

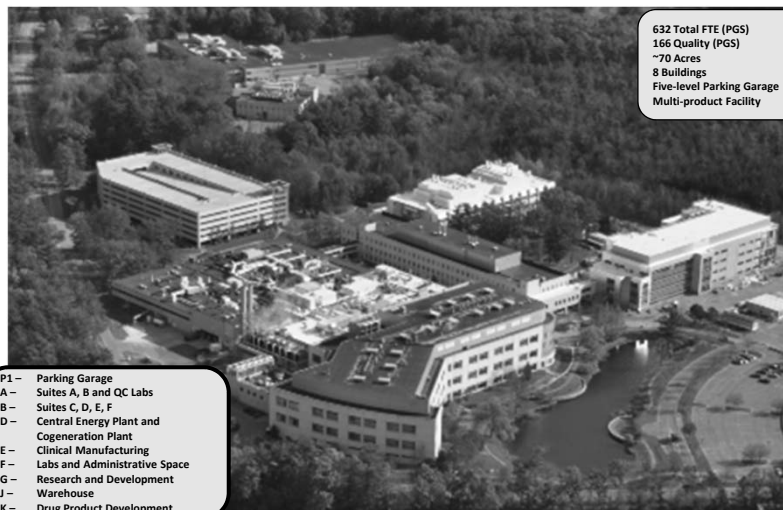


Continuous Temperature Monitoring

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1

Pfizer Andover Site



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2

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



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3

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



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4

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



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5

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**



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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



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7

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?



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8

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9