Full- Service CDMO

IDIFARMA *is an independent, privately-owned pharmaceutical CDMO based in Spain and specializing in highly potent drugs.*

With an experienced staff of 100+ people and over 100 international clients, IDIFARMA provides a full range of services covering most of the lifecycle of any pharmaceutical product ***from first pre-formulation trials to commercial manufacturing:*** *drug formulation, development and validation of analytical methods, quality control and batch release in the EU, stability studies, regulatory affairs, GMP contract manufacturing and packaging for clinical or commercial use.*

Its state-of-the-art facility features a purpose-built ***high containment plant for GMP manufacturing of oral solid dosage forms,*** *for both highly potent and non-potent drugs.*

IDIFARMA*'s expertise, capabilities and proven track record make it the perfect partner for the development of your projects.*

IDIFARMA
PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

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INNOVATIVE SME
Valid until Dec 9th 2018

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UNION EUROPEA
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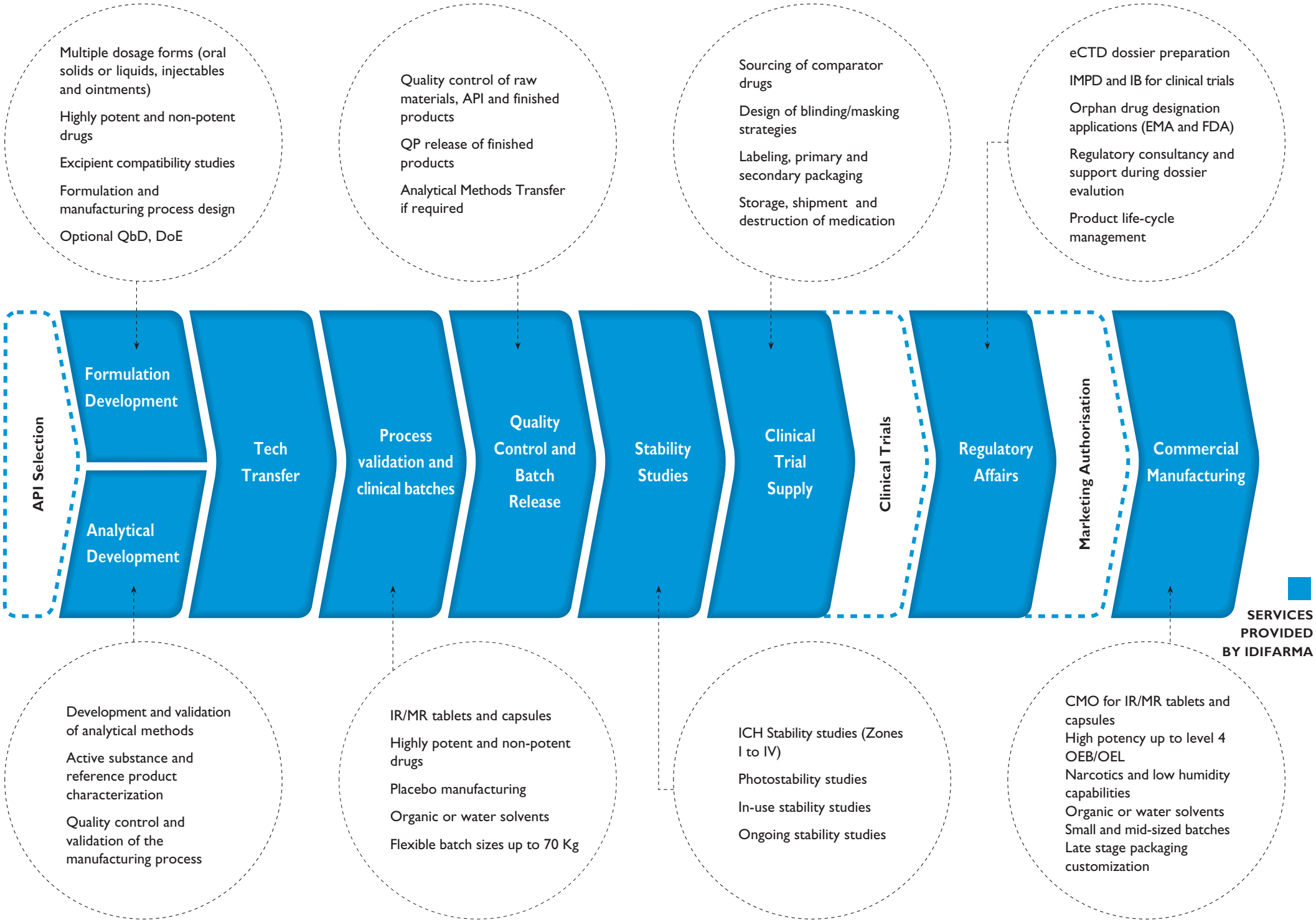
IDIFARMA
PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

Contract Development and Manufacturing

Formulation and Analytical Development
Clinical and Commercial Manufacturing
High Potency Capabilities


Multiple dosage forms (oral solids or liquids, injectables and ointments)
Highly potent and non-potent drugs
Excipient compatibility studies
Formulation and manufacturing process design
Optional QbD, DoE
Quality control of raw materials, API and finished products
QP release of finished products
Analytical Methods Transfer if required
Sourcing of comparator drugs
Design of blinding/masking strategies
Labeling, primary and secondary packaging
Storage, shipment and destruction of medication
eCTD dossier preparation
IMPD and IB for clinical trials
Orphan drug designation applications (EMA and FDA)
Regulatory consultancy and support during dossier evalution
Product life-cycle management
API Selection
Formulation Development
Analytical Development
Tech Transfer
Process validation and clinical batches
Quality Control and Batch Release
Stability Studies
Clinical Trial Supply
Clinical Trials
Regulatory Affairs
Marketing Authorisation
Commercial Manufacturing
SERVICES PROVIDED BY IDIFARMA
Development and validation of analytical methods
Active substance and reference product characterization
Quality control and validation of the manufacturing process
IR/MR tablets and capsules
Highly potent and non-potent drugs
Placebo manufacturing
Organic or water solvents
Flexible batch sizes up to 70 Kg
ICH Stability studies (Zones I to IV)
Photostability studies
In-use stability studies
Ongoing stability studies
CMO for IR/MR tablets and capsules
High potency up to level 4 OEB/OEL
Narcotics and low humidity capabilities
Organic or water solvents
Small and mid-sized batches
Late stage packaging customization