

The Role and Purpose of Data - before, during and after Qualification

PDA New England Chapter / ISPE Boston Area Chapter Joint Meeting

May 17, 2017

Woburn, MA

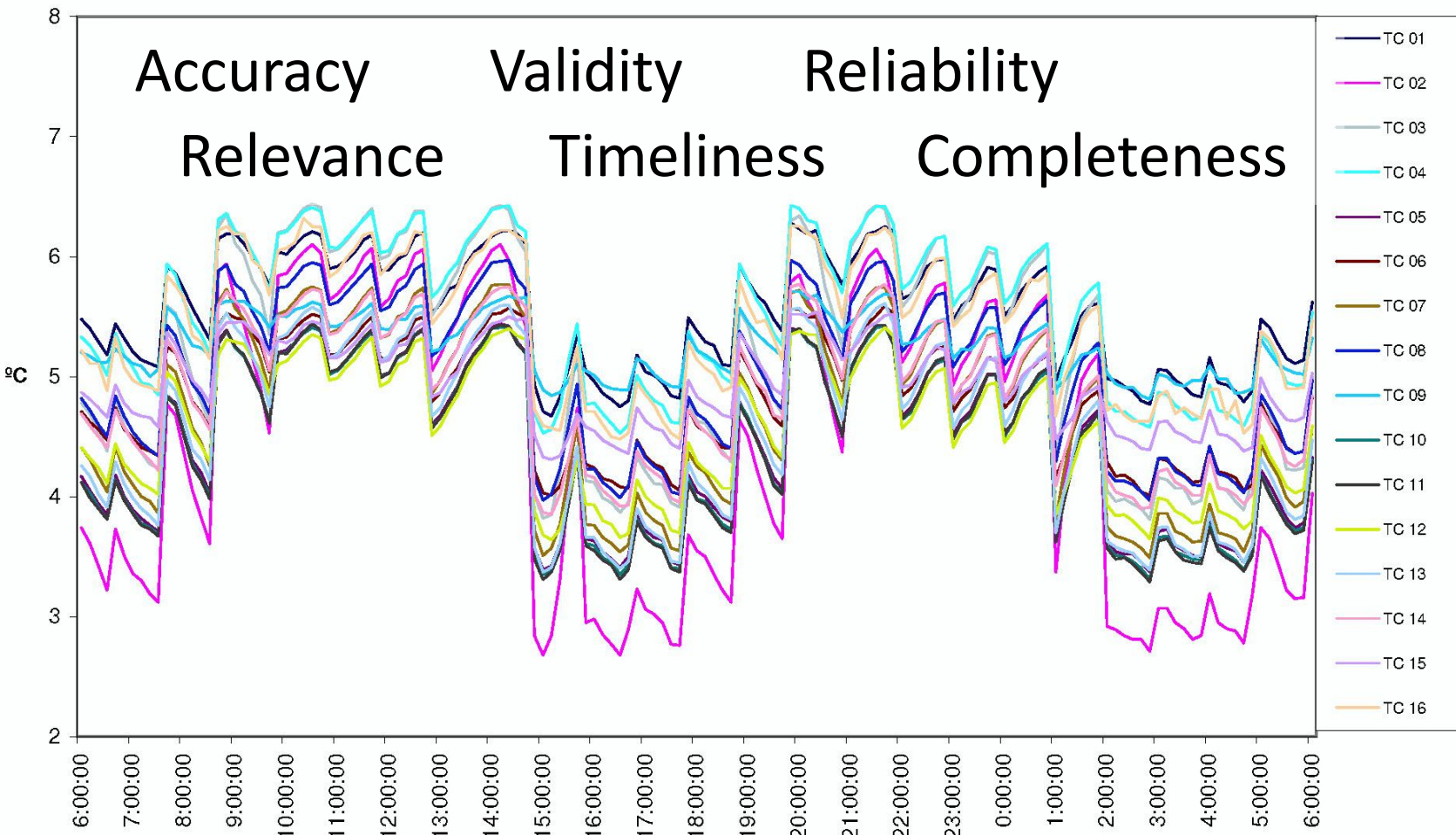
Sylvan Poeckh



What is Data?

- Facts that can be used in calculating, reasoning or planning (*Merriam-Webster*)
- Information expressed as numbers for use especially in a computer (*Merriam-Webster*)
- Information in a raw or unorganized form (*www.businessdictionary.com*)
- A set of qualitative or quantitative variables (*Wikipedia*)
- A subset of items that can be assembled or processed to produce meaningful information (?)

Characteristics



Role vs. Purpose

ROLE - an assumed function; the 'what'

- Measurement values that represent a process or condition
- Also includes derived and statistical values

PURPOSE - the objective or reason; the 'why'

- Provides the acceptance criteria values and the test result...
- Which tells us if the process or condition met our expectations (*compliance!*)

INFORMATION!

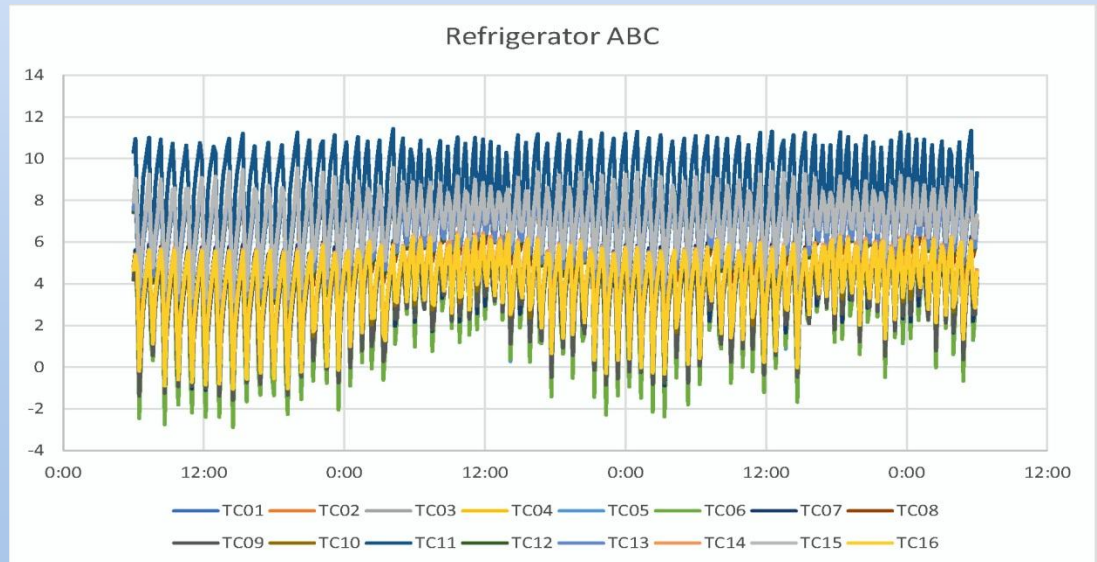
Equipment Design and Manufacturing



- Target industry
- Customer requirements
- Data collection and retention capability
- Performance specifications
- Pre-qualification
- Feedback / Analytics

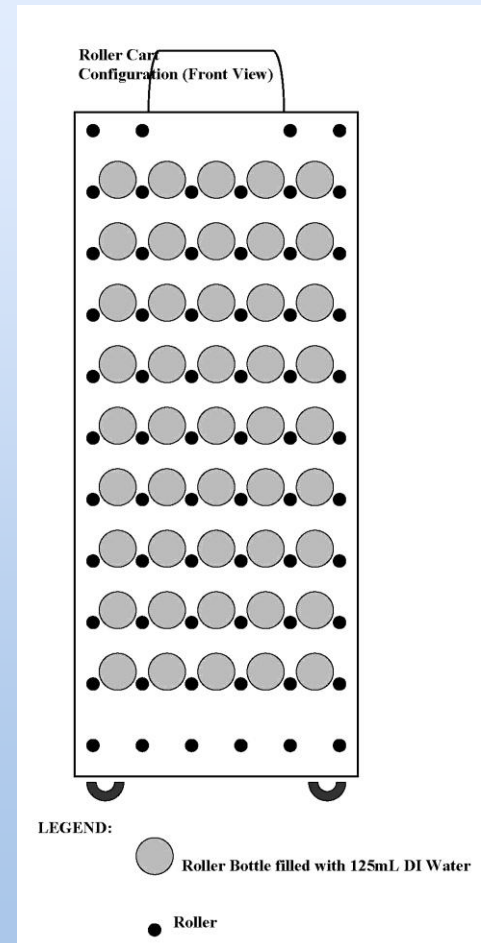
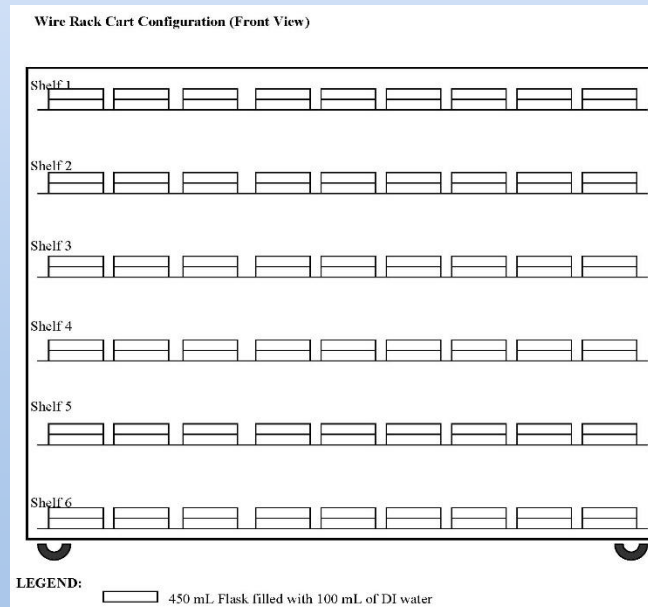
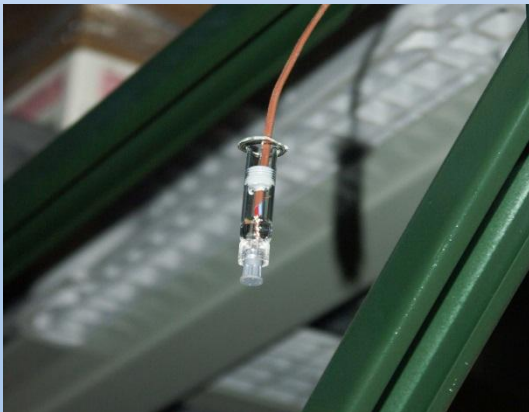
Purchasing

- Analysis / Analytics
- Assessing business needs
- Assessing IQ, OQ and PQ requirements
- Communicate with vendor(s)
- Avoid unnecessary features



Qualification

- Defined Requirements
- Defined Acceptance Criteria
- Results & Supporting Data
- Quantity
- Quality

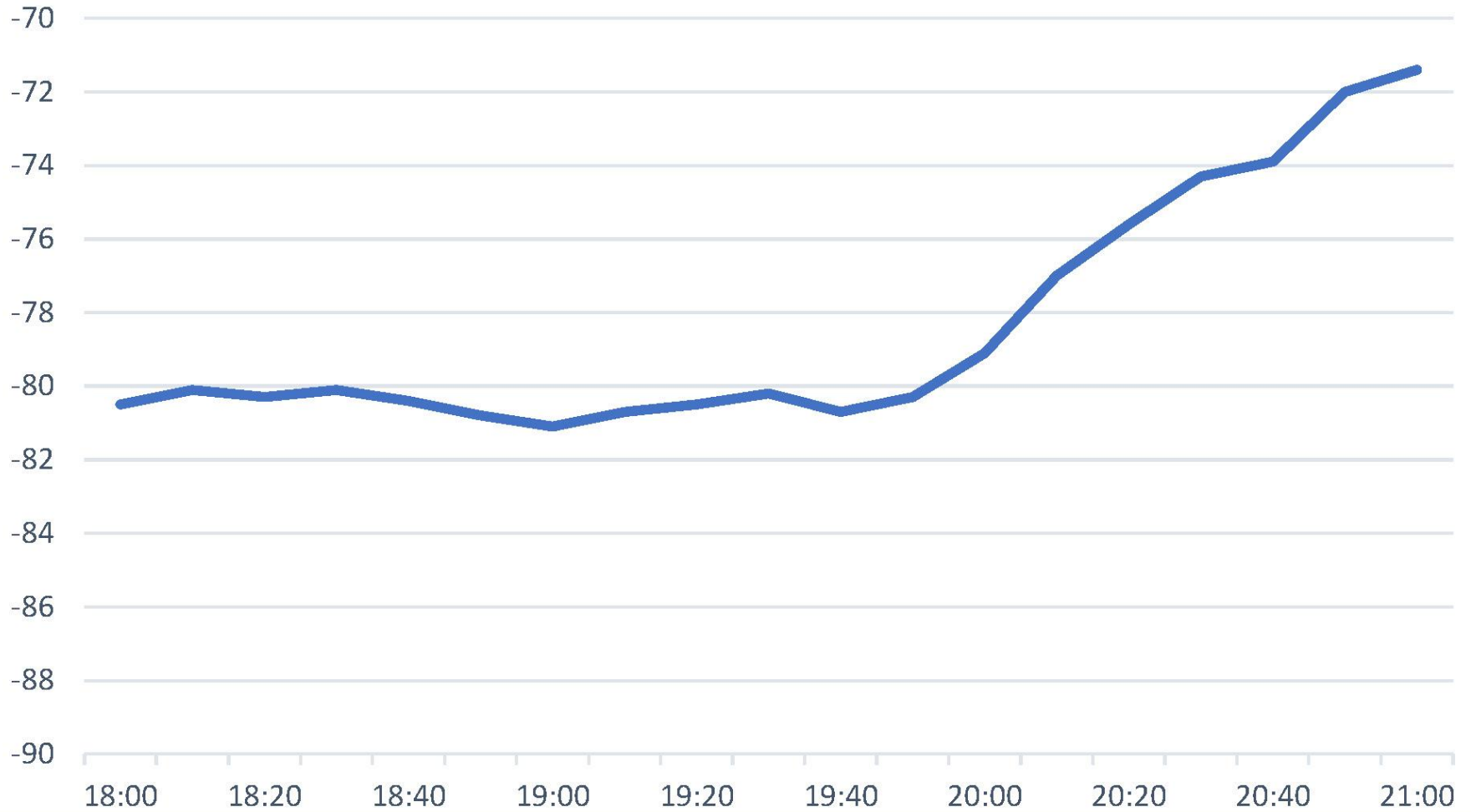


Qualification Data

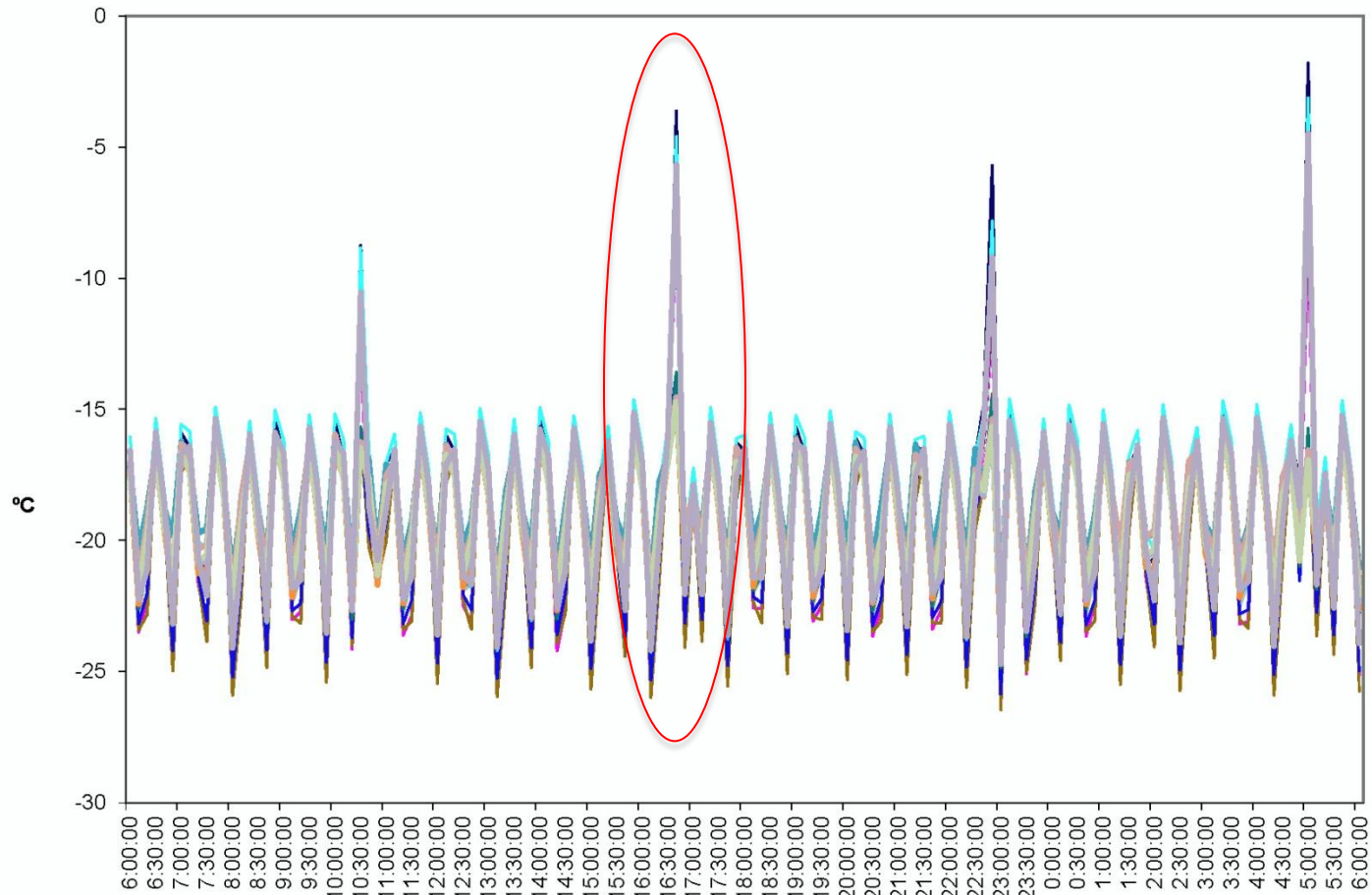
- **Pragmatic** – Is this practical and does it add value?
- **Quantity** – What is the right amount?
- **Quality** – measurement instruments, data logging system, sampling locations...
- **Statistical tools** – use them (with care)
- **Data visualization tools** – use them (with care)
- **Anything odd** – don't ignore a potential problem
- **Black box testing** – ask the vendor for calculation methods



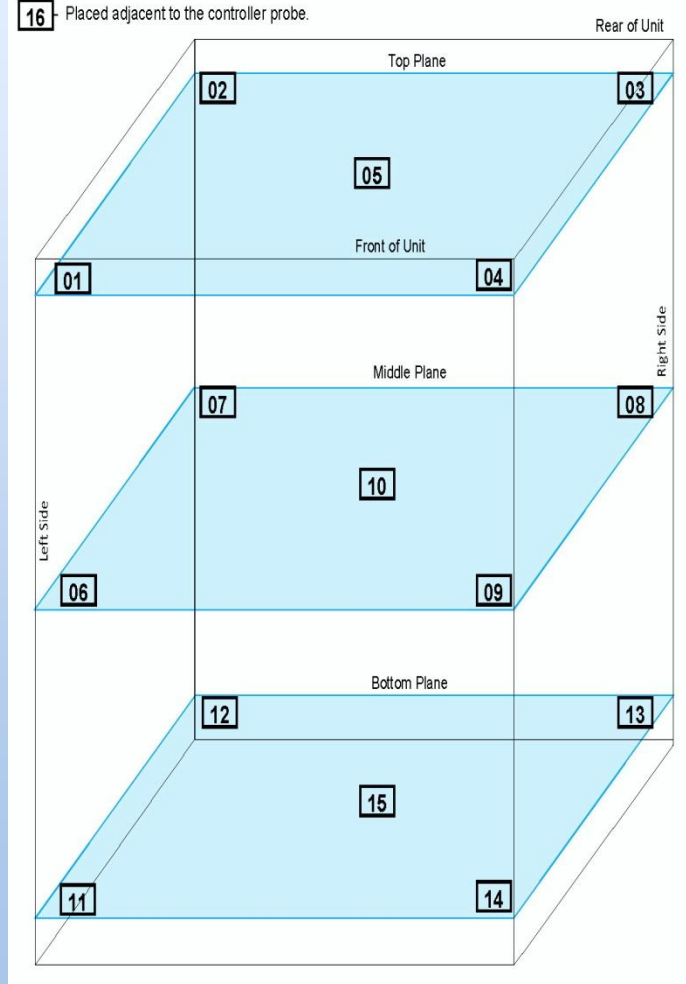
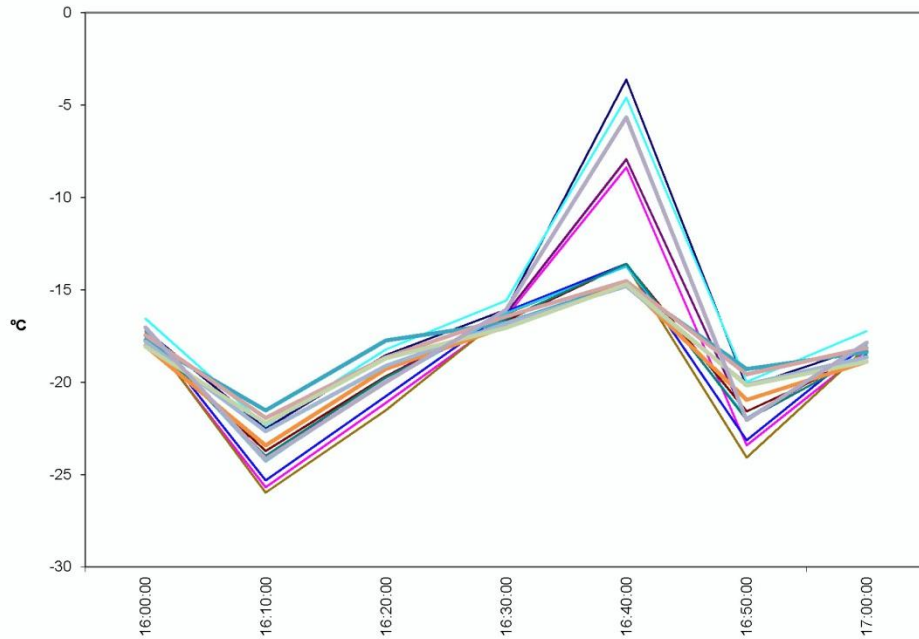
Freezer XYZ



Example 1 – Taking a closer look

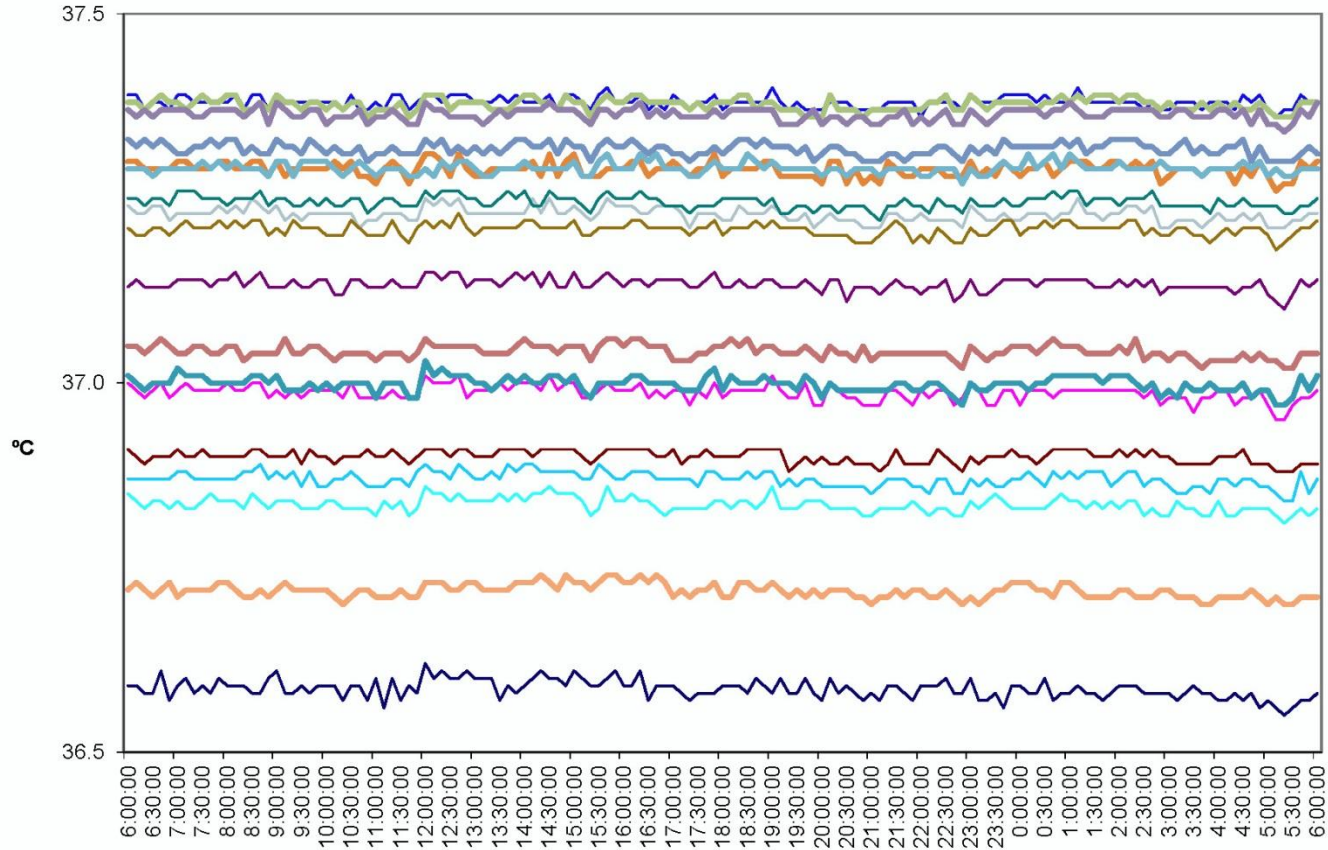


Example 1 – Taking a closer look

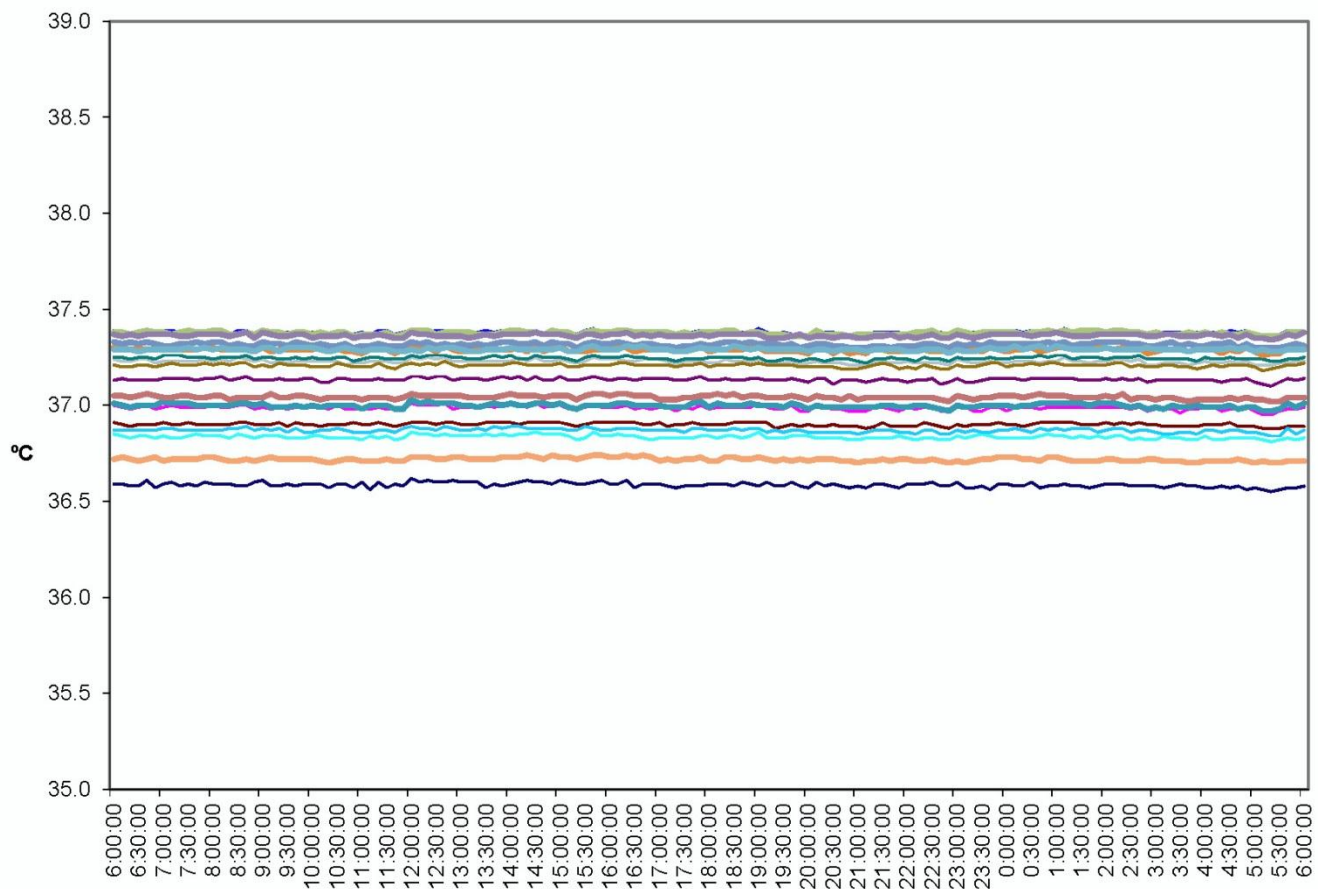


Date	Time	TC01	TC02	TC03	TC04	TC05	TC06	TC07	TC08	TC09	TC10	TC11	TC12	TC13
1-May-17	16:00:00	-17.19	-17.35	-17.24	-16.56	-17.22	-17.73	-17.23	-17.08	-17.16	-17.58	-17.74	-18.04	-17.8
1-May-17	16:10:00	-22.52	-25.69	-24.32	-22.36	-24.05	-23.73	-25.98	-25.32	-24.26	-23.98	-21.53	-23.43	-22.66
1-May-17	16:20:00	-18.53	-21.12	-19.79	-18.23	-19.68	-19.67	-21.52	-20.76	-20.02	-19.73	-17.74	-19.28	-19.12
1-May-17	16:30:00	-16.08	-16.45	-16.32	-15.59	-16.29	-16.68	-16.31	-16.17	-16.26	-16.58	-16.79	-16.99	-16.82
1-May-17	16:40:00	-3.62	-8.38	-7.97	-4.6	-7.93	-13.62	-13.67	-13.59	-13.74	-13.59	-14.68	-14.68	-14.8
1-May-17	16:50:00	-20.24	-23.42	-22.09	-19.99	-22.04	-21.59	-24.08	-23.15	-21.95	-22.04	-19.29	-20.96	-20.13
1-May-17	17:00:00	-18.06	-18.26	-18.05	-17.24	-18.08	-18.57	-18.11	-17.91	-17.99	-18.5	-18.37	-18.89	-18.65

Example 2 - Presentation



Example 2 - Presentation



Example 3 - Presentation

	MIN	MAX	AVG
TC01	36.6	36.6	36.6
TC02	37.0	37.0	37.0
TC03	37.2	37.3	37.2
TC04	36.8	36.9	36.8
TC05	37.1	37.2	37.1
TC06	36.9	36.9	36.9
TC07	37.2	37.2	37.2
TC08	37.4	37.4	37.4
TC09	36.8	36.9	36.9
TC10	37.2	37.3	37.2
TC11	37.0	37.0	37.0
TC12	37.3	37.3	37.3
TC13	37.3	37.3	37.3
TC14	37.0	37.1	37.0
TC15	37.4	37.4	37.4
TC16	37.3	37.4	37.4
TC17	37.3	37.3	37.3
TC18	36.7	36.7	36.7

	MIN	MAX	AVG
TC01	36.6	36.6	36.6
TC02	37.0	37.0	37.0
TC03	37.2	37.3	37.2
TC04	36.8	36.9	36.8
TC05	37.1	37.2	37.1
TC06	36.9	36.9	36.9
TC07	37.2	37.2	37.2
TC08	37.4	37.4	37.4
TC09	36.8	36.9	36.9
TC10	37.2	37.3	37.2
TC11	37.0	37.0	37.0
TC12	37.3	37.3	37.3
TC13	37.3	37.3	37.3
TC14	37.0	37.1	37.0
TC15	37.4	37.4	37.4
TC16	37.3	37.4	37.4
TC17	37.3	37.3	37.3
TC18	36.7	36.7	36.7

Operation

- What was learned from qualification?
- Maintaining compliance
 - Monitoring
 - Data collection and retention
 - Maintenance
- Data management system / process
- Redundancy
- Vigilance(!)

Summary and Q&A

