WOCKHARDT

WORLD-CLASS CONTRACT MANUFACTURING ORGANISATION

Extraordinary service every day

www.wockhardt-knowhow.com

Meet Neil.

He'll bring your concepts to life.

"Technology transfer is complex and challenging. To get the best results, we're constantly thinking outside the box."

Neil Wynne:
a Wockhardt Technical Development Director

Meet Heather.

She makes sure everything's running precisely to plan.

"Whether it's arranging your next Business Review meeting, scheduling deliveries or reviewing critical timings, customer satisfaction is key."

Heather Brunyee:
a Wockhardt Contracts Executive

Meet Peter.

He's got a keen eye for detail.

"Our testing regimes are stringent. The integrity of your product is what counts."

Peter Sheppard:
Wockhardt Quality Control Manager

Meet Ash.

He'll take care of your schedule.

"Aligning quality and production timelines is crucial. There's no room for error - the final outputs have to be perfect."

Ash Kanade:
a Wockhardt Head of Scheduling and Planning

Contract Service Solutions

WOCKHARDT

Our Know How

- 4 decades of pharmaceutical manufacturing experience
- 40+ contract manufacturing clients
- 70+ products produced globally for contract manufacturing clients
- 12 fill/finish facilities (over 1.5 million sq ft high-quality manufacturing capacity)
  - 3 in Europe, 1 in U.S., 8 in India
- Flexible end-to-end service (full turnkey)
- Clinical & commercial batch supply
- Full QA/QC in-house support
- Regulatory compliance
- Backed by 7,000+ strong team including 500+ development scientists, including 150 PhDs

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Our Know How

Overall projects are managed by our highly responsive and dedicated Contract Manufacturing Department

supported by local teams at each facility / group of facilities

- Business & Client Management
- Technology Transfer & Project Management

Our strong CM team are experts in:

- Drug Development & Analytical support
- Manufacturing
- Quality Assurance & Quality Control
- Regulatory Compliance
- Logistics
- Planning
- Engineering
- Purchasing

Our Stability and Growth

- A growth global company +21% (CAGR Global – 2000 to 2009)
  - Two Thirds of business revenue is from EU & US operations
- Wockhardt UK Growth of 14% and 13% in 2008/2009 respectively
  - Growth at 3 to 4 times Industry standard
  - Our dedicated and established Contract Manufacturing Division is growing rapidly, exceeding global initiatives
- New investment in Lyophilisation, Cartridges & Pen Assembly
  - New State-of-the-Art Lyophilisation facility in Aurangabad, India (SEZ – Shendra)
  - Investment in replacement cartridge filling line in the UK (August 2010) – Two fully integrated cartridge filling lines
  - Small scale injector pen assembly capabilities (moving to automation early 2011)
  - Strong Focus on Contract Manufacturing
- Strategy – To focus on our global capabilities to nurture and expand the business

Exceeding Expectations – Our Difference

- Value-added services - differentiate ‘you’ as a client
- Security of supply
  - Quality assured, Regulatory compliance, Financial stability and significant growth momentum
  - Business continuity – multiple locations across geographies
- Full Turnkey – end to end product supply – clinical & full scale (inc. API)
- Breakthrough, rapid service
  - On-time delivery, Responsiveness
- Cost-effective manufacturing
  - Special Economic Zones, Low cost geographies, continuous process optimisation / improvements

Our Global Services

‘Full Turnkey’ value-added service

- Manufacture of API
- Formulation development
- Analytical method development and validation
- Small scale clinical / commercial manufacture
- Scale-up & large scale commercial manufacture
- Product release (QA specialists and QPs)
- Extensive QC capabilities (Micro, Chemical, ICH Stability)
- Packaging and shipping
- Global network of facilities
  - qualification of back up facilities for our clients

Global Capabilities

WOCKHARDT
CONTRACT MANUFACTURING

Specialists in the **development and Contract Manufacture** of pharmaceuticals

WOCKHARDT	GLOBAL MANUFACTURING CAPABILITIES											
	INDIA								UK	IRELAND	FRANCE	USA
CONVENTIONAL	**BADDI**	**BIOTECH PARK**	**EOU**	**CHIKALTHANA**	**WALUJ**	**DAMAN 1**	**DAMAN 2**	**SEZ**	**WREXHAM**	**PINEWOOD**	**QUIMPER**	**MORTON GROVE**
REGULATORY STATUS	MHRA/FDA	MHRA/FDA	MHRA/FDA	MHRA/FDA	MHRA/FDA	MHRA	MHRA	MHRA/FDA Approvable (New Site)	MHRA/FDA	MHRA/IMB	EMEA	FDA
Tablets	✓		✓	✓		✓	✓					
Capsules	✓		✓	✓		✓	✓				✓	
Powders				✓						✓		
Sachets				✓							✓	
Liquids	✓									✓		✓
Suspensions	✓									✓		
Sprays												✓
Drops												✓
Creams	✓					✓				✓		
Ointments	✓					✓				✓		✓
Gels	✓					✓				✓		
STERILES												
Small Volume Parenterals		✓		✓				✓	✓			
Large Volume Parenterals – Glass								✓				
Sterile Pre-filled Syringes		✓										
Sterile Ophthalmic Solutions – Plastic Vials		✓										
Lyophilisation								✓	✓			
Cartridges		✓							✓			
Injectable Dry Powder Cephalosporins					✓							
SPECIALISED												
Controlled Drugs	✓		✓	✓					✓			
Cephalosporins Oral Solids					✓							
High Potency							✓					

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Small & Large Volume Parenterals | Lyophilisation | Cartridges | Pre-Filled Syringes | CDs | High Potency | Tablets | Capsules | Powders | Liquids

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Our European Facilities

Pinewood, Ireland

MHRA/IMB Approval

Specialised & Standard Dosage Forms

Quimper, France

EMEA Approval

Standard Dosage Forms

Wrexham, UK

MHRA/FDA Approval

Lyophilisation, Sterile Injectables, Cartridges, Specialised & Standard Dosage Forms

Our Indian Facilities

Biotech Park, Aurangabad
MHRA/FDA Approval
Sterile Injectables

Chikalthana, Aurangabad
MHRA/FDA Approval
Sterile Injectables, Specialised & Standard Dosage Forms

Eou, Aurangabad
MHRA/FDA Approval
Specialised & Standard Dosage Forms

Site under qualification

SEZ, Aurangabad
MHRA/FDA Approvable
Completion end of 2010
Lyophilisation, Large and Small Volume Parenteral Injectables

Our Indian Facilities

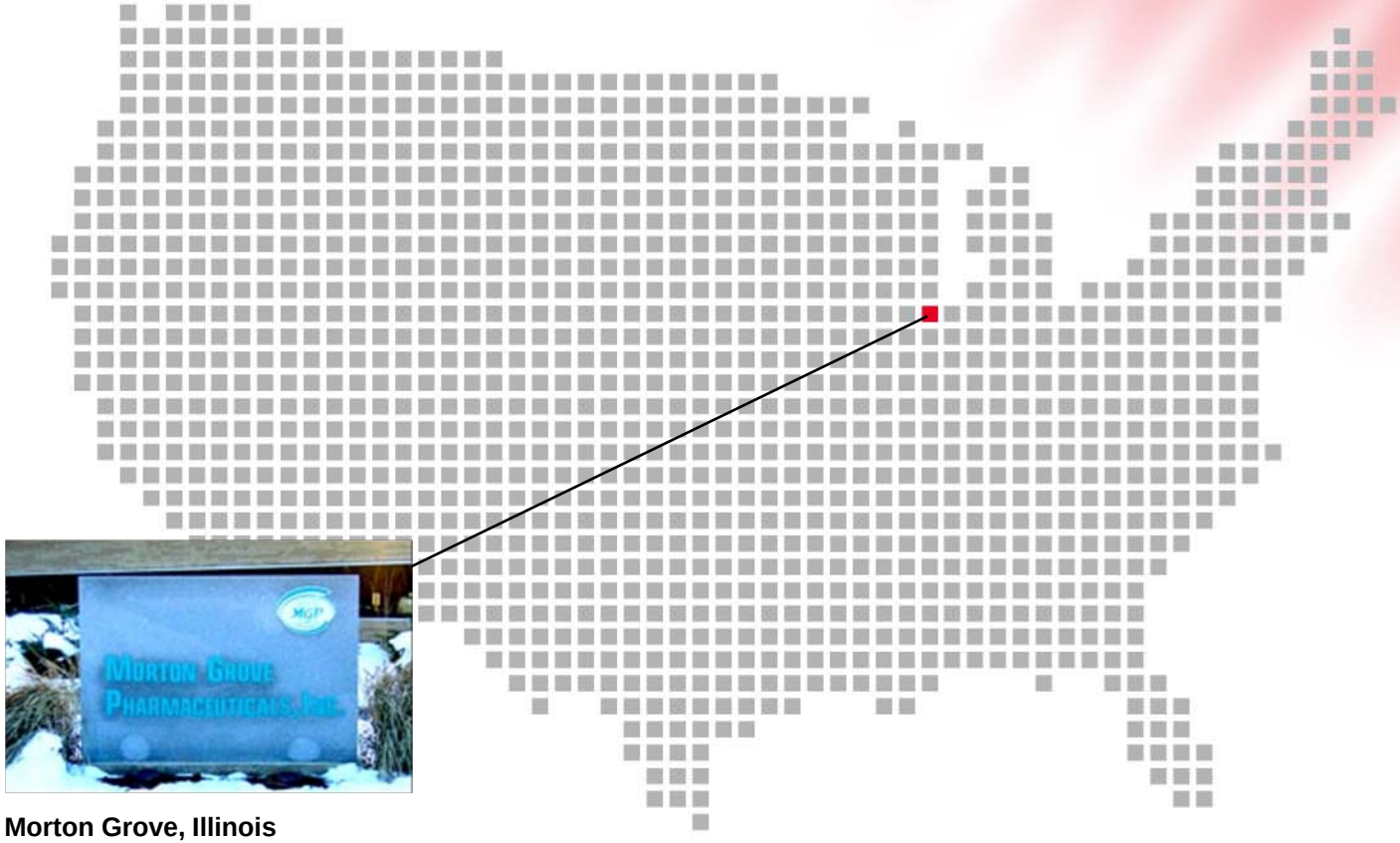
Baddi, Himachal Pradesh
MHRA/FDA Approval
Standard Dosage Forms

Daman1, Bhimpore
MHRA Approval
Standard Dosage Forms

Daman2, Kadaiya
MHRA Approval
Specialised & Standard Dosage Forms

Waluj, Aurangabad
MHRA/FDA Approval
Sterile Injectables, Specialised Dosage Forms

Our US Facility



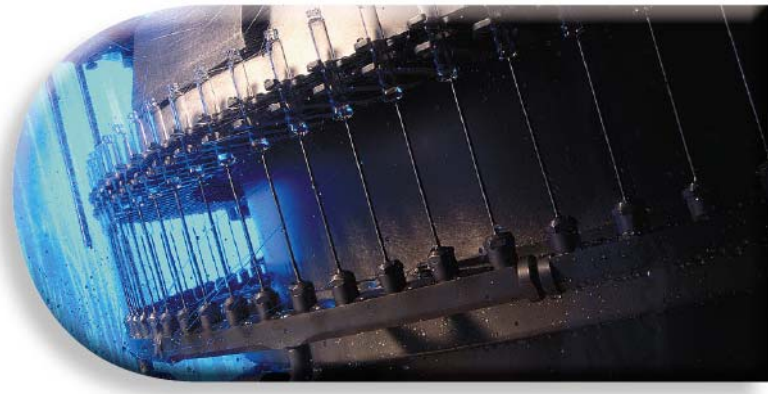
Morton Grove, Illinois

FDA Approval

Standard Dosage Forms

Sterile Injectables (SVP & LVP)

- State-of-the-art technology
- Aseptic procedures throughout (also able to handle terminally sterilised products).
- Partner of choice – two major patented US drugs
- Capability by form:
  - Vials 2mL to 100mL
    (UK, Biotech Park, Waluj Cephalosporins)
  - Ampoules 1mL to 20mL (UK)
  - Sterile Ophthalmic Solutions, various siz
    to 15mL
    (Biotech Park)
  - Cartridges 1.2, 1.5, 2.7 & 3mL
    (UK, Biotech Park)
  - PFS 0.5 to 5mL (Biotech Park)
  - LVP 100mL to 500mL (Shendra – SEZ)



Lyophilisation

- Significant investment to upgrade our lyophilisation capabilities
  - Aurangabad, India upgrade to add 48m^2 capacity to be completed mid 2010 - space for additional 24m^2
- Purpose built, fully automated lyophilisation facilities
- Fully compliant with FDA and MHRA requirements
- Vial sizes from 2mL to 100mL
- Development & commercial scale manufacturing
- Large scale permanent refrigerated storage
- Fully automated warehouse system
- Low cost geography
- Lyophilised ampoule capability in the UK

Specialised Products

- High potency tablets & capsules, non-beta-lactams, non-cytotoxics and non-sex hormones (Daman Kadaiya)
- Controlled drug handling authorisation
  (UK Home Office Schedule 1, UK, Baddi, EoU, Chikalthana)
- MHRA ‘specials’ license for unlicensed products (UK)
- Cephalosporins – tablets / sterile powders (Waluj)

Solid Dose Products

- Over twenty five years experience
  from small scale batches to high volume production
- Manufacturing across 5 Indian facilities:
  - Plain/film/sugar coated tablets
  - Press coating (tablet in tablet)
  - Sustained release tablets
    (matrix/enteric coated and granules)
  - Sustained release capsules
    (coated granules/wurster coating)
  - Combined formulations
  - Bi layer tablets
  - Effervescent tablets

Sachets and Powders

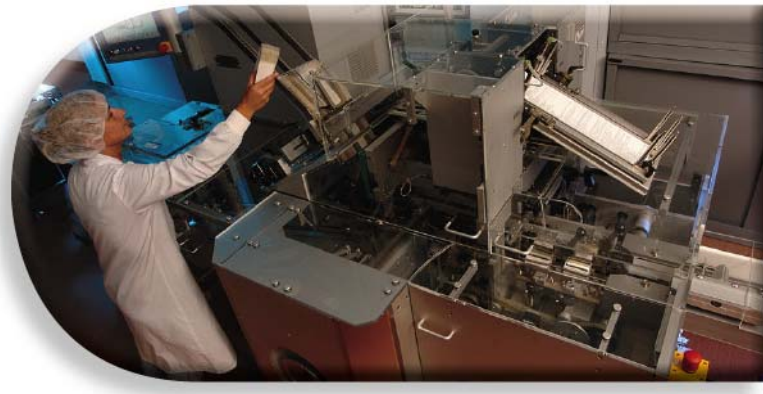
- State-of-the-art facility acquired:
  Pinewood (Ireland), employing 350+ people
- Non-beta-lactam (penicillin) sachets
  - Chikalthana
  - Negma Laboratories, France
- Non-beta-lactam powders
  - Chikalthana
  - Pinewood

Liquids, Gels, Ointments and Creams

- Long standing expertise in the formulation of semi-solids initiated in India (Baddi)
- Acquired facility, Morton Grove (US) for oral and topical liquid formulations
- Acquired facility, Pinewood (Ireland) expanded Wockhardt's production capabilities by 50 million finished packs per year
- High capacity denture fixative cream Pinewood / Daman

Packaging & Inspection

- Flexibility to customise primary and secondary packaging options in accordance with client requirements
- Inspection and Packaging capabilities include:
  - fully automatic, semi-automatic or manual visual inspection methods
  - Small scale pen assembly and labelling (moving to automated process within 12 months)
  - automatic leak detection (ampoules)
  - high speed labelling of all presentations
  - PVC tray thermoforming & cartoning for all presentations
  - Quality Assurance packaging and label



Our Know How - API Manufacturing

- FDA and MHRA approved, cGMP compliant API manufacturing facility
- Multipurpose plant manufactures several products at a time
- State-of-the-art facility dedicated to cephalosporin APIs
- State-of-the-art Biotech Park facility for recombinant insulins/EPO/WEPOX
- Flexible manufacture - high value/low volume products through to high volume

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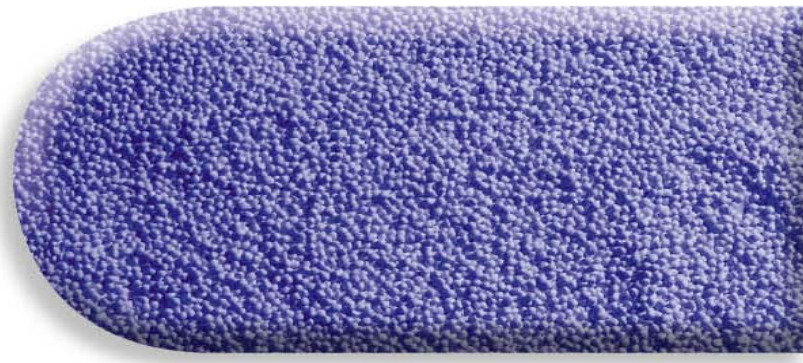
Our Know How - API Manufacturing

- 150+ APIs developed to date, 50+ in the last 3 years
- 30+ DMFs filed during the last 3 years
- 70+ R&D scientists, with 20+ PhDs
- Supported by a dedicated analytical group of 40 scientists, with 5 PhDs
- High pressure, high temperature (to 250ºC) & low temperature (to -70ºC) reactions handled
- Macrolide production



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Business & Project Management

- UK Headquarters
  - Access / proximity to US/EU clients
  - Co-ordination of time zones
  - Understanding of US/EU regulatory, quality & IP standards
- Wockhardt's Business & Project Managers are the window to our company.
  - Work closely with development and operational groups to ensure your timelines are met
  - Responsible for ensuring communication is consistent and effective throughout the project life cycle and beyond
- Our Project Management & Technology Transfer ensures your process is:
  - Robust
  - Repeatable
  - Meets and exceeds pre-defined acceptance criteria
  - Meets and improves on pre-defined timelines
  - Meets pre-defined costs

Our Know How - Technical Development

- Focus on the commercialisation of your molecule for fast market placement
- Synchronisation of formulation development with process and analytical requirements

Pre-Formulation & Formulation Development services:

– Characterisation of physical properties
– Chemical reactivity and forced degradation studies
– Excipient compatibility studies
– Preliminary process identification
– Commercial formulation development
– Process development optimisation

Our Know How - Technical Development

- Fast development and validation of methods to meet testing requirements
- In-house local & global analytical development capabilities
- Molecule stability

Analytical Development services:

- Molecule characterisation
- Method development and validation
- Cleaning residuals development and validation
- Dissolution and drug release profiling
- Forced degradation studies
- Specifications development
- Stability monitoring to ICH guidelines

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Group Quality Policy

- Quality is of supreme importance in Wockhardt and is supported by people at all levels, in all functions
- Continuous satisfaction of customers is our focus - it means meeting the requirements of internal and external customers with speed - right the first time, every time
- Quality is built into process - we must ensure consistency through continuous follow up and adherence to established Company policies and procedures
- Quality is measurable and continuous feedback and improvement is a part of our Quality improvement process
- Continuous communication with Wockhardians and their involvement is critical for Quality

Our Quality Assurance

- Validated Document management systems
- Regulatory submission support (CMC)
- Production and process system controls
- Vendor and material management
- Quality improvement – continuous audits
- Quality management review – for each client & internal
- Corrective/Preventative action – continuous improvement
- Internal self assessment audits
- QP release to client or market

Custom Research Solutions

Niche facilities & skills for development

- Oncology Products
- Peptide Products
- Cephalosporins
- Potent Substances
- Sterile Injectables in Pre-Filled Syringe & Pen device
- Sterile Ophthalmic & Otic Dosage Forms
- Oral Solids in Sachet

Pre-formulation & Formulation Skills

"NICE" (New Improved Chemical Entities) Approach

- Synthesis of Single Isomer
- Identification & Synthesis of Key Metabolite
- Development & Synthesis of Prodrug
- Device Salt Selection Strategies
- Development of Stable & Novel Polymorph having niche characteristics

"NCE" (New Chemical Entity) Development & Scale-up

- Chemical Process development
- Analytical Development, Validation & Stability
- Scale-up of Chemical Process from Milligram to Kilogram Scale
- Supply of NCEs for Preclinical / Clinical Studies
- Pre-formulation of NCEs
- Formulation Development for Preclinical / Clinical Studies

Brand Extension

Brand Extension & Product Portfolio Building

- NDA Development through 505(b)(2)
- Suitability Petitions
- New Modified Release Dosage forms of existing drugs
- Dose Reduction / Optimization Strategies
- Specific Targeted Drug Delivery Systems

Capabilities in Chemical Research

API development, Scale and Supply

- DMF & Non-DMF development of any type of APIs and Intermediates
- Scale-up of Chemical Process from Laboratory to Pilot-plant to Plant Scale
- Supply of APIs for Development, Scale-up and Commercialization of Formulations
- Expertise in handling Chiral Synthesis & Resolution, Peptide Synthesis
- Skills in High Temperature & Pressure, Cryogenic and Organometalic Reactions
- Dedicated GMP Pilot-plant facility to cater 50-100 Kg of APIs

Impurities and Polymorph development

- Isolation & Characterization of Impurities
- Synthesis of Impurities
- Development of Stable and new Polymorphic forms
- Desired Particle Size and Particle Geometry
- Complete back-up of Analytical Instruments
- Dedicated teams for Impurities and Polymorph development

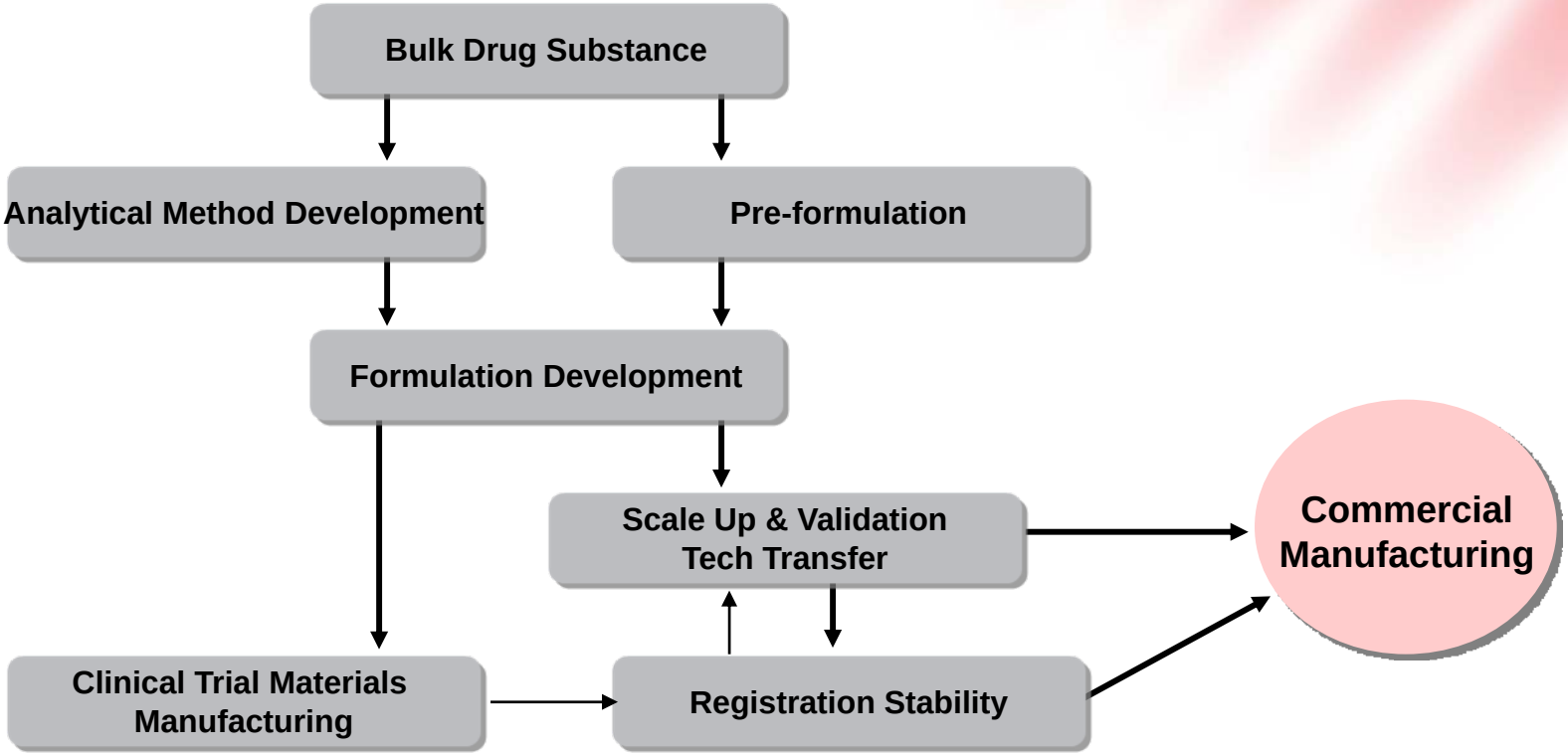
Capabilities in Formulation Development, Scale-up & Supply

- Development, Scale-up and Technology Transfer of all type of Dosage forms
- All type of Injectable dosage forms with delivery devices such as Pens, PFS, Cartridges
- Ophthalmic & Otic dosage forms
- Quick development of Immediate Release Solid and Liquid Orals
- Developing and commercializing Modified, Dual, Delayed Release Products
- Development of Bi-layer, Multi-layer, Tablet-in-tablet technologies
- Effervescent, Orally Dissolving, Chewable, Sublingual Tablets
- Development of Platform Technologies for complex products
- Regulatory and IP Support for all Filing activities
- GMP compliant Pilot-plant for scale-up
- USFDA/MHRA/AFSAPS/EMEA Approved
- Manufacturing locations across Globe

Capabilities in Analytical Development

- Extensive instrumentation support for development of NCEs and Formulations
- State-of-art instruments such as UPLC, HPLC, GC, NMR, XRD, DSC, LC-MS, GC-MS, FTIR, Malvern Particle Size Analyzer and Dissolution Apparatus
- Skilled and dedicated teams for method development, validation and routine analysis
- Fully function and audited Stability Centre with Walk-in chambers
- Microbiological Testing

Our Global Services



Why Wockhardt? - Your Partner of Choice

- Proven ability to manage long-term supply contracts
- Understand the importance of quality and reliability
- Understand the dynamics of being a service provider
- Ability to manage growth and integrate operations
- Ability to maximise your cost efficiency
- Flexible global operations keep costs highly competitive

From quality-driven processes to proven problem-solving strategies, our end-to-end service is redefining Contract Manufacturing

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