Pacific Rim GLP Consulting and Training

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2/6/20

Housekeeping Issues, etc.

- Welcome
- Turn off (or silent) cell phones and pagers
- No texting
- Restrooms
- Informal, ask questions
- Breaks
- Lunch
- Evaluations
- Introductions

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Debi Garvin – MS, RQAP-GLP

- MS from NM State in population genetics
- In QA probably too long
- Initially PRI, then ABC and Pan-Ag, FDA, pharma
- Independent 1992-2015
- FDA 2015-2017
- RQAP-GLP
- Active in SQA (past pres)
- Farmer at heart!!

Cabernet's Pinot Blanc 1999 National Champion

Garrett Garvin with Oregon State Fair Champion Market Goat 2006

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Why is Compliance so Critical???

- Regulators decision to approve pesticides and establish tolerances and PHIs is dependent on our data
- Every "blip" in the data reduces the confidence in the data
- Forgetting to document indicates personnel are overworked which compromises data integrity.
- Numerous "mistakes" indicates that personnel are either overworked, incompetent, or not adequately trained
- At times the raw data may be sent to the reviewers
- If persons working on studies do not understand the critical nature of what they do, then confidence is lost in the overall study and the outcomes

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Nutshell

- GLPs are minimum standards to assure that data and studies are transparent, fully reported, of scientific integrity, and would hold up in a court of law if needed.

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Kennedy Hearings

- The issues raised in July are at the very heart of the regulatory process. Although judgments in that process may reasonably differ, all judgments are made from the same foundation—scientific data.
- If the integrity of that data is questioned, then the whole regulatory process is questioned. If the data are proven false and misleading, then the regulatory decisions may be tragically wrong. Accurate science is the best protection the American people have from an unsafe and ineffective drug supply.

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HISTORY

- 1978 - Original FDA regulations
- 1982 - OECD GLPs first published
- 1982 - UK GLPs published
- 1982 -Japanese GLPs published
- 1983 - Original EPA regulations
- 1986 - Revised FDA regulations
- 1989 - Revised EPA regulations
  - Broaden scope
- 1998- OECD GLPs revised/PMRA adopted GLPs
- OECD Application of GLPs to Field Studies
- 2002 – OECD Consensus document on multi-site studies

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