A tool to detect sources of variation

Mike's rule to detect sources of variation – The Range/x_{bar} – Test

The Range/x_{bar} test is ideal for the evaluation of test methods and/or measuring systems

- An ideal test method would be capable to achieve a Range equal to zero, i.e. the method is 100% repeatable
- One can display this Range in a Range chart, resulting ideally in a flat line; the range-chart would be in control.
- Testing different products/materials with the same ideal test method would therefore deliver values outside the limits; the x_{bar} chart would be "out of control".

Justification:
- Range is a function of the within subgroup variation, i.e. whatever sample you will measure twice, the ideal method will always deliver zero Range (max-min values).
- X_{bar} is a function of the between subgroup variation and will for sure deliver different values for different samples.
- The X_{bar} control limits are solely a function of the Range (within subgroup variation) and must be therefore identical to the X_{bar} line (U_{cl}/L_{cl} (X_{bar}) = $x_{barbar} \pm A_2 Range_{bar}$

Conclusion:
- The better the test method / measuring system will be, the smaller the within subgroup variation will get.
- The smaller the within subgroup variation will get, the more difficult it will be to keep X_{bar} within control; i.e. X_{bar} out of control will detect real differences between samples, the real variation.

The author does not take any responsibility for contents and correctness.

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com