

Global Clinical Supply Services



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Storage and Distribution

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Cold Chain Management

Over-encapsulation



Anderson Packaging, Inc.
An AmerisourceBergen Company



AmerisourceBergen Packaging Group is a worldwide leading provider of customized and differentiated packaging solutions to pharmaceutical manufacturers and healthcare providers. AmerisourceBergen Packaging Group is one of three divisions of the AmerisourceBergen Corporation. With revenue in excess of \$70 billion, AmerisourceBergen Corporation is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets with a focus on the pharmaceutical supply chain. Servicing both pharmaceutical manufacturers and healthcare providers, the Company provides drug distribution and related services designed to reduce costs and improve patient outcomes.

AmerisourceBergen Packaging Group companies supply pharmaceutical packaging services across the product lifecycle, from Clinical Supply services and pipeline development, launch support and commercialization services, as well as long-term commercial supply. AmerisourceBergen Packaging Group features Clinical Supply services through subsidiaries Anderson Packaging and Brecon Pharmaceuticals.

Anderson Packaging, located in Rockford, Illinois, United States, provides a broad range of contract packaging services to the North American as well as worldwide clinical and commercial pharmaceutical markets.

Brecon Pharmaceuticals, located in Hay-on-Wye, Wales, United Kingdom, supplies contract packaging services for European and worldwide clinical and commercial pharmaceutical markets.



Project Management

Our service-focused approach starts with our on-site project management. Dedicated customer project managers bring real-world experience and global insights to each program, providing our customers peace of mind that their project will meet key deliverables. Our teams have an extensive record of success, affording our customers practical knowledge and insightful guidance for each project and its unique challenges.

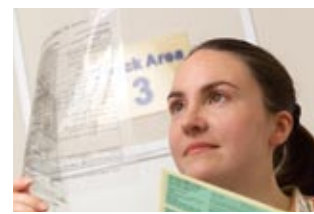
Global Clinical Supply Services

Our network of Clinical Trial professionals is dedicated to meeting the exacting demands of our customers, with reliability, uncompromising quality, and unparalleled customer service. We employ experienced associates across our global network of clinical support services, from trial design to execution. Our value as a clinical partner comes from relentless attention to detail across our organization, ensuring projects successfully keep to comprehensive timelines and successfully navigate even the most challenging applications.

Customers enjoy attentive service, ownership, and the responsiveness of a global network, taking comfort in the knowledge that their program will receive localized service and attention. Our cross-continent approach allows for regional clinical services support, with Anderson Packaging operating in North America and Brecon Pharmaceuticals in Europe, while offering expert trial oversight and supply across the globe. Electronic connectivity across our global network affords unrivaled around-the-clock support and insight.

Our expert teams are supported by best-in-class facilities and equipment for Packaging, Laboratory Services, Storage and Returns Management, as well as Global Distribution. We employ systems designed to ensure safety and security in clinical supply, with ongoing investment to help enable our unrelenting commitment to excellence across our business.

From the smallest Phase I to the largest Phase IV, we support all phases of clinical trials. We value each and every partnership and the responsibility with which we have been entrusted. We earn our business each day by delivering on our promise to meet and exceed our customers' expectations.





Clinical Trial Planning Support

Truly successful clinical trials begin with the collaboration of skilled and experienced teams versed in the challenges of trial execution and rooted in practical hands-on knowledge. Our support services provide insights into best practices and optimization of supply strategies, ensuring planning accuracy and performance for key study deliverables.

QP Services

Our staff includes Qualified Persons with the highest credentials in accordance with European Union standards and requirements. QP support is provided to ensure regulatory compliance for European clinical trials.

Our Qualified Persons bring extensive industry knowledge across the broad range of medicinal products, with expert services including:

- Auditing and Consultant Services
- Chemistry Manufacturing and Control (CMC) Filing Guidance
- Regulatory Filing Support
- Laboratory Analytics
- Import and Export Support
- Product Release

Comparator Sourcing

We provide turnkey comparator sourcing in every part of the world, including access to the AmerisourceBergen distribution network as an extensive resource for comparator supply. Customers benefit from timely product acquisition and cost-effective sourcing, including assurance of appropriate product dating and lot continuity.

Protocol Interpretation

Our experienced staff works closely with customers to provide insights into clinical design and development, with practical knowledge and history to provide informed and collaborative guidance. Our expertise affords our customers efficiency and risk minimization, while ensuring the most cost-effective solution for the application, including package design and distribution planning.

Package Design

Expertise in protocol analysis combined with in-house prototyping solutions allows our customers insightful and imaginative package design, ensuring the unique needs of each and every trial are met. Designs are tailored to trial requirements, including blinding, compliance, child resistance, as well as optimizing size and function.

Distribution & Logistics Planning

The needs and requirements of executing successful global studies demand that thorough planning be taken for each stage of the logistical supply chain. Our team provides key insight into initial development, packaging execution, as well as long-term global distribution planning to ensure timely and responsive service.

Language Translation / Multi-language Labeling

Global clinical trials require expert services to meet the needs of regional studies. Our global network of linguists ensures precise translation and timely service, keeping programs to schedules and assuring regulatory compliance. Proven systems provide accuracy in label development and in-process label application.

Randomization

The integrity of clinical testing is paramount in establishing a trusted partner. Our in-house services for randomization ensure secure data generation, application in clinical trial packaging, as well as secure systems for storage and distribution.

Clinical Trial Packaging Services

Our packaging systems provide flexible solutions for each application and project scope, including manual, semi-automated, and fully automated technologies. On-line inspection systems ensure product safety and maintain trial integrity. The versatility of equipment platforms offers technological solutions for each trial, regardless of scale. We maintain best-in-class equipment for reliable and effective packaging for each and every product. We accommodate product needs for light and oxygen sensitivity, temperature controls, and low-humidity environments.

Encapsulation Services

We offer discreet over-encapsulation technologies to ensure study integrity and appropriate product blinding. Placebo capsule filling as well as filling of API drug product is offered to support the needs of early stage trials. Verification of product contents ensures each capsule meets the stringent requirements for product delivery.

Blistering

We feature several form-fill-seal platforms capable of supporting thermoformed and cold formed (foil-foil) blister packaging. Our lines are equipped with on-line vision inspection to ensure fill accuracy for every cavity.

Compliance Prompting / Child Resistant

We offer a wealth of experience in successfully testing package designs, balancing the requirements for barrier to entry for children with patient-friendly accessibility for adults. Our design team provides management to facilitate the entire testing process allowing our customers to focus on study execution.

Bottling

Bottle fill technologies support both small scale and large scale clinical trials. Lines are equipped for oral solids, including tablets, capsules, and softgels, as well as precise powder filling.

Pouching

Pouching applications include both horizontal and vertical form-fill-seal for powders, gels, and oral solids. In addition, we offer horizontal overwrapping solutions for both primary and secondary packaging applications.

Parenteral Labeling

Precision labeling solutions accommodate parenteral applications, including vials and ampoules, syringes and injectable devices, transdermals and eye care applications. We offer extensive experience for demanding product requirements, including refrigerated or frozen storage and light sensitivity.

Kit Assembly

Patient kits are organized and assembled with precision, ensuring the correctness of contents and location of individual pieces. Inspections ensure that each and every kit produced meets exacting standards for patient use. Global sourcing solutions provide our customers flexibility for total turn-key supply of ancillary components, including syringes, swabs, diluent, needles, as well as printed and unprinted components.

Device Assembly

We offer solutions for even the most complex package assembly, including unique devices for injection or inhalation.

Expiry Date Extension

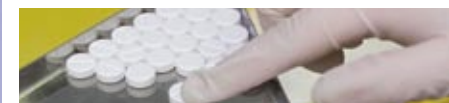
Package reprocessing for text and instructional changes, updates to expiration dating, and other reformatting is accomplished with confidence by proven systems and attention to detail.

Specialty Products

We offer solutions for specialized medicines, providing an isolated packaging and storage environment appropriate for the unique needs of each investigational drug. Our global clinical supply services network offers product segregation through specialized and dedicated facilities for the following product types:

Biologics
Hormonal Products
Potent Compounds

Cytotoxins
Penicillins
Controlled Substances Sch I-V



Package Design Development Services

Rapid Prototyping, In-House Tooling Fabrication, Engineering and Automation



Design and development services are key in the clinical development and ultimate commercialization of new products. We offer solutions from early stage development to drug filing and successful launch execution. We bring imaginative solutions and practical knowledge to each challenge, ultimately delivering packages that meet the needs for blinding, child resistance, and compliance, while focusing on delivery effectiveness and engaging the needs of patients for convenience and accessibility.



Audited and Approved by the following agencies:

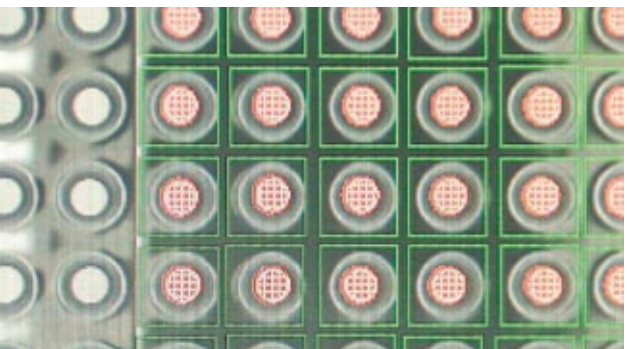
The United States Food and Drug Administration (FDA)
The United States Drug Enforcement Agency (DEA)
The UK Medicines and Healthcare Products Regulatory Agency (MHRA)
The German Ministry of Health

Web Portal / IVRS-IWRS

Worldwide clinical development demands 24-hour connectivity. Our automated systems interface with third party IVRS and IWRS services as well as custom applications for seamless support. Studies benefit from project customization based on the needs and requirements of each program, with support across the globe. Web-based interactivity allows customers to develop personalized reporting, order management and accounting, site supply, inventory analysis, metrics reporting, as well as project status tools. Proprietary collaborative tools create an environment of real-time project management, ensuring up-to-the-minute tracking of project status and deliverables.



Automated Inspection Systems



Ensuring the integrity of trial materials is paramount. We offer the best in inspection technologies to maintain the highest levels of product safety. Sophisticated on-line camera systems inspect for correctness throughout the packaging and labeling process, ensuring accuracy in every package produced. Inspection systems confirm presence and correctness of drug product, as well as all study materials. In addition, inspection systems ensure accuracy of print application for all variable information, including batch information, product dating, and randomization. Label inspection systems provide assurance that every label produced is verified against supplied data. All systems are extensively validated, as well as vigorously maintained and challenged.

Laboratory Services

Stability Storage and Testing

Room Temperature Conditions
Intermediate Conditions
Accelerated Conditions
2-8° C
25° C / 60% RH 30° C
65% RH 40° C / 75% RH

Analytical Testing

HPLC and GC Analysis
Dissolution Testing
TOC Analysis
FTIR and UV / Vis Analysis
Water Determinations
USP/EP/BP Analysis
Titrations
Particle Size Distribution

Microbiological Testing

Environmental Testing
USP/NF Monographs
AOAC, BAM, Standard Methods,
and Customer Testing Procedures

Method Development

Development and optimization
of existing methodologies.

Method Validation

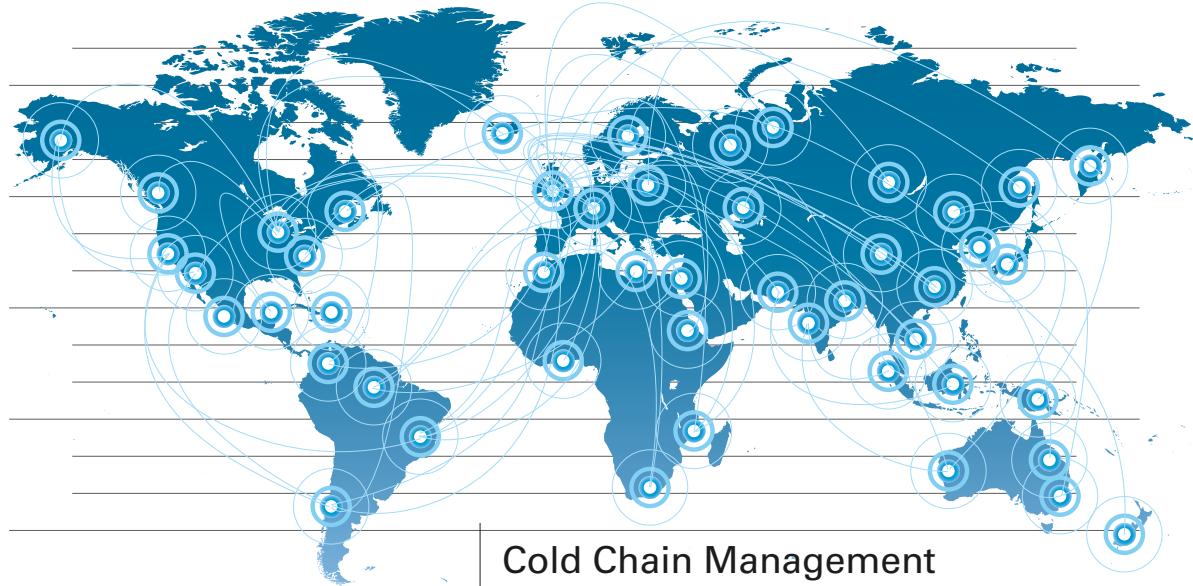
Validation of methodology for various
stages of the drug product life cycle.

Generation of protocols and detailed
validation reports.

Our on-site laboratory services support each step through the clinical development process, offering extensive resources and responsive services. Testing is performed according to ICH guidelines, ensuring data reliability and regulatory compliance. We invest in best-in-class equipment, and our staff is trained and accredited in the most comprehensive laboratory standards.

Global Storage and Distribution

We offer a worldwide network of storage and distribution systems to ensure successful clinical trial supply. Controlled storage is offered across two continents, with a global depot network to ensure seamless delivery around the globe. Our well-trained staff provides assurance that each pack shipped is afforded precision and timely processing, including 24-hour turnaround from request. On-line systems provide extensive on-demand reporting for around-the-clock monitoring and accessibility for all trial stakeholders.



Cold Chain Management

We feature cold chain support for worldwide compliance and distribution. We offer extensive capacity to accommodate refrigerated and frozen storage requirements, with excursion monitoring for package production. Packaging and storage locations offer extensive capacity and computerized temperature monitoring. Distribution is supported with qualified shipping systems and environmental monitoring throughout the supply network.



Secure Storage

Storage and distribution facilities meet the highest standards for controlled accessibility and security monitoring. Our facilities feature secure storage of Schedule I-V controlled substances, audited by the United States Drug Enforcement Agency and the United Kingdom's Home Office.



Returns Management

Detailed returns accountability provides our customers reliability and confidence in secure returns management. Detailed reporting and destruction management ensures accountability and proper chain of custody throughout the trial lifecycle.

Facilities

Customer trials are supported by multiple state-of-the-art facilities for Packaging, Storage, and Distribution located on two continents. With over 16 packaging facilities, we service the unique needs of each investigational medicine with tailored solutions. Each site maintains the highest standards and extensive audit history, including rigorous governmental regulatory agency reviews and thorough industry inspections. We welcome site visits and qualification audits.



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