

## Pharmatherm the Steam Quality Specialists

Steam Quality Test Service, PharmaTherm offer an 'Independent Steam Quality Test and Validation Service' our engineers are trained 'Test Persons HTM2010' and understand how to complete steam isolations safely following HS&E requirements when dealing with pressurized steam distribution systems in modern Pharmaceutical facilities.

### Steam generation systems that we are familiar with:

- ❖ BOSCH
- ❖ STILMAS
- ❖ MECO
- ❖ MMM
- ❖ GETINGE
- ❖ STERIS (Finn-Aqua)
- ❖ Pharmatec
- ❖ Spirax Sarco
- ❖ Fulton
- ❖ MUELLER

### Steam Generation that we are familiar with:

- ❖ Plant Steam
- ❖ Process Steam
- ❖ Clean Steam
- ❖ Pure steam

### Pharmatherm Steam Quality Testing:

#### **Steam Quality Test Equipment:**

PharmaTherm use the SQ1 Portable Steam Quality test equipment. The SQ1 test kit has proven to be extremely reliable and to meet with all of the industry requirements. The SQ1 steam quality test kit provides accurate and validated test results.

#### **Pharmatherm's calibrated steam quality test equipment includes:**

portable balances, test weights, SQ1 test kit, Digitron two channel temperature meter, Lascar data logger (temperature), a printer and laptop. All of our test equipment is calibrated annually and is traceable to national standards. Calibration certificates are issued in the steam quality test report.

#### **Steam Quality Test SOP Documentation:**

PharmaTherm offer a fully documented steam quality test SOP that meets with the industry the standards EN285, CFPP 01-01 formerly (HTM2010), HTM2031, cGMP & USP. Steam supplies used for moist heat steam sterilization would need to comply with the EN285 standard.

### **How does the CFPP 01-01 affect us:**

The CFPP 01-01 Choice Framework for Local Policies and Procedures document was introduced in May 2014 and has replaced the standard HTM2010. Pharmatherm recommends that all pharmaceutical and hospital installations in Ireland meet with the EN 285: 2006 +A2:2009

### **PharmaTherm recommends:**

Pharmaceutical companies based in Ireland subject to HRA (formerly IMB) audits should review the following with respective heads of Engineering, Validation and Quality Departments.

- References to the standard HTM 2010 should be removed from all site protocols
- References in protocols should reference EN 285: 2006 +A2:2009 Sterilization - Steam Sterilizers Large sterilizers
- A decision to implement the new standard CFPP 01-01: Part C should be made
- Site SOP's should be reviewed and updated to reflect the changes to the current standards in place

### **Steam Quality Test Report:**

The PharmaTherm steam quality test report is clear and concise documenting the test method, raw data and the test results analysis. Detailed HS&E and SOP's are submitted prior to the steam quality testing for approval.

Pharmatherm's test reports carry a signed declaration on the status of the tests: Pass / Fail. The steam quality test report meets with cGMP documentation standards so that it can be audited internally, externally and submitted to the regulator.

Contact Pharmatherm for a steam quality test quotation however large or small the project maybe. We aim to provide a competitive validation service. Please 'don't delay and contact PharmaTherm today' email: [info@pharmatherm.ie](mailto:info@pharmatherm.ie)

See the Pharmatherm website please log onto [www.pharmatherm.ie](http://www.pharmatherm.ie)



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