ALMAC

Ultra-Low Temperature Packaging & Distribution Solutions



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With more than 55 years' experience, we offer a wide range of specialised packaging solutions to meet, and deliver your product launch and ongoing commercial needs.

Almac Pharma Services was one of the first European CDMOs to support Gene Therapy product launches and currently provides solutions for over 25% of EU approved/ pre-registration ATMPs. Our specialist teams in Dundalk, Ireland and Audubon, US offer a wealth of expert knowledge, deep understanding, and a partnership enabling the processing and release of your tailored treatment, on time.

We specialise in providing unique, tailored solutions supporting your Advanced Therapy Medicinal Product (ATMP) and other specialist product launches through Just-in-Time labelling, packaging, and serialisation at ultra-low temperatures (-20°C to -80°C) offering clients a uniquely tailored experience ensuring every step of the highly complex process is adjusted to meet your specific requirements.

Our bespoke offering enables your life saving ATMP to be processed and released to patients exactly when needed within as little as 20 hours. Offering a flexible range of solutions, we partner with each client to define and agree a tailored, robust and commercially scalable process that meets your needs, taking into consideration:

- Temperature requirements (-20°C to -80°C)
- Allowable time out of condition (ambient/ dry ice packaging)
- Conditioning time requirements
- Final pack-out configuration (inc. ancillary components)
- Level of serialisation aggregation required
- Temperature controlled distribution and global supply chain

Our dedicated teams of fully qualified and licenced QPs are onhand offering a personalised end-to-end consultancy service to guide you through the challenging landscape of specialist product launch.

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Almac's expertise in temperature-controlled logistics, combined with our long established relationships with reputable, experienced, and trusted supply chain providers, offers you a comprehensive end-to-end service. This guarantees expedited delivery of your product direct to patient. Our use of innovative shippers, temperature monitors, and digital platforms which enables real-time visibility into product and shipper conditions, as well as location of the shipment, ensures your valuable Gene Therapy will not be compromised during transit.

Through our work with a variety of ATMPs, we recognise there is little commonality, and each is distinctive in its requirements to guarantee product integrity throughout the entire process.

We understand the specific needs of each product, and with our unique experience and tailored offering, we can identify and work within the individual constraints. Such as, managing the time spent out of temperature and the affects this can have on the efficacy of the drug product, or having a weightbased Gene Therapy product which requires country-specific packaging, complete with patient specific information on each pack, and to be distributed accordingly.

Tailored Treatment. Delivered through:

- **Hand-in-hand consultancy**
  Collaboration with our clients is the most vital aspect of our approach. Our experienced team of technical experts works intensively with each client to gain a deep understanding of both their product and its patients, before mutually agreeing a customised approach to manage and deliver the treatment exactly when required. Ongoing consultancy, including access to our highly skilled QP team, is available throughout to help navigate you through each step of the process and supporting your successful product launch.
- **Risk mitigation**
  We have implemented robust and timely processes, underpinned by Quality Risk Management all of which are designed to protect the integrity of your product whilst ensuring it gets to the patient on time.
- **Proven track record**
  As a result of the nature of these tailored therapies, it is imperative to partner with an experienced CDMO with teams who understand the complexities of managing and handling specialist products. Our proven track record is underpinned by our history, partnerships; we have the expert knowledge, deep understanding, and unique experience to help you deliver your tailored treatment, on time.

Almac is proud to be a trusted partner with our clients in being able to ensure your tailored treatment is delivered.

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