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Joint Committee on Pharmaceutical Excipients

March 20, 2024

Proposed revision to NSF/IPEC/ANSI 363 – Pharmaceutical Excipients (363i17r1)

Revision 1 of NSF/IPEC/ANSI 363, issue 17 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by April 10, 2024** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

The proposed revision will update Sections 6.3 and 8.2.4.

Background

There are 2 clauses that address change, Section 6.3 - Planning for Change and Section 8.2.4 - Changes to requirements for products and services. Readers are unaware of the difference.

If you have any questions about the technical content of the ballot, you may contact me in care of:

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[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/IPEC/ANSI Standard
for Pharmaceutical Excipeints –

Good Manufacturing Practices for Pharmaceutical Excipeints

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6 Planning

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6.3 Planning of changes

Changes to the QMS shall be performed in a structured manner with consideration for, as appropriate, the:

— intended changes can be realized;
— changes to roles and responsibilities;
— impact of the two previous points on interested parties;
— risks and opportunities arising from the changes have been evaluated; and
— impact on objectives and the plan to realize them.

Note: A change that may impact quality of the excipient or service provided is covered in 8.2.4

If it has been determined that a change impacts an interested party, then that party shall be notified.

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8 Operation

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8.2 Requirements for products and services

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8.2.4 Changes to requirements for products and services

Top management shall establish and maintain a robust change control program under the QMS (see 8.5.6). This program shall be designed to ensure that excipient quality is assessed and maintained in accord with principles of quality risk management when changes are planned and implemented, respectively.

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