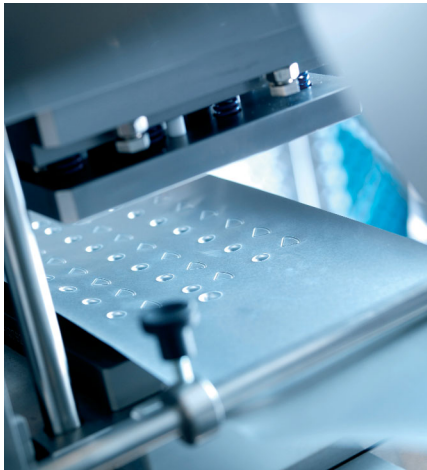


## Business review – capabilities



### Pharmaceutical development services

Vectura's pharmaceutical development services revenues are generated by providing specialist product development services to other pharmaceutical companies, primarily licensing partners, to continue the development of products or technologies licensed from Vectura until complete transfer has been achieved.

### Commercial and business development

Vectura's Commercial team, responsible for business development and licensing, maintains good relationships with international pharmaceutical companies and undertakes market analysis for all products under development. In addition, the team provides the market analysis and competitor information that is required to identify valuable new product opportunities. The major licensing deals Vectura has concluded to date demonstrate the strength of the Group's commercial and business development skills.



### Development

Vectura's Development team has demonstrated its ability to develop products through stages of pre-clinical and clinical development. The team supports the development of Vectura's own products as well as those developed on behalf of other companies. Key functions include liaising with thought-leaders, clinical investigators and experts in the design of clinical trials (and associated pre-clinical development programmes), and the selection and management of specialist respiratory and other clinical research organisations (CROs) responsible for conducting clinical trials.

### Regulatory affairs

The Regulatory team at Vectura is experienced in global pharmaceutical product registration and inhaled product development. The Regulatory team provides regulatory support for Vectura's own programmes and for those of its partners, and works closely with all functions within Vectura, advising on regulatory strategy and data requirements to ensure timely approvals. The team is responsible for the preparation and maintenance of Clinical Trial Authorisations (CTAs) and Marketing Authorisations (MAs) and preparation of responses to questions on a worldwide basis as required. Submission of dossiers and liaison with individual regulatory authorities is also undertaken as appropriate.

### Quality

Quality in a pharmaceutical product development environment ensures that the products produced and the data intended to support regulatory submissions are generated in compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), collectively referred to as GxP.

Vectura has a Manufacturer's Authorisation for Investigational Medicinal Products, MIA(IMP) 20066 from the Medicines and Healthcare products Regulatory Agency (MHRA). An MIA(IMP) is a requirement of the EU Clinical Trials Directive, now embodied in national legislation, and allows for manufacture, assembly and release of clinical trial supplies by the Group's Qualified Person.

Vectura is also certified under ISO 13485:2003 Medical devices. In order to achieve the ISO 13485 certification, Vectura's device engineering and contract manufacturing processes were inspected by an authorised quality standards organisation (Lloyds Register Quality Assurance), which found the quality system to be of sufficiently high standard to allow Vectura to self-certify its inhaler devices as being fit for market use in Europe.



- 1 GyroHaler® multi-dose "passive" DPI with sealed foil blisters
- 2 Vectura's blister-filling machine in operation
- 3 Vectura adheres to GxP at all times

### Manufacturing operations

The Manufacturing Operations team is responsible for the late-stage development of Vectura's respiratory products, and ensures that such products can be validated and commercialised successfully in client or contract manufacturing facilities. The team is responsible for global supply chain operations as Vectura's products are distributed worldwide.

Vectura's strategy is to produce clinical trials supplies up to pilot-plant scale. The Group then uses contract manufacturing organisations for larger-scale manufacturing for late-stage development and commercial supply, as well as for some smaller-scale manufacturing where it is more economical to do so.

### Intellectual property

Vectura's intellectual property is a valuable asset that underpins its past, present and future success. The Group aims to secure multi-layered registered protection for its products, processes and technology platforms, which has the potential to provide highly effective protection.

Vectura's patent portfolio includes in excess of 100 families of patents and patent applications, covering inventions made by the Group's researchers as well as inventions the Group has acquired or licensed from third parties. The Group actively protects and maintains this patent estate.

Additional value continues to be obtained from Vectura's intellectual property estate from licensing its rights for the development of non-pulmonary products, for example, Baxter International Inc. and its subsidiaries are licensed to use certain of Vectura's patents for ADVATE®, Adept® and Extraneal® products, which are sold on the market.

### Facilities

Vectura currently operates from three leased facilities in the UK. The first of these is an approximately 50,000 square-foot laboratory, office and manufacturing facility in Chippenham, Wiltshire. This facility is approved for GMP manufacturing of Investigational Medicinal Products for clinical trials. Vectura's Nottingham facility comprises approximately 30,000 square feet of laboratories and offices. On the Cambridge Science Park, Vectura occupies a 4,200 square-foot laboratory and device engineering unit.



- 1 Vectura's strength lies in its specialism; the knowledge, experience and technical capabilities to develop inhaled pharmaceutical products
- 2 Vectura's committed and motivated workforce is constantly looking to innovate and evolve
- 3 The active pharmaceutical (API) needs to be formulated so it can be inhaled to reach the targeted area of the lung
- 4 Vectura has one of only a handful of facilities globally that has been specifically designed to manufacture inhaled products



