Life Science Road Map – from discovery to approval

Working in partnership with you from early-stage drug discovery to regulatory approval. We'll help you navigate the scientific, technical and regulatory roadblocks to support the delivery of your next-generation therapeutic. With more than 30 years of analytical excellence and cutting-edge technologies, we have the insight, experience and capabilities to support every stage of your journey.

1 EARLY DISCOVERY

- Screening support
- Identification & characterisation
- Formulation screening
- Purification
- Excipient compatibility
- Enantiomeric analysis
- Electrophoresis (gel and capillary)

2 DRUG DEVELOPMENT CHARACTERISATION

- Chemical characterisation full suite (NMR, MS, FTIR)
- Wet chemistry (TOC, UV & Integrated Spheres, HF, Osmometry)
- Physical and structural characterisation (XRPD, Solubility, Bio-availability, Particle sizing)
- Forced degradation
- Upscaled materials testing
- Process validation
- Impurity profile (Process/degradation)
- Method development (chromatography)
- Investigative support and troubleshooting
- Impurity isolation and characterisation & trace analysis
- Creation of reference materials (NMR, MS)
- Elemental analysis (ICP-OES, ICP-MS)

3 MEDICAL DEVICE & PACKAGING

- Medical device testing
- Investigative troubleshooting expertise
- Bespoke extractables and leachables studies (Mass Spectrometry, LC-MS, GC-MS, ICP-MS)
- Dosage uniformity
- Medical device chemical testing to ISO-10993:18
- Sterility testing
- Microbiology analysis
- Integrity
- Syringe functionality
- Container closure testing

4 SAFETY & ICH STABILITY

- Toxicological assessment
- Cleaning validation
- Investigative expertise
- Impurity isolation and characterisation
- Product stability
- Trace analysis
- Formulation design support
- Nitrosamine testing

5 REGULATORY SUBMISSION SUPPORT

- Method development
- Clinical trials support including similar product testing
- Validation for submission support
- Raw materials testing
- Packaging, extractables and leachables (ISO 10993:18)
- Pharmacopeial testing (EP, USP, JP, CP, ICH Q6B)
- Dissolution testing
- Support with CMC strategy
- Priority Response Service

For more details please contact RSSL
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