Continuous Temperature Monitoring

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Pfizer Andover Site

632 Total FTE (PGS)
366 Quality (PGS)
~70 Acres
8 Buildings
Five-level Parking Garage
Multi-product Facility

A: Parking Garage
A: Suites A, B and QC Labs
B: Suites C, D, E, F
D: Central Energy Plant and Cogeneration Plant
E: Clinical Manufacturing
F: Labs and Administrative Space
G: Research and Development
J: Warehouse
K: Drug Product Development
Pfizer Andover Site

Shared Pfizer Global Supply (PGS) and Worldwide Research, Development and Medical (WRDM) site

- PGS – Commercial and clinical drug substance and drug substance intermediate production
  - Suite AB: Fermentation suite for microbial vaccine production – Dedicated facility
  - Suite CD: multi-product suite for Mammalian Antibody, Protein, Fusion Protein Production
  - Suite EF: multi-product suite for Mammalian Antibody, Protein, Fusion Protein Production
- Building A and F: Quality Control Analytical and Microbiology laboratories
- Cell Banking Suite
- WRDM product development, process development, and clinical manufacturing functions

Warehouse Initial Qualification

- Warehouses are qualified in Summer and Winter months to represent the coldest and warmest temperatures that could be encountered
- Regulatory requirement to maintain qualified systems in a validated state and periodically assess to ensure they remain qualified
Warehouse Requalification

- Warehouses are requalified at a specified frequency; ie. 1, 3, or 5 years seasonally
- Requalification could include review of the following:
  - Change history
  - Maintenance
  - Operational records
  - Re-mapping
- Manufacturing facilities are becoming increasingly challenged to provide additional capability at a lower cost
- Utilization of technology available to ensure a qualified state

Continuous Temperature Monitoring Approach

- Alarmed temperature monitoring in lieu of periodic temperature mapping
- Permanent probes would be placed based on data collected during mapping activities such as
  - Warmest location
  - Coldest location
  - Representative areas based on storage of materials
- At defined intervals, the data collected would be reviewed to determine the performance of the area…
  - If adverse trends or events are identified this would trigger further investigation
  - If no trends are identified then the review is completed and filed
Efficiency and Savings

- Contracted Cost for seasonal mapping
  - $40 – 66K per season or $80 – 132K for both seasons
- Estimate for additional permanent probes being installed
  - ~$100K
- Personnel time for execution is substantially less
  - Time to set up, run, take down, analyze data, and generate a report vs assessment of generated data for trends and a report

Discussion Points

- What is the appropriate number of temperature sensors required, or the placement of these temperature sensors?
- What should the frequency be for trend analysis? How are trend analysis documented?
- Is periodic temperature mapping still required? How often?
Questions?
Please use the microphone indicated so our recording includes audio of your question