ALMAC

Partnering to Advance Human Health

Brochure

Almac Souderton Facility Expansion 2025

Customer Audit Guide

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C15G17

About this document

Almac’s North American Headquarters at 25 Fretz Rd, Souderton PA has enabled production, warehousing and distribution capabilities since its implementation in 2010.

To support continuing growth in demand for these capabilities, and to respond to changes in the clinical trials market, in 2023 Almac embarked on a major expansion of the Souderton facility in 2023 to meet the demand for these capabilities and in response to changes in the clinical trials market.

The expansion will continue to support the wide range of products that have historically been handled within Almac's Souderton facility, and customers should not anticipate a change to services. Cornerstone Almac Clinical Services activities, including the Pharmaceutical Quality System, operational procedures and organizational structures will remain familiar to our customers who have previously visited in Souderton.

Further information on these items can be found in our Pennsylvania Site Master File.

Contact List

For any specific questions related to expansion of the Almac Souderton facility please contact:

Troy Suessmuth

Director of Quality
Main: 610-666-9500
Email: troy.suessmuth@almacgroup.com

Principal Project Partners

The Almac expansion project team comprises personnel from multiple functional areas including Quality, Logistics, Validation, Engineering, Information Services, Facilities, Electrical Control & Instrumentation.

The team members have played key roles in successfully delivering other large-scale facility changes – indeed many were instrumental in the initial delivery of the Souderton facility.

This brings continuity to the facility expansion along with an in-depth understanding of regulatory obligations, customer expectations and operational requirements.

The Almac team has partnered with third party experts with extensive experience of large-scale projects in the pharmaceutical sector including:

Architects

CRB Group is a leading provider of sustainable engineering, architecture, construction and consulting solutions. With offices throughout USA, Canada and Europe, including Philadelphia, Pennsylvania, CRB specialize in solutions for the global life sciences and food & beverage industries.

Cost Consultants

Currie & Brown is a world-leading provider of cost management, project management and advisory services. With principal offices in USA, Europe and Asia, Currie & Brown operate across a broad range of public and private sectors including pharmaceuticals and life sciences, healthcare, utilities and renewables.

Structural / Civil Engineers

Barry Isett & Associates Inc. is a full-service engineering firm with locations in Delaware and Pennsylvania. Services offered include surveying, structural engineering and civil engineering, grant writing, landscape design, environmental engineering and sciences and the development of Geographic Information Systems.

MEP / Fire Protection Engineers / Commissioning

Genesis Engineers is a full service project delivery firm providing expertise in engineering, construction management and commissioning services for technically-driven projects. Genesis Engineers specialize primarily in the pharmaceutical, biotechnology and healthcare industries, while maintaining a strong presence in the industrial and commercial marketplace.

Construction Managers

Cyma Builders & Construction Managers is a leading provider of world-class construction services within the building construction sector in the United States. Based in Pennsylvania, Cyma Builders & Construction Managers specializes in the life science and pharmaceutical sectors but have also partnered with corporate, healthcare and university clients.

Expansion Scope

The Souderton facility comprises 2 buildings.

Building 1 is primarily an administrative building and provides work spaces for Almac Clinical Services, Almac Clinical Technologies and Central Management personnel over three-stories.

Building 2 is a two-story production and logistics building that supports Almac Clinical Services material storage, production and distribution activities and Almac Sciences analytical and stability services.

The facility expansion is focused on Building 2 and expands the building footprint by 79 000 ft^2 to 190 634 ft^2. Existing, established processes and procedures will continue to be applied within the new areas.

Phase 1 of the expansion, which completed in Sep 2025, has delivered the following major changes:

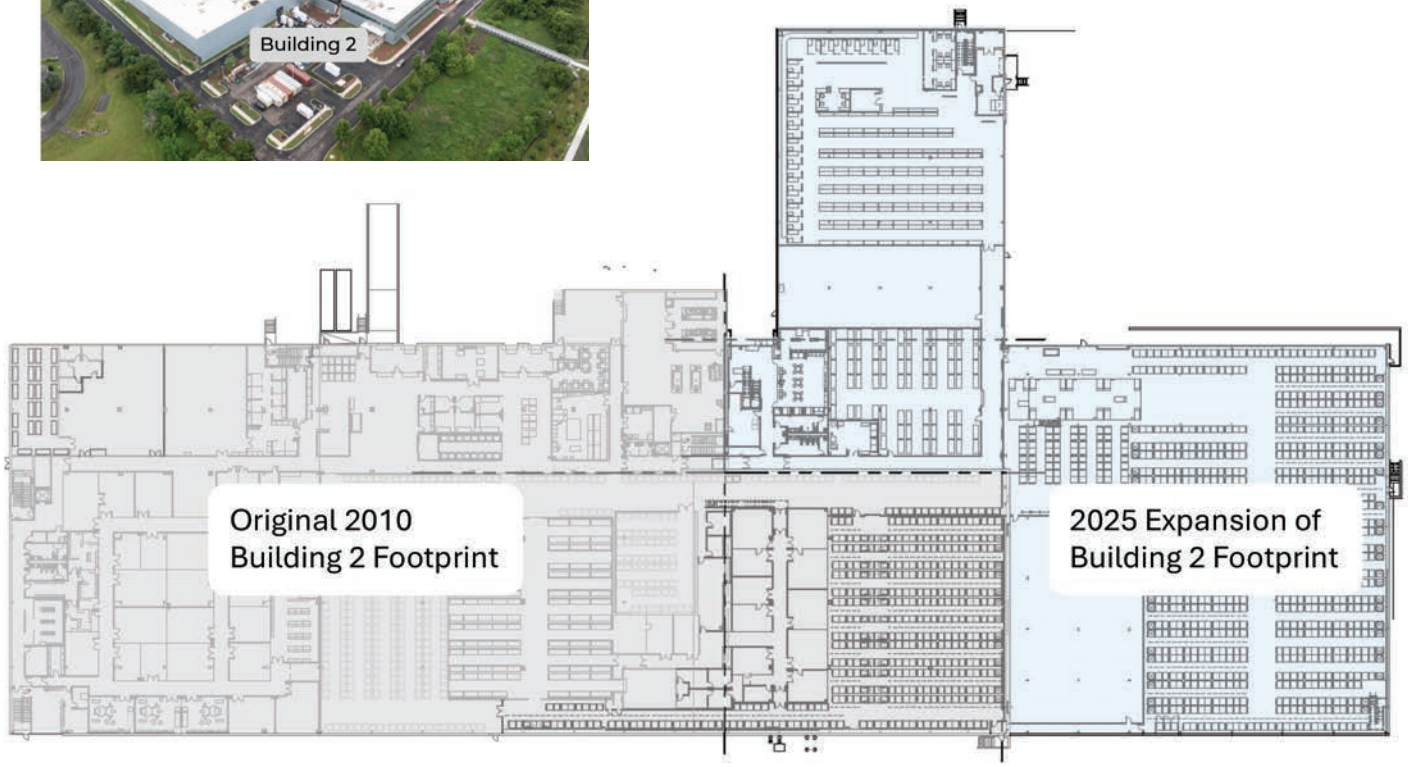
- New 15-25°C warehouse
- New ultra-low temperature mobile freezer corral
- New distribution warehouse

The enablers for these changes include the implementation of new air handling units and a new environmental monitoring system (EMS), along with extending existing access and surveillance controls and electrical back-up strategy. The expansion has also delivered various site improvements including introduction of a new parking lot.

Phase 2 of the expansion will complete during 2026 and will deliver significant increases in 2-8°C storage, 2-8°C production, -20°C production & Just-in-Time production capacity. These changes will be delivered by reconfiguring areas within the existing building footprint and hence phase 2 will start immediately upon completion of phase 1.

2026 will also see the implementation of a reach-in storage unit within the Souderton facility that will provide additional capacity for material at -80°C to -60°C and -25°C to -15°C. This unit is situated within the new 15-25°C warehouse and aligns with the reach-in units that have been successfully implemented in the Almac Clinical Services North Carolina and Craigavon facilities.

Further details of Souderton expansion phase 2 and implementation of the ultra low temperature reach-in unit will be provided during 2026.



Building 2 Infrastructure

Materials of Construction

The Building 2 expansion has been constructed with materials that are structurally and aesthetically consistent with the original building:

- Foundations: Concrete spread footings with 2 story structural steel
- Floors: Concrete slab
- Exterior walls: Masonry with structural steel stud
- Interior walls: Masonry with steel stud gypsum board
- Roof: Thermoplastic Polyolefin

Utilities

Utilities continue to be provided by:

- Water service: North Penn Water Authority
- Sanitary sewer: Lower Salford Township
- Electricity: PECO Energy
- Natural gas: PECO Energy

Air Handling

Environmental conditions in the expansion area are provided by 3 additional air handling units (AHU):

- AHU-2-16 New ultra-low temperature mobile freezer corral
- AHU-2-17 New distribution warehouse
- AHU-2-19 New 15-25°C warehouse

Supporting plant includes redundant boilers and chillers.

Electrical Back-up

The existing Building 2 electrical back-up strategy has been supplemented with 3 additional 1000kW Caterpillar C32 skid-mounted diesel generators. This enables a total of 4 generators, fed through paralleling switch gear, to ensure electrical continuity for critical systems. Within the scope of the phase 1 expansion this includes security and life safety systems, environmental monitoring system (EMS) and building management system (BMS) controllers, freezer corral fan coil units and mobile freezers.

Environmental Controls and Monitoring

Within the new areas of Building 2, separate instances of the Schneider Electric EcoStruxure system provide EMS and BMS functionality.

The BMS instance:

- Maintains environmental conditions
- Provides alert alarms which indicate potential maintenance issues
- Monitors emergency generator activity

The EMS instance:

- Continuously monitors and reports environmental conditions
- Provides action alarms for conditions which may impact product quality, including environmental conditions and mobile freezer general alarms

Alarms are automatically communicated to responsible persons via cell phone and electronic messaging. Access to the system and to specific functionality is controlled via Active Directory user groups. Authority checks are required to make changes and 21 CFR Part 11 compliance is supported through application of electronic signatures and maintenance of audit trails and electronic records.

Security

Existing Building 2 security measures have been extended to the expansion areas:

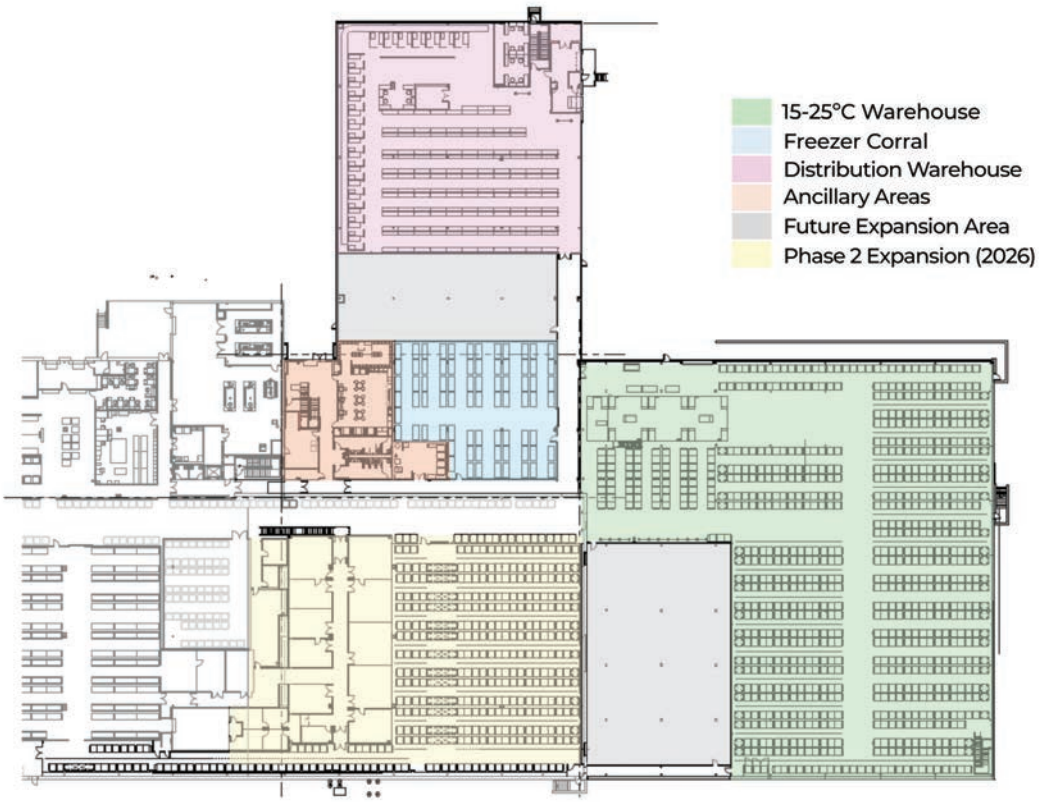
- Intruder detection sensors at perimeter doors and windows
- Closed circuit TV monitoring activities at key access and operation points
- Controlled access points to restrict personnel movement based on job responsibility and regulatory security provisions. Access cards are issued and provisioned using the CCure ID badging system. The authority to issue access cards to employees, including the granting of specific access permissions, is restricted to senior Almac management.

Network Infrastructure

The existing Network Operations Center in Building 1 and the redundant data center in Building 2 continue to power network connectivity throughout the Souderton facility.

A new Intermediate Distribution Frame (IDF) room and communications cabinet have been introduced in Building 2 under change control to extend network connectivity to the expansion areas.
Wireless access points have been implemented throughout the new spaces to enable secure wireless operational transactions.

Building 2 Expansion Floor Plan



Material Storage & Distribution

The Building 2 expansion provides areas for the storage of pharmaceutical materials, including raw materials, in-process materials and finished goods. Access to all material management areas is restricted per TSA Certified Cargo Screening requirements.

All storage locations are reflected in Almac Clinical Services global ERP system (COSMOS).

Temperature in all material storage areas is continuously monitored and alarmed via the validated Environmental Monitoring System (EMS).

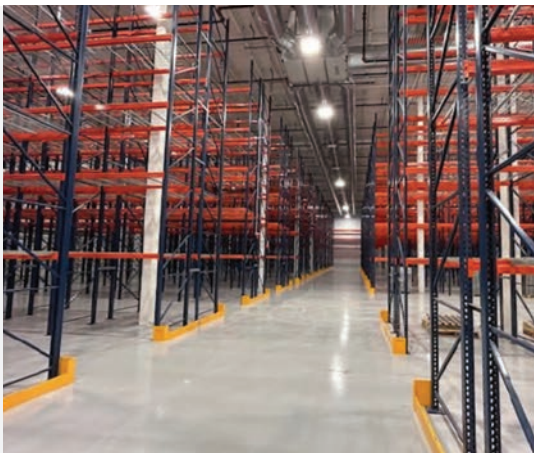
In addition the areas have been designed to maintain relative humidity ≤65%. This is also monitored via the EMS.

Location	Temperature	Capacity
15-25°C Warehouse	**15-25°C**	**7310 pallets**
Distribution Warehouse	**15-25°C**	**416 pallet equivalents**
Ultra-low Temperature Freezer Corral	**15-25°C**	**76 freezers**

15-25°C Warehouse

The 15-25°C warehouse is approximately 36,100ft² and 40 ft high.

Capacity is optimised by use of narrow aisle pallet racking and wire-guided forklifts. The new warehouse expands the 15-25°C storage capacity of Building 2 to 7310 pallet spaces.



Ultra-Low Temperature Freezer Corral

The Ultra-Low Temperature Freezer Corral is approximately 5,400ft² and accommodates up to 76 freezers. The area has been designed to manage the variable heat load that is subject to the number of freezers that are active within the space.

Freezers can operate at different ultra-low temperature ranges, however -80°C to -60°C is the most prevalent operating range. Each freezer includes compressor redundancy and is individually monitored and alarmed via the Environmental Monitoring System. As further redundancy, Almac maintains a ratio of empty freezers.

Distribution Warehouse

The Distribution warehouse is approximately 13,850ft^2 and comprises finished goods storage, distribution order processing and dispatch areas.

The finished good storage area accommodates the equivalent of 416 pallets of finished clinical patient kits on racked shelving to facilitate picking of clinical distribution orders

The distribution processing area includes 21 segregated workstations for the verification and packing of individual clinical supply orders and a Quality Control area for the physical audit and release of distribution orders. A conveyor system facilitates efficient transfer of packed shipments to dispatch.

The dispatch area is an interface between Building 2 and the external environment. Fast action doors mitigate the impact of outdoor temperature and humidity, and pest control measures are focused on the entry point. Outside the building the distribution dock accommodates courier collection vans. A canopy affords protection from the elements during loading activities and a receiving area for courier drivers enables them to alert Almac personnel to their presence without providing any access to the facility.

TSA Certified Cargo Screening Program

The material handling area of Building 2 is a TSA Certified Cargo Screen facility. This is achieved by ensuring the following security measures:

- Individuals: Personnel responsible for handling goods are properly designated and trained and clear the appropriate background checks.
- Facility: Screening areas are clearly designated, identified and secure.
- Documentation: Documentation must be in place to ensure proof of employee training, employee screening and package identification.

At the outset of the expansion, plans were reviewed with TSA to outline how existing security measures will be extended to the expanded material handling area. TSA has now inspected the new areas and authorised their use.

Pest Control

The expansion areas have been added to the established Almac Clinical Services pest control program, ensuring Building 2 remains free from infestation by rodents, birds, insects and other vermin.

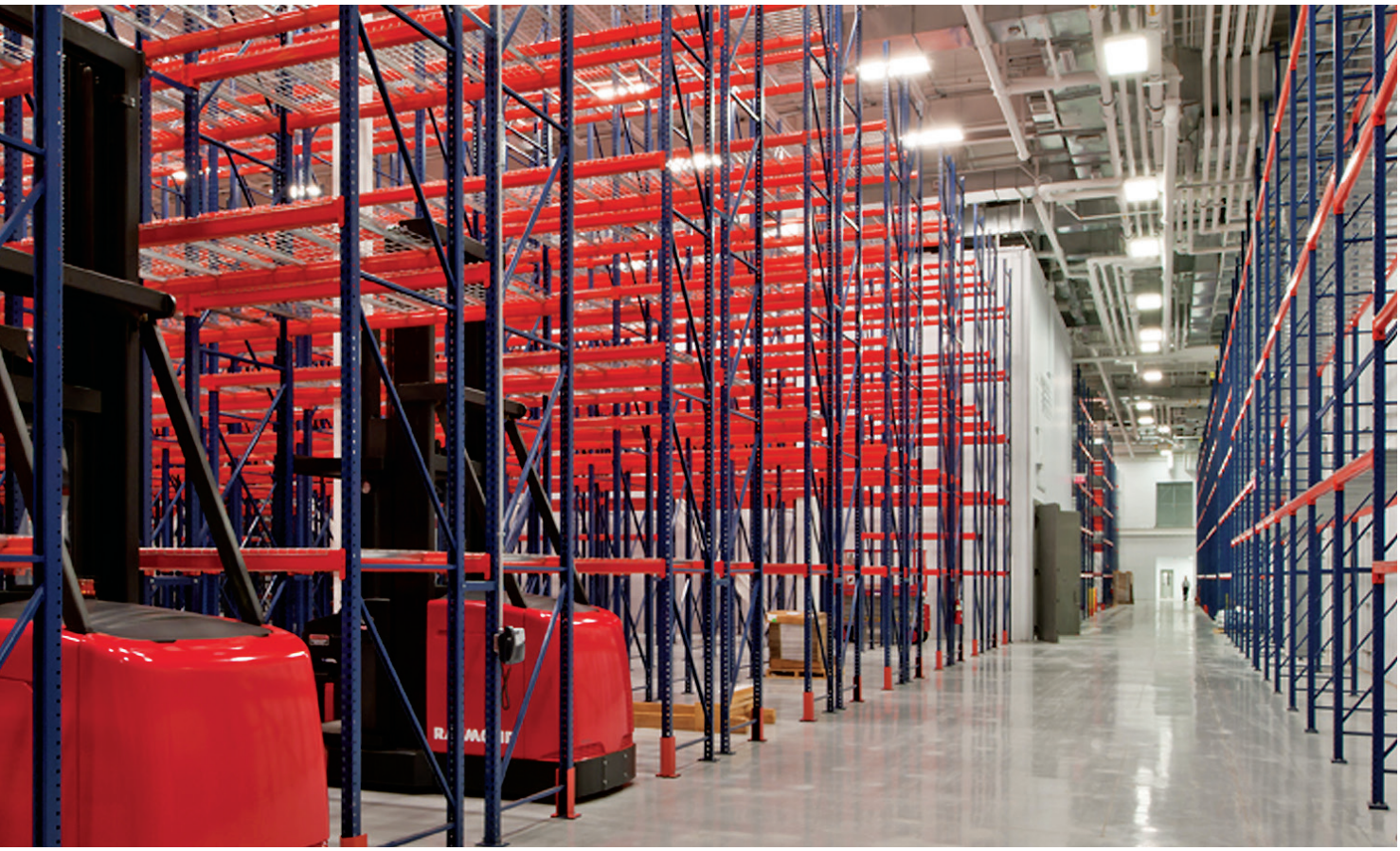
The pest control program incorporates the use of strategically placed pest control devices including interior rodent stations, insect light traps, monitor/glue boards and exterior rodent stations. Pest control services are provided by an approved vendor and include at least monthly inspections by a trained technician along with semi-annual chemical treatments along the exterior perimeter only. The monthly vendor inspections are supplemented by bi-weekly inspections performed by Almac Quality Control staff.

Licensing and Registration

Almac Clinical Services holds licenses or registrations for the Souderton, PA site with the Food & Drug Administration, Drug Enforcement Agency and PA Department of Health.

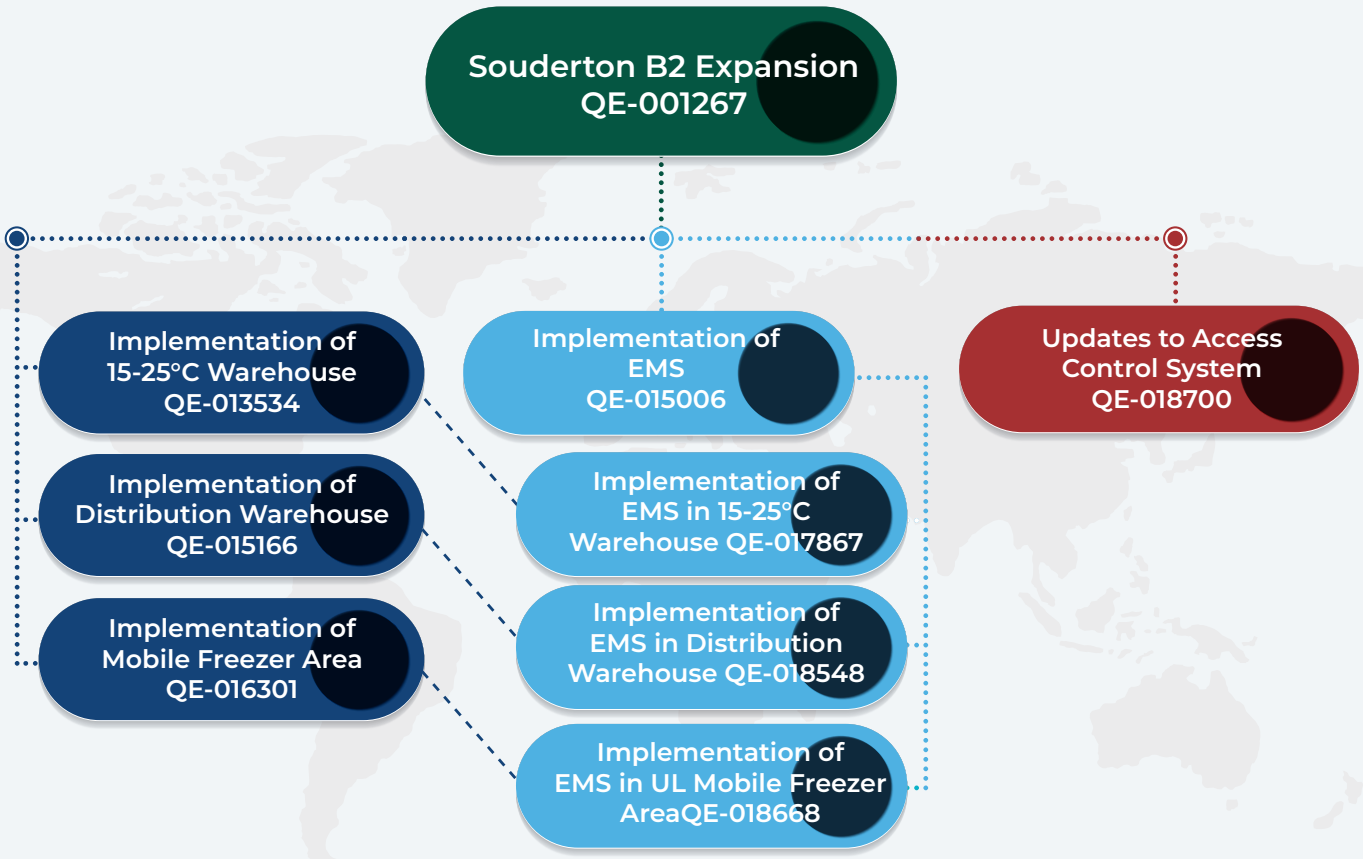
The expansion of the Souderton facility does not change the facility address or the range of activities performed at the Souderton site. Therefore no changes to licenses or registrations have been necessary.

The scope of the expansion has been communicated to the Pennsylvania Department of Health and the Almac Site Master File has been revised to reflect the changes to the facility layout and area capacities.



Managing Change

The Almac change control process incorporates impact assessment, risk assessment and regulatory review to identify the actions required to manage delivery of a change and maintain compliance.



The expansion of the Souderton facility is governed by change control QE-001267. This change control will remain in a status of 'In Change Execution' through 2026 when phase 2 will complete.

Under the change plan for QE-001267, individual change controls have been established for each area of the expansion. These define the change actions which have been identified as pre-requisites for operational start-up in each area. Almac Quality approval of a completed area-specific change control constitutes authorisation to commence use of that area for GxP activities.

In addition to creating new physical spaces, the expansion of the facility has also been the driver for implementation of a new Environmental Monitoring System (EMS). This has been implemented under change control QE-015006, with further change controls managing the phased roll-out of the system to each expansion area. The EMS supporting existing areas of the facility remains unchanged.

Controlled changes have also been made to the existing access control system to manage access within the new GxP areas of the facility.

Qualification of GxP Facilities & Systems

Validation of the facility expansion followed global regulatory standards and aligned with the original implementation method, using ASTM E-2500 verification principles.

Both business and GxP requirements were verified during commissioning that was completed by teams from Almac Engineering Projects, Almac Electrical Control & Instrumentation, and Genesis Engineering. Commissioning documentation was compiled and executed in a manner that meets Almac and GxP standards, ensuring compliance and enabling the leveraging of testing into Validation.

Validation activities concentrated on GxP requirements. The appropriate extent of testing required to confirm that each space or system fulfilled the User Requirements Specification (URS) and was suitable for its intended use was identified through a Validation Risk Assessment (VRA).

Validation activities for phase 1 of the facility expansion, including temperature mapping/monitoring of storage/processing areas, were managed under the following validation project references:

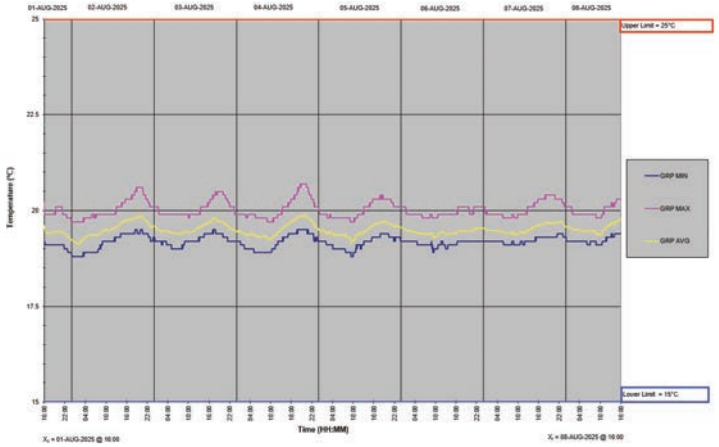
Validation Project	Project Reference
Environmental Monitoring System	**VAL1951**
15-25°C Warehouse	**VAL1952**
Ultra-low Temperature Freezer Corral	**VAL1953**
Distribution Warehouse	**VAL1954**

The change controls governing delivery of each expansion area include change actions verifying successful completion and Almac Quality approval of validation protocols. This establishes validation of GxP spaces and supporting systems as pre-requisites for Almac Quality authorization to commence use of the new areas.

Temperature Mapping

15-25°C Warehouse

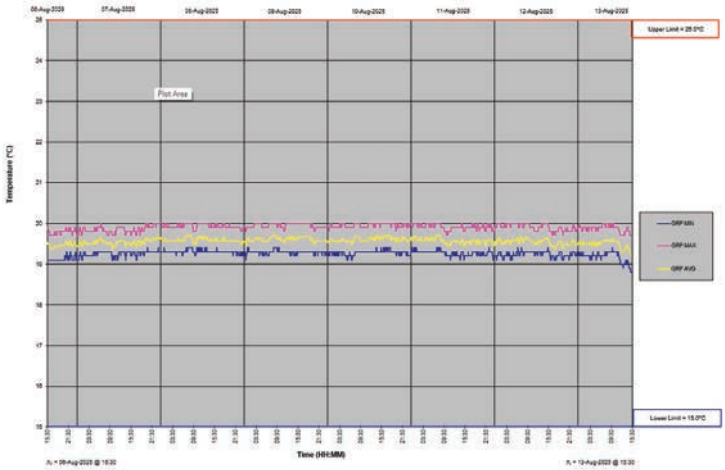
Results of 7 day temperature mapping study



Validation release of the 15-25°C Warehouse was provided by the Validation Control Group on 13 Aug 2025

Ultra-Low Temperature Freezer Corral

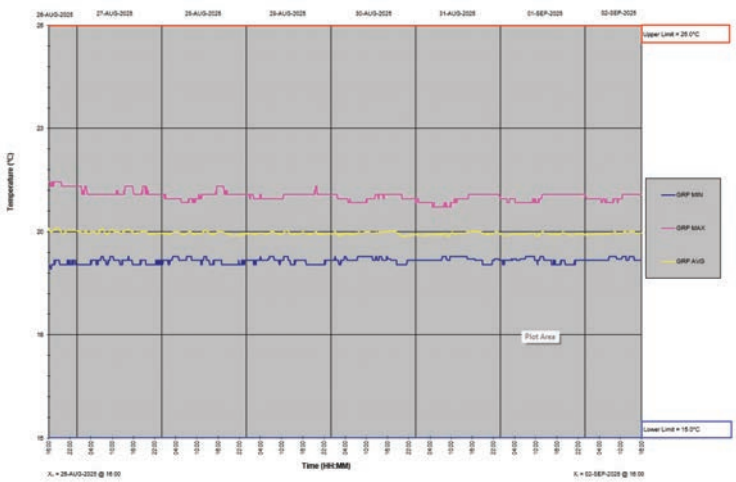
Results of 7 day temperature mapping study



Validation release of the Ultra-low Temperature Freezer Corral was provided by the Validation Control Group on 15 Aug 2025

Distribution Warehouse

Results of 7 day temperature mapping study



Validation release of the Distribution Warehouse was provided by the Validation Control Group on 10 Sep 2025

Operational Start-up

The new 15-25°C warehouse, mobile freezer corral and distribution warehouse have been delivered under area-specific change controls. These change controls identified the actions which were pre-requisites for safe, secure and GxP-compliant use of each space. Almac Clinical Services Quality approval of these change controls signified that all pre-requisite change actions had been completed and hence constituted authorization to commence operational use of the areas.

Area	Change Control	Approval Date
15-25°C Warehouse	**QE-013534**	**22 Aug 2025**
Ultra-low Temperature Freezer Corral	**QE-016301**	**22 Aug 2025**
Distribution Warehouse	**QE-015166**	**12 Sep 2025**

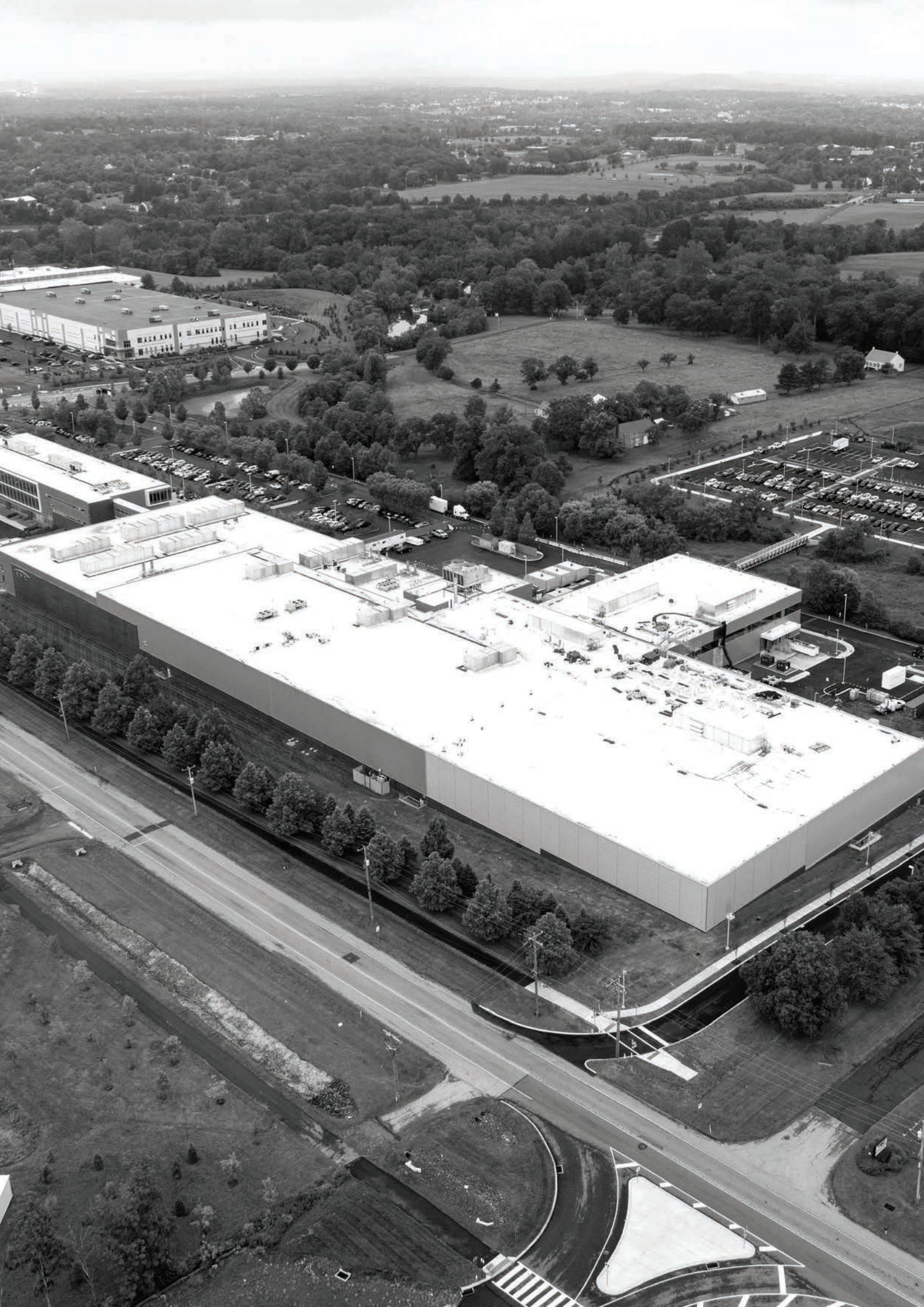
Movement of material between warehouse locations and repositioning mobile freezers are standard materials management activities that are routinely performed by experienced Almac Clinical Services Warehouse personnel in accordance with established processes and procedures. These normal material management activities have commenced in the new areas.

- 15-25°C material received into the Souderton facility is being stored in the new 15-25°C warehouse.
- Material that has been stored in the existing 15-25°C warehouse has been moved to the new warehouse
- Storage of finished goods and processing of distribution orders is transitioning to the new distribution warehouse.
- The majority of existing mobile freezers containing ultra-low temperature material are being transferred to the new freezer corral.

Because the existing and new material storage areas are all within the expanded footprint of Building 2, the material movements involved short distances along smooth floors within one continuous validated space.

Recognising that start-up in the new areas would be an atypical, concentrated period of material movement, change controls were established to provide a formal record of these activities and the associated due diligence tasks:

	Change Control
Movement of 15-25°C material	**QE-019117**
Movement of ultra-low temperature freezers	**QE-017391**



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Get in touch

Global HQ
+44 28 3836 2436

US HQ
+1 215 660 8500

Asia Pacific HQ
+65 6309 0720

EU HQ
+353 42 932 0718

Durham, NC, USA
+1 (919) 479 8850

Japan
+81 3 4233 9178

clinicalservices@almacgroup.com