INTERNATIONAL FOOD ADDITIVES COUNCIL QUALITY SYSTEMS, FOOD SAFETY AND GOOD MANUFACTURING PRACTICES AUDIT GUIDE FOR FOOD ADDITIVES AND GRAS SUBSTANCES

IFAC GMP Audit Guide - Revision 1
Published 2019

ACKNOWLEDGEMENTS
This Guide was prepared by the International Food Additives Council (IFAC) through its Food Safety Committee. IFAC is a global association representing manufacturers and users of food ingredients, including food additives and GRAS substances. IFAC strives to promote science-based regulations, standards and specifications for food ingredients worldwide.

INTRODUCTION

In the food industry, it is the responsibility of the manufacturer of a finished food product to ensure the safety and quality of all components of that food. Through the auditing of food additive and GRAS substance producers, a finished food manufacturer is able to determine whether adequate controls are in place to ensure its producers are capable of providing product components of suitable safety and quality. The IFAC Quality Systems, Food Safety, Good Manufacturing Practices Audit Guide for Food Additives and GRAS Substances (IFAC Audit Guide) is a tool to assist in evaluating the manufacturing practices and quality systems of food additive and GRAS substance manufacturers. It is also a helpful reference to assist food additive and GRAS substance manufacturers in meeting appropriate cGMP requirements to assure consistent product safety and quality.

The IFAC Audit Guide is applicable whenever a food additive or GRAS substance manufacturer is audited, and may be used in conjunction with the IFAC Quality Systems, Food Safety and Good Manufacturing Practices Guide for Food Additives and GRAS Substances (IFAC GMP Guide). Although the IFAC GMP Guide does not guarantee legal compliance, it is intended to have international application and address relevant national regulations, including the U.S. Food Safety Modernization Act, and specifications provided by the Food Chemicals Codex, Codex Alimentarius (JECFA), the European Commission and others. While the audit may include other areas such as delivery logistics and order processsing, the IFAC Audit Guide is intended to address Title 21, Part 117 of the U.S. Code of Federal Regulations and Current Good Manufacturing Practice (CGMP) requirements relating to food additive and GRAS substance manufacture.

CONTENT AND USAGE

The IFAC GMP Guide was used as the basis to construct the questions contained in the IFAC Audit Guide, and should serve as the primary source for evaluating responses provided by the auditee. The auditors should be familiar with the introduction, definitions, and general guidance that are contained within the IFAC GMP Guide, and should refer to the Guide if further details are needed.

The IFAC Audit Guide is intended to address the foundation of the requirements, and not all of the details, necessary to manufacture food additives and GRAS substances in compliance with 21 CFR Part 117 and applicable cGMPs. It may not include all of the appropriate questions for a specific audit, nor may all of the points be appropriate to every audit. As an international document, it also cannot specify all national legal requirements, nor cover in detail the particular characteristics of every food additive and GRAS substance. However, its use is intended for individuals experienced and competent in the area of auditing who should be diligent in selecting which areas of Good Manufacturing Practice are relevant to a specific particular audit and in determining the appropriateness of questions (and the answers provided) based on the characteristics of the food additive or GRAS substance manufactured, the processes employed, and specific requirements of the food additive or GRAS substance user.

FORMAT

The IFAC Audit Guide is formatted to provide detailed questions arranged in the same sequence as in the IFAC GMP Guide. This format is frequently useful as a training tool for personnel of both the auditing company and one being audited.

INTERNATIONAL FOOD ADDITIVES COUNCIL
QUALITY SYSTEMS, FOOD SAFETY AND GOOD MANUFACTURING PRACTICES AUDIT GUIDE FOR FOOD ADDITIVES AND GRAS SUBSTANCES

Table I: Detailed Questions in Sequence of the IFAC Quality Systems, Food Safety and Good Manufacturing Practices Guide for Food Additives and GRAS Substances

	NOTES
4. FOOD SAFETY & QUALITY MANAGEMENT SYSTEM-FOOD ADDITIVE GRAS SUBSTANCE QUALITY SYSTEMS	
4.1 General Requirements	
4.2 Documentation Requirements	
4.2.1 General	
4.2.2 Written Plan and Documentation of Preventive Controls -Does the plan address requirements for FSMA compliance?	
4.2.3 Quality Manual -Is there a Quality Manual? -If there is a Quality Manual, is it current? -If the Quality Manual is not current, is there a suitable alternative? -Does the Quality Manual include a quality policy, a description of the Quality Management System and a commitment of intent to meet food safety and GMP requirements for food additives and/or GRAS substances?	
4.2.4 Control of Documents -Are there procedures that describe the document control system? -Is there a list of Standard Operating Procedures (SOPs) for areas of the operation affecting quality and food safety? -Does the document control system cover the written procedures used in the manufacture of food additives and GRAS substances? -How are current SOPs (e.g., operating procedures, work instructions, manufacturing instructions and test methods) made readily available to employees?	

-Is there an SOP for writing, issuing and updating SOPs? -What is the procedure for periodic review of SOPs? -What is the system to assure that unneeded or obsolete documents are removed from use? -Are only current versions of the documents being used? -Are documents and changes to documents reviewed and approved by designated qualified personnel? -Are documents that impact product quality and food safety reviewed and approved by the quality unit or other designated qualified personnel independent from production? -How are documents controlled (electronic and paper copies)? -Is training performed after updates to procedures are issued? -Are obsolete versions withdrawn from use? -How are obsolete versions identified? -If electronic documentation is used, does it meet the requirements for document control and security?	
4.2.5 Control of Records -Are records of monitoring, instances of non-conformance material to food safety, corrective actions, verification, and the efficacy of preventive controls and corrective actions kept for at least two years, per Section 103(g) of FSMA? -What is the system used to track, control, and maintain all records that relate to the requirements of the Food Safety & Quality System? If subcontractors are used, do records include pertinent quality data? -Where electronic signatures are being used, are they controlled to provide equivalent assurance to written signatures? -Is the record retention policy justified and what is the rationale? -Is this described in a written records retention policy? -Does the record retention policy meet the requirements of FSMA Section 103(g) for a minimum of two years? -Are the records legible, indelible, signed, dated and kept in a suitable environment to minimize deterioration or damage? -Are records stored in a manner that they are readily retrievable, or, if stored offsite, are they readily retrievable within 24 hours of request for official review and in facilities that provide a suitable environment to minimize deterioration or damage? -Is the food safety plan permanently stored and accessible onsite?	

4.3 Change Control -Are there adequate written procedures for a change control system for those changes that may have an impact on the quality and safety of the food additive or GRAS substance or their conformance to GMP? -Does it include review and approval of changes to raw materials, processes, documents, and equipment? -Does a unit independent from production (e.g. the Quality Unit or Regulatory Affairs) have the responsibility and authority for the final approval of changes? -Are changes evaluated with respect to effectiveness and impact on food safety and quality? -Does the change control system consider the significance of the change and require consideration for notifying customers?	
4.4 Quality Management	
4.4.1 Management Commitment -How has Management demonstrated the importance of customer satisfaction and compliance? -Is it documented in a formal statement such as a corporate Food Safety & Quality Policy? -Are quality objectives established, periodically reviewed and updated as needed? -If so, are these reviewed for progress and effectiveness?	
4.4.2 Customer Focus -What is the policy for accommodating customer or third party audits of the facility? -How are customer requirements determined and translated into the Quality Management System (QMS)?	
4.4.3 Quality Policy -Does the policy include management commitment to the policy? -Is there evidence that management was involved in developing the policy? -What evidence is there that all personnel are aware of the policy and its implementation in the facility? -Does the policy support continual improvement of the Quality & Food Safety management system?	
4.4.4 Hazard Analysis and Risk-Based Preventive Controls	
4.4.4.1 Hazard Analysis -Do you have a program for hazard analysis and risk-based preventative controls (i.e. HACCP)?	

-When was the last time the hazard analysis and risk-based preventative control plan reviewed, and was it updated if needed?	
4.4.4.2 Hazard Identification and Mitigation -Does the hazard analysis and risk-based preventative control program identify and evaluate hazards that may be associated with the facility or that may be intentionally introduced into the facility? -Have these hazards and their evaluation been documented? -Where appropriate, is there a written supply chain management program or a written recall program?	
4.4.5 Planning	
4.4.5.1 Quality Objectives -What measurable objectives for GMP compliance have been established for conformance to the Food Safety & Quality System and GMP requirements?	
4.4.5.2 Quality Management System Planning -What process is there for identification of adequate resources needed for adherence to GMP? -Is there any observable evidence that adequate resources have been provided to ensure conformance to GMPs and food safety? -How is the integrity of the QMS maintained when changes are made?	
4.4.6 Responsibility and Authority -Are there clearly-written job descriptions? -Do these describe their roles/responsibilities for GMPs? -Where are the Quality Unit's authority and responsibilities clearly defined in writing? -What documentation shows the Quality Unit has independent authority to approve or reject raw materials, packaging components, intermediates and finished product batches? -What controls are in place for the responsibilities of the Quality Unit that have been delegated to other personnel? -What role does the Quality Unit play in investigating deviations, failures and complaints? -How does the Quality Unit document their approval or rejection of new suppliers of quality critical materials and services? -How does the Quality Unit achieve their responsibility for the review of appropriate production records and ensure that deviations are investigated?	

-How does the Quality unit document their approval or rejection of changes to processes, specifications, procedures and test methods that may affect quality? -Does the quality unit have a self-inspection program for the QMS? -Are the individuals delegated by management with oversight for development and review of the food safety plan qualified by relevant experience or training which is documented in writing? -How often does the management representative report on the conformance of the Food Safety & Quality System to top management?	
4.4.6.1 Internal Communication -How are GMPs and regulatory requirements, food safety & quality policies, objectives and procedures communicated throughout the organization? -How is the effectiveness of the QMS evaluated? -How is top management informed of food safety & quality critical situations?	
4.4.6.2 Recalls -Is there a documented recall procedure? -Is it consistent with regulatory recall requirements? -Does it define roles and responsibilities? -Are all appropriate employees familiar with the recall policy and plan and/or is it reviewed/updated periodically? -Are mock recalls conducted to assess recall plan effectiveness? -Have there been any Reportable Food Registry events in the past two years? -Have there been any recalls in the past two years? -Is there a system in place to facilitate communication of reportable food safety incidences with the customer and regulatory authorities?	
4.4.7 Management Review	
4.4.7.1 General -Does top management hold periodic reviews to confirm continued conformance to the Food Safety & QMS? -Are management reviews documented? -How is top management involvement demonstrated? -How are the opportunities for improvement and the need for changes captured, reviewed, implemented and recorded?	
4.4.7.2 Review Input -Does the management review input include, for example, audit results, customer complaints and feedback, product conformity, process performance,	

status of corrective and preventive actions and relevant regulatory/legislative changes?	
4.4.7.3 Review Output -Does the review output address resources needed for improvement of the preventive control/food safety & QMS and define actions to be taken? -Are recommended actions documented?	
5. PERSONNEL AND RESOURCE MANAGEMENT	
5.1 Provision of Resources -Does there appear to be adequate resources to perform and supervise the operations necessary for producing, packaging, testing, storing and releasing food additives and GRAS substances in compliance with applicable GMP requirements?	
5.2 Personnel	
5.2.1 General -How are qualifications (training, experience, and education) documented and related to the assigned tasks? -If used, who reviews the qualifications of consultants to assure they have sufficient education, training and experience to advise on the subject for which they are retained? -Are consultants and contractors appropriately trained before being allowed into the facility?	
5.2.2 Competence, Awareness and Training -Is there a SOP for identifying training needs and providing the necessary training on a regular basis? -What are the qualifications for individuals performing GMP training? -Are job-specific training requirements clearly defined? -Does training address GMPs, hazard analysis and risk-based preventative controls and food defense as they relate to the employee's functions? -How does the training program ensure that personnel understand that deviations from procedures may have an impact on the customer's product quality? -Is there personal hygiene training for personnel handling product so they understand the precautions necessary to prevent the contamination of the food additive and/or GRAS substance? -How is it documented? -What records are kept to demonstrate that GMP training is conducted in a timely manner for new and temporary employees as well as consultants and contractors?	

-What is the frequency of continuing GMP training and is it sufficient to ensure that employees remain familiar with applicable GMP requirements? -How broadly is the training conducted within the site? -How are training effectiveness and employee competency assessed? -How is training and qualifications documented for each employee? -How are changes in regulatory requirements monitored, interpreted, and communicated to employees?	
5.2.3 Personnel Hygiene -How are personnel hygiene requirements and protective equipment specified and communicated to employees? -Are personnel observed to comply with requirements for cleanliness, special clothing, protection, jewelry and hair coverings as required in the various manufacturing, packaging and testing areas? -Is there appropriate signage for such requirements? -Are personnel required to report any health conditions that may have an adverse effect on the product? -Where can lab and operating personnel store and consume food, beverage, or tobacco products? -What measures within the facility have been taken to prevent unauthorized and unescorted access to critical processing operations and other sensitive areas? -Are personnel observed to be in compliance?	
5.3 Facility Infrastructure	
5.3.1 Buildings and Facilities -Are there adequate space and environmental controls to ensure product integrity and to preclude mix-ups or cross-contamination, especially in drying, milling, blending, packaging and warehousing operations? -Where the food additive or GRAS substance is exposed, are there adequate measures to prevent contamination? -What other materials are produced or stored in close proximity to food additive or GRAS substance production or where it is exposed to the environment? -Does the facility use or produce highly sensitizing or toxic substances? If so, what controls are used to prevent contamination of the food additive or GRAS substance? -What evidence is there that these measures are effective? -Are facilities maintained in a good state of repair? -Are there adequate laboratory facilities to perform required testing?	

-Is there adequate space around finished food additive and GRAS substance locations in the warehouse to facilitate cleaning?	
5.3.2 Equipment -How is equipment commissioned prior to initial use? -Is equipment maintained in a good state of repair? -If processing occurs outdoors what controls are in place to minimize risk to food additive and GRAS substance quality?	
5.3.2.1 Equipment Construction -Is equipment constructed so that product-contact surfaces are not reactive, additive, or absorptive and will not adversely affect the product? -Is equipment designed and used in a manner that minimizes the potential for contamination of product with lubricants, coolants, metal or seal fragments, or other extraneous materials? -If product exposure to, or contamination with, lubricants or coolants is possible, are these materials suitable for use in food applications? -What provisions are made for monitoring the product for metal contamination where appropriate? -How is the equipment designed, where necessary, to minimize the possibility of contamination from operator contact in operations such as unloading of centrifuge bags, use of transfer hoses, and operation of drying equipment and pumps?	
5.3.2.2 Equipment Maintenance -Is there a system for cleaning, inspecting and approving equipment for use in manufacturing after maintenance and repairs have been performed? -Are there SOPs and appropriate documentation for inspection (monitoring the condition) and maintenance of equipment and for measuring and test instruments? -Do the SOPs assign responsibilities; include schedules; describe methods, and equipment, and materials to be used? -Are records kept of preventive maintenance, repairs, and use?	
5.3.2.3 Computer Systems -If computerized systems are used in a manner that can impact food additive and/or GRAS substance quality, have they been demonstrated to consistently function as expected? -What process is used to control changes to systems and programs that can have an effect on the quality of the product (see 4.3), to assure that changes receive	

the proper review and approval with regard to potential effects before being instituted and that only authorized personnel can make such changes? -Are personnel trained subsequent to changes? -How is access to computerized systems limited in order to protect records from tampering, and prevent data alteration? -If passwords are used as a security measure, are there provisions for periodic changing of passwords? -Are there designees for all critical system operations and emergencies? -What is the procedure for reviewing and updating security access when a person leaves the department or company? -Is their access to the system or their access codes to the system revoked in a timely fashion? -What backup systems are in place, such as copies of programs and files, duplicate tapes, or microfilm, and has retrievability of information from master tapes and backup tapes been verified? -Are there procedures in place for disaster recovery, in the event of a power outage, loss of server and computerized systems, etc.?	
5.3.3 Utilities -What utilities are used in the production, storage or transfer of materials that could impact food additive or GRAS substance quality? -How have these utilities been assessed and appropriate action taken to assure they do not contaminate the food additive or GRAS substance?	
5.3.4 Water -If water is used in the manufacture of the food additive or GRAS substance, what is its source and is it suitable for its intended use? -Is there an internal written specification for process water? -Where water can impact food additive or GRAS substance quality: • If the water is not potable, has a risk assessment been performed to evaluate the potential impact on food safety? • Have adequate controls been implemented to ensure food safety? • Are the controls effective? • How is process water periodically monitored for chemical and microbial quality? • Is the process water supplied under continuous positive pressure or are other means used to prevent back flow?	

• Where the water is purified on-site, are there chemical and microbial quality standards and action limits for such water, with an established monitoring program? • Where the water is purified, is the purification system periodically sanitized and appropriately maintained? • If chemical or microbial action limits for process or purified water are exceeded, how are the cause investigated, the problem corrected, the impact of the contamination of products manufactured with the water assessed, and the results of the investigation documented?	
5.4 Work Environment -Are exposed materials protected from overhead contamination? -Are production, including packaging, areas that present potential for contamination properly controlled and equipped with exhaust or other appropriate systems?	
5.4.1 Air Handling -Does the manufacturing area have the appropriate air handling system to protect the food additive and GRAS substance? -How was the requirement defined? -Was it documented? -Has the effectiveness of the air handling systems been verified to ensure the required protection for its intended use? -If air is recirculated to areas where product is exposed, is it filtered and controlled to eliminate cross-contamination? -Are such filters periodically checked and replaced and where is this documented?	
5.4.2 Controlled Environment -Is the manufacturing environment appropriately controlled for the process taking place to protect the food additive or GRAS substance against deterioration and contamination? -How is it monitored? -If a special environment is required, is it continuously monitored? -In the event of an interruption to the special environment, is the impact upon the quality of the food additive or GRAS substance evaluated and documented?	
5.4.3 Cleaning and Sanitary Conditions -Are facilities maintained in an appropriately clean, sanitary and orderly manner? -Where food additive or GRAS substance quality can be adversely impacted, are there adequately detailed SOPs for sanitation and cleaning?	

-How is compliance monitored and documented? -Do the SOPs assign responsibilities; include schedules; describe methods, equipment, and materials to be used; and require maintenance of records? -How is waste segregated and how are storage containers identified? -What is the frequency of disposal? -Has the manufacturing and packaging environment been evaluated for the potential for contamination by physical or chemical materials or by microbes in the area?	
5.4.4 Pest Control -Where necessary, is there a program to protect quality critical materials and product from contamination due to insects, rodents, birds, and other vermin (including domestic animals)? -What evidence is there to show that it is adequate? -Where necessary, how are windows, doors, or other openings to the outside adequately protected from entry by pests? -If raw materials or intermediates are stored in silos, tanks, or other large containers, how are the vents adequately protected to prevent entry of birds and insects? -If used, are rodenticides, herbicides and pesticides appropriately evaluated? -If an outside party performs pest control, how is that party's performance and compliance monitored? -Does the party use a site map and issue a report? -Is the report reviewed by the manufacturer? -Are pest control records kept? -What corrective and preventive measures have been taken? -If the nature of raw material (such as botanicals) results in unavoidable contamination, has the food safety risk been evaluated? -What measures have been taken to monitor or control the unavoidable contamination?	
5.4.5 Lighting -Is there adequate lighting? -Is the lighting protected from shattering in areas where the product may be exposed?	
5.4.6 Sewage and Refuse -Is waste clearly identified? -Is waste removal separated from exposed product(s)?	

-Where the food additive or GRAS substance is open to the environment, is the plumbing system designed to prevent contamination of the food additive or GRAS substances? -Are drains of adequate size? -Are drains equipped with an air break or other mechanism to prevent back flow?	
5.4.7 Washing and Toilet Facilities -Are there adequate hand washing and drying facilities at appropriate locations in the plant? Are all in good repair? Do they provide hot and cold water, soap or detergent, and have air dryers or single service towels? -Are there clean, readily accessible toilet facilities that are maintained in good repair? -Are there facilities for showering and/or changing clothes?	
6. OPERATIONS	
6.1 Planning of Operations -Is a process flow diagram or other suitable description of the process steps available for the audited products? -Is the unit operation batch or continuous or some combination of the two? Is the food additive or GRAS substance produced in equipment dedicated to its manufacture or is the equipment also used for other products? -Has the process been fully described regarding: • reactions • purifications • critical steps • operating parameters • process limitations • impurities • key tests needed for process control • product specifications • sampling plans • test and release procedures -Have process parameters critical to food safety & quality been defined, and if parameters are exceeded, is the effect on food safety & quality known? -Is there a system for identifying major equipment, instruments, and production lines? Is this information included in batch production and control records where appropriate? -Is there a system for addressing allergen control?	
6.2 Customer-Related Processes	

6.2.1 Determination of Requirements Related to the Product -Is there a system to determine customer requirements related to the product and supply of the product? -How does the manufacturer communicate the agreed customer requirements to the appropriate personnel?	
6.2.2 Review of Requirements Related to the Product -Is there a procedure in place to assure that the manufacturer and the customer have mutually agreed upon the specifications and other requirements? -If not, what is the alternative process?	
6.2.3 Customer Communication -Is there a system to assure that any mutually agreed customer-initiated changes are promptly incorporated? -Is there an adequate system in place to assure that significant process changes, including the use of subcontractors, and their effects on the food additive or GRAS substance are communicated to the customer (see Section 4.3)?	
6.3 Design and Development -How are design and development activities translated into plans for manufacturing?	
6.4 Purchasing	
6.4.1 Purchasing Process -What is the program to qualify or disqualify suppliers of raw materials, packaging components and services that might affect quality, and to verify that they have capability to consistently meet agreed-upon requirements? -Does the supplier qualification program include periodic audits by qualified auditors (or other verification techniques) when deemed necessary based on risk assessment? -What is the program for the evaluation and approval of subcontractors? Does this program include periodic audits of subcontractors? -What system is in place to follow up on corrective actions for audit findings for suppliers and subcontractors? -Are materials purchased against an agreed specification? -How is it ensured that materials are only purchased from approved suppliers? -Are materials purchased that might result in the food additive or GRAS substance being at risk with regard to BSE/TSE, allergens, GMO, etc.?	
6.4.2 Purchasing Information	

-Have the specifications, which were approved by the Quality Unit or their designee, for the raw material or packaging component been provided to the supplier for review and concurrence? -What system is in place to assure that revisions to the specifications are provided on a timely basis to the supplier? -What system is in place to assure that suppliers and subcontractors notify the company of significant changes? -How are relevant contract manufacturers and laboratories notified of the requirement to adhere to appropriate sections of the Guide?	
6.4.3 Supplier Qualification and Periodic Verification -Has a risk assessment been conducted for the purchased raw materials to ensure they are suitable for the intended use? What documentation is used? -Describe the supplier and quality critical raw material qualification system and evaluation criteria. What documentation is used? -Describe the supplier audit process and rationale for frequency of audit.	
6.4.4 Verification of Purchased Product -Are procedures in place covering the means to quarantine quality critical materials on receipt until they have been approved? -Is sampling for release performed according to a plan that assures that the sample is representative of the batch? -Are methods of sampling designed to prevent contamination and cross-contamination? -Do bulk deliveries have controls to assure material purity and freedom from contamination (e.g. dedicated tankers, tamper-evident seals, certificate of cleaning, testing, and/or audit of the supplier)? -Are there adequate written and approved instructions and specifications for food safety/quality critical material sampling and testing, including investigation of nonconforming results? -If food safety/quality critical materials are accepted on certificate of analysis (COA), are they tested or otherwise verified prior to use? -If food safety/quality critical materials are accepted on COA, have suppliers been appropriately certified or qualified, including verification and periodic monitoring of the results on the COA?	
6.5 Production and Service Provision	
6.5.1 Control of Production and Service Provision	
6.5.1.1 Production Instructions and Records	

-How is the execution of significant processing steps verified? -Are records available and readily retrievable for each batch of food additive or GRAS substance produced and does it include complete information relating to the production and control of each batch? Do records include information such as: • date/time each step was completed • identification of persons performing and checking each significant operation • identification of major equipment and lines • material inputs to enable traceability • in-process and laboratory control result • statement of yield, unless not quantifiable (e.g. as in some continuous processes • inspection of the packaging and labeling area before and after use, • labeling control records • description of sampling performed • failures, deviations and investigations • results of final product inspection	
6.5.1.2 Equipment Cleaning -If equipment is not dedicated, are there data to show that cleaning procedures for non-dedicated equipment are adequate to remove the previous materials? -What controls are used to prevent cross-contamination and how have they been justified (e.g., model product)? -Are there written cleaning procedures and do they contain sufficient detail to allow operators to clean each type of equipment in a reproducible and effective manner? -For continuous processing: is the frequency of cleaning specified and justified? -Have cleaning procedures been demonstrated to be effective? Is there an adequate system for documenting cleaning and use of the equipment (e.g., a cleaning and use log)? -Are utensils and sampling devices cleaned and stored in a proper manner to prevent contamination?	

-Has the cleaning process been allergen-sanitation validated (if applicable)? -If product is campaigned, is there an established interval between complete cleanings of the equipment and has it been justified?	
6.5.1.3 Recovery of Solvents, Mother Liquors and Second Crop Crystallizations -Are recovered solvents re-used in the same step of the process or can they be used in other processes? -If fresh and recovered solvents are commingled, are the recovered solvents sampled and assayed and found to be satisfactory prior to commingling? -How is the quality of commingled solvents monitored on an established schedule? -If secondary recovery procedures are performed on mother liquors or filtrates, how are the recovered materials shown to meet applicable specifications? Are these recovery procedures written? -How is traceability maintained?	
6.5.1.4 In-Process Blending or Mixing -Are there defined blending/mixing parameters? -Where finished product is blended or mixed, how has the reproducibility of the blending or mixing process to ensure homogeneity been demonstrated? -Is the blending/mixing equipment completely emptied between batches or between campaigns? If not what controls are applied? -Are nonconforming batches blended or mixed with other lots that do conform to specifications? -How are tailings or partial containers of food additives or GRAS substances handled?	
6.5.1.5 In-Process Control -Are process controls in place to control critical material attributes? -Are in-process samples taken and test results recorded? How are in-process samples disposed of? -Have personnel performing in process testing been trained and is the training documented? -Do manufacturing instructions describe how to use in-process control data to control the process? -Have actions to be taken when the results are outside specified limits been defined? -What is the fate of materials that fail to meet specifications or are produced when the process has been demonstrated to be outside specified limits?	

6.5.1.6 Records of Equipment Use -How is the sequence of activities for each piece of equipment demonstrated (i.e., production, maintenance and cleaning)?	
6.5.1.7 Packaging	
6.5.1.7.1 Packaging Systems -Is there a written procedure for clearing the packaging area after each packaging operation, and cleaning before the next operation, especially if the area is used for packaging different materials? -How are labels controlled? Is there an SOP for the receiving, reviewing, handling, storage, issuance, and accountability of pre-printed labels? -If labels are printed as needed, what system is used to verify the accuracy of the labels? -Is there a procedure to ensure that the printed labels contain the correct information?	
6.5.2 Verification of Processes for Production and Service Provision -How has the current process been shown to be capable (i.e., has it been demonstrated to operate consistently to produce final material that meets established specifications from batch to batch)? -What techniques are used to demonstrate ongoing process capability? -How is it reviewed? What determines the need for re-verification?	
6.5.3 Identification and Traceability	
6.5.3.1 Traceability -Is there a system in place to trace food safety/quality-critical materials upstream and downstream; are there details provided about the product and facility from which the product was initially received as well as information about the product's destination to an appropriate level of the supply chain that ensures food safety? How is the appropriate level determined? -Is an identification code associated with each lot of incoming food safety/quality-critical material to enable traceability in the manufacturing operation? -Are batch/lot numbers assigned such that they are not duplicated and enable tracing of all processes and batch records for each batch?-If processing is on a continuous basis, how is a batch defined? -Is the timeframe during which a particular batch of food safety/quality-critical material was processed through the plant documented?	

-If a new lot number is assigned to a reprocessed lot, can it be traced to the original batch? -If multiple sites produce this material, how can the manufacturing site be determined? -How often are mock recalls performed? -When was the last mock recall performed at this facility? -What is the frequency of mock recall in the facility? -Was the mock recall successful in identifying all recalled product and its location?	
6.5.3.2 Inspection and Test Status -Are food safety/quality-critical materials approved before being used in production? -Have requirements been defined for continuously fed food safety/quality-critical materials? -What controls are exercised to assure that quality-critical materials are not used in a batch prior to release by the Quality Unit? -How are containers and equipment labeled to clearly identify the contents and, if appropriate, the stage of manufacture? -What system is used to identify the status of all quality-critical materials, intermediates and finished products? -If filled unlabeled containers are set aside for future labeling, is there sufficient identification to determine chemical identity, quantity, lot number, and other information needed for traceability? -Is there an effective system for monitoring and retesting or re-evaluating stored quality-critical materials to assure that they are not used beyond their recommended expiration or use date? -Are quarantine procedures established with designated areas, labels, or with a suitably controlled computer system?	
6.5.3.3 Labeling -Does the final product label contain adequate information to identify the contents, quantity, batch number, and manufacturer? -If special storage conditions are necessary, based on the results of stability testing, are they specified on the label?	
6.5.4 Preservation of Product	
6.5.4.1 Handling, Storage and Preservation -Is the warehouse clean and well organized, and materials easily located?	

-Is there adequate space for pest control and housekeeping? -Does the food additive or GRAS substance manufacturer have any scientific evidence (e.g., stability data) to indicate acceptable conditions for the storage of the food additive or GRAS substance? -Is it known if humidity, temperature, or protection from light, etc., are necessary controls to protect the food additive or GRAS substance? -Are these controls in place? -Are appropriate records in place to demonstrate the implementation of these controls? -Where raw materials or intermediates are stored in silos, tanks or other large containers, how is the dispensing of such materials monitored for appropriate accuracy? -If materials are stored outside, do the containers give acceptable protection to the contents? -Are labels indelible? -Are such containers cleaned before their contents are subjected to further processing? -How is stock rotation managed (e.g., First in First out, First expired First out)?	
6.5.4.2 Delivery and Distribution -Are adequate distribution records maintained for all product shipments? -Do shipping records allow traceability of the batch to specific consignees and vice versa in case of retrieval? -How long are the records retained? -Is there an SOP for conducting a product retrieval or market withdrawal? -How and when was the procedure last verified?	
6.6 Control of Measuring and Monitoring Devices -Are there procedures for calibration of quality-critical equipment and for measuring and test instruments? -Do the procedures: assign responsibilities; include schedules; describe methods, equipment, and materials to be used, including standards traceable to national standards; define re-calibration frequency and limits for accuracy and precision and require maintenance of records? -If calibration operations are performed in-house, do the procedures specify handling and storage conditions for the traceable standards? -Is there a procedure specifying that equipment and instruments cannot be used if they are beyond the calibration due date?	

-What actions does the calibration procedure describe to be taken regarding measurements done using equipment or an instrument that is subsequently found to have been beyond the due date or out of calibration limits, and does it require documentation of such actions? -How is the current calibration status of food safety/quality-critical instruments and equipment known to users? -Where are records or logs maintained for calibration operations?	
7. PERFORMANCE EVALUATION	
7.1 General -Do monitoring and measuring activities include the QMS as well as parameters that define food additive or GRAS substance quality?	
7.2 Monitoring and Measurement	
7.2.1 Customer Satisfaction -How is customer satisfaction determined? -Are parameters such as customer complaints and return of food additives or GRAS substances covered? -Does this analysis drive improvement activities?	
7.2.2 Internal Audit -Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the Food Safety & Quality System? -Are audits performed at specified intervals? Are audits scheduled on the importance and status of the activity performed? -Are internal audits documented? -Are management personnel aware of the audit findings and the corrective actions to be taken? -Are necessary steps taken to correct any areas of non-compliance based on the findings and recommendations of the internal audits? -Who is responsible for implementing the corrective actions? -How are corrective actions documented? -Do follow-up audit activities include verification of the effectiveness of corrective actions?	
7.2.3 Monitoring and Measurement of Processes -Are critical process control points and product characteristics under control? -Are appropriate techniques applied to verify this?	

-Are there documented procedures defining the implementation and control of these techniques? -What monitoring occurs of the management system process and process failures? -How are out of trend and deviations noted? What actions are taken when these happen?	
7.2.4 Monitoring and Measurement of Product -Are test methods documented? -What evidence is there that the test methods are fit for purpose? -If the food additive or GRAS substance is claimed to be compliant to compendial requirements, are the test methods those defined in the appropriate pharmacopoeia? -If not has the test method been shown to provide equivalent results? -Is there an adequate system for reviewing and implementing compendial changes? -Are periodic reviews of product quality and conformance measures conducted?	
7.2.4.1 Laboratory Controls -Do laboratory records contain: • A sample description? • Batch number? • Date sample was taken? • Test method reference(s)? • Raw data? • Calculations? • Test results and their comparison to specification? • Identity of analyst(s) and the date each test was performed? -Are reagents and solutions properly labeled? -Are reagents traceable to records describing their preparation? -Do reagents have an expiry date indicated? -Is there a procedure in place for these activities? -Are there records of any standardization? -Are reference standards properly labeled and stored in a manner to protect them from deterioration? -Are COAs from suppliers of primary reference standards available? -Is there a procedure for qualification of secondary reference standards including definition of the requalification period?	
7.2.4.2 Finished Product Testing and Release	

-Are there complete written and approved instructions for performing testing of final product that specify methods, equipment, operating parameters, acceptance specifications? -How does the Quality Unit perform batch release including review of appropriate manufacturing, packaging, labeling, and testing records before batches are released for sale? -Is every product batch tested and approved before shipment? -If not, has the use of reduced testing been justified? -What controls are applied to assure that the food additive or GRAS substance conforms to the documented specifications when the food additive or GRAS substance is manufactured using a continuous process?	
7.2.4.3 Out-of-Specification Test Results -Is there an SOP for investigation of Out-of-Specification (OOS) results and retesting, including a target time frame for completing investigations? -How are the results evaluated? -Under what conditions may an OOS result be discounted? -If statistical methods are used in the evaluation of an OOS are they documented in the relevant SOP? -Are investigations completed and matters resolved before batch release? -Has the impact on laboratory operations, other equipment, batches, products, etc. been considered?	
7.2.4.4 Retained Samples -Are retained samples kept for every batch for an appropriate shelf life? How is this shelf life defined? -Does it relate to the shelf life assigned to the food additive or GRAS substance? Is this documented? -Is the retained sample size at least twice the amount required to perform all specification testing? -Are retained samples appropriately packaged and stored?	
7.2.4.5 Certificates of Analysis -Does the food additive or GRAS substance manufacturer provide certificates of analysis for each batch? Do they comply with recognized guidance? -Does the certificate of analysis contain sufficient information for the intended use of the food additive or GRAS substance? -How are the results determined for each test reported on the COA? Is skip lot testing performed and indicated?	

7.2.4.6 Impurities -Are impurities known and limits established? -Have appropriate safety data, requirements of official compendia and/or sound GMP considerations been considered in establishing those limits? -Are manufacturing processes adequately controlled in order to avoid exceeding such limits? -Is testing performed on the finished material for residual solvents (especially those used in crystallization and final washes) if used in the process? -Are these results included on the COA?	
7.2.4.7 Stability -Is stability or historical data available to support the recommended storage conditions? -If an expiration/re-evaluation interval has been assigned, what is it and how is this interval determined? -If an expiration/re-evaluation interval is assigned, where is it listed so as to inform the customer? -Was the expiration/re-evaluation interval based on data from literature, a stability study on this product or a similar product (e.g., "model product" approach)? -If a "model product" approach is followed, is there a scientifically sound and documented rationale for the selected products? -Is there a written stability program, approved by the Quality Unit that specifies sample size, storage conditions, testing intervals, and tests to be performed? -Does the container used in stability testing simulate the market container? -Are assay methods for stability testing stability indicating? -How are stability data reviewed and trends monitored, adverse trends addressed, and appropriate management notified?	
7.2.4.8 Shelf Life/Retest Periods -How is shelf life determined for the food additive or GRAS substance? -How are shelf life data reviewed, trends monitored, adverse trends addressed and appropriate management notified for the food additives or GRAS substances? -Is a shelf life expectation and/or retest period may be assigned to each food additive or GRAS substance and communicated to the customer?	
7.3 Control of Nonconforming Product	

-Is there a procedure for determining the fate of final product that fails to meet specifications (e.g., reprocessing, downgrading to a lesser grade, release with agreement of the customer, destruction)? -What records are maintained of nonconforming product, related investigations and corrective actions? -How are nonconforming products clearly identified and segregated to prevent unintentional usage or sale? -If product is to be destroyed, is it tracked, controlled, and destroyed in a timely and appropriate fashion? -Are records of such destruction maintained? -Is there a procedure that describes how a food additive or GRAS substance can be retrieved from distribution? Are records kept of such activities?	
7.3.1 Reprocessing -If reprocessing (i.e., repeating steps that are already part of the normal process) is performed, where are complete written instructions found including any additional testing that may be required?	
7.3.2 Reworking -If reworking (i.e., performing steps that are not part of the normal process) is performed, is there a documented review of risk to food additive or GRAS substance quality and approval by the quality unit? -Is rework properly controlled? -Is rework stored properly to protect it from exposure to chemical, microbiological and extraneous matter? -Is rework properly labeled and documented to maintain traceability to the original lot? -If reworking is performed, is there sufficient investigation, evaluation and documentation to assure that the final product is at least equivalent to other acceptable product, meeting all established standards, specifications and characteristics? -Is the impact on stability, impurities, etc., considered and are appropriate controls applied for these issues? -Are individual non-conforming batches blended with others?	
7.3.3 Returned Food Additives and GRAS Substances -Is there a procedure for handling returned goods, including proper identification, segregated storage, testing, and Quality Unit involvement in the evaluation and determination of its fate?	

-Where are records of returned goods maintained and do those records include the appropriate information? -If returned goods are to be reprocessed or disposed of, is it done according to a procedure, with Quality Unit involvement? -Where is it documented?	
7.4 Analysis of Data -Is the effectiveness of the QMS evaluated? -What measures are used and what data is considered to perform this analysis? -Are there periodic reviews of key indicators? What are these indicators?	
7.5 Improvement	
7.5.1 Continual Improvement -What inputs drive continual improvement activities? How are these managed? -What procedures are established for investigation of nonconforming products, returns, complaints, etc.? -How are these causes determined and how are appropriate parties, including management, notified?	
7.5.2 Corrective Action -Are procedures for corrective actions implemented to address the root causes of nonconforming products, returns, and complaints? -Are there procedures in place to cover how customer complaints, retrievals, etc., are received and what actions are taken?	

INTERNATIONAL FOOD ADDITIVES COUNCIL QUALITY SYSTEMS, FOOD SAFETY, AND GOOD MANUFACTURING PRACTICES AUDIT GUIDE FOR FOOD ADDITIVES AND GRAS SUBSTANCES

Table II: Reminder Phrases in Sequence of the IFAC QUALITY SYSTEMS, FOOD SAFETY, AND GOOD MANUFACTURING PRACTICES AUDIT GUIDE FOR FOOD ADDITIVES AND GRAS SUBSTANCES (GMP Guide)

GMP Guide Section	Item	Comments
4. FOOD SAFETY & QUALITY MANAGEMENT SYSTEM-FOOD ADDITIVE GRAS SUBSTANCE QUALITY SYSTEMS		
4.1 General Requirements		
4.2 Documentation Requirements		
4.2.1 General		
4.2.2 Written Plan and Documentation of Preventive Controls	• FSMA	
4.2.3 Quality Manual	• Quality Manual • Quality Policy • Quality Management System (QMS) • GMP	
4.2.4 Control of Documents	• Document Control System • SOPs for Operations • Written Procedures • Employee Access • SOP for Developing SOPs • Periodic Review • Process for Removal • Current Documents • Qualified Personnel Review • Quality Unit Review	

	• Document Control • Training • Withdrawal • Identification • Electronic Documentation	
4.2.5 Control of Records	• FSMA Section 103 • System for Records • Subcontractors • Electronic Signatures • Record Retention • Written Policy • FSMA 103(g) • Storage • Retrievable	
4.3 Change Control	• Written Procedures • Review/Approval • Independent Review/Approval • Effectiveness/Impact • Significance	
4.4 Quality Management		
4.4.1 Management Commitment	• Customer Satisfaction/ Compliance • Documentation • Periodic Review	
4.4.2 Customer Focus	• Customer/Third Party Audit Policy • Customer Requirements	
4.4.3 Quality Policy	• Management Commitment • Management Development • Personnel • Continual Improvement	
4.4.4 Hazard Analysis and Risk-Based Preventive Controls		
4.4.4.1 Hazard Analysis	• Hazard analysis and risk-based preventative controls program • Review/Update	

4.4.4.2 Hazard Identification and Mitigation	• Facility-Specific • Intentionally Introduced • Documentation	
4.4.5 Planning		
4.4.5.1 Quality Objectives	• Measurable Objectives • Conformance to System/GMP	
4.4.5.2 Quality Management System Planning	• Identification of Adequate Resources • Evidence • Integrity of QMS	
4.4.6 Responsibility and Authority	• Job Descriptions • Experience/Training • cGMP Roles/Responsibilities • Quality Unit Responsibilities • Independent Authority • Controls for Delegated Responsibilities • Deviations/Failures/Complaints • Approval/Rejection • Demonstrate Achievement of Review/Investigation • Document Approval/Rejection • Self-Inspection	
4.4.6.1 Internal Communication	• Communication Throughout Organization • QMS Effectiveness • Inform Management	
4.4.6.2 Recalls	• Documented Procedure • Regulatory Requirements • Defined Roles/Responsibilities • Employees • Periodic Review/Update • Mock Recalls • Reportable Food Registry • Two Years	

	• Communication with Customers/Regulators	
4.4.7 Management Review		
4.4.7.1 General	• Periodic Review • Documentation • Demonstration of Involvement • Improvement Opportunities	
4.4.7.2 Review Input	• Audit Results • Customer Complaints/Feedback • Product Conformity • Process Performance • Status of Corrective/Preventive Actions • Regulatory/Legislative Changes	
4.4.7.3 Review Output	• Resources Needed • Define Actions • Documentation	
5. PERSONNEL AND RESOURCE MANAGEMENT		
5.1 Provision of Resources	• Adequate Resources	
5.2 Personnel		
5.2.1 General	• Documentation of Qualifications • Consultant Qualifications • Consultant Training	
5.2.2 Competence, Awareness and Training	• Training SOP • GMP Training Qualifications • Defined Training Requirements • cGMPs/hazard analysis and risk-based preventative controls/Food Defense • Deviation/Quality • Personal Hygiene • Documentation • Training Records • Training Frequency	

	• Breadth of Training • Employee Documentation • Regulatory Changes	
5.2.3 Personnel Hygiene	• Communication • Compliance • Signage • Health Conditions • Storage/Consumption of Food/ Beverage/Tobacco • Unauthorized/Unescorted Access	
5.3 Facility Infrastructure		
5.3.1 Buildings and Facilities	• Cross-Contamination • Prevention • Proximity to Other Materials • Highly Sensitizing/Toxic • Contamination Prevention Controls • Effectiveness • Good State of Repair • Adequate Lab Facilities • Adequate Space for Cleaning	
5.3.2 Equipment	• Commissioned • Good State of Repair • Outdoor Processing	
5.3.2.1 Equipment Construction	• Product-Contact Surfaces • Minimization of Potential Contamination • Suitability of Extraneous Materials • Metal Contamination • Operator Contact	
5.3.2.2 Equipment Maintenance	• Post-Maintenance Cleaning/ Inspecting/Approving System • Inspection SOP/Documentation • Responsibilities • Records	

5.3.2.3 Computer Systems	• Consistent Function • Process to Review Changes • Training • Tampering and Data Alteration • Passwords • Critical System Operations and Emergencies • Personnel Changes • Timely Revocation of Rights • Backup Systems • Disaster Recovery	
5.3.3 Utilities	• Impact on Quality • Contamination	
5.3.4 Water	• Source of Water • Process Water • Non-Potable Water Impact on Food Safety • Controls • Effectiveness of Controls • Chemical/Microbial Quality • Positive Pressure/Backflow • Purification Standards • Purification System Sanitization • Microbial Action Limits	
5.4 Work Environment	• Overhead Contamination • Controls in Production Areas • Glass Breakage Policy	
5.4.1 Air Handling	• Air Handling System • Defined/Documented Air Handling Requirement • System Verification • Cross-Contamination • Filter Maintenance	
5.4.2 Controlled Environment	• Appropriate Controls	

	• Monitoring • Special Environment/ Continuous Monitoring • Interruption to Special Environment	
5.4.3 Cleaning and Sanitary Conditions	• Clean Facilities • SOPs for Sanitation/Cleaning • Compliance Monitoring/ Documentation • Waste Segregation • Frequency of Disposal • Physical/Chemical Contamination	
5.4.4 Pest Control	• Pest Control Program • Verification • Windows/Doors/Openings • Vents • Rodenticides/Herbicides/ Pesticides • Outside Party Performance/ Compliance • Site Map/Report • Manufacturer Review • Pest Control Records • Corrective/Preventive Measures • Unavoidable Contamination	
5.4.5 Lighting	• Adequate Lighting • Shatter Protection	
5.4.6 Sewage and Refuse	• Waste identification • Waste removal • Plumbing in Open Environment • Drain Size • Back Flow	
5.4.7 Washing and Toilet Facilities	• Hand Washing/Drying Facilities • Good Repair • Hot/Cold Water • Soap/Detergent	

	• Hand Dryer/Towels • Toilet Facilities • Showering/Changing Facilities	
6. OPERATIONS		
6.1 Planning of Operations	• Process Flow Diagram • Unit Operation • Dedicated Equipment • Process • Critical Process Parameters • Identification System • Allergen Control	
6.2 Customer-Related Processes		
6.2.1 Determination of Requirements Related to the Product	• Customer Requirements • Communication	
6.2.2 Review of Requirements Related to the Product	• Manufacturer/Customer Agreement • Alternative Processes	
6.2.3 Customer Communication	• Customer-Initiated Changes • Significant Process Changes	
6.3 Design and Development	• Manufacturing Plans	
6.4 Purchasing		
6.4.1 Purchasing Process	• Supplier Qualification/ Verification Program • Periodic Audits • Subcontractor Program • Subcontractor Audits • Corrective Action • Specification • Approved Suppliers • BSE/TSE, Allergens, GMOs	
6.4.2 Purchasing Information	• Supplier Review of Specifications • Timeliness • Significant Changes	

	• Contract Manufacturers/ Laboratories	
6.4.3 Supplier Qualification and Periodic Verification	• Risk Assessment • Documentation • Supplier/Quality Critical Raw Material Qualification System • Supplier Audit Process and Frequency	
6.4.4 Verification of Purchased Product	• Quarantine Procedures • Sampling for Release • Sampling Methods • Bulk Delivery Controls • Sampling/Testing Instructions and Specifications • Testing/Verification of Materials on COA • Supplier Certification/ Qualification	
6.5 Production and Service Provision		
6.5.1 Control of Production and Service Provision		
6.5.1.1 Production Instructions and Records	• Significant Processing Steps • Batch Records	
6.5.1.2 Equipment Cleaning	• Non-Dedicated Equipment Procedures • Cross-Contamination Controls • Cleaning Procedures • Cleaning Frequency • Effectiveness • Cleaning and Use Log • Utensil/Sampling Device Cleaning • Allergen-Sanitation Validation • Campaign Cleaning Interval	
6.5.1.3 Recovery of Solvents, Mother Liquors and	• Re-Use in Same or Other Processes • Comingling	

Second Crop Crystallizations	• Monitoring of Comingled Solvents • Secondary Recovery Procedures • Traceability	
6.5.1.4 In-Process Blending or Mixing	• Blending/Mixing Parameters • Reproducibility • Equipment Emptying and Controls • Non-Conforming Batches • Tailings/Partial Containers	
6.5.1.5 In-Process Control	• Process Controls • In-Process Samples • Training • Manufacturing Instructions • Results Outside Specified Limits	
6.5.1.6 Records of Equipment Use	• Sequence of Activities	
6.5.1.7 Packaging		
6.5.1.7.1 Packaging Systems	• Clearing/Cleaning Procedures • Label Controls/SOP • Label Printing Procedures	
6.5.2 Verification of Processes for Production and Service Provision	• Capability • Ongoing Capability Techniques • Review and Re-Verification	
6.5.3 Identification and Traceability		
6.5.3.1 Traceability	• Traceability System • Identification Codes • Batch/Lot Numbers • Continuous Processing • Documentation of Process Timeframe • Reprocessed Lots • Multiple Sites • Mock Recall Frequency and Success	
6.5.3.2 Inspection and Test Status	• Pre-Production Approval	

	• Continuously-Fed Materials Requirements • Batch Release Controls • Container/Equipment Labels • Identification System • Filled Un-Labeled Containers • Stored Materials Systems • Quarantine Procedures	
6.5.3.3 Labeling	• Content Identification • Special Storage Conditions	
6.5.4 Preservation of Product		
6.5.4.1 Handling, Storage and Preservation	• Warehouse • Pest Control/Housekeeping • Acceptable Conditions • Controls for Humidity/ Temperature/Light • Dispensing of Stored Materials • Outside Storage • Labels • Container Cleaning	
6.5.4.2 Delivery and Distribution	• Distribution Records • Shipping Records/Traceability • Record Retention • Product Retrieval SOP • Verification Procedure	
6.6 Control of Measuring and Monitoring Devices	• Calibration Procedures • Handling/Storage Conditions • Due Dates • Location of Logs	
7. PERFORMANCE EVALUATION		
7.1 General	• QMS • Quality Parameters	
7.2 Monitoring and Measurement		
7.2.1 Customer Satisfaction	• Determination	

	• Customer Complaints/Returns • Improvement Activities	
7.2.2 Internal Audit	• SOP/Procedures/Policies Verification • Specified Intervals • Documentation • Personnel Informed • Corrective Action	
7.2.3 Monitoring and Measurement of Processes	• Critical Control Point Controls and Verification • Documentation of Techniques • Monitoring • Out of Trend/Deviation Actions	
7.2.4 Monitoring and Measurement of Product	• Documentation of Test Methods • Fit for Purpose • Compendial Requirement Compliance or Equivalent Results • Compendial Change Review/ Implementation • Periodic Review	
7.2.4.1 Laboratory Controls	• Contents • Reagent/Solution Labeling • Reagent Traceability • Reagent Expiry Dates • Reagent Procedures • Standardization Records • Reference Standard Labeling • COA Availability • Secondary Reference Standard Qualification	
7.2.4.2 Finished Product Testing and Release	• Instructions • Batch Release Review • Batch Testing/Approval	

	• Conformance of Specification Controls	
7.2.4.3 Out-of-Specification Test Results	• SOP for OOS Investigation • Evaluation of Results • Discounts • Statistical Methods • Investigations/Matters Resolved • Impact on Lab Operations	
7.2.4.4 Retained Samples	• Sample Shelf Life • Product Shelf Life/Documentation • Required Size • Packaging/Storage	
7.2.4.5 Certificates of Analysis	• COA for Each Batch • Intended Use • Determination of Results	
7.2.4.6 Impurities	• Known Impurities • Established Limits • Process Controls • Residual Solvents • Results in COA	
7.2.4.7 Stability	• Stability/Historical Data • Expiration/Re-Evaluation Interval • "Model Product" Approach • Written Stability Program • Containers • Assay Methods • Review of Data/Trends	
7.2.4.8 Shelf Life/Retest Periods	• Shelf-Life Determination • Shelf-Life Data Review/Trends	
7.3 Control of Nonconforming Product	• Failure to Meet Specifications • Nonconforming Product Records • Identification/Segregation • Destroyed Product Procedures/ Records	

	• Product Retrieval	
7.3.1 Reprocessing	• Written Instructions • Additional Testing Requirements	
7.3.2 Reworking	• Documented Review of Risk • Control of Rework • Rework Storage • Rework Labeling • Rework Documentation • Impact on Stability/Impurities • Blending of Non-Conforming Batches	
7.3.3 Returned Food Additives and GRAS Substances	• Returned Goods Procedures • Records Maintenance • Reprocessing/Disposal • Documentation	
7.4 Analysis of Data	• Evaluation of Effectiveness • Measures/Data • Periodic Review of Key Indicators	
7.5 Improvement		
7.5.1 Continual Improvement	• Continual Improvement Inputs • Investigation Procedures	
7.5.2 Corrective Action	• Implementation of Procedures • Customer Complaints/ Retrievals	