

# Summary of capabilities

## Allentown, PA, US

### Overview

Long-established provider of ambient and cold packaging, storage, and distribution for clinical trials, defining best practices for the industry. Track record of excellence in managing high volumes of clinical supplies: 70,000+ shipments annually, including temperature-controlled/monitored materials (up to -80°C)

| Facility facts |                                                                                                                          | Offerings                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Opened         | 1999                                                                                                                     | <ul style="list-style-type: none"> <li>Comprehensive service line supporting all aspects of clinical trial supply, including over-encapsulation, primary and secondary packaging, labeling, regulatory support, distribution, returns, and destruction</li> <li>Full support for clinical studies in all phases of development</li> <li>Support for compounds that are light-sensitive, highly potent compounds, and/or compounds with zero tolerance for time out of environment (TOE)</li> <li>Commercial secondary packaging services for syringe/pre-filled syringe/pen /auto-injector assembly and labeling</li> <li>Comprehensive engineering services enable streamlined/customized production, including in-house tool manufacturing, CAD services for packaging design, and in-house 3D print capabilities</li> <li>State-of-the-art logistics automation system, enabling future scalability</li> </ul> |
| Audited by     | FDA, DEA, TSA, NBP, ANVISA                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Licenses       | DEA controlled substance manufacturer/distribution/import/export (schedule I-V), TSA cargo screening, VAWD accreditation |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Contact info   | 7554 Schantz Rd.<br>Allentown, PA 18106<br>United States                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

### Allentown clinical storage and packaging capabilities:

| Capacity and services |                                     |       |                                 |                |  |
|-----------------------|-------------------------------------|-------|---------------------------------|----------------|--|
| Storage conditions    | Controlled ambient (15°C to 25°C)   |       | 247,000 sq. ft. (23,300 sq. m.) | 21,000 pallets |  |
|                       | Refrigerated (2°C to 8°C)           |       | 70,100 sq. ft. (6,510 sq. m.)   | 6,445 pallets  |  |
|                       | Frozen                              | -20°C | 4,000 sq. ft. (372 sq. m.)      | 230 pallets    |  |
|                       |                                     | -30°C | 1,200 sq. ft. (112 sq. m.)      | 75 pallets     |  |
|                       |                                     | -40°C | 20 units                        |                |  |
|                       |                                     | -70°C | 21 units                        |                |  |
|                       |                                     | -80°C | 139 units                       |                |  |
|                       | Controlled substance (15°C to 25°C) |       | 7,445 sq. ft. (688 sq. m.)      | 898 pallets    |  |
|                       | Controlled substance refrigerated   |       | 216 sq. ft. (19.5 sq. m.)       | 4 pallets      |  |

## Allentown clinical storage and packaging capabilities

| Capacity and services                                     |                                    |                                                                                                                               |
|-----------------------------------------------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Engineering and facilities                                | Backup power and redundant systems | Diesel and natural gas generators for systems and all controlled temperature units                                            |
|                                                           | Environmental                      | Monitored 24/7 by the building automation system with alarms sent to on-site monitoring personnel                             |
|                                                           | Security/access                    | On-site security staff 24/7/365                                                                                               |
|                                                           |                                    | CCTV monitoring                                                                                                               |
|                                                           |                                    | Employee access to secured areas via system-managed electronic badges                                                         |
| Primary packaging and manufacturing (33 production rooms) | Capabilities                       | Bottle filling for solid dosage forms (automated and manual)                                                                  |
|                                                           |                                    | Automated blistering, cold form and thermoform, single and multi-fill                                                         |
|                                                           |                                    | Over-encapsulation and placebo manufacturing                                                                                  |
|                                                           | Controls/environments              | Low humidity                                                                                                                  |
|                                                           |                                    | Light-sensitive                                                                                                               |
|                                                           |                                    | Containment suites                                                                                                            |
|                                                           |                                    | Dedicated washrooms                                                                                                           |
| Secondary packaging (29 production rooms)                 | Capabilities                       | Bottle/vial/card labeling/de-labeling                                                                                         |
|                                                           |                                    | Carding/walleting in-line and mobile                                                                                          |
|                                                           |                                    | Syringe assembly and labeling; manual, semi-automated, and automated                                                          |
|                                                           |                                    | Needle safety device (NSD); manual and semi-automated assembly                                                                |
|                                                           |                                    | Pen/auto-injector semi-automated assembly                                                                                     |
|                                                           |                                    | Blinding of multiple components                                                                                               |
|                                                           |                                    | Patient kit assembly and consolidation                                                                                        |
|                                                           | Controls/environments              | 19 CRT ambient (15°C to 25°C) rooms                                                                                           |
|                                                           |                                    | 6 refrigerated (2°C to 8°C) rooms                                                                                             |
|                                                           |                                    | 4 frozen (-20°C) rooms                                                                                                        |
|                                                           |                                    | Light-sensitive packaging                                                                                                     |
|                                                           |                                    | Bar code control (Production Assembly Scanning System—PASS) for identification, confirmation, material reconciliation of kits |

## Allentown clinical storage and packaging capabilities

| Capacity and services |                                                       |                                                                     |
|-----------------------|-------------------------------------------------------|---------------------------------------------------------------------|
| Label services        | Services                                              | Label proof design and approval including regulatory review of text |
|                       |                                                       | Text translation (ATLAS <sup>SM</sup> software)                     |
|                       |                                                       | Variable text                                                       |
|                       |                                                       | Cold chain labeling (refrigerated and frozen)                       |
|                       |                                                       | Expiry date labeling/relabeling                                     |
|                       |                                                       | Manual and semi-automated application                               |
|                       |                                                       | Just-in-time and late-stage customization (upon evaluation)         |
|                       | Types                                                 | Booklet labels                                                      |
|                       |                                                       | Single and multi-panel labels                                       |
|                       |                                                       | Auxiliary and expiry update labels                                  |
| Engineering services  | Capabilities                                          | In-house tool manufacturing, 3D print technology, CAD services      |
| Enhanced services     | Demand and supply management, modeling and simulation | Comparator sourcing and management                                  |
|                       | Clinical ancillary management                         |                                                                     |
| Distribution          | Pick and pack services                                | Returns, storage, destruction                                       |
|                       | Domestic and international transportation management  | Total transportation management services                            |
|                       | Reusable shippers                                     |                                                                     |

# From molecule to medicine

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