

Product Quality Considerations for Emergency Use Authorizations (EUAs)

FDA Small Business Regulatory Education for Industry (REdI)

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A quality product of any kind consistently meets the expectations of the user – drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

One Quality Voice for Patients

FDA U.S. FOOD & DRUG ADMINISTRATION

OPQ **Collaborates** so that Quality Medicines are Available to Patients
Innovates
Communicates
Engages



"In 2013, I was hospitalized with H1N1 along with 6 other patients. I was the only one who survived. I am more than a statistic. I am a mother!"
- OPQ Reviewer

One Quality Voice for Patients. *We are Patients, Too.*

www.fda.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Collaborates
OPQ **Innovates** so that Better Medicines are Available to Patients
Communicates
Engages



"My grandson was born prematurely. Thanks to the lung surfactant he received, that my colleague worked so hard on, he has grown into a healthy little boy."
- ONDP Reviewer

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FDA U.S. FOOD & DRUG ADMINISTRATION

Collaborates
Innovates
OPQ **Communicates** to Patients that they can Trust the Next Dose of Medicine
Engages



"My friend whose medical struggles and early death definitely factored into my decision to join the FDA in 1993"
- ONDP Scientist

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FDA U.S. FOOD & DRUG ADMINISTRATION

Collaborates
Innovates
Communicates
OPQ **Engages** asking YOU to Join us in a Commitment to Quality in the Name of the Patient



"My eldest son was diagnosed with insulin dependent diabetes in 1992, and developed an injection site reaction to pork insulin. He was a subject in phase III clinical trial for Humulin."
- ONDP Scientist

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We Are Patients, Too.

Learning Objectives

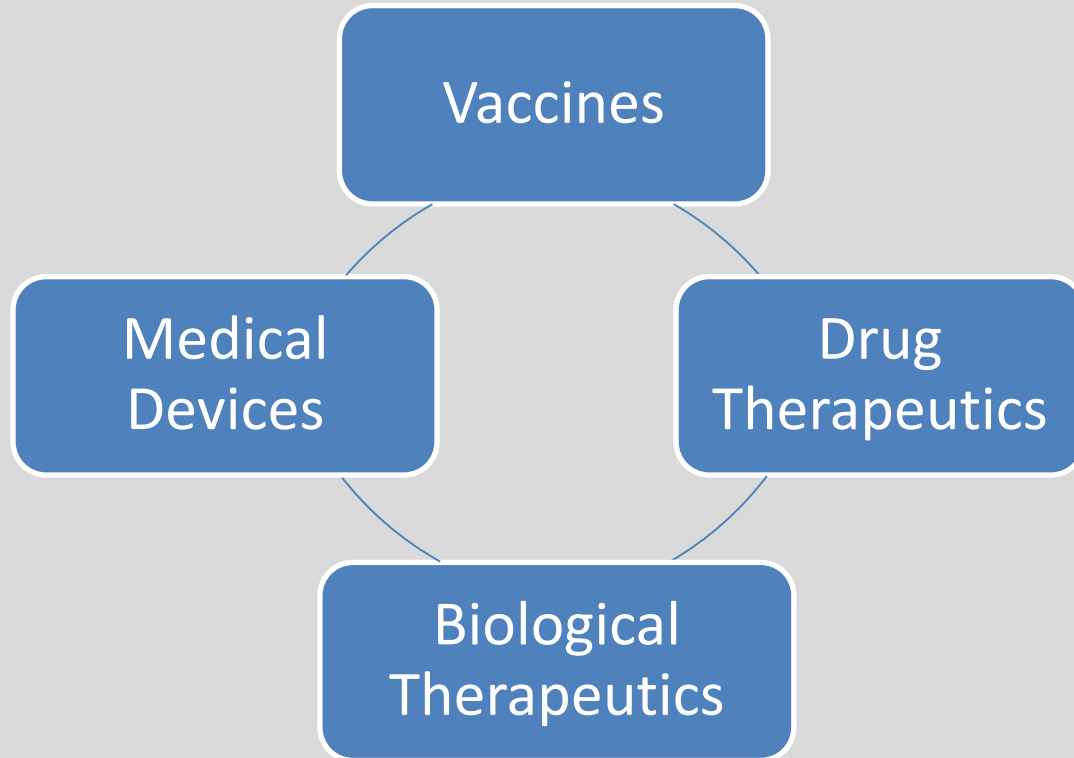
- Discuss product quality considerations for an EUA



EUA

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

COVID-19 EUAs



What are some product quality considerations for an EUA?

Product Quality Considerations



- The Agency encourages early interaction when submission of an EUA is being considered by a sponsor

Product Quality Considerations



- Pre-EUA activities may include
 - Discussions about the potential EUA product
 - Discussions about the best way to submit information prior to formal submission of an EUA
 - Discussions about the formal submission contents

Product Quality Considerations



- OPQ strongly encourages early interactions especially if the potential product incorporates novel strategies or components

Product Quality Considerations

- Examples of novel strategies or components
 - New dosage forms
 - New manufacturing technologies
 - New components
 - New analytical procedures
 - New data analysis strategies

Product Quality Considerations



The EUA should include sufficient, relevant information with data to assure the identity, strength, quality, and purity of the proposed product

- Information can be incorporated into the submission via right of reference (e.g. drug master files, new drug applications, etc.)

Product Quality Considerations



- Candidate products for EUAs can be either approved products or unapproved products
- Each bucket of candidate products presents unique anticipated areas of concern from a product quality perspective

Product Quality Considerations



- Examples of **Anticipated Areas of Concern** for approved products proposed for a new use in an EUA
 - New packaging configurations
 - Scale-up of manufacturing
 - Ability to supply sufficient product to meet demands of EUA and approved uses
 - Compatibility considerations
 - Ex. Approved tablet requires crushing and sprinkling on food or preparation as suspension for administration under EUA

Product Quality Considerations



- Examples of **Anticipated Areas of Concern** for unapproved products proposed in an EUA
 - Inadequate drug substance characterization
 - Lack of stability data to support viable retest period (drug substance) or expiration period (drug product)
 - Lack of understanding of critical quality attributes
 - Inadequate analytical procedures

Product Quality Considerations



Information provided should answer key product quality questions such as:

- **Who** will manufacture the drug substance and drug product?
- **How** are the drug substance and drug product made?
- **What** are the components of the drug product?

Product Quality Considerations



Information provided should answer key product quality questions such as:

- **What** characterization data is available to confirm that the process yields the target compound?
- **What** is the overall control strategy to ensure the quality of the product?
- **How** will the drug product be packaged? Administered?

Product Quality Submission Tips



- Describe the drug product
 - Include information on the drug substance, excipients, packaging, and any co-administered or co-packaged components (e.g. diluents, etc.)
 - Provide qualitative and quantitative compositions
 - Include information on any delivery or dosing device, if appropriate
 - Include information on the quantity of finished product on hand

Product Quality Submission Tips



- List all potential/proposed manufacturing and testing sites and their responsibilities
 - Identify sites for all manufacturing stages including but not limited to:
 - Intermediates
 - Drug substance
 - Drug product
 - Final packaging/labeling
 - Testing

Product Quality Submission Tips



- List all potential/proposed manufacturing and testing sites and their responsibilities
 - Identify US and non-US sites
 - Include information on the site's current cGMP status
 - Include information on the capacity/surge capabilities of the manufacturing site(s)

Product Quality Submission Tips



- Describe processes for the drug substance and drug product
 - Include information on controls for critical steps
 - Include information on in-process tests
 - Discuss scalability of processes

Product Quality Submission Tips



- Provide specifications and batch analysis results for the drug substance, drug product, components, etc.
 - Include information on the analytical procedures used during testing
 - Provide justification for the proposed testing strategy
 - Address the omission of tests, if applicable

Product Quality Submission Tips



- For sterile products, provide information on
 - Overall control strategy for sterility assurance
 - Appropriate validation information
 - Sterility testing procedures and results
 - Container closure integrity

Product Quality Submission Tips



- Include available stability data and recommended storage conditions
 - Include in-use stability data and recommended in-use storage conditions, if applicable
- Define the retest period for drug substances
- Define the expiration dating period for drug products and co-packaged components (e.g. diluents)

Product Quality Submission Tips



- Include labels and other labeling
 - Be sure all required and relevant product quality information is included in labels and other labeling
- Include instructions for administration
- Describe instructions for handling, if applicable

Product Quality Submission Tips



- Provide instructions for preparation, if applicable
 - Specify different preparations of adult dose versus pediatric dose, if applicable
 - Ex.: dissolve XX mg of product in XX mL of diluent to reconstitute

Product Quality Submission Tips



- For combination products such as drug-device combinations:
 - Meet early with FDA to discuss submission strategy for these products
 - Ensure information is submitted to permit review by all relevant Centers
 - Data necessary to support an EUA may differ based on contribution to combination product

Summary

- The product quality considerations for an EUA are similar to the considerations needed for any development program
- Early dialogue with OPQ can help to identify the product quality submission requirements for the candidate product

Knowledge Check #1

New molecular entities cannot be submitted for consideration under an EUA.

1. True
2. False

Knowledge Check #2

Products authorized under an EUA can only be manufactured in the United States.

1. True
2. False

Resources

Slide Number	Cited Resource	URL
6	Guidance For Industry and Other Stakeholders: Emergency Use Authorization Medical Products and Related Authorities (finalized January 2017)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities
7	COVID-19 EUA Information	https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization# covid19euas

Contact Us

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Questions



