knoell
worldwide registration

THINK GLOBALLY, ACT LOCALLY

# TECHNICAL WRITING & QUALITY ASSURANCE

## Technical Writing

Focus on product-specific content and save time – we ensure consistent documentation for your submissions.

### Transform study data into submission-ready reports

- Expertise across study types, such as field soil dissipation and magnitude of residue
- Skill with new or unusual projects, such as pollen and nectar reports
- Proficiency with analytical reports, including ILV, method validation, COA, and residue, backed by laboratory experience
- Track record for effective collaboration with study directors from protocol preparation to report finalization

### Summarize data to meet regulatory requirements

- Capability with OECD summaries for study reports and journal articles in all areas (e.g., methods, mammalian toxicology, metabolism, ecotoxicology, E-fate, etc.)
- Experience developing OECD summary templates or working with client-customized templates
- Generation of new residue trial summary spreadsheets per JMPR or EFSA guidance
- Production of field trial efficacy summary reports
- Track record of effective collaboration with study directors from protocol preparation to report finalization

### Leverage experience to efficiently compile submission documents

- JMPRs & US and Canadian tolerance petitions
- EU dossier documents (e.g., SANCO, Annex I renewals, etc.)
- Tier I residue tables & GAP tables
- Inert ingredient submissions

### Provide quality control

- Reviewing, formatting, and copyediting documents for consistency
- Adjusting grammar, word choice, and flow for readability, particularly for translated documents
- Formatting issued reports to meet PRN 2011-3 and electronic submission requirements for submission to EPA

## Quality Assurance

Take advantage of our expertise in US EPA GLPs, US FDA GLPs, and OECD GLP principles – in person and remotely (eQA).

### Support studies

- Perform protocol, conduct/in-phase, raw data, and report audits
- Coordinate and review field audits and associated QA statements
- Areas of expertise include: storage stability, analytical chemistry, sample processing, method validations, instrument validations, magnitude of residue, field soil dissipation

### Ensure compliance

- Develop and implement GLP documentation
- Prepare and review SOPs & establish audit schedules
- Design GLP training and produce training documents
- Other support
- Perform facility audits
- Maintain archives
- Examine and evaluate QA systems, procedures, and policies
- Consult on concerns regarding GLP compliance
- Provide support for agency audits and inspections

### knoell as your go-to partner for registration - worldwide

Founded in 1996, knoell is a leading provider of global regulatory services. Our strength is to be where it matters: with sites in Europe, Asia and North America and an extensive network of co-operation partners, we combine global know-how with local experience and intercultural competence. For further information on our services, please contact us:

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