

RCS's capabilities include...

New Animal Drugs

- All facets of phase-filing new animal drug applications including NADAs, generic NADAs, and Minor Use, Minor Species (MUMS) applications
 - Regulatory strategy
 - Electronic submissions
 - Liaison to the FDA's Center for Veterinary Medicine (FDA-CVM)
 - Protocol development, review and submission
 - Manage CVM pre-submission conferences
 - Study report review and submission
 - Major and minor technical sections
 - Draft technical documents
 - Draft labeling and FOI Summaries
 - Compile and submit Chemistry, Manufacturing and Controls (CMC) section
 - Minor Use, Minor Species determinations
 - Generic New Animal Drug Applications
 - New Animal Drug Applications
 - Drafting SOPs



EPA Pesticide Products

- All facets of pesticide registration
 - Technical Grade Active Ingredient (TGAI) and end-use product registration
 - Liaison to the US EPA
 - Review, draft, compile and submit applications for new active ingredients or new end-use products
 - Protocol review
 - Regulatory strategy
 - Manage EPA pre-development conferences
 - State registrations
 - Labeling review
 - Compliance issues
 - Waiver requests
 - Amendments, Notifications and non-Notifications
 - Adverse Event (AE) reporting
 - Drafting SOPs
 - Child-resistant and senior use effectiveness testing

