FDA Inspection: Preparation Checklist

conducted for

Pines Manufacturing

Conducted on
16 Nov 2018 04:16 PM

Prepared by
Mike Chadwick

Location
6402 Torreyanna Cir, Carlsbad, CA 92011, USA

Completed on
16 Nov 2018 05:09 PM

Score
95/105.0 - 90.48%

Failed Responses

This section lists responses that were set as "failed responses" in the template used for this audit

Question	Response	Details
Administration	To Do	WIll send final email blast after 5pm.
Reception Area Staff	To Do	We have a new receptionist that we need to remind about the FDA Inspection.
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	
Documentation of staff protocol training	To Do	Will work on this with Marianne.
Documentation of additional staff training (if applicable)	To Do	
Signed and dated monitoring visit log	To Do	
All monitoring pre-visit letters and monitoring reports	To Do	Will double check.
Temperature logs for applicable equipment (refrigerators, freezers, storage cabinets, etc.)	To Do	Will get a copy.

Actions

#1. Hi Marianne! I'll meet you later at 5pm about something we need to discuss. For the mean time, please read about FDA Inspections. Thanks!

Assignee:	Marianne.Angeli.reception@safetyculture.com
Priority:	HIGH
Due Date:	16 Nov 2018 05:00 PM
Audit:	16 Nov 2018 / Pines Manufacturing / Mike Chadwick
Linked to item:	Reception Area Staff
Status:	To Do

#2. Hello Andrew! May I have a copy of the temperature records please? I need it by 5pm today.

Assignee:	Andrew.E.tech@safetyculture.com
Priority:	HIGH
Due Date:	16 Nov 2018 05:00 PM
Audit:	16 Nov 2018 / Pines Manufacturing / Mike Chadwick
Linked to item:	Temperature logs for applicable equipment (refrigerators, freezers, storage cabinets, etc.)
Status:	To Do

Site Preparation for FDA Inspection - 95/105 90.48%

Question	Response	Details
Administrative		Score (18/20) 90.00%
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	

Question	Response	Details
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		Score (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	

Question	Response	Details
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	

Question	Response	Details
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		Score (18/18) 100.00%
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	

Question	Response	Details
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	

Question	Response	Details
Pharmacy		Score (17/17) 100.00%
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	I'm sure I have this will will double check,
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		Score (13/14) 92.86%
Locate, compile, organize, and review documents for accuracy and completeness		

Question	Response	Details
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

Question		Response	Details
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 about the preparation and some tasks to do.	
Sign off	Mike Chadwick	16 Nov 2018 04:57 PM