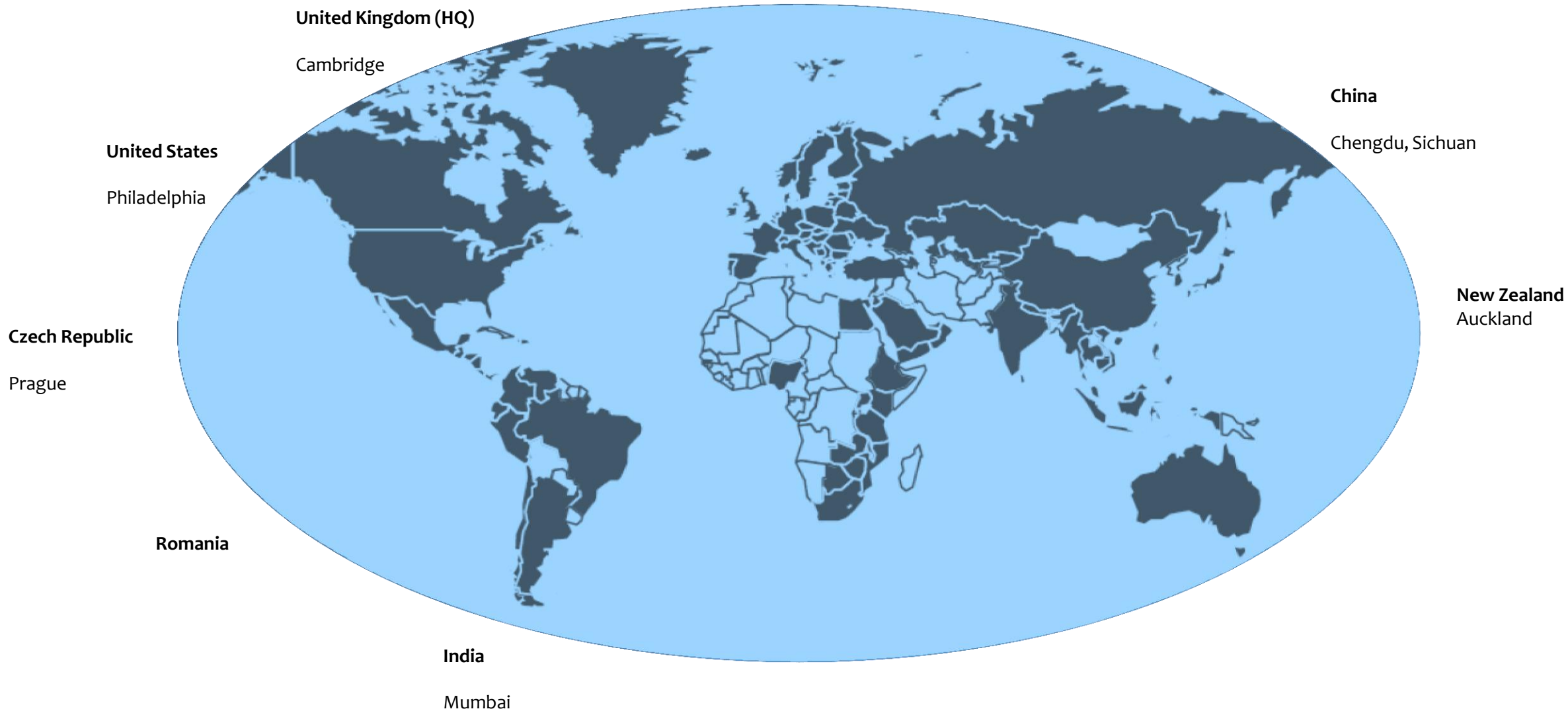
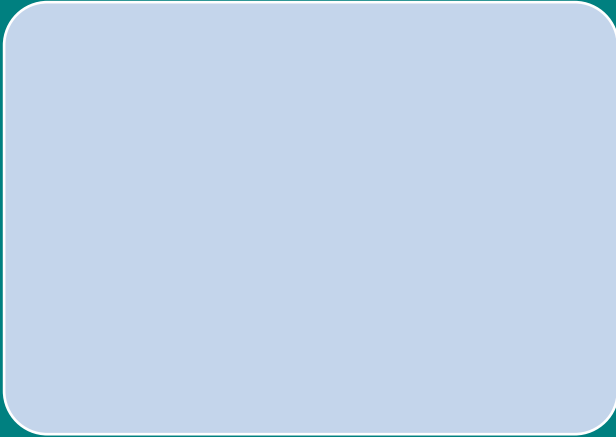


Introduction to NOVOCAT FARMA Formulation Development Services

Our Global Footprint



Research Facilities



NOVOCAT has expanded its R&D capabilities into a 1500 square meter, state-of-the-art lab to meet the increasing formulation and analytical testing demands from its global client pool located at Barcelona



NOVOCAT formulation scientists operate a Good Laboratory Practice (GLP) compliant analytical facility, registered with International Accreditation New Zealand (IANZ), under a co-development agreement with Auckland University I



Product Expertise and Capabilities



SOLID ORAL DOSAGE FORMS

- Tablets & capsules, including modified/delayed/controlled release/ MUPS/ fixed-dose combinations
- Oral disintegrating tablets/films, effervescent tablets



LIQUIDS & SEMI-SOLIDS*

- Liquids, suspensions, syrups
- Powder for oral suspension
- Creams, lotions, gels, ointments
- Ophthalmic drops, Otic/nasal drops



STERILE INJECTABLES*

- Clear injectable solutions
- Pre-filled syringes
- Lyophilized powder for suspension for injection
- Liposomes (Micro and Nano tech)

- QbD Implementation for new product development
- Developing drug products with patent non-infringing drug formulations for US, Europe, Canada, Brazil, South Africa, Australia, WHO-PEPFAR markets.
- End to end product delivery support from product identification to IP evaluation, formulation, scale-up, technology transfer, BE studies, registration, assistance in query response, life cycle management and licensing.

*Through channel partners

R&D Team Head: Profile



R&D expertise

USA	EU	Canada	Australia and Asia-Pacific	Russia/CIS	South Africa
13	29	5	25	17	13

- More than 30 years of experience in heading R & D Teams
- Co-inventor of more than 30 registered patents, and delivered more than 100 products for diverse global markets (see regional distribution below)
- **4 First-to-File (Para IV)** products developed for US Market, involving **3-Platform PCT patents**.
- Expert in QbD development for new products, CRAMs business model and evaluating REMS strategies.
- Involved in globalization of product development by “**bridging/cloning**” to different regulated markets

R&D Team Expertise



Designation	Avg. Experience	No. of Personnel	Qualification	Market Expertise	Dosage Forms Handled	Therapeutic Areas
Technical Team						
Team Leaders Formulation	12-19 years	6	Ph. D / Masters in Pharmacy.	<ul style="list-style-type: none"> ➤ US ➤ Europe ➤ Canada ➤ LATAM ➤ ASEAN ➤ Australia/New Zealand ➤ GCC ➤ Russia/CIS ➤ MENA ➤ WHO-PEPFAR 	<ul style="list-style-type: none"> ➤ Tablets/Capsules <ul style="list-style-type: none"> ▪ Immediate Release ▪ Extended release ▪ Controlled and Delayed release ➤ Oral liquids <ul style="list-style-type: none"> ▪ Solutions ▪ Suspensions ➤ Liposomes ➤ Dermal / transdermal ➤ Emulsions ➤ Depotherapy ➤ Ophthalmic ➤ Injectables 	<p>Anti-Neoplastic (Oncology): Abiraterone, Erlotinib</p> <p>Anti-Hypertensive (Cardiovascular): Atenolol/ Nifedipine ER Tablet in Capsule</p> <p>Immunomodulators (Multiple Sclerosis): Fingolimod, Teriflunomide, Dimethyl Fumarate DR</p> <p>Anti-Coagulants: Dabigatran</p> <p>Metabolic Disorder (Diabetes): Metformin ER, Sitagliptin/Metformin</p> <p>Gastric Acid Secretion Inhibitor: Esomeprazole MUPS Tablets</p> <p>Anti-retroviral: Darunavir, Tenofovir</p> <p>Antidepressants (CNS): Duloxetine DR, Fluoxetine DR</p> <p>Anti-inflammatory/allergy: Ebastin ODT, Fexofenadine/Pseudoephedrine ER, Zileuton ER</p>
Team Leaders Analytical		6				
Senior Managers Formulation	8-12 years	6	Master of Science / Masters in Pharmacy			
Senior Managers Analytical		6				
Junior Scientists Formulation	5-6 years	5	Masters in Pharmacy / Masters in Science / Bachelors in Pharmacy / Bachelors in Science	<ul style="list-style-type: none"> ➤ US ➤ EU ➤ Rest of World 	Immediate and Extended release oral dosage forms	
Junior Scientists Analytical		18				

List of Equipment



Dispensing

- Microbalance and Weighing Balance

Sifting & Milling

- Vibratory Sifter
- Oscillating granulator
- Multimill
- Manual Sifter

Fluid Bed Processing Room

- Laboratory Stirrers
- Magnetic Stirrers with heater
- High Shear Homogenizer
- Hot Plate
- Peristaltic Pump
- Fluid Bed Processor with 6" Wurster
- Tray Dryer
- Planetary Mixer
- Weighing Balance

Granulation Room I & Blending

- Rapid Mix Granulator
- V-Blender (2L, 8L)
- Octagonal Blender

Granulation Room II

- Extruder 60- Spheronizer 250

Compression Room I

- Mini Tablet Presses
- CEMECH R & D Tablet Press
- Dehumidifier
- Weighing Balance

Compression Room II

- Mini Rotary Tableting Bilayer
- Weighing Balance

IPQC Room

- Hardness Tester
- Halogen Moisture Analyzer
- Karl Fischer Titrator
- DT Apparatus
- Tapped Density Tester
- Electromagnetic Sieve Shaker
- Friabilator
- Brookfield Viscometer
- Vernier Caliper
- pH Meter

Liquid Formulation

- Stirrer
- Homogenizer
- SS Jacketed Mixing Tank
- SS Vessels

Packing

- Elmach Blister Packing Machine
- Pouch Sealing Machine
- Leak Test Apparatus

Capsule Filling Room

- MF 30 Deluxe Manual Capsule Filling Machine
- Dehumidifier
- Weighing Balance

Coating Room

- Peristaltic Pump
- Automatic Coating for Tablets
- Stirrer
- Colloidal Mill
- Homogenizer
- Weighing Balance

List of Equipment



Gas Chromatography Room

- Gas Chromatography Assembly

Dissolution Room

- Electrolab Dissolution Tester (3) 8 bowls with Auto sampler
- LabIndia Dissolution Tester (3) 14 bowls with auto sampler

Instrumentation Lab

- pH Meter
- Karl Fischer Titrator
- Melting Point Apparatus
- UV-VIS Spectrophotometer
- UV Cabinet
- Vacuum Oven
- Micro Osmometer

Hot Lab

- Water Batch Temperature Controller
- Wrist Shaker
- Hot Plate
- Hot Air Oven

HPLC Room

- Shimadzu HPLC (16)
- Shimadzu UFLC (1)
- Agilent HPLC (8)

Balance Room

- Analytical Balance
- Micro Balance
- Semi Micro Balance

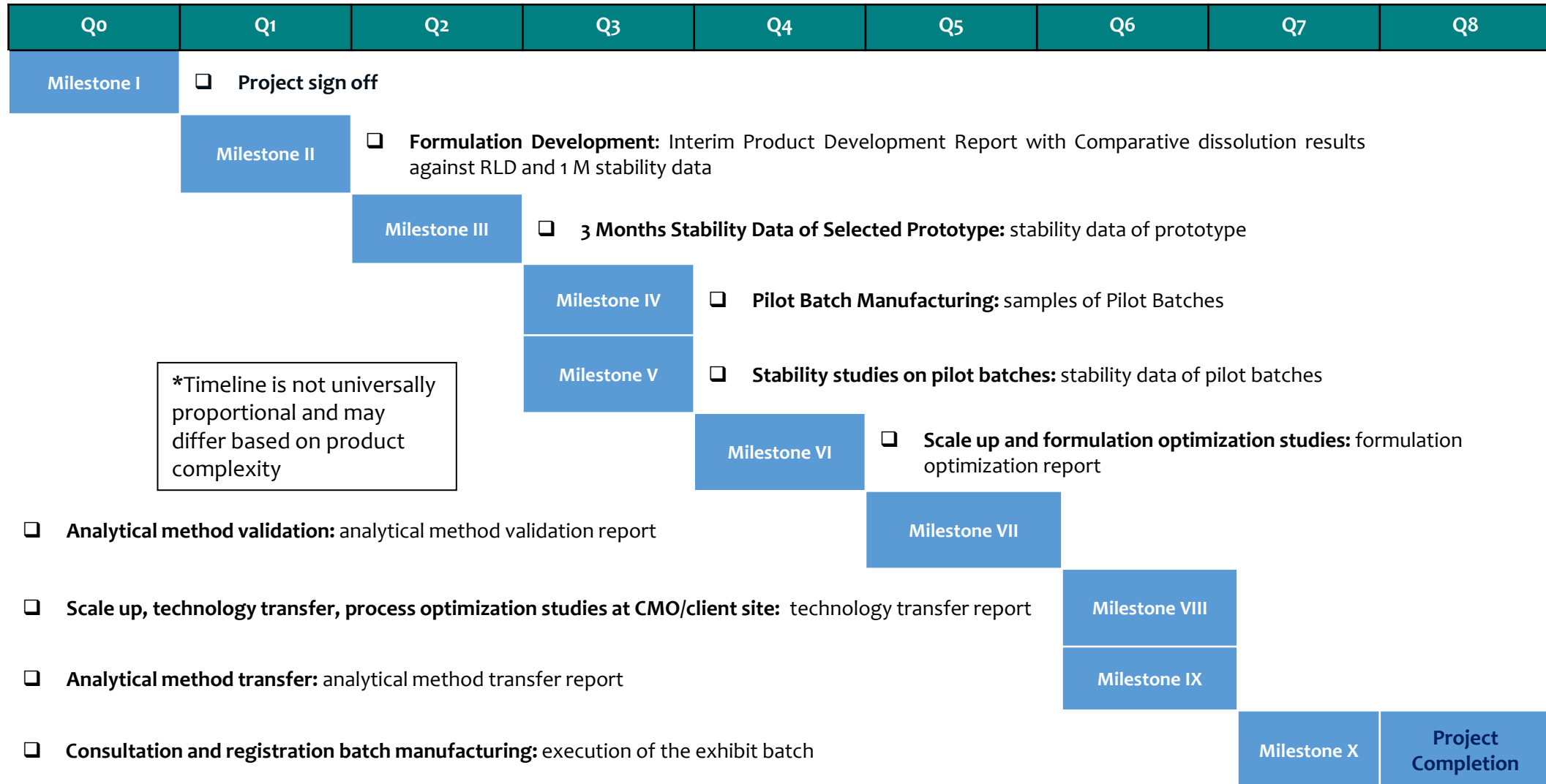
Wet Lab

- Fume Hood Refrigerator
- Cooling Chamber
- pH Meter
- Pure Water System
- Ultrasonic Bath Cleaner
- Centrifuge
- Balance
- Cyclo Mixer
- Orbital Shaker

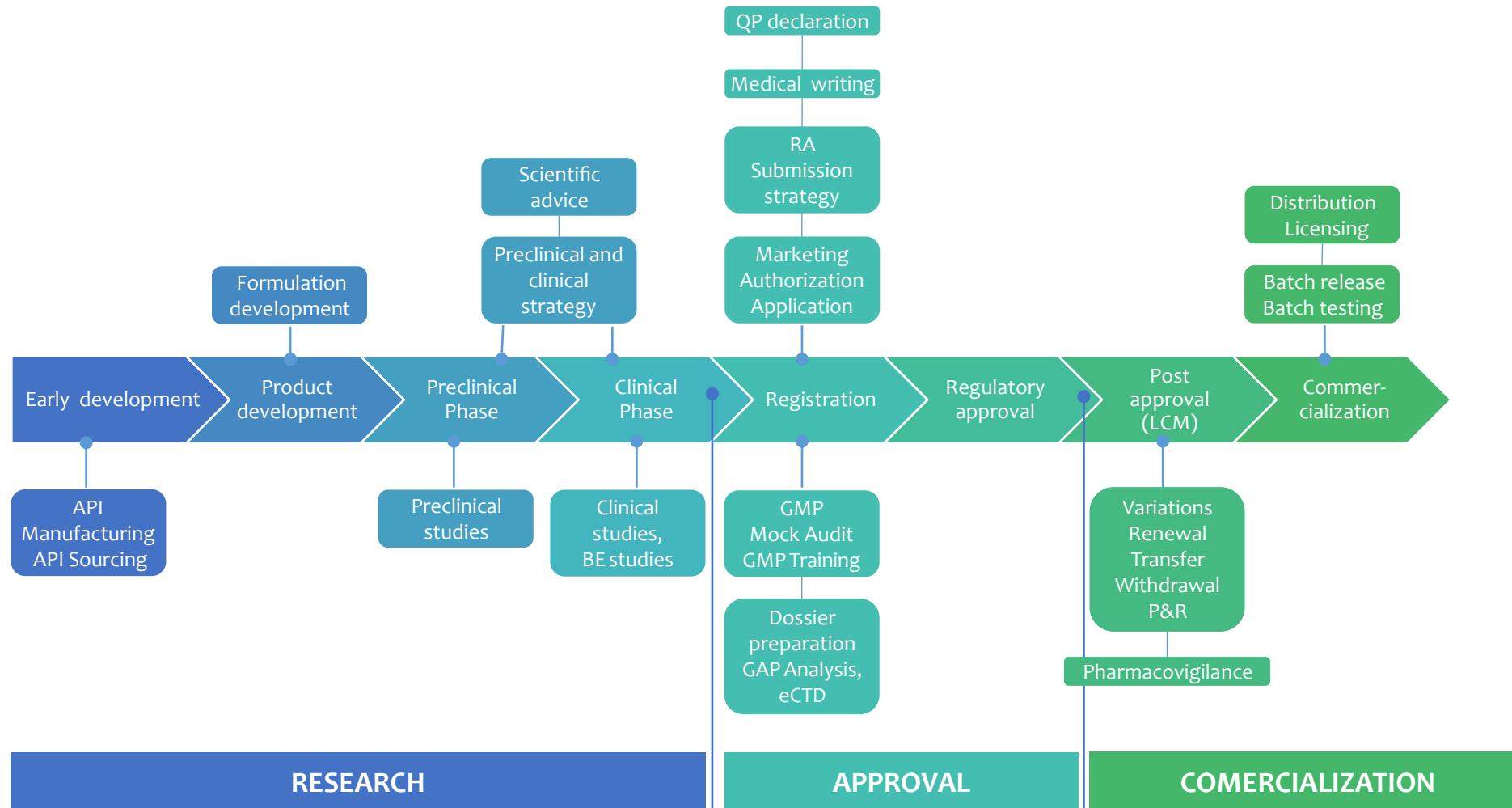
Stability Room

- Stability Chambers for:
 - $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{RH} \pm 5\% \text{RH}$
 - $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{RH} \pm 5\% \text{RH}$
 - $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \text{RH} \pm 5\% \text{RH}$
 - $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \text{RH} \pm 5\% \text{RH}$
 - $2^{\circ}\text{C} \text{ to } 8^{\circ}\text{C}$
- Photo Stability Chamber
- Cold Cabinet

Product Development to Technology Transfer



Full Process Overview



Business Models



- Fee for Service
- Co-Development
- Portfolio Development / Management
- Lab to Market

ELC Product List



- **ELC's current Product Development portfolio:**

Active Ingredient	Dosage Strengths	Pharmaceutical Form	Therapeutic Area
Abiraterone	250mg	Tablet	Oncology
Ticagrelor	60mg, 90mg	Tablet	Cardiovascular
Apixaban	2.5mg, 5mg	Tablet	Cardiovascular
Azilsartan Medoxomil	20mg, 40mg, 80mg	Tablet	Cardiovascular
Sacubitril/ Valsartan	24/26mg, 49/51mg, 97/103mg	Tablet	Cardiovascular
Apremilast	10mg, 20mg, 30mg	Tablet	Immunology
Canagliflozin	100mg, 300mg	Tablet	Metabolic Disorder
Canagliflozin/ Metformin	50/500mg, 50/1000mg, 150/500mg,150/1000mg	Tablet	Metabolic Disorder
Linagliptin/Metformin	2.5mg:1gm, 2.5mg:500mg, 2.5mg:850mg	Tablet	Metabolic Disorder

- **Name your product...**

**THANK YOU
FOR YOUR ATTENTION**