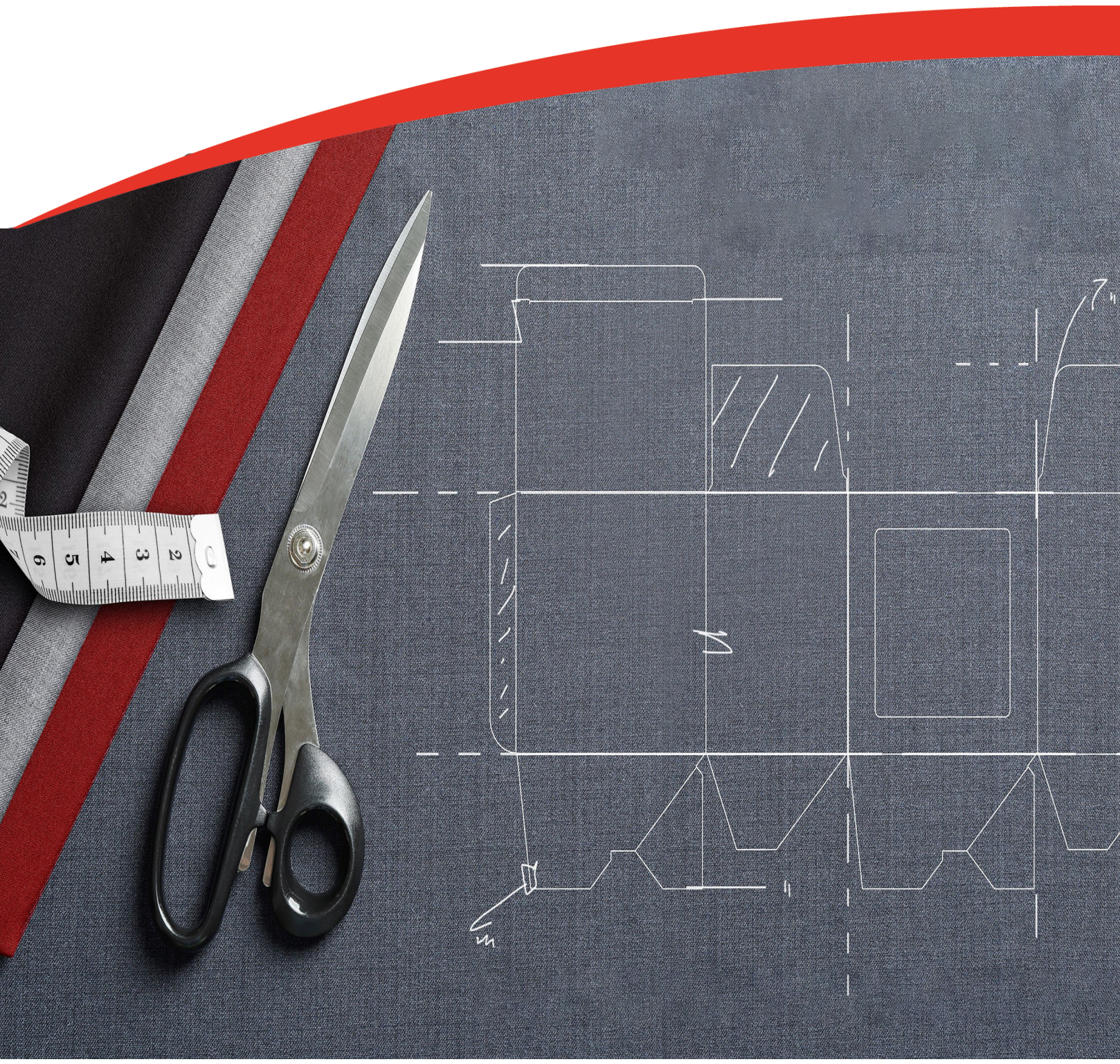
ALMAC

Partnering to Advance Human Health

Almac Pharma Services

Tailor-made Pharmaceutical Development & Commercial Solutions



About Almac Pharma Services

Almac Pharma Services is a world leading outsourcing partner to the global pharmaceutical and biotechnology industry.

With over 50 years' experience and state-of-the-art, custom designed facilities in Europe and the US, our global reach and local expertise provides flexible, quality-led solutions from early and late phase pharmaceutical development, product launch, commercial drug product manufacture, commercial packaging, serialisation through to commercial storage & distribution.

As a member of the wider Almac Group, we are a stable, privately owned business which is growing globally in line with increased client demand.

We understand your product is unique. We offer you a unique relationship combining:

- Over 50 years experience in commercially packing all dosage forms & all therapy areas
- Deep industry knowledge
- Full global regulatory compliance
- 1,200+ skilled, trained & passionate employees

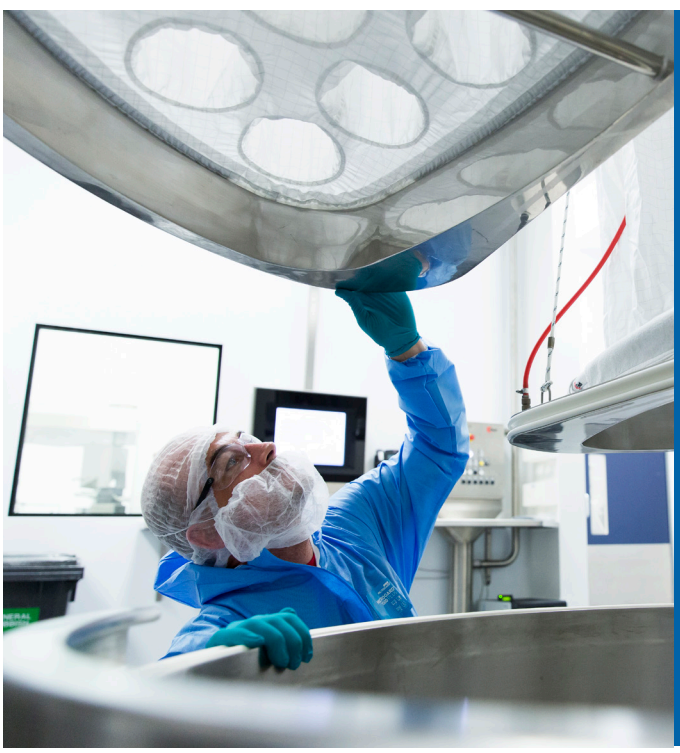
and delivering efficient, reliable results every time.

Pharmaceutical Development Services

Addressing the increasing pressure to bring clinical candidates through your pipeline faster, and with greater efficiency, we provide expert pharmaceutical development solutions.

Our scientists can develop clinical candidates into optimum formulations and manufacture solid oral dose products for all stages of clinical trials.

From developing a fit-for-purpose formulation for First-in-Human (FIH) trials, to scaling up for late phase trials and ultimately commercialisation, our pharmaceutical drug product development solutions are customised to meet your specific requirements.



We offer numerous support capabilities, including:

- Dedicated non- GMP facilities supporting enhanced speed and flexibility to the formulation and process development phase
- Scalable solutions using the same operating principles, enabling a seamless transition between non-GMP and GMP phases
- GMP manufacturing of clinical trial material from Phase I-III and onwards to registration batch manufacture
- Analytical method development and validation, stability, microbiological and release testing
- Available GMP footprint for product commercialisation, post-development

Our drug product development service spans early to late phase clinical programs, offering technical expertise, dedicated project management and a track record of on-time delivery.

Drug Product Development

Almac operates non-GMP and GMP facilities, allowing seamless transition between formulation, process development and clinical trial material manufacturing. We specialise in the following solid oral dose formulations with batch sizes ranging from grams to 100 kilograms:

- API in capsules or bottles, including micro-dosing
- Formulated blends in capsules or bottles
- Coated tablets and mini-tablets
- Multi-particulates: granules, beads/pellets
- Sachets and stick packs
- Immediate and modified release
- Fixed dose combination products

Early & Late Stage Development

Early Phase Development

Our experienced formulation development scientists can develop a range of oral dose formulations to support your early and late phase clinical trials including registration and ongoing commercial supply.

With both non-GMP and GMP facilities, flexible and efficient solutions are provided to develop a fit-for-purpose formulation and manufacture early phase clinical trial materials. For phase I FIH supplies, we offer a range of solid oral dose solutions including drug in capsule, bottle, conventional solid oral dose presentations & prototypes.

We have a range of technology available to work with APIs with varying properties including dry blending, compression, dry and wet granulation, coating and encapsulation.

High Potency Processing

Almac processes compounds with OELs as low as 0.05µg/ m3 /8 hours in non-GMP and GMP facilities. Many of our GMP processing suites are explicitly designed for processing highly potent APIs.

We have the capability to process potent compounds using a wide variety of techniques including dispensing, compression, blending, encapsulation, dry & wet granulation and tablet coating.

Late Phase Development

Our expertise covers the development of dosage forms including immediate and modified release capsules & tablets, fixed dose combination products, powder/ granule filled sachets, multi-particulates (bead/pellets into capsules) and mini-tablets.

Our manufacturing technologies and processing scales range from hundreds of grams for small-scale process investigation studies to hundreds of kilograms for phase III/IV, registration batches and commercial supply.

We understand the best way to ensure a smooth regulatory review process for an NDA or MAA is to clearly present a complete work package as defined through Quality by Design (QbD). By understanding the parameters that are critical to the quality of the product and the safety of the patient, we build quality into the product from the start, implementing effective control strategies.

Processing capabilities

Our non-GMP and GMP development facilities have complementary equipment trains and integrated technical teams to facilitate technology transfer.

We are equipped to deliver drug product through blending, coating, roller compaction, encapsulation, high shear granulation, sachets/stick packs, fluid bed processing, blistering and bottling capabilities to support clinical stability programmes and tableting.

Analytical Services

Controlled Release Drug Delivery Design & Manufacture

We combine our deep expertise in solid oral dosage form development and controlled release technologies to produce well-characterised and reproducible dosage forms that release within specifications.

Small and large scale technologies enable us to meet your unique needs for controlled release drug products.

Our formulations and manufacturing processes are robust and scalable, easing transfer between development and commercial facilities, whether in-house or directly with you.

Our capabilities at small and large scale include:

- Tablet compaction
- Perforated pan coating
- Fluid bed coating
- Encapsulation
- Wet and dry granulation
- Aqueous and organic solvent applications
- Powders, granules, multi-particulates (bead, pellet, mini-tablet), capsules & tablets
- Fixed-dose combinations
- Bimodal drug release profiles

Analytical Services

With comprehensive dedicated drug product analytical testing laboratories we provide timely, quality data to not only support your regulatory submission but to aid critical business decisions regarding packaging, shelf life and supply chain to ensure your valuable drug product reaches your patients in optimum condition.

We provide method development and validation, IPC testing, stability testing and release analysis of the product. In addition, we offer in-house microbiological capabilities supporting all phases of development.


G30/500

Commercial Manufacturing

Scaling up from our development assets and expertise through registration and launch into commercial supply or transferring existing commercial products, we can address your commercial manufacturing needs.

Scalable Solutions

Our manufacturing operations have been designed to enable scalability. With GMP development, clinical supply and commercial manufacturing on a single site, a smooth project management process and continuation of scientific knowledge is guaranteed.

Technology Transfer

Facilitating product transfer you will have a dedicated Product Supply Manager who leads an experienced multi-disciplinary team. T

his ensures the transfer process is as simple, clear and as defined as possible and delivers a consistent process that is repeatable and robust.

Solid Oral Dose Manufacture

Our range of commercial scale dry blending and wet granulation technology supports the manufacture of:

- Tablets
  - Immediate and modified release
  - Uncoated and coated (including functional coatings)
- Capsules
  - Hard gelatin capsules (powders, pellets)
- Powders
  - Granules
  - Powders for reconstitution
- Mini-tablets
  - Stick pack filling with counting system

With sizes from 10kg up to 2.5 tons, our range of state of-the-art processing equipment can flex depending on your particular batch size.

Commercial Packaging & Labelling

We offer a wide range of commercial packaging solutions to meet your product launch and ongoing commercial supply needs.

Primary Packaging - tablets, capsules & powders

- Blistering (thermoform & cold form)
- Bottling
- Sacheting / stick packs

Secondary Labelling, Packaging and Assembly

- Vials
- Ampoules
- Syringes
- Wallets
- Cartons
- Dose packs
- Complex kit assembly

Advanced packaging technologies

- Humidity sensitive products with desiccant insertion
- Multi-product combination blisters
- Large blister formats
- Just-in-time (JIT) packaging

Packaging and Artwork Design

Our dedicated in-house packaging and design team provides a full suite of design services.

CBE-30 Filing

We offer support for Changes Being Effected 30 (CBE-30) filing where required.

Rapid Launch Packaging

Our specialised team can pack and distribute drug product within 24-48 hours upon FDA approval.

Repackaging

We offer rapid repackaging ensuring minimal disruption to your product supply chain.

Specialised Packaging

Pack Design & Prototype Generation
From initial regulatory data and texts, early stage artwork mock-ups with concept development through to full support of post-approval update activities.

Vial, Syringe & Complex Medical Kit Assembly
We offer a range of secondary labelling and packaging solutions for biopharmaceutical products including vials, ampoules, pre-filled syringes, pens and medical devices.

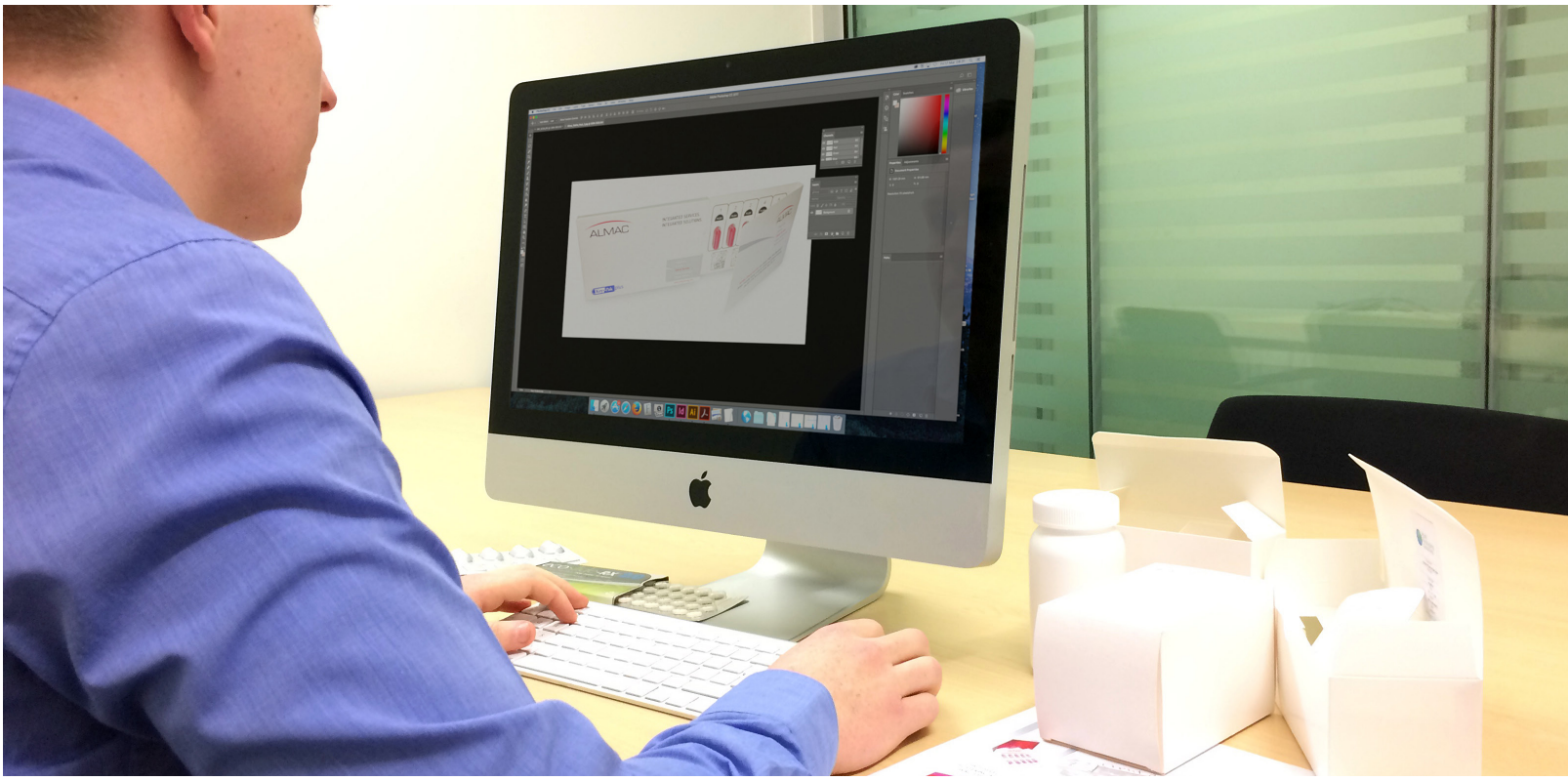
With bespoke kit assembly technology our Semi Automated Packaging System (SAPS) provides a best-in class, streamlined and efficient packaging solution for the specialised packaging of complex pharmaceutical kits, medical device components, combination products and biologic packs.

Paediatric Packaging
Complementing our experience in developing and manufacturing paediatric dosage forms, we provide innovative, child resistant specialised packaging in the form of stickpack capability.

Serialisation
Providing flexible serialisation solutions to meet all your serialisation needs, our partnership with Optel ensures our serialisation technology not only meets, but surpasses, current serialisation legislation and is adaptable to all upcoming regulations.

Humidity Sensitive Product Packaging
Providing protection to humidity sensitive drug products our specialised relative humidity (RH) (as low as 20%) controlled blistering suites, enable the packing of your environmentally sensitive tablets / capsules into specialised blister packaging.

Orphan Drugs
When speed and agility are imperative to ensuring your valuable drug product reaches the patient as quickly as possible, our commercial packaging facilities are highly flexible to accommodate niche packaging campaigns.



EU Product Launch

Our dedicated product supply team are experts in navigating market requirements and supporting clients to successfully launch their orphan / niche drug products.

We have extensive practical experience of launching pharmaceutical products into the marketplace and manage a multidisciplinary project team in quality, packaging design, regulatory and distribution, ensuring milestones are met and that your market entry strategy is successful.

We have supported many of the industry's recent first-in-class, innovative orphan drug launches in areas such as Cystic Fibrosis, Muscular Dystrophy, Hemolysis and Short Bowel Syndrome.

In our experience, it's never too early to start to think about your pharmaceutical product launch.

We take pride in our ability to support our clients with varying time frames, from as far as 24 months before submission of their MAA to those with shorter time frames, post submission.

We provide expert guidance on launch strategy and offer the following tailored solutions:

Pre-submission

- QP Declaration & Site of Release
- Packaging Design

Submission

- Named Patient Supply / Early Access Programmes
- Country Groupings / Blue Box
- Artwork Origination
- Shipment Validation
- EU Import Testing
- Product Tax Status

Approval, launch & ongoing commercial supply

- Product Ordering
- QP Release
- Serialisation
- Product Distribution to Pharmacy
- Product Invoicing

By integrating all of your pharmaceutical and distribution needs for your product launch into a single supply team, you will minimise your effort and maximise your return.

Distribution & Storage

Distribution

Working with a select number of approved distribution partners, from express couriers through to dedicated pharmaceutical carriers specialising in temperature controlled road freight and airfreight, we provide a range of tailored distribution services; from large scale deliveries to wholesalers; to single unit distribution direct to pharmacies.

Prior to proceeding with a distribution strategy for your product we conduct a distribution risk assessment, considering all key factors to ensure consistency and repeatability in all activities for each product dispatched. To ensure all products reach the end-user in optimum conditions we complete a full validation of shipping/packaging configurations.

Our teams work with you, the packaging suppliers and distribution partners to design a configuration and develop and execute a full validation programme to ensure the solution is fit-for-purpose. We can extend this process to include route qualification where 'dummy' shipments can be made to test the performance of the system in transit.

In addition, we identify all paperwork requirements in relation to import, export and customs documentation early in the project thereby mitigating any risk of delays to your shipment. Utilising our bespoke ERP system, we provide end-to-end traceability of all materials on site from receipt, storage, processing and final dispatch.

Storage

A wide range of commercial storage solutions are available for solid oral dosage forms and sterile biopharmaceuticals for both niche/orphan drug products and large scale commercial market volumes.

Multiple modular temperature mapped and qualified GMP warehousing and storage capacity is available for raw and in-process materials in addition to finished goods.

Across our facilities in Europe and the US we have significant frozen (-20°C and -80°C) and refrigerated (2–8°C) storage units which complement our controlled ambient (15-25°C) storage capabilities.

The temperature of each facility is continuously monitored by a BMS with any temperature excursion from the defined limits escalated in real time.

In addition, our Drug Enforcement Administration (DEA) and UK Home Office accreditation allows us to store schedule II-V controlled substances.


FIRE
EXIT

Flexible GMP Floor space

Build or buy challenge

Flexibility, cost and time are key criteria in evaluating options in a 'build or buy' decision for your technology to ensure your products are released on time and to enable you to respond immediately to changes throughout your product development programme.

We offer dedicated, flexible, qualified GMP floor space to suit your individual requirements for tailored product development and manufacturing of all dosage forms including oral and sterile drug product.

Capabilities include:

- 1,500m^2 customisable GMP floor space
- Scalable GMP modules offer sizes from 22m^2 to 300m^2
- Suitable for development, GMP manufacture, drug product manufacture and/or kit assembly
- Fully flexible processing capabilities of a majority of all dosage forms including oral or sterile drug product
- Module classification: Class 10,000 / 100,000
- Power, compressed air, purified water, RH control and bespoke services added upon request

Versatile capacity

This customisable space can be used to suit your own requirements enabling you the option to place custom and/or dedicated manufacturing equipment at any of our state-of-the-art facilities.

You can also contract our highly qualified scientific and/or operational staff to manage the entire operation over the commercial life of your drug product.

Expertise

With over 50 years' experience, Almac possesses a wealth of technical expertise to support the delivery of your complex, time sensitive capital projects. Operations are therefore guaranteed to be performed under Almac's existing robust and thorough quality system.

Our dedicated engineering and scientific experts can also support the design, installation, qualification, technology transfer and commercialisation of your product to ensure on time delivery of project milestones.

This operating model allows you to perform your own processes and focus on your core manufacturing activities in a flexible facility that enables you to move rapidly and cost effectively through your drug development program.

Contact us today to discuss your specific project and find out more about our tailored solutions.

almacgroup.com

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