CUSTOM

PHARMA SERVICES

Development & Manufacturing

For **Clinical** & **Commercial**

WANT TO KNOW MORE?

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custom**pharma**.co.uk

We are **experts** in taking your compound from **clinical** and **product development to product launch and beyond.**

THE CUSTOM DIFFERENCE

At Custom Pharma Services, we are a full-service contract development and manufacturing organisation (CDMO) for clinical and commercial medicinal products.

We take great pride in the quality of support we offer our clients – at whatever stage of their journey they need us. We can help them with every aspect: from pre-formulation development, through all of the clinical phases, to product launch and beyond.

Our experienced development team includes chemists, pharmaceutical scientists, process engineers, quality assurance experts and project managers. Together, we build tailored, innovative solutions to address our clients' specific challenges, particularly around Oral Solid Dose (OSD) formulation: our reputation is built on our ability to identify ground-breaking ideas to support the development of even the most complex pharmaceutical products.

Founded in Brighton on the UK's south coast in 1979, we are approved by the MHRA. Our broad spectrum of expertise across all OSD forms includes bio-enhancement of poorly soluble compounds as well as the ability to handle highly potent drugs and controlled drugs.

Our focus is 'molecule first' and our aim is to work collaboratively with every client: a truly partnership approach.

When you ask who can offer you the experienced and skilled professional input you need in clinical and commercial pharmaceutical development and manufacturing, the answer is Custom Can.

> Working with Custom can be your winning formula – whatever you need, Custom Can."

Chris Davison
Chief Executive Officer

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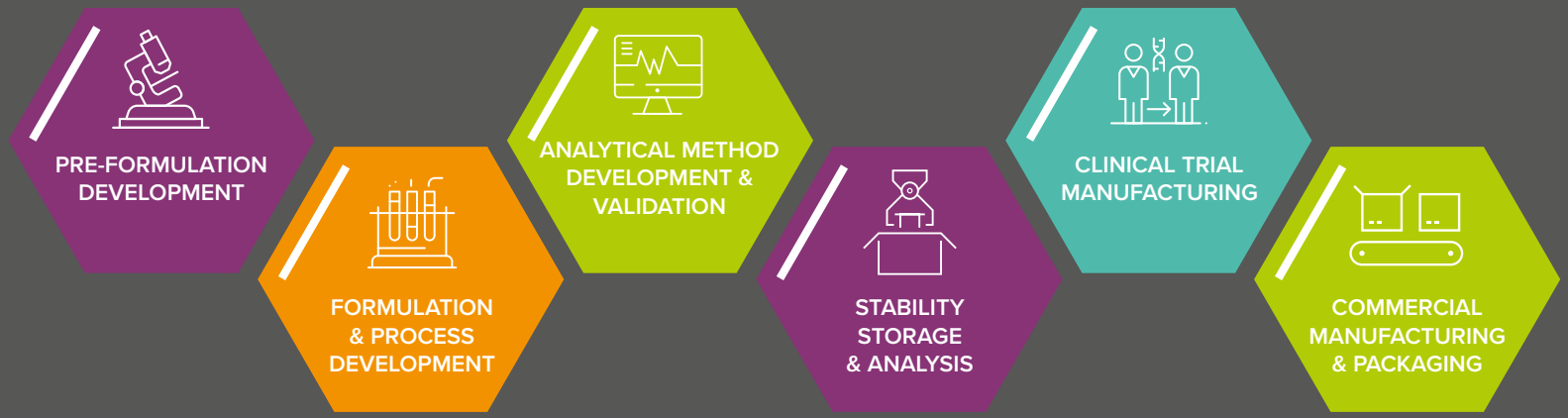
AN OVERVIEW OF SERVICES

Custom Pharma Services has been providing development and manufacturing services to the pharmaceutical industry since 1979. We are the partner who has the expertise and experience to take your compound through the product lifecycle – from pre-clinical and product development, including all the clinical phases, to product launch and beyond. So, when you need a partner that can make a difference, Custom Can!



We would like you to consider us as an extension of your own project team, providing outstanding facilities with expertise and understanding of drug product development and manufacture.

With over 40 years of experience in a wide range of oral solid dosage forms (including tablets, capsules and powders), we offer fast, efficient and responsive solutions for all your needs.

All this is underpinned by dedicated project managers who will ensure we meet your time, budgetary and technical requirements at every stage.

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PRE-FORMULATION DEVELOPMENT

Drugs are seldom administered to patients as pure compounds, instead they are formulated into medicinal products: but many that start their development journey don't make it to market, failing for a variety of reasons from inefficacy or toxicity to commercial or manufacturing problems.

Our pre-formulation experts help spot those potential pitfalls early by investigating the physical and chemical properties of drug substances (in isolation or in combination with excipients), identifying early predictors and generating information vital to the formulator in developing stable and safe dosage forms with good bioavailability.

- **Solid form screening and characterisation**
- **API material characterisation**
- **API solubility assessment**
- **API developability**
- **Excipient compatibility**
- **Accelerated Stability Assessment Programme (ASAP)**

> The team at Custom are flexible, pragmatic and a pleasure to work with. Apart from being timely in responding, Custom works to a high standard and they are also very transparent which builds trust."

— Modepharma
O. Gupta, Director

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FORMULATION & PROCESS DEVELOPMENT

Our formulation development starts with the end in mind: we work with you to define a Quality Target Product Profile. This provides us with the unique requirements for your product and allows us to take a ‘molecule first’ approach to development.

Our scientists follow a Quality by Design methodology, utilising risk management tools to develop high quality formulations with robust and reliable manufacturing processes. We use well-designed and executed experiments to generate high quality data, enabling effective decision-making and reducing risks as the development progresses.

Our facilities include a formulation development laboratory and a GMP pilot plant operated by dedicated, experienced technicians and formulation scientists.

- **Solid oral dosage forms (Tablets, Capsules and Powders)**
- **Modified release**
- **Age-appropriate formulations e.g. paediatric**
- **Bio-enhanced formulations**
  - **Amorphous solid dispersions, including spray drying**
  - **Co-crystal preparations**
- **Process Development and Optimisation**
- **Process Scale Up**

> Custom is an integral part of our development team, taking a flexible and highly collaborative approach.”
>
> **— Actimed Therapeutics Ltd**
> Head of Regulatory Affairs and Technical Development

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ANALYTICAL SERVICES

We have analytical scientists specialising in method development and validation, finished product quality control, raw materials testing and stability evaluation.

These experts take a scientific and risk-based approach to developing and maintaining the analytical procedures used to test and characterise your product. Whether it is verification or modification of existing methods – or the development of new analytical methods – our analysts will follow pharmacopeial requirements and internationally recognised ICH guidelines designed to ensure that safe, effective and high-quality medicines are developed and registered efficiently.

- **Method development and validation**
- **Phase appropriate method development and lifecycle management**
- **Method transfer and verification**
- **Forced degradation studies and impurity profiling**
- **Discriminating dissolution methods**
- **Dissolution biowaiver studies**

> Custom's analytical skills are amongst the best in the UK and Europe."
>
> **— Haoma Medica Ltd**
> Chief Development Officer

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STABILITY SERVICES

Stability evaluation is vital to any drug product. Our analytical scientists will ensure any degradation pathways and other quality critical attributes are understood and controlled over time. This will make certain the efficacy and safety of the product is maintained over its shelf life.

We offer stability storage and analysis over a range of storage conditions, following ICH guidelines to cover all climatic zones and determine the product shelf life. Additionally, we can perform Accelerated Stability Assessment Programme (ASAP) studies that enable our scientists to quickly and accurately determine product shelf-life at an early stage of development.

- **Accelerated Stability Assessment Programme (ASAP)**
- **ICH stability testing for shelf-life determination**
- **Annual commercial stability at ICH conditions**
- **Bulk and photostability studies**

> Working with Custom is a truly collaborative partnership. Custom's team of project managers and technical experts are dedicated to the success of our development projects ensuring the focus is on the patient at all times."

— Proveca
Head of Business Operations

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CLINICAL TRIAL MANUFACTURING

Supporting Phase I, Phase II and Phase III clinical trials, we can manufacture these important batches of drug product to support this critical stage of development.

Phase I, Phase II and Phase III clinical trial manufacturing:

- **cGMP batch manufacture and primary packing**
- **Dedicated Pilot Plant**
- **Drug in capsule to as low as 1mg per capsule**
- **Placebo-to-match tablets and capsules for blinded trials**

> We are very proud of our portfolio company, Kigelia Pharma and of the team at Custom Pharma Services, for securing the first Veterinary Drug Licence through our joint venture with DDC."

— Seronera Capital Partners
Rajesh Sood, Managing Partner

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COMMERCIAL MANUFACTURING & PACKAGING

Certified by the Medicines and Healthcare Products Regulatory Authority (MHRA), we have licences for the manufacture of medicines, controlled drugs, specials and Investigational Medicinal Products (IMPs) in a wide range of formulations including solid dose, powders and hard gel capsules.

We do this for existing and new formulations, for branded and generic pharmaceuticals, and can provide innovative solutions for hard-to-manufacture, niche products.

Our adaptable primary packaging lines offer clinical, commercial or stability blister and bottle packaging.

- **Technology transfer**
- **Scale-up**
- **Process validation**
- **Product & process remediation and troubleshooting**
- **Bottle and blister packing**
- **Tamper evidence and serialisation**

4000m² packaging facility
1,700m² temperature monitored warehouse

1 billion tablets / year
150 million capsules / year

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PROJECT MANAGEMENT

We are proud to work closely with our clients to help bring lifesaving and life-enhancing products to patients all over the world.

Our multi-disciplinary teams take an approach that is flexible, agile, streamlined and timely: everything we do is geared to ensuring we meet your expectations and deliver your project on time and on budget.

Our project managers have experience of working within the pharmaceutical industry and have managed programmes from both clinical and commercial sectors. Acting as key members of your product and process development team, these dedicated project managers ensure all your technical requirements are met and work with you to resolve any regulatory challenges you encounter.

As well as their technical expertise, they are skilled communicators, updating you at every stage on the progress of your project through the development cycle and responding quickly and appropriately to your individual needs.

> Your project becomes our project: our passion is built on our ability to find innovative solutions that deliver."

Jan Phillips
Quality & Compliance Director

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CPS 07/2023/v4

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