

# 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 required 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?

