NSF Standard(s) Impacted: NSF/ANSI 455-4 Good Manufacturing Practices for OTC

Background:
Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Harmonization the standard format to match 455-2 GMP for Dietary Supplements, and 455-3 GMP for Cosmetics under the ISO Format.

Changing the table of context and section, numbering to be consistent with both standards. Updated title 4.2, made some grammar change on clause 4.2.5, removed title 4.3 and renumbered section 4.3 under 4.2 to harmonization for OTC is the table of contents for audit requirements.

Recommendation:
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of strike-out and additions by grey highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration; etc.

4.2 Leadership and commitment

4.2.1 Management participates in the design, implementation, monitoring, and maintenance of the company quality system. [ICH Q10]

4.2.2 Management conducts reviews of process performance and product quality. [ICH Q10]

4.2.3 Management has established a quality policy and quality objectives. [ICH Q10]

4.2.4 The organization shall prepare a quality manual describing the quality management system, the quality policy, and the organization’s commitment to quality management system requirements and quality risk management.

4.2.5 Internal communications assure the flow of appropriate information throughout the organization regarding the Standard and applicable regulatory requirements. Senior management is notified in the event of critical quality issues.

4.3 Organization roles, responsibilities, and authorities

4.3.1 A quality unit is defined – including quality assurance (QA) and quality control (QC) – that is independent of production. [21 CFR § 211.22]

4.3.2 Quality unit personnel have established roles and responsibilities covering requirements defined in 21 CFR Part 211, and procedures have been established to carry out these responsibilities. [21 CFR § 211.22 & 21 CFR § 211.184]

4.3.3 QA operations and authority have been established for manufacturing records. [21 CFR § 211.22 & 21 CFR § 211.184]
4.3.4 4.2.9 QA operations determine if all specifications have been met (raw material, components, in-process, final product specifications) and assign batch disposition (approve / release or reject) on each finished batch for distribution. [21 CFR § 211.22 & 21 CFR § 211.192]

4.3.5 4.2.10 Procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects, and related actions. [21 CFR § 211.180 & ICH Q10]

4.3.6 4.2.11 Procedures have been established that define work requirements for personnel to ensure hygienic practices have been implemented to prevent microbial contamination. [21 CFR § 211.28]

4.3.7 4.2.12 Procedures have been established to include appropriate protective garments, personal hygiene, hand washing and sanitization, etc., prior to starting work and at any time where personnel can become soiled / contaminated. [21 CFR § 211.28]

4.3.8 4.2.13 Personnel shall be qualified and have adequate training, experience and / or education necessary to perform job functions. [21 CFR § 211.25]

4.3.9 4.2.14 Personnel who are designated as supervisors have the education, training and experience or any combination thereof to perform assigned functions. [21 CFR § 211.25]

Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

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Is this a revision of a previous Issue Paper (if yes put original issue number): No
Submission Date: ______________

Please submit to: Joint Committee Secretariat, Rachel Brooker at rbrooker@nsf.org or to standards@nsf.org

*Type written name will suffice as signature