An Introduction to Custom Pharma Services

CUSTOM
Pharma Services

Who is Custom Pharma Services?

- Established in 1979, Custom Pharma Services has grown to become the go-to resource for contract development, manufacturing and packaging solutions in the United Kingdom and across Europe

- Specialist in tablets, powders and hard gel capsules (immediate and modified release) development and manufacture

- **Site Capabilities**
  - **GMP approved for UK, Europe and International markets**
  - **IMP, Specials, Manufacturers Licences**
  - **Home Office controlled drug manufacture & supply**
  - **Certified for the manufacture and release of hormones**

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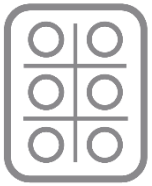
What services do we offer?

CLINICAL AND PRODUCT DEVELOPMENT

COMMERCIAL MANUFACTURING



COMMERCIAL PACKAGING

PROJECT MANAGEMENT

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CLINICAL AND PRODUCT DEVELOPMENT

- **Preformulation screening**
  - Solubility/stability assessment
  - Excipient screening
  - API properties for process-ability
- **Formulation Development**
  - Solid dose, powders, tablets, hard gel capsules
  - Immediate and modified release expertise
- **Analytical Development**
  - Method development and validation
  - Full technical transfer of existing methodologies
  - In-house ICH stability testing

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CLINICAL AND PILOT MANUFACTURING

- **Matching placebo manufacturing**
- **Phase I clinical manufacturing**
  - Small scale manufacturing equipment and facilities are available within the GMP areas
  - Micro-filling API in capsule using the Mettler Toledo Quantos Dosing System
- **Phase II & III clinical manufacturing**
  - Small medium and large batches from bench scale to full commercial batches
- **Clinical Trial Packaging**
  - Custom offers a range of packing and repackaging options for clinical supplies through strategic partnerships
- **Pilot scale manufacturing**

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COMMERCIAL MANUFACTURING

- Facilities of 2200 m^2
- Technical Grade air handling (but achieve Grade D)
- Tablets
  - 1.5 billion a year
  - Immediate and modified release
  - Film, sugar coated & tablet printing
- Hard gel capsules
  - 250 million a year
- Bulk powder blending and filling

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COMMERCIAL MANUFACTURING

- **Single quality assurance function across Custom Pharma Services**
  - Fully licensed IMP and CMO facilities regulated by the
  - UK MHRA
  - Full time QP's available on site at Custom Pharma Services

- **List of available manufacturing licenses**
  - cGMP MIA 4102 – UK MHRA
  - UK Specials Licence
  - IMP Licence – clinical trial products
  - Wholesale Dealers Licence
  - Home Office Controlled Drugs Licence

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COMMERCIAL PACKAGING

- **Total Facility of 4000 m^2**
  - Packing facilities (960 m2 Class D)
- **Blister packing capacity in excess of 50 million packs/year**
- **Packaging options**
  - Clinical, commercial and stability packaging
  - PVC/PVDC, ALU/ALU (including cold form), ACLAR
  - Bottle filling and labelling
  - Tamper-evidence sealing
- **Serialisation in line with current legislation timing**
- **Warehouse 1700 m^2**

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PROJECT MANAGEMENT

- Dedicated team of industry qualified Project Mangers
- Integration into your existing project team
- Responsible for delivering of your programme
  - Budget
  - Timelines
  - Product delivery

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Summary Custom's Clinical to commercial offering

- **Full service offering for NCE and generic drug development and contract manufacturing within the UK**
- **Dedicated research and development team offering;**
  - Formulation & Analytical development
  - Process and method optimisation and validation
  - Stability assessment and shelf life determination
  - Clinical trial and Pilot scale material manufacturing
  - Regulatory support for CTA compilation through partnership
  - Clinical trial packaging
  - QP release for clinical use
- **Commercial contract manufacturing offering;**
  - Commercial manufacturing
  - Regulatory support for dossier compilation through partnership
  - Commercial packaging
  - QP release commercial use
- **All services listed offered as standalone or as an integrated package**
- **Interested in standard fee for service and JV opportunities**

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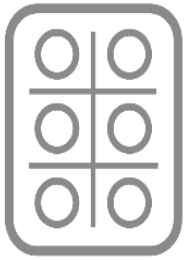
From clinical to commercial, Custom Can!

Clinical and Product Development

Commercial Manufacturing



Commercial Packaging

Project Management

Thank you

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QUESTIONS?

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