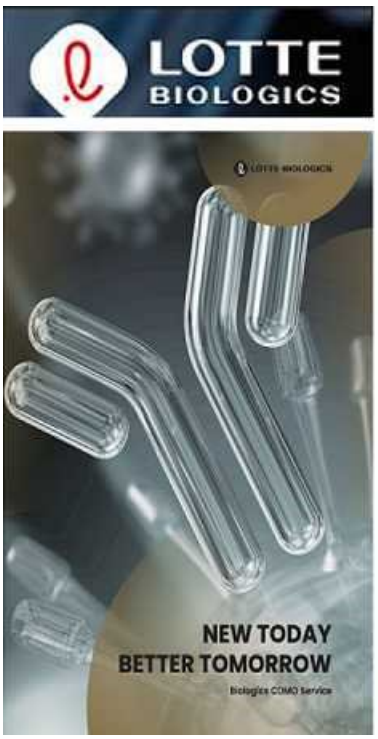


East Syracuse, NY, US

The Syracuse site has 35,000L Drug Substance manufacturing, storage, and quality control capabilities. The facility is fully GMP operational with clinical and commercial capabilities.

As of today, the facility received multiple product approvals from more than 60 different global regulatory bodies including FDA, EMA, PMDA, and MFDS

INSPIRED BY SCIENCE...EMBRACING DIVERSITY...FOSTERING TALENT...CONNECTING LIVES

SmartSearch Plus+ Search Operators:

Note: *All Search Operators must be in CAPITAL LETTERS *

NEAR → finds one term next to another term, 8 words apart by default or (x) words away as in NEAR(x) contained in (a) PDF Guidance or (b) 21 CFR

e.g. 'Quality' NEAR 'supplier' – same as ('Quality' NEAR 'supplier') –

finds PDF Guidances or 21 CFRs where 'quality' is next to 'supplier' 8 words apart

AND → finds ALL terms BOTH contained in (a) PDF Guidance or (b) 21 CFRs clause

e.g. 'Quality' AND 'supplier', ('Quality' 'supplier')

finds PDF Guidances or 21 CFRs where 'quality' AND 'supplier' are both found

1 of 1

Rs clause

finds PDF Guidance or 21 CFRs clauses where 'quality' or 'supplier' is found

e.g. 'Quality' NOT 'supplier', same as (Quality' NOT 'supplier')

finds PDF Guidance or 21 CFRs clauses where none of the terms specified are found

Wildcard '*' → finds words that contain any character after leading characters speficified contained in (a) PDF Guidance or (b) 21 CFRs clauses

Postmarket* NEAR device* safety NEAR report*

SmartSearch Filters

FDA Regulation (21 CFR/Guidance) 📚

Select value

👩‍🤝‍👨 FDA Agency (CBER/CDRH/CDER)

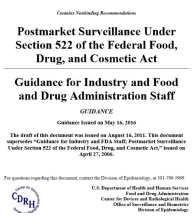
Select value

🔎 FDA Search Results Shown Below 👀

51 results for '***Postmarket* NEAR device* safety NEAR report****'

Click to Sort SmartSearch Results

media-81015-Postmarket-Surveillance-Under-Section-522-Guidance


Consider Nonbinding Recommendations

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry and Food and Drug Administration Staff

GUIDANCE

Guidance Issued on May 16, 2016

The draft of this document was issued on August 16, 2011. This document supersedes "Guidance for Industry and FDA Staff; Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act," issued on April 27, 2006.

For questions regarding this document, contact the Division of Epidemiology, at 301-796-5969.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Division of Epidemiology

Balancing-PreOostmrkt-Data Collection for PMAs

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

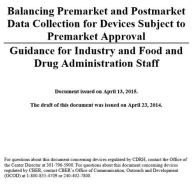
Guidance for Industry and Food and Drug Administration Staff

Document issued on April 13, 2015.

The draft of this document was issued on April 23, 2014.

For questions about this document concerning devices regulated by CDRH, contact the Office of the Center Director at 301-796-5900. For questions about this document concerning devices regulated by CBER, contact CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

Balancing Premarket and Postmarket Data


Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval

Guidance for Industry and Food and Drug Administration Staff

Document issued on April 13, 2015.

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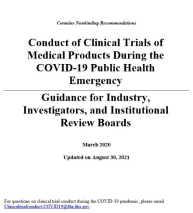
Conduct-of-Clincial-Trial-During-COVID 19-QA Updated 08.30.21


Contains Nonbinding Recommendations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

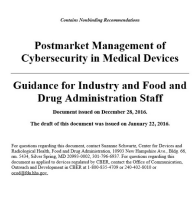
Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Updated on August 30, 2021

For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicalbrookes.COVID19@fda.hhs.gov.

Postmarket-Management-of-Cybersecurity-in-Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff


Contains Nonbinding Recommendations

Postmarket Management of Cybersecurity in Medical Devices

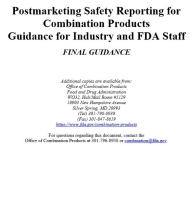
Guidance for Industry and Food and Drug Administration Staff

Document issued on December 28, 2016.

The draft of this document was issued on January 22, 2016.

For questions regarding this document, contact Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5434, Silver Spring, MD 20993-0002, 301-796-6837. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach, and Development at CBER at 1-800-835-4709 or 240-402-8010 or ocod@fda.hhs.gov.

Postmarketing Safety Reporting for Combination Products

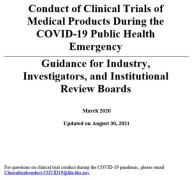

Postmarketing Safety Reporting for Combination Products
Guidance for Industry and FDA Staff

FINAL GUIDANCE

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub Mail Room 4129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-8930
(Fax) 301-847-8619
http://www.fda.gov/combinationproducts

For questions regarding this document, contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

Conduct-of-Clincial-Trial-During-COVID 19-QA Updated 08.30.21


Contains Nonbinding Recommendations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Updated on August 30, 2021

For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicalbrookes.COVID19@fda.hhs.gov.

Medical Device Classification Product Codes

Contains Nonbinding Recommendations

Medical Device Classification Product Codes

Guidance for Industry and Food and Drug Administration Staff

Document issued on April 11, 2012.

The draft of this document was issued on January 3, 2012.

For questions about this document regarding CDRH or CBER-regulated devices, contact the CDRH 1500A Program at 1500a_program@fda.hhs.gov or (301) 796-5640.

New-Contrast-Imaging-Indication-Considerations-for-Devices-and-Approved-Drug-and-Biological-Products

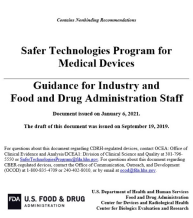
Guidance for Industry:
New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products

additional copies are available from:
Office of Combination Products, OFA 2
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane, Rockville Pike
Rockville, MD 20857
(301) 827-4640
(Fax) 301-827-2385
http://www.fda.gov/oc/combination

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products (OCP) in Office of the Commissioner
Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)

December 2009

Safer-Technologies-Program-Guidance


Contains Nonbinding Recommendations

Safer Technologies Program for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 6, 2021.

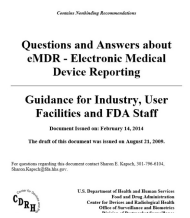
The draft of this document was issued on September 19, 2010.

For questions about this document regarding CDRH-regulated devices, contact OCEA, Office of Clinical Evidence and Analysis/DCRA1, Division of Clinical Science and Quality at 301-796-5700 or SafeTechnologiesProgram@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

[Questions-and-Answers-about-eMDR---Electronic-Medical-Device-Reporting---Guidance-for-Industry--User-Facilities-and-FDA-Staff-(PDF)](#)



Contains Nonbinding Recommendations

Questions and Answers about eMDR - Electronic Medical Device Reporting

Guidance for Industry, User Facilities and FDA Staff

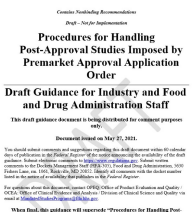
Document Issued on: February 14, 2014

The draft of this document was issued on August 21, 2008.

For questions regarding this document contact Sharon E. Kapsch, 301-796-6134, Sharon.Kapsch@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics

[Procedures-PAS-Guidance-Draft](#)



Contains Nonbinding Recommendations

Draft – Not for Implementation

Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance document is being distributed for comment purposes only.

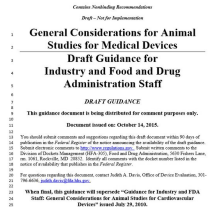
Document issued on May 27, 2021.

You should submit comments and suggestions regarding this draft document within 60 calendar days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document contact OPEQ Office of Product Evaluation and Quality / OCEA Office of Clinical Evidence and Analysis - Division of Clinical Science and Quality via email at DHDecisionSciences@fda.hhs.gov.

When final, this guidance will supersede "Procedures for Handling Post-

[General-Considerations-for-Animal-Studies-for-Medical-Devices---Draft-Guidance-for-Industry-and-Food-and-Drug-Administration-Staff](#)



Contains Nonbinding Recommendations

Draft – Not for Implementation

General Considerations for Animal Studies for Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

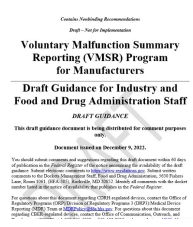
Document issued on: October 14, 2015.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Judith A. Davis, Office of Device Evaluation, 301-796-6546, judith.davis@fda.hhs.gov.

When final, this guidance will supersede "Guidance for Industry and FDA Staff: General Considerations for Animal Studies for Cardiovascular Devices" issued July 29, 2010.

[Voluntary Malfunction Summary Reporting](#)



Contains Nonbinding Recommendations

Draft – Not for Implementation

Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

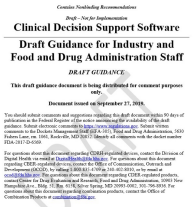
This draft guidance document is being distributed for comment purposes only.

Document issued on December 9, 2022.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rooms 1061, 1035 (E-101), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH regulated devices, contact the Office of Regulatory Programs (ORP) in the Center for Biologics Evaluation and Research (CBER) Medical Device Reporting (MDR) Team at MDRPolicy@fda.hhs.gov. For questions about this document regarding CBER regulated devices, contact the Office of Communication, Outreach, and

[Clinical Decision Support Software](#)



Contains Nonbinding Recommendations

Draft – Not for Implementation

Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

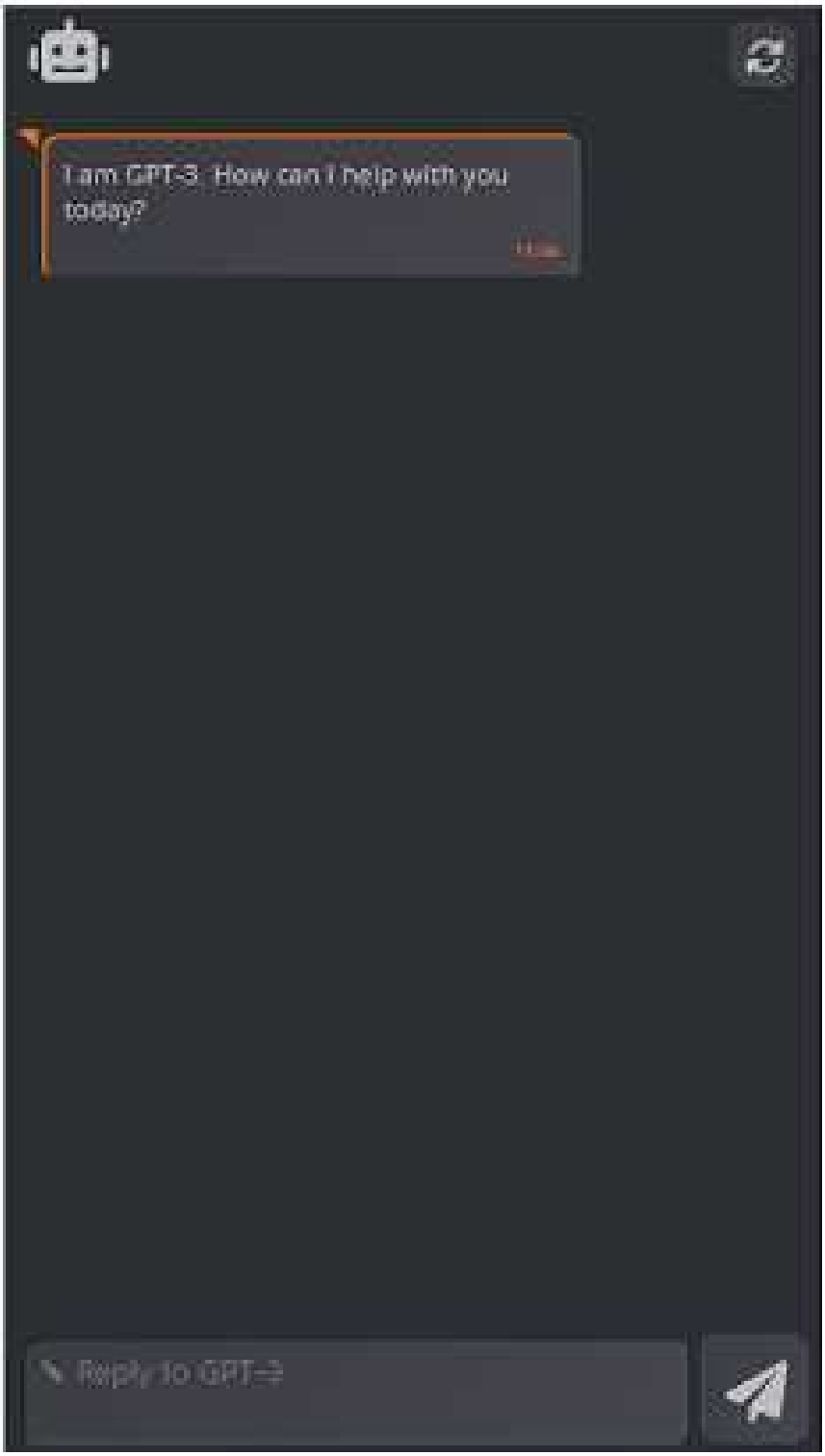
This draft guidance document is being distributed for comment purposes only.

Document issued on September 27, 2019.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number FDA-2017-D-5569.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health via email at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding combination products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, RM. 6318, Silver Spring, MD 20993-0002, 301-796-5930. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

1 2 3 4 »



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