



# Global formulation development and manufacturing capabilities

With over 30 years' experience, Quotient Sciences provides full service support for small molecule non-sterile programs, from dosage formulation development through to GMP clinical trial manufacturing and commercial drug product supply.

## Key features

- Pharmaceutical development and clinical manufacturing facilities in the US and UK
- High-potency containment facilities and manufacturing expertise
- API salt selection, polymorphism and characterization studies
- Pre-clinical formulation development and supply
- Formulation development of oral, inhalation, nasal and topical products
- Wide range of technologies to address solubilisation challenges
- Phase I and Phase II clinical trial manufacturing
- Real-time adaptive manufacturing
- Batch sizes ranging from small scale (less than 250g) to large scale (up to 500Kg) for tablet/capsule drug products and up to 300 litres for liquid presentations
- Clinical packaging, labelling and global distribution for Phase I and Phase II
- Process validation and registration batches
- Phase III clinical manufacturing and commercial drug product supply

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Our team works in partnership with clients to understand molecule properties and define the optimal pharmaceutical development & manufacturing program.”

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## Dosage forms

- Solid oral dosage forms (IR/MR/SR/ODT tablet and IR/MR/SR/multi-particulate pellet capsule products)
- Oral and nasal (dry powder, solution, suspension, nebulized) dosage forms
- Lipidic (SEDDS, SMEDDS, solutions, semi-solids) dosage forms
- Solution and suspensions
- Enhanced solid oral dosage forms (SDD, micronized, HME, microfluidized nano particulate systems)
- Parenteral (IV, IM, SC)
- Gels and creams (topical, rectal)

## Formulation techniques

- Spray dried dispersions (SSD)
- Micronization by air jet milling
- Hot melt extrusion (HME)
- Nanomilling by microfluidization
- Pellet layering and coating
- Compression (single station and rotary single, bilayer and trilayer units)
- High shear wet or melt granulation
- Fluid bed drying
- Dry granulation
- Encapsulation (solid, semi-solid and liquid)
- Tablet and capsule film coating (IR/EC)
- Wurster granulation and coating
- Homogenization for suspension products

## Solid dosage manufacture equipment

	Up to 1Kg	1 - 10Kg	10 - 75Kg	>75Kg
Wet granulation	Key Granulator 1L, Glatt TMG 1/6 (1L and 5L)	Collette MP20 Mixer T.K Fielder PMA 25L GEA PharmaConnect Key Granulator 5L	T.K Fielder PMA 65 Liter	Fluid Air Granulator (Jacketed) PX-250
Fluid bed drying	Mendel MFB-1 (11.5L and 18L) w/ Wurster and top spray Vector fluid bed systems O'Hara FBGB1 fluid bed w/ Wurster insert and bottom spray		Mendel MFBH- 5/8 (20L and 48L) w/Wurster and top spray	Fluid Air Fluid Bed Dryer Model 0120 (270L) with Wurster and top spray
High shear blending	GEA Pharma Connect 1L and 10L			
Blending	5, 10L Bohle Bin Blenders Maxiblend V Blender (2qt) V-blender 2/4/8/16 Turbula T2F Mixer	5,10 and 20L Bohle Bin Blenders V-blenders (1/2/3/5/10) Maxiblend V blender (4/8/16qt) GEMCO V blender (1cft) Turbula T10B Mixer Pharmatech MBO25 Blender (1 - 30L)	40L, 300L Bohle Bin Blenders GEMCO 5 cft Double cone blender 5cft Pharmatech MB100 Blender (25, 50, 100L) Bohle Bin Blender (40L)	300L and 1000L Bohle Bin with drum lifter GlobePharma V Blender (10cft) Keith V-blender 20 cu.ft
Dry granulation	Vector micro roller compactor			
	Gerteis MiniPactor Vector TFC 220 pilot scale roller compactor			

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## Solid dosage manufacture equipment (continued)

	Up to 1Kg	1 – 10Kg	10 – 75Kg	>75Kg
Milling	Quadro Comill 196 Quadro Comill 1975			
Coating	ProCepT perforated pan coater Bench scale Torpac capsule coater O'Hara Lab Coater MX (12" pan)	O'Hara Lab Coater IIX (15"/17"/19" pans) O'Hara Lab Coater MX (19" pan)	O'Hara Lab Coater IIX (24/30" pan)	O'Hara Coater (48" pan) O'Hara Coater XXL (60" pan)
Encapsulation	Profill 100/300 Quantos Xcelodose 600			
	Harro Hofliger Modu-C LS with Low dose drum dosing unit Zanasi LZ-64 Bonapace In-Cap Encapsulation machine CFS1200 Liquid Capsule Filler			
		Bosch GKE 330 (18,000/hr) Bosch GKF Capsylon 705 (42,000/hr) IMA Zanasi 40F		Bosch Capsylon 1500 (92,000/hr)
	Bosch Model GKF330 Encapsulator Bosch GKF Capsylon 1505 Encapsulator Chemi-Pharm Model 301 Manual Encapsulator Capsugel Ultra-8			
Compression	Carver Single Station Press Stokes Single Station Press Stokes Trilayer Press Manesty F3 single punch		Korsch XL 400 Press Globe Pharma Minipress-II Manesty BB3B 27 station single/ bilayer Manesty Beta Press 16 station Manesty XPress 25 Station Hercules Press 25 Station Kikusui Libra Press 36 Station Kikusui Aquarius Press 36 Station Manesty BB3B 27 station single/ bilayer Manesty Beta Press 16 station	
		Riva Piccola minipress Korsch XL 100 (B and D) Press Riva Piccola Press Manesty F3 single punch Manesty Beta Press 16 station		
Weight sorting	SADE SP B20 3000/hour SADE SP 120 4500/hour SADE P2 x2 3600/hour SADE SP140 (8000/hour) Bosch KKE1700 (100,000/hour) Bosch KKE1700 (100,000/hour)			
Particle size reduction	Fitzpatrick Comminutor fitz mill Quadro Comil 196 Quadro Comil 1975 Glen Micro Hammer Mill Stansted FPG12500 Microfluidiser Nano-milling Caleva Extruder 20 Caleva Spheroniser 250 MC-ONE micronizer Sturtevant 2" micronizer			

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## Solid dosage manufacture equipment (continued)

	Up to 1Kg	1 - 10Kg	10 - 75Kg	>75Kg
Hot melt extrusion	Leistritz 16/18mm Twin Screw HME + K-Tron precision powder feeder, Pelletizer, Chiller			
Spray drying	ProCepT spray dryer SPX Anhydro MS-35 (aqueous and solvent)	GEA Niro Mobile MinorTM Spray Dryer SPX Anhydro MS-35 (aqueous and solvent)		
Freeze drying	Cool Safe			

## Liquid and semi-solid manufacture (research and production scale)

	Up to 1Kg	1 - 10Kg	10 - 75Kg	>75Kg
Mixer	Oden Mixer and filler (single head and multi head liquid filler) Lightning Mixers Silverson SL2T high shear mixer Silverson L4R1 high shear mixer Silverson AX/AIR Mixer/Homogeniser IKA Ultra Turrax 25 high shear mixer IKA VOS Overhead stirrer IKA RW47 Overhead mixer Heidolph overhead RZR2021 mixer			
		35/125/200/285/350 L round bottom flasks 77 L flat bottom flask		
		Silverson homogeniser L5M 275UHS MP5 Lightnin Mixer		
Filling	Pamasol Inhalation Filler and Crimper (50 units/hour) Flexicon PF6 peristaltic filling machine CFS liquid and semi-solid filling system Single Oden Servo Filler (install 3x Fill Line) Sachets - AlphaPack PM Kinex Pneumatic Capping Machines KAPS-ALL EB-550 and EB-650A Electronic Torque Testers Pharmatest PT-LT Bottle Leak Tester			

## Packaging

	Up to 1Kg	1 - 10Kg	10 - 75Kg	>75Kg
Blister packaging	Sepha EZ II Blister Thermo and Cold Forming Packing			
Bottle packaging	Kinex Pneumatic Capping Machines Electronic Torque Testers Bottle Leak Tester Sure Torque Cap Machine ST100 Kapps All Torque Tester Relco Induction Cap Sealer ICS1H Kirby Lester Tablet/Capsule Counter KL50			

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## Laboratory equipment

	Equipment
HPLC	Waters, Agilent, Alliance and Shimadzu HPLC systems with
Detectors	DAD, CAD, UV and PDA Radiometric, refractive index and FSA
UPLC	Waters, Acquity, and Shimadzu UPLC systems
Spectrophotometry	Agilent UV/VIS Spectrophotometer, Shimadzu UV/VIS Spectrophotometer
FTIR	Perkin Elmer, Agilent
Raman	Thermo Scientific DXR Raman microscope, Nicolet Almega XR Dispersive Raman Microscope with large sample environment for spectroscopy of powders and suspensions.
Microscopy	Olympus BX50 polarising optical microscope, Light microscopy with image analysis software. Polarized light microscopy
Thermal analysis	Perkin Elmer Diamond DSC, Perkin Elmer Jade DSC, Perkin Elmer STA 6000 Simultaneous Thermal Analyzer,
Microcalorimetry	TA Instruments TAMiii Calorimeter containing both solution calorimeters and perfusion microcalorimeters, Calorimetry Science Corporation Isothermal titration Calorimeter.
X-ray diffraction	Panalytical X'Pert PRO diffractometer with an X'celerator detector
Surface/sorption analyzers	2 Hiden Isochema IGA sorption analyzers, VTI Vapor Sorption Analyzer
Water content	Mettler Toledo, Metrohm 831 Coulimetric, Volumetric, Oven Karl Fisher LOD Moisture Balance
Gas chromatography	Thermofisher GC with direct and headspace sampling with NPD & FID detectors
Dissolution	ATG and Distek Dissolution Baths (50 mL to 1L) with automated samplers Distek Bathless Sotax, Pharmatest Dissolution Baths
Disintegration	Copley DTG2000 disintegration tester
Inhaled testing	Andersen cascade impactor Next Generation Impactor Delivered dose apparatus
Particle size analysis	Sympatec RODOS particle size analyzer (wet and dry) Malvern Mastersizer 2000
Powder flow	Copley BEP 2 flow analyzer (bulk, tapped density, Angle of Repose, Carrs Index, Hausner ratio)
Endotoxin	Endosafe PTS

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## Laboratory equipment (continued)

	Equipment
Viscometer	Brookfield Viscometer cup
Osmometer	Micro osmometer
Balances	Balances - Micro to Top Loading
General	Centrifuges Shakers (wrist, orbital) pH Meters Muffle Furnace Schleuniger and Holland Hardness Testers Ovens and Vacuum ovens
Stability chambers	Stability Chambers Cycling Forma Science Incubators

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