing continuous measurements
- GageRR destructive testing continuous measurements
- GageRR attribute measurements

GHTF Process Validation Guidance for Medical Devices

http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf

- Product verification instead of process validation for small series
- OQ = Design of Experiments (DoE)
- PQ = Control Charts and Capability Index = Statistical Process Control (SPC)

Obtaining Process Understanding through DoE

- Quality Function Deployment
- Transfer function
- Linking Critical Quality Attributes CQA to Critical Process Parameters CPP
- DoE prerequisite for SPC
- DoE Tutorial
- DoE Catapult exercise

Dag 2: 09.00 – ca. 16.30

Sampling

- Confidence Interval on Mean
- Confidence Interval on Standard Deviation
- Confidence Interval on Proportions
- Sample Size calculation
- AQL (Acceptable Quality Level)
- LQ (Limiting Quality)
- VL (Verification Level)
- ISO Standards 2859, 3951, 21247.
- Risk Priority Numbers RPN and AQL/VL

Control charts

- Shewhart charts (Only applicable when there is no systematic variations in subgroups and no batch to batch variation)
- Individual charts (Only applicable when data are normal distributed data)
- Pre-Summarize charts (always applicable)

Capability Indices

- Cp, Cpk (Only applicable when process is in statistical control)
- Pp, Ppk (Only applicable when data are normal distributed)
- Ppfit, Ppkfit (Always applicable)
- Cc (Has to replace Cpk for two sided tolerances when using tolerance chains)

PQ is not about proving what you have made is OK, but on proving what you are going to make will be OK

- How to evaluate 3 PQ runs taking both within and between batch variation into consideration