Current Regulatory Issues

Although regulations have not changed in any great detail over the last decade confusion exists in the interpretation of standards particularly in the area of qualification of sterilisation processes, namely autoclaves.

This is due to a number of factors:

- Increased movement of personnel between companies
- More rigorous interpretation of regulations by auditors
- In-house industry blindness
- Adherence to corporate standards
- Inconsistency of auditors from different regions

A situation exists within companies that both quality and validation departments do not know what to expect in an audit.

This confusion and inconsistency within the industry is unnecessary, there is no ambiguity in the guidelines. They are clearly written.

Our checklist below aims to allow the user to evaluate the status of their validation policy in light of the expectations of both auditors and regulations and covers some of the more noteworthy topics.

Validation Requirements	Yes	No
Calculations taken from 60's after the Start of Hold Time *Are Calculations taken from the start of hold time? There is no settling down period e.g. 60's delay time*		
Superheat *Are you incorrectly allowing superheat in the load?* *Are you incorrectly allowing superheat for the 1st 60s of plateau period (≥5 ℃) and the remainder of the plateau period (≥2 ℃)?* *Have you taken corrective action for excessive superheat that exceeds the limits in HTM and not continuously excusing it as a deviation?*		
Maximum/ Minimum Loads *The practice of maximum and minimum loads is only allowed to be conducted in the presence of an air detector.*		

Current Regulatory Issues

Validation Requirements	Yes	No
Pressure/ Temperature Correlation *Are you conducting a Pressure/Temperature correlation throughout the entire hold-time and not just at the midpoint?*		
Equilibration Time *Are you using the correct equilibration times?* *For chambers smaller than 800L equilibration time is 15 secs, for chambers larger than 800L the equilibration time is 30 secs.*		
Air Detectors *Are you testing air detectors during the Requalification studies?* *Are you performing weekly function tests?*		
Chart Record Interpretation *Do you have a chart record interpretation procedure in place?* *Have you documented that the relevant personnel are trained and can correctly interpret the charts? (Are they assessed regularly?)*		
Steam Quality Testing *Are you conducting routine steam quality testing?*		
Pre-validation Studies *Are you complying with Annex 1 of the European Community Guide to Good Manufacturing Practice that states:* *"Before any sterilisation process is adopted its suitability for the product and its efficacy in achieving the desired sterilising conditions in all parts of each type of load to be processed should be demonstrated by physical measurements and by biological indicators where appropriate. The validity of the process should be verified at scheduled intervals, at least annually, and whenever significant modifications have been made to equipment. Records should be kept of all results"*		

Current Regulatory Issues

Validation Requirements	Yes	No
Placement of Thermocouples *Have you demonstrated (through a series of Pre-validation studies) that the thermocouple locations chosen are the most difficult areas to sterilise?* *Placement of thermocouples during the initial performance qualification mustd be adequately noted so that they can be placed in the exact same locations during the Requalification studies.* *Can you demonstrate that the placement of thermocouples during the original Performance Qualification studies are consistent with Requalification studies and standard operating procedures?*		
Load Assembly Standard Operating Procedures *Do load assembly SOP's adequately illustrate the positioning and layout of loads?* *Do load assembly SOP's match the original Performance Qualification?*		
Requalification Study Comparison to Performance Qualification *Can you demonstrate comparison studies are being conducted between the Performance Qualification and the following Requalification studies? (Are they documented?)*		
Load Dryness Testing/ Liquid Loss Testing *Are you conducting Load Dryness / Liquid Loss testing as part of the Performance Qualification and as part of annual Requalification of each load type?*		
Vent Filter Sterilisation *Is the sterilisation of the air vent filter fitted to the autoclave treated as a porous load e.g. deaeration times, equilibration times, calculations?*		
Bioburden *Are you incorrectly autoclaving items that require sterilisation by performing a "Bioburden Reduction Process"/ "Santisation Process"?*		