CSV Audit Checklist

- Risk
  - Defining the System
    - Development
      - COTS
      - Customized
      - Homegrown
      - SourceCode
        - Access or Escrow
        - Storage
        - Versioning
      - Development With the System
    - Regulated Activities
      - Predicate Rules
        - Explicitly Regulated
        - Implicitly Regulated
      - Part 11eReS
        - Created
        - Modified
        - Maintained
        - Archived
        - Retreived
        - Transmitted
        - (but not paper records transmitted electronically)
        - HA Notified of eReS Use?
    - Assess what is the system "really" doing
      - Safety Data
      - Submissions Data
      - GxP Decision Making
      - "Convenience, but we rely on the paper?"
      - What is required for paper records?
    - Data Transfers
      - Security
      - Privacy
- Mitigation
  - Robust Processes & Procedures
  - eData Integrity
    - Audit Trail
      - ALCOA
      - Original Preserved
      - What Changed
      - When did it change
      - Who did it?
      - Why did it change?
    - Validation
      - Owned by Business not IT
      - Infrastructure
      - Application
      - Database or Business Level (Instance)
      - Study/Project Specific
      - GDP
        - Format
        - Execution
      - Maintenance
        - System/Equipment Maintenance
        - Validation Maintenance
          - Change Control
          - Periodic Assessment
      - Facility
        - Server Room
        - Electrical Stability
        - Redundancy for Criticals
        - Environmental
          - Controls
          - Monitoring
          - Records
        - Fire/Water Protection
      - Security
        - Physical Security
          - "Locks"
          - Process
          - Ways to Bypass
        - Logical Security
          - Passwords
          - Firewalls
          - Anti-virus
          - Separation between Critical and High Risk Systems
    - Encryption
      - Local Encryption
      - Transfer Encryption
    - Disaster Recovery/Business Continuity Plan
      - Ask for both DRP and BCP
      - Tested?
      - Effective
      - Process
      - Procedures
      - Global, Local, or BOTH?
      - Training
    - Procedures & Training
      - General
        - Matrix
        - CV/Resume'
        - Training Records
      - System Specific
      - Project Specific