APPENDIX E

COMPARISON OF FOOD GMPS TO QUALITY SYSTEMS AND OTHER GMPS

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
Key Provisions				
▪ Personnel - Disease control - Cleanliness - Education and training, supervision ▪ Plants and grounds - Grounds - Plant design and construction ▪ Sanitary operations - General maintenance - Substances used for cleaning - Pest control - Sanitation of food-contact surfaces - Storage and handling. ▪ Sanitary facilities and controls - Water supply - Plumbing - Sewage disposal - Toilet facilities - Hand-washing facilities - Rubbish and offal disposal ▪ Equipment and utensils ▪ Processes and controls - Raw materials - Manufacturing operations ▪ Warehousing & distribution	▪ Management responsibility - Management commitment - Customer focus - Quality policy - Planning - Responsibility, authority, and communication - Management review ▪ Resource management - Provision of resources - Human resources - Infrastructure - Work environment ▪ Product realization - Planning of product realization - Customer-related processes - Design and development - Purchasing - Production and service provision - Control of monitoring and measuring devices ▪ Measurement, analysis, and improvement - Monitoring and measurement - Control of nonconforming product - Analysis of data - Improvement ▪ Quality management system - Documentation requirements	▪ Management responsibility ▪ Marketing ▪ Specification and design ▪ Procurement ▪ Production and production control ▪ Product verification ▪ Measuring and test equipment ▪ Nonconformity ▪ Corrective action ▪ Handling and post-production ▪ Documentation and records ▪ Personnel ▪ Product safety and liability ▪ Quality methods	▪ QS Requirements - Management responsibility - Quality audit - Personnel ▪ Design Control ▪ Document Controls ▪ Purchasing Controls ▪ Identification and Traceability ▪ Production and process Controls ▪ Acceptance Activities ▪ Nonconforming Product ▪ Corrective and Preventative Action ▪ Labeling and Packaging ▪ Handling, Storage, Distribution, and Installation ▪ Records ▪ Servicing ▪ Statistical Techniques	▪ Organization and Personnel - Responsibilities of quality control unit - Personnel qualifications and responsibilities ▪ Buildings and facilities - Design & construction - Sanitation & maintenance ▪ Equipment - Design, size, & location - Construction, cleaning, & maintenance ▪ Control of components and drug product containers and closures ▪ Production & process controls - Written procedures, deviations - Change in components - Equipment identification - Sampling and testing of in-process materials and drug products - Control of microbiological contamination - Reprocessing ▪ Packaging and labeling control ▪ Holding & distribution ▪ Laboratory controls - Testing and release for distribution - Stability testing ▪ Records and reports

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Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
				▪ Returned & salvaged drug products
Training				
▪ Appropriate training for food handlers and supervisors in proper food handling techniques and food protection principles. ▪ Training should ensure awareness of the dangers of poor personal hygiene and insanitary practices.	▪ Personnel training necessary to meet organization needs; identification of training needs through a gap analysis ▪ Appropriate level of training in hygiene practices by job function (basic-level and advanced-level training) ▪ Training in sensory evaluation and identification of hazards and associated controls ▪ Training of personnel in appropriate hygienic practices ▪ Training and reevaluation of testing personnel	▪ Training all levels of personnel within the organization: Selection & training of recruited personnel & personnel transferred to new assignments ▪ Training of executive management in quality system operation and criteria for evaluating the effectiveness of the system ▪ Training of technical personnel (including marketing, procurement, and product & process engineering personnel) in statistical techniques, process capability studies, statistical sampling, data collection & analysis, problem identification, problem analysis, and corrective action ▪ Training of supervisors and workers in their respective tasks, such as equipment operation, reading & understanding of documentation provided ▪ Formal qualification of personnel performing specialized operations ▪ Motivation and quality awareness ▪ Measuring quality achievements and	▪ Management responsibility to define training needs for personnel ▪ Training in current GMP regulation and how individual job functions relate to the overall quality system ▪ Training for temporary work under special environmental conditions	▪ Training in the regulations applicable to each employee ▪ Additional training for supervisory personnel to ensure the safety, identity, strength, quality, and purity of the product ▪ Personnel who provides training must be qualified to do so

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Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
		recognition of good performance		
Audits				
Audits are not explicitly specified	▪ Internal audits at planned intervals to determine whether the quality management system (1) conforms to the planned arrangements and (2) is effectively implemented and maintained ▪ Selection of auditors should ensure objectivity and impartiality (auditors should not audit their own work) ▪ Internal audits of management system records, hygiene, housekeeping, and other functions ▪ Management review of internal audit results	▪ Internal audits of the quality system at regular intervals to evaluate the effectiveness of the various quality system elements ▪ Audit needs to have a plan with a clearly defined scope and reason (i.e., routine verification, organizational change, consumer complaints, etc.) ▪ To avoid conflict of interest, auditors should not audit their own work ▪ Audit results should be documented with specific examples of deficiencies and noncompliance and suggestions of corrective/preventive actions ▪ Review and evaluation of the quality system by company management members, customers, or qualified independent auditors ▪ Quality system audits should consist of (1) specific findings, (2) overall effectiveness of the quality system in achieving quality objectives, and (3) considerations for updating the quality system with changes brought about by new technologies, quality	▪ Management needs to establish procedures for quality audits of its documented quality system and ensure that they are performed ▪ Only those records that demonstrate the quality auditing system are to be made available to an FDA inspector. FDA does not have access to the actual audit reports	▪ Audits are not explicitly specified but are embodied within the required record review process. ▪ Annual record review to evaluate the applicability of quality standards, need for changes in specifications, manufacturing processes, or control procedures.

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Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
		concepts, market strategies, customer requirements, etc.		
Documentation				
No documentation requirements explicitly specified, except for supplier certification for cleaning compounds and raw materials.	▪ Records of quality management system reviews ▪ Personnel records ▪ Product realization process records ▪ Records of customer-related product requirement reviews ▪ Records of design and development inputs, outputs, reviews, verification, and validation ▪ Design and development changes and reviews including control process changes ▪ Supplier selection evaluation records ▪ Production process validation records where verification is not possible ▪ Monitoring and measuring device calibration and verification records ▪ Internal audit records ▪ Records of production inspection and tests ▪ Records of nonconforming products ▪ Corrective and preventive action records.	▪ Sufficient documentation of achievement of required product quality and food safety ▪ A method for removing and disposing of documents that are out of date ▪ Documents include: specifications, test procedures, inspection instructions, work instructions, operational procedures, quality manuals, laboratory procedures, and quality assurance procedures ▪ Records should be for verification of operation of quality system ▪ Examples of records include: inspection reports, test data, qualification reports, validation reports, audit reports, calibration data, and regulatory inspection reports.	Explicitly requires that all of the following records be readily available to FDA inspectors ▪ Device master record: device, production process, quality assurance, packaging and labeling, and installation specifications. ▪ Device history record: date of manufacture, quantity manufactured, quantity distributed, acceptance records (of DMR), identification label and control numbers. ▪ Quality system record: procedures and documentation of activities ▪ Complaint files: compliant files to determine if investigation needed. If so, record of investigation	Explicitly requires that all of the following records be readily available to FDA inspectors ▪ Equipment cleaning & use log: Must contain dates, times, products, lot numbers, and signatures ▪ Component, drug product container, closure, and labeling records: Supplier names, lot numbers, receiving codes, test results, individual inventory records, documentation of labeling examination, and records of rejected materials ▪ Master production & control records: Prepared, dated and signed by one individual and checked by another ▪ Batch production and control records: documentation of completion of each significant step in manufacturing ▪ Laboratory records: All data, test method modification records, stability testing results ▪ Distribution records: Date

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				and quantity shipped ▪ Complaint files
Evaluation/Validation				
There are no evaluation/validation requirements to determine whether a performed activity is achieving its goal. Only for raw materials, the facility is to "verify" compliance using supplier certification or some other method.	▪ Evaluation of information relating to customer perceptions of whether the organization has met its customer requirements ▪ Evaluation of the effectiveness of the actions taken, such as training and education ▪ Evaluation of the ability of results of design and development to meet requirements ▪ Physical, chemical, microbiological, shelf-life, and sensory evaluations ▪ Evaluation of design and development changes on constituent parts and product already delivered ▪ Reevaluation of testing personnel ▪ Quality system effectiveness evaluation ▪ Evaluation of the need for action to prevent occurrence of nonconformities ▪ Validation of product shelf-life through market research and transit tests	▪ Process and product design qualification and validation involving periodic evaluation of the design at significant stages ▪ Validation of the process and product design through small-scale trial and sample tests ▪ Periodic reevaluation and requalification of the product to ensure that it meets all specified requirements ▪ Product verification ▪ Evaluation of training effectiveness	▪ Verification of product design, i.e., testing to determine whether the design output meets the functional and operational requirements of design inputs ▪ Design validation with lab testing of prototypes ▪ Process validation and revalidation in case of changes or process deviations ▪ Validation of computer software when it is used as part of production or the quality system ▪ Evaluation of the need for an investigation of a nonconforming product ▪ Retesting and reevaluation of the nonconforming product after it has been reworked	▪ Process validation ▪ Evaluation of product and process deviations ▪ Verification of yield calculations and component charge-ins by different people

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	▪ Ensuring that the product meets customer requirements through specific target user groups or test marketing ▪ Design and development validation, revalidation upon design and development changes ▪ Process validation ▪ Test method validation			