Good Laboratory Practices — Why all the fuss?

Ray McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America

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What is CropLife America?

- National trade association representing the crop protection industry in the U.S.
- About 90 members – manufacturers, formulators, distributors, service companies
- Focus on crop protection products
- Advocate legislation, regulation, science, & communications in support of the industry
- Members include the major sponsoring companies for GLP studies

Why GLP?

- Credibility of pesticide regulatory system
- “Trust us,” isn’t good enough
- Sound support for risk assessment decisions by Office of Pesticide Programs
- Reassuring the public that “someone is watching”
- Portability of pesticide registration packages, country to country

GLPS Regulation - 40 CFR Part 160

Scope & Applicability

§160.1(a) … This part is intended to assure the quality and integrity of data submitted pursuant to [FIFRA and FFDCA] …

Inspection of a Testing Facility

§160.15(a) A testing facility shall permit an authorized employee or duly designated representative of EPA … to inspect the facility and …all records … required to be maintained regarding studies to which this part applies.….

OECD – GLP – MAD

- Organization for Economic Cooperation and Development: 30+ “developed” member countries; establishes international standards for government programs.
- Robust program dealing with Good Laboratory Practices.
- Agreement on Mutual Acceptance of Data, sets stage for members to accept with confidence studies conducted in other member countries.
- History: 1989, 1995, 1997

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Mutual Acceptance of Data

OECD Member countries shall:

- Monitor compliance with GLP Principles, based on laboratory inspections and study audits;
- Designate an authority to monitor compliance; and
- Require the management of test facilities to declare that a study was carried out in accordance with GLP Principles.

Mutual Acceptance of Data

- Member countries shall recognise the assurance by another Member country that test data have been generated in accordance with GLP Principles if such other Member country complies with [MAD provisions]
- National GLP Compliance Programme should be the responsibility of a properly constituted, legally identifiable body adequately staffed and working within a defined administrative framework.

Mutual Acceptance of Data

Ensure adequate number of Inspectors, depending on:

- number of test facilities
- frequency of assessing facilities
- number and complexity of studies
- special inspections or audits requested by Regulatory Authorities

Mutual Acceptance of Data

- A mechanism should be available whereby test facilities may have their compliance with GLP Principles monitored by the appropriate (National) GLP Monitoring Authority.
- …the area(s) of expertise of the test facilities inspected should be included in the annual overviews, using eight broad categories: [Toxicity, Environmental fate, Residue chemistry, etc.]

How do others address MAD?

- Facilities are accredited or certified for GLP work to conduct specific types of studies.
- Accredited facilities are typically listed publicly by the government agency
- A new facility may request a prequalification inspection for accreditation.
- Inspections for recertification are scheduled on a 2- to 4-year basis.
- Facilities bear the cost of the inspection and audit.

Who administers GLP inspections?

- Australia: National Association of Testing Authorities; (industry, government and professional bodies)
- Japan: Agricultural Chemicals Inspection Station
- Canada: Standards Council of Canada; (government and private sector)
- USA: EPA, Office of Enforcement and Compliance Assurance; (government only)

USA

- No mechanism of entry for new test facilities, except submission of GLP studies
- Audits and inspections scheduled at EPA's discretion: how are decisions made?
- ~1400 test facilities in the country
- 50 to 80 facilities audited/inspected each year
- Perceived inconsistencies in scheduling
- No cost to facility or sponsor for audit and inspection

Sponsoring companies

- Conduct prequalifying and periodic audits and inspections of all facilities they employ.
- Scheduled based on sound business principles:
  - Sponsor's experience with individual facilities;
  - Types & number of studies each facility conducts;
  - Record of performance.
- High level of expertise; often more rigorous than EPA's inspections.
- Individual facility is subject to audit & inspection by all its sponsor/clients.

USA – next steps

- Bolster GLP audit/inspection system to:
  - Meet expectations of OECD partners;
  - Establish sound financial footing, protected from budget uncertainties;
  - Maintain solid support for US registrations;
  - Foster a robust and vibrant CRO industry.
- Who can be a “duly designated representative of EPA”, to conduct audits and inspections?
- How can we harness the tremendous expertise and resource now invested in audits and inspections?

USA – Next Steps

- What lessons can we learn from –
  - International partners – OECD member countries
  - Comparable programs in other government agencies
  - Private programs
- What does a viable economic model look like?
  - Risk-based scheduling of audits/inspections;
  - What are costs born by sponsors, CROs, others?
  - Who organizes and administers a program?
  - How are costs assessed, shared, paid?
- How does a new facility break into the business?

USA – Next Steps

- What legislative and regulatory amendments might be needed?
- Who are the partners to plan and participate in these next steps? What is the role of each?
- How do we guard against excesses, biases, and deficiencies in implementing next steps?

More information

Ray McAllister, Ph.D.
Senior Director, Regulatory Policy
Phone: 202.872.3874
rmcallister@croplifeamerica.org

Barb Glenn, Ph.D.
Senior VP, Science & Reg. Affairs
Phone: 202.833 4474
bglenn@croplifeamerica.org

www.twitter.com/croplifeamerica

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