

Animal Health services

Enabling safe, cost-effective products – molecule to market

Ecosystem of service offerings for Animal Health – Discovery to Manufacturing



Discovery

- Assay biology
- ADME & PK
- Protein sciences
- Antibody discovery
- Cell line engineering
- Genomics and translational biology
- Mechanistic hepatotoxicity prediction
- NGS and multi-omics analysis
- **Target dossiers**
- Systems modelling (QSP)
- Drug repurposing
- Synthetic chemistry
- Library synthesis
- Peptide synthesis
- Medicinal chemistry
- Nucleoside and carbohydrates



Development

- Route scouting
- Salt and polymorph screening
- Process design, optimization and development
- Process engineering data generation
- Analytical development
- Process hazard analysis
- Stability studies and regulatory support
- Central laboratory services encompassing clinical/safety lab
- Bioanalytical services for biologics
- ICH stability studies
- Statistical analysis, bracketing and matrix approach
- Commercial stability studies
- Development microbial and mammalian expression systems
- Manufacturing process characterization
- Tox to clinical supply
- Large-scale cGMP manufacturing 100L, 500L and 2000L (single use)
- Material supply for commercialization
- Virus clearance studies

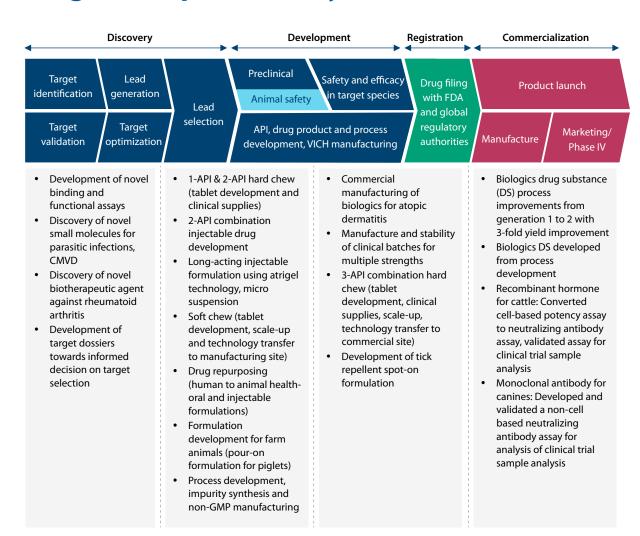


Manufacturing

- Pre-formulation and preclinical development
- Formulation development (chewable tablets, spot-on and pour-on)
- **Enabling formulation approaches** (SDD, HME)
- Injectable product development (RTU, Iyo, nano suspensions/emulsions, extended release depot)
- Analytical method development and validation
- Scale-up and technology transfer
- Registration batches
- Small-scale supply of API and intermediates for preclinical
- Tox to clinical supply large-scale cGMP manufacturing through dedicated model or external partner
- External partner identification based on capabilities (cryogenic, hydrogenation, cvanation etc.)
- Material supply for commercialization
- Vertical integration of supply chain



Programs executed across Animal Health drug development lifecycle





Syngene can be a strategic partner for your requirements across Small Molecules, Biologics

Small Molecules



Chemical Development

- Development of APIs (all classes except antibodies and steroids)
- Commercial manufacturing and supplies



Formulation Development

- Development of different dosage forms, clinical supplies
- Product life cycle management support (API, formulation, packaging & regulatory changes and compliance)
- Commercial manufacturing



Analytical & Stability Testing

- Commercial Center of Excellence
- Analytical testing services

Biologics

Development & Manufacturing



- DS development and manufacturing
- Formulation development, process characterization studies. advanced protein characterization, clinical & commercial manufacturing, bulk harvest testing, virus clearance studies, stability studies

Bioanalytical Service



- Immunoassay development and validation for pharmacokinetics, pharmacodynamics, biomarkers and immunogenicity
- Cell-based potency assay development and validation
- Analysis of trial samples as per GLP/GCLP, USFDA/EMA guidelines

To learn more about our Animal Health services, contact our team









About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2.2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA.

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com







