A Sponsors Perspective on Research in the Global Marketplace

... it’s not just about geography
Expanding Marketplace

- Chemistry
  - New Actives
  - New Formulations
  - New Mixtures
  - Globalization of Registrations

- Biotechnology
  - New Input Traits
  - Multiple Stacks
  - Increased Global Acceptance
  - No Clear Guidelines
Motivation for Globalization

- Traditional registration activities were driven at a country by country level.
  - Guidelines varied by registration authority
  - Data from one country often differed with data from another country
  - Differences in statistical interpretation of data
  - Duplication of effort (same data generated for different countries)
  - More countries were starting to require data.
- The global food community can no longer handle these variances... change had to occur.
Change Has Occurred

- Over the past decade, many lab based studies have been transitioned to a globally acceptable format.
- Over the past five years, regulatory agencies have been increasingly open to global residue data packages.
  - Mutual Acceptance of Data
  - Harmonized Review
  - Overall Reduction in the Number of Trials Required
  - Broader Global Registrations
  - Streamlined Import Tolerances leveraging on global data
- To date, these have been approved on a case-by-case basis.
Outline

• Sponsor Benefits to Globalization
• Evolving Regulatory Perspective
• Harmonization of Guidelines
• Impact on NA Field Research Community
Sponsor Benefits to Globalization

- **Simplification**
  - Historical guidelines have a wide range of guideline requirements.
    - Number of Sites – Range from 1-20 per regulatory authority
    - Matrices Collected – Not consistent from one guideline to the next
    - Crop Groups – 12-33
    - Geographical Regions – Vary wildly depending on guideline
    - GLP Compliance – Required only in NA, EU, Brazil & Australia
    - Analytical Data – Corrected vs. Uncorrected
    - Interpretation of Results – Statistics Allowed or Required for MRL calculation Vary Wildly
Sponsor Benefits to Globalization

• Minimize Number and Globalize GAPs
  – The opportunity for a streamlined registration of limited formulations and use patterns discourages country by country use patterns.

• Reduce Import/Export Issues
  – Harmonized MRL would minimize restrictions

• Mutual Acceptance of Data
  – Potential to submit a global package for one review
    • Minimize report writing
    • Minimize data review
    • Minimize variations in interpretation of data
Evolving Regulatory Perspective

- Agencies are finding value in harmonization
  - Major Agencies Requiring MOR Data Are:
    - NA (EPA/PMRA/NAFTA)
    - EU (91/414)
    - Australia (APVMA)
    - Brazil (ANVISA)
    - Japan (MHLV)
    - China (MoA-ICAMA)
Evolving Regulatory Perspective (Continued)

• Regulatory Agencies Have Become Receptive to Mutual Review/Acceptance of Data Base on:
  – Work Sharing
  – Efficiency
  – Robust Data Package
  – Consistent Global Decisions
  – Harmonized MRL’s
Harmonized Guidelines

- Due to changing sponsor and regulatory perspectives, significant progress has been made in guideline harmonization
  - OECD 509 Guideline – Crop Field Trials
    - US-EPA co-authored and accepts this guideline
    - Harmonized provisions to conduct field studies, declines, and sampling regiments.
    - Changes in bridging programs, sampling, number of trials.
      - 40% reduction for comprehensive/global submissions
      - Global geographical representation of trials by crop
Impact on the NA Field Research Community

• Globalization is happening and will lead to:
  – Fewer studies per crop per site, more global locations
  – More crops and crop groups
  – A higher percent of ‘advanced’ MOR trials
    • Decline and/or reverse decline
    • Processing
    • Multiple rates, formulations, and mixtures
Impact on the NA Field Research Community

- Competitive Advantages for companies that
  - Can offer research at multiple sites and on a broad range of crops
  - Demonstrate familiarity with new/global guidelines
  - Can offer research pan-American and pan-Global
    - Consistent notebooks, field notebooks
    - Protocols
    - SOPs
    - Reports
    - Global GLP credentials
  - Can offer both study direction and field performance
  - Can offer laboratory services
Questions?