

Current Good Manufacturing Practice Self-Audit for compliance with 21 CFR 507

Self auditor _____

Facility name _____

Audit date _____

CGMP Self-audit summary		Self-audit date
1.	Number of compliance (Yes boxes checked)	
2.	Number of not applicable (N/A boxes checked)	
3.	Total number of questions	70
4.	% compliance (#1/(70 - #2)) x 100	



507.14 Personnel		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Does management take reasonable precautions to ensure that all people working in direct contact with animal food, equipment, and packaging materials are Qualified Individuals?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. Is there documentation that all Qualified Individuals have the education, training, or experience, or combination thereof, necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Is there documentation that all Qualified Individuals receive training on animal food hygiene and animal food safety, including the importance of employee health and personal hygiene?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. Do Qualified Individuals maintain adequate personal cleanliness?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. Do Qualified Individuals wash hands in adequate hand-washing facilities when appropriate?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	6. Do Qualified Individuals remove and/or secure jewelry and other personal objects to prevent them from falling into animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	7. Do Qualified Individuals store clothing and other personal belongings outside the manufacturing area?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	8. Are necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food packaging materials being taken?	



507.17 Plant and Grounds		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	9. Are grounds maintained (equipment stored properly, litter and waste removed, weeds and grass within immediate vicinity of facility are trimmed to not harbor pests)?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	10. Are driveways, yards, and parking areas maintained so they are not a source of contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	11. Is there adequate drainage on grounds so sitting water is not a source of contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	12. Is the facility suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	13. Is waste treated and disposed of in a way that does not constitute a source of contamination in areas where animal food is stored?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	14. Is the facility constructed so that drips or condensate from fixtures, ducts, and pipes do not serve as a source of contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	15. Is adequate ventilation (mechanical or natural) provided where necessary and appropriate to minimize vapors (steam) and fumes?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	16. Is adequate lighting provided?	



507.17 Plant and Grounds <i>continued</i>		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	17. Are light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food made of shatter-proof glass?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	18. Are protective coverings being used where necessary and appropriate to prevent contamination of bulk feed stored outdoors?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	19. Are areas over and around the bulk animal food controlled to eliminate harborages of pest?	



507.19 Sanitation		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	20. Is the animal food stored outdoors in bulk being checked on a regular basis for pests, pest infestation, and product condition related to safety of the animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	21. Are the building, structures, and fixtures clean and maintained?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	22. Are animal food-contact and non-contact surfaces of utensils and equipment clean, maintained, and stored to protect against contamination of animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	23. If wet cleaning is being used, are animal-food contact surfaces sanitized and dried before use?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	24. Are cleaning compounds and sanitizing agents safe under conditions of use?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	25. Are toxic materials being stored only for maintaining clean and sanitary conditions, laboratory test procedures, plant and equipment maintenance and operation, or those necessary for use in plant operations?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	26. Are the toxic materials in #25 identified, used, and stored in such a way to protect against contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	27. Are other toxic materials (pesticides, fertilizers, etc.) stored in an area where animal food is not manufactured, processed, or exposed?	



507.19 Sanitation <i>continued</i>		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	28. Is pest control in place and effective?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	29. Is trash stored and disposed of properly?	



507.20 Water Supply and Plumbing		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	30. Is water safe for its intended use and drawn from an adequate source?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	31. Is running water at a suitable temperature and pressure?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	32. If it is water reused, is it safe for its intended use and not add contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	33. Does plumbing carry sufficient amounts of water for intended use?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	34. Does plumbing sufficiently carry sewage and liquid waste from the facility so it is not a source of contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	35. Does plumbing provide sufficient floor drainage?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	36. Does plumbing ensure no backflow from piping system empty wastewater or sewage near areas of manufacturing or animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	37. Is sewage and liquid disposal waste disposed of through an adequate sewage system or through other adequate means?	



507.20 Water Supply and Plumbing <i>continued</i>		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	38. Does the facility provide employees with accessible toilet systems that are kept cleaned and well-maintained?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	39. Does the plant provide hand washing facilities to prevent employees' hands from becoming a potential source of contamination?	



507.22 Equipment and Utensils		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	40. Are all equipment and utensils designed and constructed of such material and workmanship to be adequately cleaned and properly maintained?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	41. Are all equipment and utensils designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	42. Is equipment installed to facilitate the cleaning and maintenance of the equipment and adjacent spaces?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	43. Are all animal food contact surfaces made of nontoxic materials that withstand the environment of their use, the action of animal food, and the action of cleaning compounds, cleaning procedures, and sanitizing agents and maintained in a way to protect animal food from being contaminated?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	44. Are all holding, conveying, manufacturing, and processing systems designed, constructed, and maintained in a way to protect against the contamination of animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	45. If freezers and cold storage compartments are used to hold animal food, are they fitted with accurate temperature-measuring devices?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	46. If there are instruments and controls used in measuring, regulating, or recording temperature or other conditions to control or prevent the growth of undesirable microorganisms, are they accurate, precise, adequately maintained, and adequate in number for their designated uses?	



507.22 Equipment and Utensils <i>continued</i>		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	47. Is compressed air or other gas mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment used in such a way to protect against the contamination of animal food?	



507.25 Plant Operations		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	48. Is all animal food accurately identified?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	49. Are all animal food-packaging materials safe and suitable?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	50. Is the overall cleanliness of the plant under the supervision of one or more competent individuals assigned responsibility for this function?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	51. Are adequate precautions taken so that plant operations do not contribute to contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	52. Are chemical, microbial, or other testing procedures used where necessary to identify sanitation failures or possible animal food contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	53. Is all animal food that becomes adulterated rejected, treated, or processed to eliminate adulteration, or disposed of in a manner that protects against the contamination of other animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	54. Is all animal food manufacturing, processing, packing, and holding conducted under conditions and controls necessary to minimize the potential for growth of undesirable microorganisms to protect against the contamination of animal food?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	55. Are shipping containers and bulk vehicles holding ingredients examined upon receipt?	



507.25 Plant Operations <i>continued</i>		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	56. Are all raw materials cleaned as necessary to minimize contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	57. Are all raw materials and other ingredients stored in a way that protects against contamination and deterioration?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	58. Are ingredients susceptible to mycotoxins and used in a proper manner?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	59. Are all raw materials or other ingredients that must be frozen, kept frozen and thawed properly?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	60. Is all animal food maintained, manufactured, and packaged under conditions which minimize the potential for the growth of microorganisms?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	61. Is work-in-progress and rework handled to protect against undesirable microorganisms?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	62. If water activity or pH are used to prevent the growth of microorganisms, are they used properly?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	63. If ice is used, is the water it was made from safe for use?	



507.27 Holding and Distribution		Comments
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	64. Is animal food held in appropriate places that protect from the contamination of pests, chemicals, and other products?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	65. Are unpackaged or bulk animal foods held to protect cross-contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	66. Are shipping containers (bulk, trucks, tote bags, paper or plastic bags, etc.) designed, constructed of appropriate material, and maintained to protect against contamination?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	67. Are containers properly cleaned?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	68. Are containers inspected to protect cross-contamination before loading?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	69. Do the animal food labels follow AAFCO suggestion which contains the instructions of safely using and intended animal species?	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	70. Do you accept returned products to your facility? If yes, do you have procedure to control them? Who will decide whether to accept or reject? Where are they placed? Who will justify the corrective action for them?	



