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16 May 2025

Dear Valued Customer,

In summer 2023 Almac announced the start of a major expansion of our North American Headquarters in Souderton, Pennsylvania. This expansion will not change the facility address and does not change the existing Almac service offering but will significantly increase storage and processing capacity. The expansion will be delivered in phases, concluding in 2026.

We are now pleased to inform you that the first phase of the expansion will complete in summer 2025. This phase will deliver:

- New 7300-pallet 15-25°C Warehouse
- New Distribution Warehouse with expanded pick-face and additional processing workstations
- New Mobile Freezer Area with enablers to accommodate over 70 ultra-low temperature freezers
- New environmental monitoring system (EMS) providing continuous monitoring and alarm functionality for the new areas.

This letter provides formal notification of this change in accordance with the responsibilities defined in the Technical Agreement.

How the change is being managed:

The overall expansion program is governed by a Quality-approved change control. Linked to this are change controls governing the delivery of each GxP area and system. Impact assessment and regulatory review have informed the scope of the change plan for each area/system, and the associated change actions encompass a broad range of GxP and business readiness topics including commissioning, validation, notification to regulatory authorities and SOPs.

Risk assessment has been used extensively to ensure change activities are appropriately controlled, maintaining focus on regulatory compliance, patient safety and business continuity.

Almac has maintained service levels throughout the construction period, and this will continue during operational start-up in the new areas.

A more detailed view of the approach is provided in the attached document.

Expansion phase 1 milestones:

Validation of the new EMS is due to complete in Jul 2025. Validations of the 15-25°C Warehouse, Distribution Warehouse and Mobile Freezer Area are expected to complete in August 2025.

Subsequent final Quality approval of the completed change controls for each area will authorise use of the new spaces. Almac will then commence the movement of existing material to the new areas.

The second phase of the expansion – including construction of an additional 2-8°C store, 2-8°C production rooms and -15 to -25°C production rooms - will then commence within the vacated space.



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Next steps:

Almac will provide an additional update when temperature mapping data is available and will share evidence of Validation completion and Quality approval of the change controls that are applicable to the phase 1 areas.
Further notification will be provided in 2026 prior to completion of phase 2 of the expansion.

There is no action required by you; however, we would be grateful if you share this notification of change to any parties within your organisation who may be interested.
If you have any questions, please contact your Almac representative.

Senior Quality Management			
Signature	Print Name	Position	Date
<div>Signed by:</div> <div>Troy Suessmuth</div> <div><div><div></div></div><div>Signer Name: Troy Suessmuth Signing Reason: I approve this document Signing Time: 16-May-2025 16:27:47 BST</div></div>	Troy Suessmuth	Almac Clinical Services Director of Quality	16-May-2025 16:27:52 BST

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EXPANSION OF THE ALMAC FACILITY 25 FRETZ RD, SOUDERTON, PA

COMPLETION OF PHASE 1

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1. INTRODUCTION

In summer 2023 site work commenced on a major expansion of the Almac Souderton, PA facility. The expansion will be delivered in phases, concluding in 2026. As the first phase of the expansion approaches completion, this document provides an overview of the upcoming changes and a summary of how delivery of the phase 1 changes has been controlled, and how operational start-up in the new areas of the facility will be managed to maintain business continuity and GxP compliance.

2. SCOPE OF EXPANSION

The table below summarises the major changes that will be completed in phase 1 (2025) and phase 2 (2026).

Phase 1 (Completing 2025)	Phase 2 (Completing 2026)
15-25°C warehouse (7300 pallet spaces)	2-8°C storage (2000 pallet spaces)
Distribution warehouse (expanded pickface & 21 processing workstations)	2-8°C production (additional 10 rooms)
Mobile freezer area (enablers to accommodate 70 freezers)	-15 to -25°C production (additional 2 rooms)
Environmental Monitoring System (supporting expansion areas)	Just-in-time Manufacturing area (Almac Adapt™) (expanded pickface & additional processing suites)
Office accommodation (accommodating 200+ employees)	
Site improvements (inc. parking, LEED certification, back-up power)	

Delivering the additional capacity of the new phase 1 areas has involved extending the footprint of the existing Souderton facility (Building 2), thereby maintaining all material storage areas under one roof. The phase 2 areas will be created by reconfiguring or repurposing areas within the existing building footprint. Therefore, completion of phase 1 and movement of existing material into the new areas of the facility is a pre-requisite for the start of phase 2. Appendix 1 illustrates the change to the footprint of the Souderton facility (Building 2), and the building layout at the end of each phase of the expansion.

3. APPROACH

Maintaining business continuity and GxP compliance and assuring the integrity and security of clinical supplies have been of paramount importance, informing every aspect of delivery of the phase 1 changes and the approach to release of, and operational start-up within, each new area.

3.1 CHANGE CONTROL

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. Quality approval of a completed area-specific change control will constitute 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). The initial scope of this system is limited to providing continuous environmental monitoring and alarm functionality within the new areas of the facility. The EMS supporting existing areas of the facility remains unchanged.

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

Appendix 2 illustrates the relationship between the principal change controls governing implementation of phase 1 of the expansion.

3.2 RISK ASSESSMENT

Risk assessment has been used extensively to identify risks and implement controls which have ensured operational continuity and GxP compliance have been maintained throughout construction. This includes risk assessment of site works, activities impacting utilities and building services, and activities in proximity to GxP areas.

Risk assessment has also been instrumental in establishing a robust approach to operational start-up in the phase 1 expansion areas.

3.3 VALIDATION

In accordance with Almac policy and procedures, validation of GxP spaces and supporting GxP systems is a pre-requisite for release of the new areas. The validation activities associated with phase 1 of the facility expansion, which includes temperature mapping of material storage areas, are being managed under the following validation project references:

Validation Project	Project Reference
Environmental Monitoring System	VAL1951
15-25°C Warehouse	VAL1952
Mobile freezer area	VAL1953
Distribution Warehouse	VAL1954

3.4 COMMUNICATION WITH REGULATORY BODIES

Expansion of the Souderton facility will deliver a significant increase in capacity but does not change the facility address or the Almac service offering. Therefore there are no changes to Almac’s licences.

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

At the outset of the expansion, plans were reviewed with the Transportation Security Administration (TSA) to explain how the controls within existing material storage and distribution spaces will be replicated in the new areas. TSA has been advised of the timeframe for completion of phase 1 and have been invited to review the new areas prior to release.

4. PHASE 1 OPERATIONAL START-UP

Quality approval of QE-013534 will authorise use of the new 15-25°C warehouse. From that point, 15-25°C material received into the Souderton facility will be stored in the new warehouse. Material that has been stored in the existing 15-25°C warehouse will also be moved to the new warehouse. This is necessary so that phase 2 construction of the new 2-8°C store can commence in the vacated area.

Quality approval of QE-015166 will authorise use of the new distribution warehouse. Storage of finished goods and processing of distribution orders will transition to the new distribution warehouse.

Quality approval of QE-016301 will authorise use of the new mobile freezer area. The majority of existing mobile freezers containing ultra-low temperature material will subsequently be transferred to the new area.

The new material storage areas will be directly accessible from the existing areas as illustrated in Appendix 1. Movement of material between warehouse locations and repositioning mobile freezers are standard materials management activities that are routinely performed by experienced Almac warehouse staff in accordance with existing processes and procedures. However, in this instance, as the quantity of material involved is atypical, movement of 15-25°C material will be managed under change control QE-019117 and movement of ultra-low freezers will be managed under change control QE-017391. This approach ensures that impact assessments are conducted and the material movements will involve additional Quality oversight.

5. PHASE 2

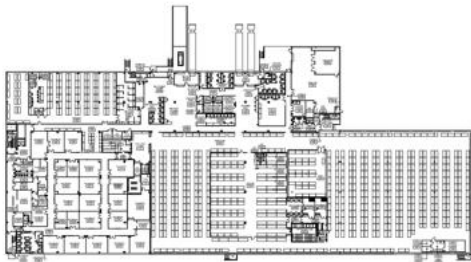
Phase 2 construction will commence as soon as the existing 15-25°C warehouse has been vacated. The controlled approach that has been applied to phase 1 will also be applied to phase 2 activities.

While phase 2 is in progress we will continue to welcome our customers to the Souderton facility for audits, operational witnessing and business meetings. Progress will be communicated as significant milestones are reached.

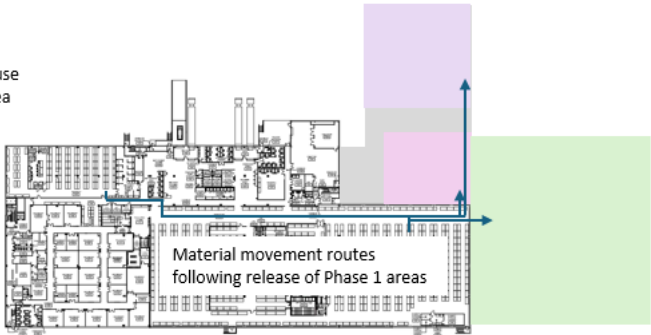
APPENDIX 1

CHANGES TO BUILDING 2 FOOTPRINT & LAYOUT PER EXPANSION PHASE

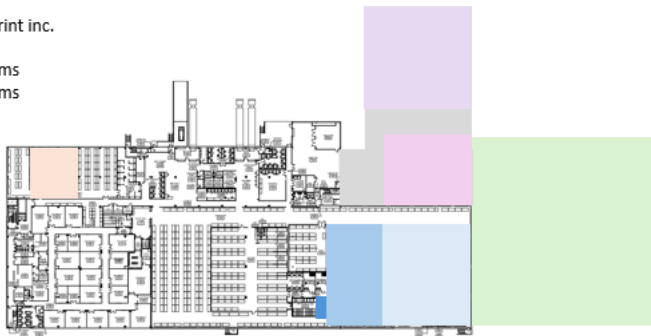
Pre-expansion:
Building 2 footprint



End of Phase 1 (2025):
Increased Building 2 footprint inc.
New 15-25°C Warehouse
New Distribution Warehouse
New UL mobile freezer area



End of Phase 2 (2026):
Reconfiguration of Building 2 footprint inc.
New 2-8°C Store
New 2-8°C Production rooms
New -20°C Production rooms
Expanded JTM area



APPENDIX 2

CHANGE CONTROLS – EXPANSION PHASE 1

