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# FDA Proposes Program To Establish Voluntary Pharma Quality Standards

By Mark Durivage, Quality Systems Compliance LLC


The FDA's Center for Drug Evaluation and Research (CDER) recently released draft guidance aimed at the development and recognition of voluntary consensus standards for pharmaceutical quality for the purpose of public comment.

In the draft guidance, CDER states its belief that recognition of voluntary consensus standards "will help promote innovation in pharmaceutical development and manufacturing and streamline the compilation and assessment of marketing applications for products regulated by CDER."

In a press release announcing the draft guidance, former FDA Commissioner Scott Gottlieb said this new program "will facilitate recognition of other standards concerning pharmaceutical quality to make the adoption of advances in drug manufacturing and application review more efficient; and encourage innovation in how drugs are manufactured."

Under the proposed FDA rules, informally recognized voluntary consensus standards related to pharmaceutical quality will be made available through a database on CDER's public website, where information sheets will accompany each standard. These

information sheets will describe the scope and the extent of CDER's informal recognition of that standard and other applicable information potentially helpful to industry and CDER staff.

For purposes of this proposed program, CDER intends to consider for informal recognition standards developed by voluntary consensus standards bodies that adhered to the following five elements of the standards development process:

1. **Openness** – The procedures or process for standards development are transparent and open, with interested parties given "meaningful opportunities" to engage in development.
2. **Balance** – Industry stakeholders are given the opportunity to take part in standards development, with no single interest group controlling the decision-making process.
3. **Due process** – The development process for the voluntary consensus standards body includes a due process provision, providing enough time for industry stakeholders to review and prepare positions to ensure the entire process is transparent and impartial and allows for resolving conflicting points of view.
4. **Appeals process** – An appeals provision is included in the standards development process to allow the standards development body to impartially address procedural appeals.
5. **Consensus** – Comments and objections are considered using "fair, impartial, open, and transparent processes" during the development of consensus.

"Once we've recognized a standard, applicants will generally not have to validate the approach outlined in the standard and can focus on appropriate use of the method and acceptance criteria," Gottlieb said. "Our hope is that establishing this program will also encourage the development of standards for emerging technologies that can improve drug quality and reduce manufacturing costs."

CDER believes this informal program will help foster and encourage innovation in pharmaceutical development and manufacturing, and streamline the assessment process of marketing applications for products regulated by CDER — especially for those products utilizing new or emerging technologies.

CDER's Pharmaceutical Quality Standards Working Group (PQSWG) will serve as a coordination and advisory group for the FDA's participation in voluntary consensus standards activities. Once CDER considers any public comments it receives regarding the issuance of this draft guidance, the PQSWG will develop an internal process for informally recognizing voluntary consensus standards and proceduralize the process and make it publicly available.

Specifically, the PQSWG will be charged will the following tasks:

- Evaluate all requests for informal recognition of voluntary consensus standards
- Confirm that each proposed voluntary consensus standard does not conflict with current statutes, regulations, or policies
- Confirm that each proposed voluntary consensus standard adheres to the five elements of the standards development process (indicated above).

If the PQSWG feels the proposed voluntary consensus standard meets qualifying criteria, the PQSWG may recommend the formation of a subgroup of subject matter experts to review the standard, recommend that an FDA laboratory evaluate the proposed standard, prepare the information sheet describing the scope and the extent of CDER's informal recognition of that standard, and then publish the information sheet on a searchable database on CDER's public website.

Recent changes in the organization, structure, and philosophy at the FDA is a positive sign for the pharmaceutical industry. By informally recognizing voluntary consensus standards, the FDA will help promote safety, efficacy, and security of drugs by fostering pharmaceutical development and manufacturing innovation and streamlining the compilation and assessment of marketing applications.

**About The Author:**

Mark Allen Durivage has worked as a practitioner, educator, consultant, and author. He is managing principal consultant at Quality Systems Compliance LLC and is an ASQ Fellow and SRE Fellow. He earned a B.A.S. in computer-aided machining from Siena Heights University and an M.S. in quality management from Eastern Michigan University. He holds several certifications including CRE, CQE, CQA, CSQP, CSSBB, RAC (Global), and CTBS. He has written several books available through ASQ Quality Press, published articles in *Quality Progress*, and is a frequent contributor to Life Science Connect. Durivage resides in Lambertville, Michigan. Please feel free to email him at mark.durivage@qscompliance.com with any questions or comments, and connect with him on LinkedIn.