VAXESS

technologies

Building Quality Assurance for Investigational Studies

GLPs, GMPs and GCPs

- ✓ 21 CFR 11, Electronic Records; Signatures
- ✓ 21 CFR 50, Protection of Human Subjects
- ✓ 21 CFR 54, Financial Disclosure
- ✓ 21 CFR 56, Investigational Review Boards
- ✓ 21 CFR 58, GLP for Nonclinical Laboratory Studies
- ✓ 21 CFR 210, cGMP in Manufacturing, Processing, Packing, or Holding of Drugs
- ✓ 21 CFR 211, cGMP for Finished Pharmaceuticals
- ✓ 21 CFR 312, Investigational New Drug Application
- ✓ 21 CFR 314, Applications for FDA Approval to Market a New Drug

GLPs, GMPs and GCPs (continued)

- ✓ 21 CFR 320, Bioavailability and Bioequivalence Requirements
- ✓ 21 CFR 511, New Animal Drugs for Investigational Use
- ✓ 21 CFR 514, New Animal Drug Application
- ✓ 21 CFR 820, Quality System Regulation
- ✓ 21 CFR 600, Biological Products: General
- ✓ 21CFR 601, Applications for FDA Approval of a Biological License
- ✓ 21 CFR 812, Investigational Device Exemptions
- ✓ 21 CFR 814, Premarket Approval of Medical Devices

Quality Assurance Objectives (Commercial)

- ✓ Ensure Product Quality and Safety
- ✓ Avoid Negative Publicity
- ✓ Improve Efficiency
- ✓ Guarantee Compliance

Quality Assurance Objectives (Investigational)

- ✓ Risk Management
- ✓ Establish Process Design
- ✓ Establish Design Control, to Ensure Product Quality & Safety
- ✓ Avoid Negative Publicity
- ✓ Improve Efficiency
- ✓ Pursue and Establish Compliance
- ✓ Satisfy Regulatory Requirements for Commercial

cGMPs – Commercial

- ✓ 21 CFR 820, Quality System Regulation
- ✓ 21 CFR 600, Biological Products: General
- ✓ 21 CFR 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
- ✓ 21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals

cGMPs – Investigational

- ✓ 21 CFR 820, Quality System Regulation
- ✓ 21 CFR 600, Biological Products: General
- ~~✓ 21 CFR 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General~~
- ~~✓ 21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals~~

Guidance for Industry, cGMP for Phase 1 Investigational Drugs

Guidance for Industry, INDs for Phase 2 and Phase 3 Studies – Chemistry, Manufacturing and Controls Information

Attack Strategy

Get “Control” of

- ✓ Documentation and Data
- ✓ Materials and Supplies
- ✓ Equipment and Facilities

Document Control

- ✓ Standard Operating Procedures
- ✓ Specifications
- ✓ Analytical Procedures
- ✓ Batch Records
- ✓ Stability Protocols
- ✓ Data

Materials Management

- ✓ Shipping & Receiving
- ✓ Release/Reject Program
- ✓ Segregation
- ✓ Appropriate Storage Conditions
- ✓ Inventory
- ✓ Packaging and Labeling

Metrology

- ✓ Design an Asset Resource
- ✓ Determine Calibration and Preventative Maintenance Needs
- ✓ Establish Frequency for Calibration and Preventative Maintenance
- ✓ Scheduling

Keys to a Sound Quality System Investigational Program

- ✓ Communication
- ✓ Transparency
- ✓ Redundancy
- ✓ Organization
- ✓ Interpret and Adapt
- ✓ Practicality

Questions?