

## How we work

With all our integrated services on one site, we deliver a collaborative approach to the development and manufacture of drug substance and drug products. Every project benefits from the knowledge and experience of multiple industry experts all working under the same roof.

Our services can be provided either on a stand-alone basis or as part of an integrated product development program, depending on client need. Our innovative approach is the result of combining fresh scientific talent with the experience of an internationally recognised leadership team.

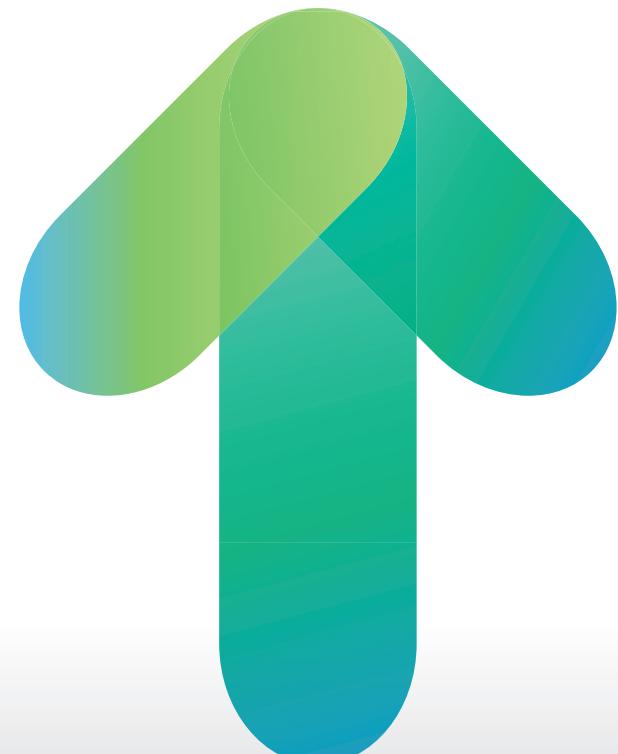
## Facilities

Our 15,000m<sup>2</sup> facility has benefited from more than 36 years of investment as a key research and development centre for Sanofi and Covance. All of our services are supported by state-of-the-art technology. The harnessing of world-class, specialist research and development knowledge from one site provides us with the competitive edge to swiftly reach our client's goals.



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TAKE PHARMACEUTICAL DEVELOPMENT  
TO THE NEXT LEVEL



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# Rethink what's possible thanks to our 15,000m<sup>2</sup> world-class facility.

Arcinova is a Contract Development and Manufacturing Organisation (CDMO), with a strong focus on process research, situated in the North of England. Our world-class, 15,000m<sup>2</sup> facility brings together a multi-disciplinary team of scientists under one roof. This collaborative approach to drug development enables us to help companies produce life changing medicines and quickly progress them to market. With decades of experience serving pharmaceutical and biotechnology companies across the globe, our experts understand the requirements to deliver outstanding results every time.



We offer a wide range of services from our state-of-the-art facility, helping our clients take their ideas for novel drugs through all clinical steps for fast progression to the market.



## Drug Substance

We offer full drug substance development, scale up and manufacture.

Capabilities include:

- Process development
- Route scouting
- Degradants and impurities synthesis to support API development
- Synthetic biology and continuous processing/flow chemistry
- cGMP kiloscale API manufacture



## Analytical Services

We support projects across the drug development pathway with the provision and interpretation of high quality analytical and microbiological data.

Capabilities include:

- Gas chromatography (headspace or direct injection), ion chromatography, HPLC and UPLC based methodologies
- Liquid/solid state NMR
- Differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA)
- ICH stability studies
- Microbiology



## Pre-formulation and Formulation Development

Our expert team can determine how best to develop fit for purpose formulation that will enable rapid entry into clinical trials.

Capabilities include:

- Solid state services (polymorph and salt screens)
- Composition and compatibility studies
- Drug substance and blends in capsules/vials
- Sterile liquid formulation



## Drug Product

We provide full development, manufacture, testing and release for a wide range of clinical product types.

Capabilities include:

- Liquids for oral administration (solutions, suspensions and emulsions)
- Capsules containing API with precision dispensing
- Vials containing API
- Nanosuspensions through ball milling or high pressure homogenisation



## Isotope Labelling

We provide radiolabelling and stable isotope labelling for both non-clinical and clinical studies (non-GMP and GMP).

Capabilities include:

- Synthesis of <sup>14</sup>C labelled compounds to support pre-clinical ADME studies and human AME studies
- Expertise in handling <sup>14</sup>C labelled gases and volatiles
- Synthesis of stable-labelled compounds incorporating <sup>2</sup>H, <sup>13</sup>C, <sup>15</sup>N or <sup>18</sup>O
- Rapid route design, allowing us to efficiently incorporate radiolabelling



## Bioanalytical Services

We offer a comprehensive service to develop, validate and implement bioanalytical assays.

Capabilities include:

- LC-MS/MS and UPLC-MS/MS
- Elemental analysis by ICP-MS and ICP-MS/MS
- GC-MS/MS
- Accurate mass spectroscopy including structural identification



## Regulatory and Consultancy

We offer regulatory and consultancy services to support our clients at every stage of their project.

Capabilities include:

- Regulatory dossiers
- Regulatory compliant archiving
- *In-silico* potential mutagenic impurity (GTI) assessments