**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Edwin Jao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1684, *edwin.jao@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

*Regarding the ICH:* Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–348–1967, *Brooke.DalSanto@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Q3E Guideline for Extractables and Leachables'' and a draft supporting document entitled ''Supporting Documentation: Class 3 Leachable Monographs.'' The draft guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In August 2025, the ICH Assembly endorsed the draft guideline entitled ''Q3E Guideline for Extractables and Leachables'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft guidance provides a holistic and risk-based framework for the assessment and control of E&L in pharmaceutical products, expanding upon existing ICH impurity guidelines. The draft guidance discusses thresholds for identifying, quantifying, and reporting E&L. The draft guidance includes draft Class 3 leachable monographs in its supporting documentation.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''Q3E Guideline for Extractables and Leachables.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 58 relating to good laboratory practice have been approved under OMB control number 0910–0119. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice in the manufacture, processing, packing and storage of finished pharmaceuticals have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 314 relating to the submission of new drug applications have been approved under OMB control 0910–0001. The collections of information in 21 CFR part 601 relating to the submission of biological license applications have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance and supporting documentation at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

**Lowell M. Zeta,**

*Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–21702 Filed 11–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2003–D–0431]**

### Medical Gases—Current Good Manufacturing Practice; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Medical Gases—Current Good Manufacturing Practice.'' This guidance is intended to assist manufacturers of medical gases in complying with regulations for current good manufacturing practice (CGMP) that become effective on December 18, 2025 (note, the conforming amendments to the CGMP requirements for combination products became effective February 2, 2026). These regulations are

specific to medical gases for human and animal use and, like all CGMP requirements, contain the minimum requirements to ensure that manufacturing processes operate under a state of control to meet prespecified quality standards for identity, strength, quality, and purity, but are tailored more narrowly to how medical gases are manufactured, packaged, labeled, stored, and distributed. This draft guidance is being issued to reflect new and revised regulations in several areas to reduce the regulatory burden, as appropriate, for the medical gas industry. This draft guidance revises and replaces the draft guidance entitled ''Current Good Manufacturing Practice for Medical Gases'' issued in June 2017.

**DATES:** Submit either electronic or written comments on the draft guidance by January 30, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2003–D–0431 for ''Medical Gases—Current Good Manufacturing Practice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 301–796–6341 or Scott Fontana, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0656.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Medical Gases—Current Good Manufacturing Practice.'' This guidance revises and replaces the draft guidance issued on June 29, 2017, entitled ''Current Good Manufacturing Practice for Medical Gases'' (82 FR 29565), which described how medical gas manufacturers could comply with applicable requirements in the general drug CGMP regulations under parts 210 and 211 (21 CFR parts 210 and 211).

''Medical gas'' is defined in section 575(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ddd(2)) as a drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state and administered as a gas. Medical gases include ''designated medical gases'' (DMGs) as defined in section 575(1) of the FD&C Act; medically appropriate combinations of DMGs; medical gases marketed under applications submitted under sections 505 (21 U.S.C. 355) or 512 (21 U.S.C. 360b) of the FD&C Act; and any marketed unapproved drugs that are medical gases.

On June 18, 2024, FDA issued a final rule (89 FR 51738) that established requirements more specifically tailored to medical gases to better address the unique characteristics of these drugs. The final rule was intended to reduce the regulatory burden, as appropriate, for the medical gas industry. This deregulatory effort addressed several areas in which either new regulations

were needed, or existing regulations required revision because they were not well-suited for medical gases. One area where new regulations were established was CGMP.

Prior to implementation of the final rule, medical gas manufacturers were subject to the general drug CGMP regulations for finished pharmaceutical under parts 210 and 211, but these regulations did not account for differences in how medical gases are manufactured compared to other drugs. Notably, medical gases are generally manufactured in a closed, sealed pressurized system; are not expected to expire or degrade under ordinary storage conditions; and are contained in cylinders that are reused many times. In addition, medical gas manufacturing involves entities downstream of the original gas manufacturer who further manufacture, process, pack, or hold medical gases. Mix-ups or the accidental use of rejected or quarantined product generally pose more of a risk to patient safety than does contamination.

Because of these differences, certain requirements in the general CGMP regulations under parts 210 and 211 were unnecessary to assure the safety, identity, strength, quality, and purity of medical gases (*e.g.,* distributing oldest stock first, use of filters, and certain requirements for controlling microbial contamination). FDA addressed these differences in the June 2017 draft guidance for industry.

However, those recommendations will no longer be applicable with the implementation of the final rule. As of December 18, 2025, medical gas manufacturers are subject to medical gas-specific CGMP regulations under part 213 (21 CFR part 213) rather than the general CGMP regulations under parts 210 and 211 (note, conforming amendments to CGMP regulations for combination products are effective February 2, 2026). The guidance announced in this notice explains how medical gas manufacturers can comply with part 213, and includes among its recommendations clarification on the following:

- Ensuring the reliability of a supplier's capabilities
- Protecting against container closure leaks
- Appropriate cleaning and maintenance of buildings, facilities, and equipment used in medical gas manufacture
- Prevention of labeling and product mix-ups
- Circumstances requiring stability testing, expiration testing, or both
- Handling of returned and salvaged medical gases

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Medical Gases—Current Good Manufacturing Practice.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 relating to electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR part 213 relating to current good manufacturing practice requirements for medical gases, including 21 CFR 213.22(d), which states that quality unit activities (such as quality agreements with suppliers) and procedures should be in writing, have been approved under OMB control number 0910–0906.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–21689 Filed 11–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA 2024–N–3945]**

### FDA's Strategy Document on Innovative Manufacturing Technologies

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the publication of FDA's Strategy Document on Innovative Manufacturing Technologies (Strategy Document), which outlines specific actions FDA has taken and the Agency's plans for fiscal years 2023–2027 to facilitate the use of innovative manufacturing technologies. As part of the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023–2027 (PDUFA VII), FDA committed to advance the use and implementation of innovative manufacturing. The actions described in the Strategy Document are based on lessons learned from FDA's experiences with submissions involving advanced manufacturing technologies as well as public input.

**DATES:** The announcement of the strategy document is published in the **Federal Register** on January 30, 2026.

**ADDRESSES:** You may submit either electronic or written comments as follows.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you