AIH Seal Required Supporting Documentation for Manufacturer Application

December 1st, 2022

Manufacturer: Business entity that manufactures or processes a homeopathic product. This includes re-processing, re-packaging and re-labeling of homeopathic products.
Brand Owner: Business entity that works with homeopathic products, for the purpose of sale, who does not manufacture, re-process, re-package or re-label those products.
Brand Owner Application: Every Year
Manufacturer Application: Every Year
Product Application: Every Product Every Three Years

Note that items in red type are under consideration for a future version of the standards.

Category	Description
Batch Record (or equivalent)	Provide a Master Batch Record (PBR) or its equivalent (eg. SOP for method of performing dilutions and the validation method) for the manufacturer (feel free to redact any proprietary information).
Certificate of Analysis	Provide the finished product specifications for a finished product.
Document Control	Provide the current master SOP list. This list should minimally include the following: • Adverse events and serious adverse event handling; • Complaint handling system; • Raw material specification handling system; • Document change; • Employee health and safety; • Incoming materials and receiving; • Label control; • Master cleaning procedures; • Material management; • Non-conformance management; • Personnel training; • Quality systems; • Recall, return and salvage procedures; • Record retention procedures; • Security procedures; • Self-inspection and auditing; • Supplier management
FDA Inspections	Provide evidence that the facility is in good standing (NAI or VAI) with FDA inspections for a period of three years. A recent letter would be acceptable or a screen shot of the recent company's

Category	Description
	standing on the FDA website. (www.datadashboard.fda.gov). If the facility has not been inspected in the last three years, provide evidence that the company has requested an FDA inspection. If the standing with the FDA is OAI, share any concerns, including warning letters generated by the FDA and how the manufacturer is addressing these concerns in a timely manner with appropriate documentation.
FTC Concerns	Share any concerns from the FTC that have arisen with the brand owner or manufacturer in the last three years and the response of the company.
HPUS Subscription	Provide evidence of either a single-user or multi-user subscription to the HPUS.
Laboratory Systems	1. Are outside laboratories used for testing? 2. What are the names and credentials of the outside lab? 3. Is the lab accredited and are their processes validated? Is the lab GLP Compliant?
Letter of Attestation	Provide a letter of attestation signed by a senior officer of the company attesting to accuracy and truthfulness of the application.
Letter of Attestation	Provide a letter of attestation of which homeopathic products the manufacturer provides for the brand owner.
Letter of Attestation	Letter of Attestation from Manufacturer that facility conforms with both GMP and HPUS manufacturing guidelines for homeopathic medicines. "I attest that the building(s), practice(s), and procedure(s) used for conducting homeopathic manufacturing activities in our facility comply with the good manufacturing practices and HPUS manufacturing guidelines."
Quality System	1. Is the Quality Department's reporting structure independent of operations? 2. Is QA or QC responsible for review of the batch record?
Registration	Provide evidence of manufacturer registration as a drug establishment for a period of three years.
Registration	Provide a screen shot of the NDC Filing on Daily Med.
Self Inspections and Auditing	Is the company audited by a third party (s)? What is the name of the company (s) and contact information? How often do they audit?
Social Compliance Policies	Provide the social compliance policy demonstrating ethics for both the brand owner and manufacturer in accordance with the standards.
State Licensure	Provide evidence that the facility is licensed within its state or jurisdiction in the last year.

Documentation Under Consideration for Future Version of Standards for Manufacturer Application

Category	Description
Deviations	Provide a description of the deviation handling system. An SOP would be acceptable.
Environmental Systems	Provide proof of warehouse storage conditions including protection from direct sunlight, temperature and humidity records for the last three months.
Facilities and Equipment	Provide evidence of water system testing for contaminants to USP Specifications, including BCC testing and UFP testing for the last three months.
Facilities and Equipment	Provide pest control contract and data demonstrating a pest free environment for the last three months.
Facilities and Equipment	Provide a floor plan to demonstrate that there are adequate facilities for operations.
Facilities and Equipment	Answer each of the following questions: • Is access to processing areas restricted? • Are measures present to minimize product tampering/sabotage? • Are employee background checks run on those who have access to sensitive areas, before hiring? • Are doors leading to the outside kept locked? • Are outbound trailers inspected before loading and sealing? Are these inspections documented? • Are outside premises well-lit at night? • Is there a guard service/security system present or is there any barrier device around the facility? If negative response, please explain.
Facilities and Equipment	Provide room cleaning logs (calendar acceptable) from at least two manufacturing rooms for the last three months.
Facilities and Equipment	Provide equipment cleaning logs (calendar acceptable) from the same two manufacturing room for the last three months.