FDA Inspection: Preparedness Checklist

4 Jan 2023 / Pines Manufacturing / Mike Chadwick

Complete

Score	95 / 105 (90.48%)	Flagged items	10	Actions	0

Company / Facility	Pines Manufacturing
Conducted on	4 Jan 2023 15:24 PST
Prepared by	Mike Chadwick
Location	6402 Torreyanna Cir, Carlsbad, CA 92011, USA (33.1176824, -117.3022493)

Flagged items

10 flagged

Site Preparation for FDA Inspection / Administrative

Administration

To Do

Will send final email blast after 5pm.

Site Preparation for FDA Inspection / Administrative

Reception Area Staff

To Do

We have a new receptionist that we need to remind about the FDA Inspection.

Site Preparation for FDA Inspection / Regulatory

Signature log (list of key site personnel and corresponding signatures; current and signed) (may be combined with the delegation log)

To Do

Need to check this with Marianne later.

Site Preparation for FDA Inspection / Regulatory

Master Subject Log (list of all subjects including name, contact information, enrollment and completion dates)

To Do

Site Preparation for FDA Inspection / Regulatory

Screening Log (names of all participants screened including enrollment date and reason for screen failure if applicable; ensure log is current and legible)

To Do

Site Preparation for FDA Inspection / Regulatory

Documentation of staff protocol training

To Do

Will work on this with Marianne.

Site Preparation for FDA Inspection / Regulatory

Documentation of additional staff training (if applicable)

To Do

Site Preparation for FDA Inspection / Regulatory

Signed and dated monitoring visit log

To Do

Site Preparation for FDA Inspection / Regulatory

All monitoring pre-visit letters and monitoring reports

To Do

Will double check.

Site Preparation for FDA Inspection / Laboratory

Temperature logs for applicable equipment (refrigerators, freezers, storage cabinets, etc.)

To Do

Will get a copy.

Site Preparation for FDA Inspection	10 flagged, 95 / 105 (90.48%)
Administrative	2 flagged, 18 / 20 (90%)

Notify all parties of impending inspection

Sponsor	Done
IRB/EC	Done
Principal Investigator	Done
Sub-Investigator(s)	Done
Study Coordinator(s)	Done
Pharmacy	Done
Laboratory(ies)	Done
Medical Records	Done
Administration	To Do

Will send final email blast after 5pm.

Legal Counsel	Done
Reception Area Staff	To Do

We have a new receptionist that we need to remind about the FDA Inspection.

Review FDA Inspection Preparation SOP

FDA Inspection Preparation SOP	Done

Identify work space for the Inspector

Work space	Done
Telephone	Done
Copier	Done
Table	Done

Review staff and clinic schedules

Review staff schedules (vacations, appointments, miscellaneous time off, etc.) to ensure staff availability	Done
Reschedule non-essential visits/meetings if possible	Done

Clinic Equipment

Ensure temperature logs for applicable clinic equipment are complete and current (refrigerators, freezers, storage cabinets, etc.)	Done
Ensure equipment maintenance and calibration records are available and current (e.g. electronic scales, electronic blood pressure cuff, etc.) (if applicable)	Done

Regulatory — 7 flagged, 29 / 36 (80.56%)

Locate, compile, organize, and review documents for accuracy and completeness

List of Principal Investigator's current active protocols	Done
Delegation log (list of personnel and delegated study responsibilities; current and signed)	Done
Signature log (list of key site personnel and corresponding signatures; current and signed) (may be combined with the delegation log)	To Do

Need to check this with Marianne later.

Master Subject Log (list of all subjects including name, contact information, enrollment and completion dates)	To Do
Screening Log (names of all participants screened including enrollment date and reason for screen failure if applicable; ensure log is current and legible)	To Do
Enrollment Log (if applicable)	Done
Randomization Log (if applicable)	Done
Protocol (all versions)	Done
Protocol amendments and clarification memorandums	Done
IRB/EC approved Informed Consent Forms (all versions including screening consent forms)	Done
Investigator's Brochure(s) and/or Package Insert(s) (all versions)	Done

IRB/EC initial protocol approval letter	Done
IRB/EC protocol amendment(s) approval letter(s)	Done
IRB/EC continuing review approval letters	Done
IRB/EC approval letter(s) for revised Informed Consent Forms	Done
IRB/EC approval letter(s) for subject recruitment materials (advertisements, videos, handouts to participants, etc.)	Done
Evidence of EAE submission to the IRB/EC/sponsor	Done
Evidence of identification and reporting of protocol violations/deviations to the IRB/EC/sponsor per IRB/EC and protocol requirements	Done
IND Safety Reports/Memos and evidence of submission to the IRB/EC	Done
DSMB summary report(s) and documentation of submission to the IRB/EC	Done
Documentation of protocol registration submission, approval, activation, and deregistration (if applicable)	Done
All correspondence to and from the IRB/EC pertinent to the study	Done
All sponsor correspondence	Done
Any other correspondence pertinent to the study (e.g. protocol team)	Done
Form FDA 1572 (all versions)	Done
Financial Disclosure Forms (Principal Investigator and Sub-Investigators listed on the Form FDA 1572	Done
CVs (Principal Investigator, Sub-Investigators, and other key staff members; current and signed)	Done
Licenses (Principal Investigator, Sub-Investigators, and other key staff members)	Done
Good Clinical Practice/ Human Subjects Protection training documentation for individuals listed on the Form FDA 1572 and any clinical research site personnel who have more than minimal involvement with the conduct of the research	Done

Documentation of staff protocol training	To Do
Will work on this with Marianne.	
Documentation of additional staff training (if applicable)	To Do
Study recruitment and retention plan	Done
Site Standard Operating Procedures	Done
Signed and dated monitoring visit log	To Do
Annual CQMP Summary Review submitted to Sponsor.	Done
All monitoring pre-visit letters and monitoring reports	To Do
Will double check.	

Clinical

18 / 18 (100%)

Ensure the following has been completed for each participant

Source documents and medical records are available for each participant (Review for ALCOA) (Alternative: Source documents and corresponding Case Report Forms (CRFs) for each participant are present, clearly identified, and systematically organized in binders or folders for ease of retrieval during the inspection)	Done
Completed Case Report Forms (CRFs) on file for each participant	Done
Original signed and dated Informed Consent Forms on file for each participant	Done
Inclusion/exclusion criteria for each participant have been met and documented	Done
All visits conducted within protocol windows	Done
Correct volume of blood and correct tube type drawn at each visit	Done
Adverse Events (AEs), and Expedited Adverse Events (EAEs) have been identified and documented appropriately	Done
All EAEs have been reported to the IRB/EC	Done
All AEs and EAEs have been reported to the sponsor per study requirements	Done

Protocol endpoints have been identified and reported appropriately	Done
Ensure study product use by all participants has been documented	Done
Protocol-required tests/evaluations have been completed and documented appropriately	Done
Protocol violations/ deviations have been identified and documented appropriately	Done
Concomitant/prohibited medications have been documented and reported appropriately	Done
All laboratory reports and other diagnostic test reports are on file and display correct participant identifiers	Done
All laboratory results have been graded appropriately by the PI or designated medical officer per the DAIDS AE Grading Table and protocol-requirements	Done
Laboratory reports have been signed by the PI or designated medical officer	Done
Premature discontinuations of participants are documented appropriately per study requirements	Done
Pharmacy	17 / 17 (100%)

Locate, compile, organize, and review documents for accuracy and completeness

CV of pharmacist(s)	Done
CVs of key pharmacy personnel	Done
Licenses of pharmacy personnel	Done
Form FDA 1572	Done
Prescriber signature list	Done
Most recent version of the protocol for which the site has IRB/EC approval	Done
Most recent version of the protocol-specific study procedures (i.e. SSP manual)	Done
Records of study product dispensation to appropriate staff member (if applicable)	Done

Most recent version of Investigator's Brochure(s) or Package Insert(s)	Done
CRPMC Drug Supply Statement (version for which site is protocol registered)	Done
Investigational agent accountability logs	Done
Participant prescriptions	Done
Documentation of study drug transfers, returns, and destruction (if applicable)	Done
Ordering/shipping receipts	Done
Participant-specific profiles (if applicable)	Done
DAIDS-approved, signed Pharmacy Establishment Plan	Done
Required pharmacy operations SOPs as listed in the PAB Pharmacy Guidelines (July 2008)	Done

Laboratory

1 flagged, 13 / 14 (92.86%)

Locate, compile, organize, and review documents for accuracy and completeness

CV of Laboratory Director	Done
CVs of key laboratory personnel	Done
Licenses of laboratory personnel (if applicable)	Done
Laboratory certifications	Done
Laboratory normal ranges	Done
Laboratory Data Management System (LDMS) records	Done
Copies of laboratory audits, action plans, and corrective action reports	Done
Specimen logs (present and readily available for review)	Done
Chain of Custody SOP (or similar process document)	Done
Corresponding control data for assays where laboratory result AEs and EAEs were identified	Done

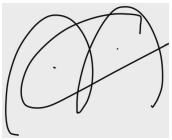
Temperature logs for applicable equipment (refrigerators, freezers, storage cabinets, etc.)	To Do
Will get a copy.	
Calibration and maintenance records for all laboratory equipment (if applicable)	Done
Corrective action reports for identified temperature excursions	Done
Vertical audit of laboratory results and corresponding QC data for results of a randomly selected sample	Done

Completion

General comments and observations

Overall, we are almost ready compared to earlier this week. A few more people to meet (Andrew and Marianne) to discuss the preparation and some tasks to do.

Sign off



Mike Chadwick
4 Jan 2023 15:33 PST