Integrated CDMO Solutions

SGS THE WORLD'S LEADING TESTING, INSPECTION AND CERTIFICATION COMPANY.

SGS.COM/CDMOSOLUTIONS

Our core capabilities

World-leading formulation contract development manufacturing organization

PRE-CLINICAL FORMULATION SCREENING

With a proven record of working with challenging molecular entities SGS find effective delivery methods for drugs that exhibit poor solubility & bioavailability or require a modified or controlled release.

FORMULATION DEVELOPMENT

Offering development for all dosage forms and drug types in all therapeutic areas. SGS have expertise in developing products for oral delivery but work across many drug delivery systems.

ANALYTICAL SERVICES

Full analytical support for developing phase appropriate validated analytical methods for drug product development and clinical release. SGS also support ICH for stability indicating testing.

GMP MANUFACTURING

MHRA and FDA inspected facilities licensed to manufacture for PH I-III medicines in a non-sterile environment. SGS specialize in niche scale commercial manufacturing that can be challenging to place with other CDMOs.

CLINICAL TRIAL SUPPLY

Primary and secondary packaging kit design and assembly, with the clinical protocol and patient population in mind.

Why work with us?

SGS' specialized CDMO site was established in 2002, based in the UK, offering MHRA & FDA inspected facilities.

- GMP licensed for IMP/IND (PH I-III) and commercial manufacturing
- NCE, small molecule, proteins, peptides, live biotherapeutics (BSL I&II) & other microbiome agents
- Unlicensed medicines
- Veterinary medicines
- Controlled drugs licenses
- Collaborated with more than 150 clients globally
- Worked on 300+ NCE and microbiome projects

Scientific expertise | Integrated CRO network
Accelerated drug development | Global regulatory compliance
Customer centric

Pre-clinical formulation screening

LOW COST, LOW VOLUME, HIGH THROUGHPUT

Our pre-clinical formulation screening platform is designed to optimize solubility and bioavailability of drug therapy entities, with the aim of providing a formulation for use in a drug product.

- **Solid state drug substance characterization**
  - DSC/TGS, XRF & XRPD
  - Elemental impurities and residual solvents testing
  - Particle size analysis and reduction via nano-milling
- **Small scale solubility screening**
  - Viscometry, turbidity, density, pH and gravimetric / microscopy
- **Prototype infusion and precipitation assessment**
  - DLS and turbidity
  - Mechanical and visual assessments
- **Batch production to support TOX / ADME stages**

RAPID TURNAROUND (~6 WEEKS)
MINIMUM API REQUIREMENTS

TAILORED SOLVENT & EXCIPIENT SELECTION

ABSORPTION & PERMEABILITY ENHANCEMENT

TOX / ADME BATCH MANUFACTURE

TYPICALLY VERY LITTLE API AVAILABILITY

KINETIC & THERMODYNAMIC SOLUBILITY IN BIORELEVANT MEDIA

FORMULATION ENABLING ACTIVITIES

Formulation development

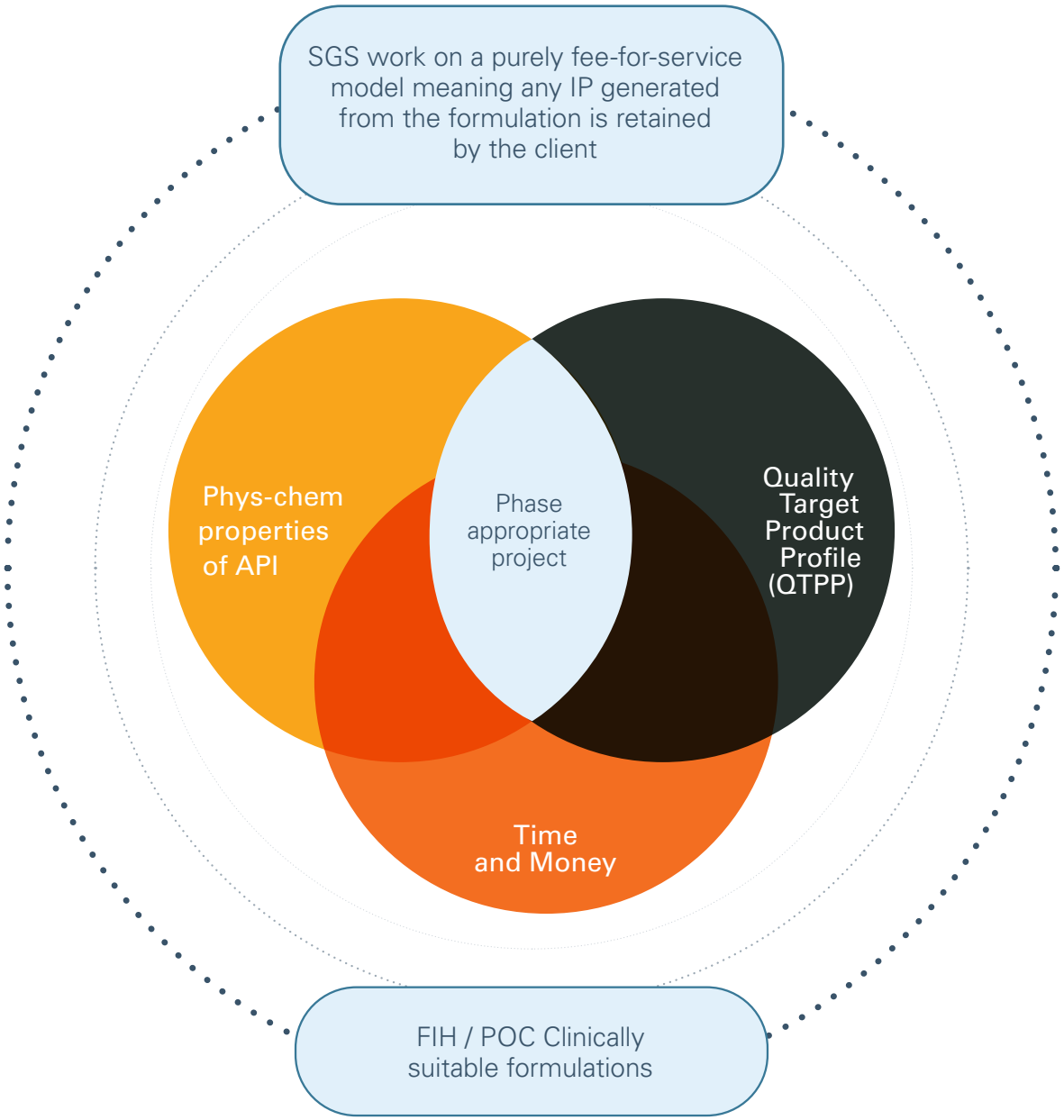
SMALL MOLECULE

SGS is widely recognized as leading experts in all aspects of pharmaceutical development and dosage form optimization for a wide range of product types, including those that have poor solubility or bioavailability.

DOSAGE FORMS

SGS can support the following:

- Oral solid dosage forms:
  - Immediate and controlled release capsules
  - Coated capsules
  - Fast dispersible
  - Micro-encapsulation
  - Multiparticulates (beads and pellets)
  - Liquid and semi-solid filled capsules
- Other dosage forms:
  - Oral liquids and suspensions
  - Topical
  - Parenteral (formulation development only)



LIVE BIOTHERAPEUTICS

SGS are experienced in formulation development and is one of the few companies licensed for the clinical manufacture of live biotherapeutics.

- Formulation development designed to enable release profiles for targeted delivery and enhanced microbiome survival rates
- Scalable manufacturing process development in our MHRA and FDA inspected facility, minimising oxygen contamination
- Primary and secondary packaging design to enhance shelf-life, with the patient population in mind

DOSAGE FORMS

SGS can support the following:

- Oral solid dosage forms:
  - Immediate and controlled release minitabs tablets/capsules
  - Coated pellets, tablets & capsules
  - Fast dispersible
- Other dosage forms:
  - Topical

Physical characterization

API & SOLID DOSAGE CHARACTERIZATION

SGS support the following characterization of API and other solid materials e.g. granule intermediates:

- Particle size by sieve analysis, and by laser diffractometry*
- Optical light microscopy to x100 to assess particle size, shape and crystallinity (crossed-polarisers)
- Powder flow through orifices (Copley Flow Meter)
- Polymorph analysis by XRPD*
- Bulk and tapped density determination for powders (USP <616>)
- True density of powders (Quantachrome helium pycnometer§)
- Moisture content by Coulometric Karl Fischer
- Physical / chemical stability of powder mixtures under variable controlled conditions
- Compaction analysis to determine plastic / brittle / elastic compaction properties
- Tablet characterization by hardness, friability, dissolution and disintegration testing
- Modulated DSC & high-resolution TGA (TA instruments SDT 650):
  - Measure melting point / glass transition temperatures
  - Fast-screening of chemical / physical incompatibilities of APIs with excipients

** Services outsourced to SGS's ISL site in Ireland*
§ Services outsourced to local third party

LIQUID DOSAGE CHARACTERIZATION

SGS support the following characterization of liquid materials e.g. oral liquids, topic gels etc:

- Solubility screening of API (with solvents / solubility enhancers) by visual / HPLC-based analysis or UV (high-throughput nano-plate screening)
- Liquid density (multiple methods including Density2Go Meter)
- Turbidimetry (Hach TL2300 turbidimeter)
- Viscometry (Brookfield DV2T and Capillary Viscometer)
- Optical microscopy to assess particle size, shape and aggregation in suspensions etc.
- Dynamic light scattering particle sizing and zetapotential measurement (Zetasizer Nano)
- Dynamic scanning calorimetry (TA Instruments SDT 650) to evaluate liquids / gels for:
  - Melt and gel phase transitions
  - Phase separations
- Physical and chemical stability testing of liquids
- Rheology (Anton Paar MCR302) for quantifying the suitability / physical stability of:
  - API suspensions and emulsions (at low shear)
  - Creams and gels (at high shear / oscillating mode)

Analytical services

SGS provides analytical services throughout the entire drug development process.

FINISHED PRODUCT ANALYTICS

SMALL MOLECULE API:

- Stability-indicating assays using UPLC & HPLC (Inc. forced degradation studies)
- Chiral analysis
- Dissolution testing and drug release profiling
- The identification and quantification of impurities
- Hardness
- Disintegration
- KF
- Microbial limits and preservative efficacy testing
- Comparator studies

MICROBIOME API:

- Identification & Quantification (cfu/TCC/VCC)
- Microbial Purity (TAMC/TYMC)
- dPCR
- Disintegration
- KF

GMP MANUFACTURE

SGS use of proven manufacturing technologies provides a low economic risk and fast entry into the first in human trial and accelerated scale-up to future clinical phases:

- MHRA licence for clinical trial and commercial manufacture
- FDA inspected 25,000 sq. ft GMP manufacturing facility
- GMP containment cleanrooms
- High containment, anaerobic and low humidity conditions
- Product specific decontamination
- Manual, semi-auto and automated manufacturing equipment

PROCESSING TECHNOLOGIES

Oral liquid solutions / suspensions

Blending

Wet and dry granulation

Extrusion / spheronisation

Direct compression (mini tablets / tablets)

Encapsulation (powder / liquids / semi solids / pellets)

Capsule banding

Coating (modified/sustained or aesthetic, tablets, capsules and pellets)

Lyophilisation

GMP Clinical Trial, Commercial Manufacturing & Packaging Services

SGS understand the complexities of bringing new chemical entities, biologics and live biotherapeutics to market. Our custom-designed clinical trial, commercial manufacturing and packaging solutions meet the unique needs of your project.

SGS provide flexible GMP manufacturing, supporting projects from FIH trials through to phase III clinical supplies manufacturing. Whether you need non-GMP feasibility studies or phase-appropriate cGMP Clinical Trial Material (CTM) production, we have the expertise to help you succeed.

MHRA/FDA & GMP approved manufacturing facility

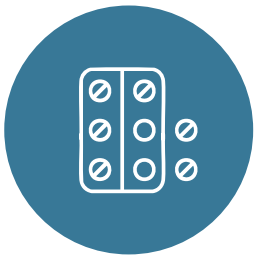
7 GMP suites

25,000 sq facility

Blending capacity*

Tableting capacity*

Capsule filling capacity*



Blister packaging capacity*

Topical creams and ointments capacity*

Liquid filling capacity*

*Bespoke flexible & mass scale manufacturing production available

Clinical trial supply

SGS capabilities, experience and expertise all support the design of primary and secondary packaging. Always with the patient population and clinical protocol in mind.

PRIMARY PACKAGING

- Bottles (HDPE and glass)
- Vials
- Blisters (thermoform and cold form)
- Nonsterile syringe fill
- Tubes and jars

SECONDARY PACKAGING

- Patient kit assembly
- Cold chain kit assembly
- Dosepaks / walleting

LOGISTICS

- Direct to clinic
- Cold chain logistics
- Returns and destruction

KIT DESIGN

- Blinding
- Randomization
- Bespoke kits designed around ancillaries

COMPARATOR PURCHASING

- Generic or branded drug sourcing

CRO SERVICES

- Clinical management
- Clinical research
- Shelf-life extension over labelling

LABEL PRINTING

- In-house single panel label print
- Multi-lingual booklets
- QR code print
- Colour printing

REGULATORY SERVICES

- IND/IMPD submission guidance
- In house QP service
- GMP auditing
- GMP certification
- UK/EU & ROW QP release

How SGS work

Project

Project

Project

Commercial group

Pre-clinical

Liquids

Solids

Development groups

LBT

Manufacturing

QC release

Raw materials

Pre production

Analytical validation

Project operations

Project introduction

Feasibility

QA / QP release

QA

Process development

QA

Stability testing

Regulatory maintenance

Project life cycle

QA / QP release

Capabilities across our network

CAPABILITIES	NORTH AMERICA	EUROPE	ASIA-PACIFIC
QC & stability testing (small molecule)	✔	✔	✔
Microbiology	✔	✔	✔
Method dev. and validation (small molecule)	✔	✔	✔
Extractables and leachables	✔	✔	✔
Nitrosamine and cytotoxic impurities	✔	✔	✔
Container testing	✔	✔	✔
Method dev. and validation (BioPharma)	✔	✔	-
QC and stability testing (BioPharma)	✔	✔	-
BioPharma characterization	✔	✔	-
Biosafety	-	✔	-
Bioanalysis	✔	✔	✔
Biological activity	✔	✔	✔
Plant / equipment qualification	-	-	✔
In-vitro toxicology	✔	✔	✔
Diagnostics	-	✔	-
Formulation dev. and Manufacturing	-	✔	-

AMERICAS

CANADA
Toronto (Markham, ON)*
Toronto (Mississauga, ON)*

USA
Chicago (Lincolnshire, IL)*
New Jersey (Fairfield, NJ)*
Boston (Hudson, NH)*

EUROPE

BELGIUM
Brussels (Wavre)*
Brussels (Wavre)*

FRANCE
Paris (Villeneuve-la-Garenne)*
Poitiers*

GERMANY
Aachen*
Berlin*
Berlin (SGS Analytics)*
Frankfurt (Taunusstein)*
Munich*
Wiesbaden*

IRELAND
Cork (Ringaskiddy)*

SWITZERLAND
Geneva (Plan-les-Ouates)*
Basel (Birsfelden)**

UNITED KINGDOM
Chester (Deeside)**
Glasgow*

ASIA

CHINA
Shanghai (Xuhui)*
Shanghai (Pudong)*

INDIA
Navi-Mumbai*

LEGEND: QC / R&D* Bioanalysis* Formulation & CDMO* Medical / clinical research*

SGS Pharma

27
Sites

12
Countries

5K+
Customers

3K+
Employees

40+
Years in drug development

1000+
Clinical trials over last five years

Contact us

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WHEN YOU NEED TO BE SURE

SGS