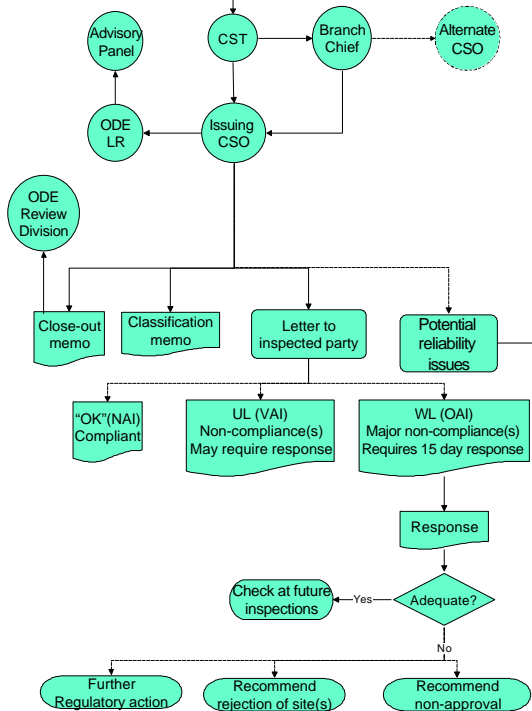
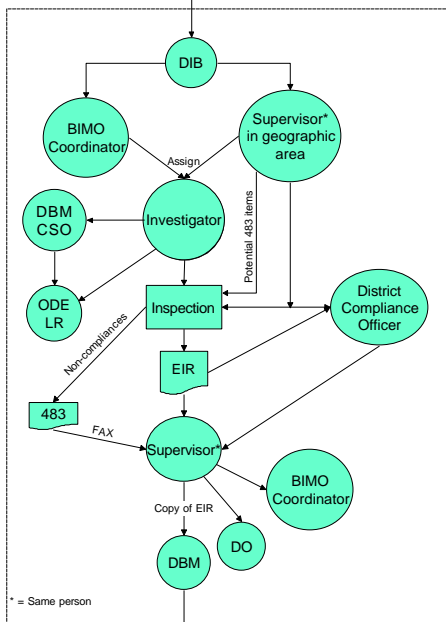
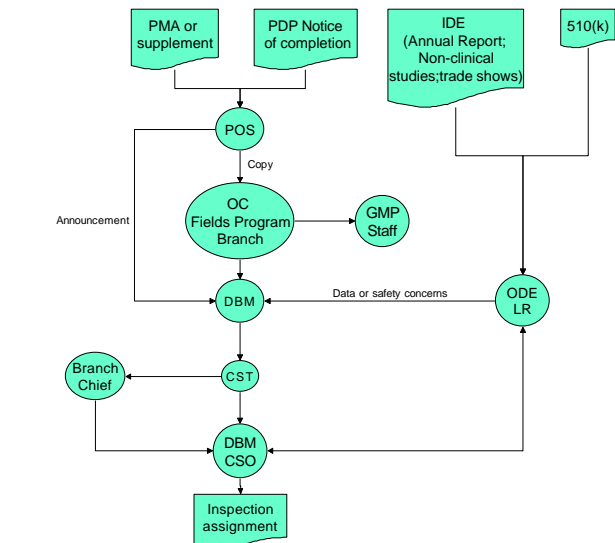


Division of Bioresearch Monitoring Process Flowchart



KEY

- 483 - form FDA 483 - list of noncompliances left with inspected party
- 510(k) - submission for clearance as substantially equivalent
- AIP - Application Integrity Policy
- BIMO - Bioresearch Monitoring
- CAP - Corrective Action Plan
- CSO - Consumer Safety Officer
- CST - Consumer Safety Technician
- DBM - Division of Bioresearch Monitoring
- DIB - Director of Investigations Branch
- DO - District Office
- EIR - Establishment Inspection Report
- GMP - Good Manufacturing Practices
- IDE - Investigational Device Exemption
- LR - Lead Reviewer
- NAI - no action indicated
- OAI - official action indicated
- OC - Office of Compliance
- OCI - Office of Criminal Investigation
- ODE - Office of Device Evaluation
- OIA - Office of Internal Affairs
- PAP - Promotion and Advertising Policy
- PMA - Premarket Approval
- PDP - Product Development Protocol
- POS - Program Operations Staff
- SOP - Standard Operating Procedure
- UL - Untitled Letter
- VAI - voluntary action indicated
- WL - Warning Letter

