

CBER Advanced Technologies Team (CATT)

Promoting the Development and Adoption of Advanced
Manufacturing Technologies

Manuel Osorio

Lead, CBER Advanced Technologies Program
Immediate Office of the Director
CBER | US FDA

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Learning Objectives

- Understand the importance of **advanced manufacturing** to public health
- Learn about CBER's efforts to **promote the development and adoption** of advanced manufacturing technologies
- Explain the **purpose** and **scope** of interactions with the CBER Advanced Technologies Team

What is Advanced Manufacturing?

- Integrating **novel technological approaches**
- Using established techniques in a **new or innovative way**
- Applying production methods in a **new domain** where there are no defined best practices or experience



Benefits of Advanced Manufacturing



- Enhance product quality as a result of a reliable and robust manufacturing process
- Reduce manufacturing costs
- Develop medicines rapidly
- Prevent shortages of needed medicines
- Improve emergency preparedness

Biological Products Regulated by CBER



**Blood, blood
components and
derivatives**

**Vaccines (preventive
and therapeutic)**

Tissues

**Cell and gene
therapies**

Xenotransplantation

Allergenics

**Related devices
(including IVDs)**

The CBER Advanced Technologies Program

Promoting the development and adoption of advanced technologies to modernize pharmaceutical manufacturing

CBER Advanced Technologies Program



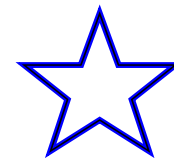
Fund advanced research and development projects to support regulatory science and innovation



Build internal scientific and regulatory expertise



The CBER Advanced Technologies Team (CATT)

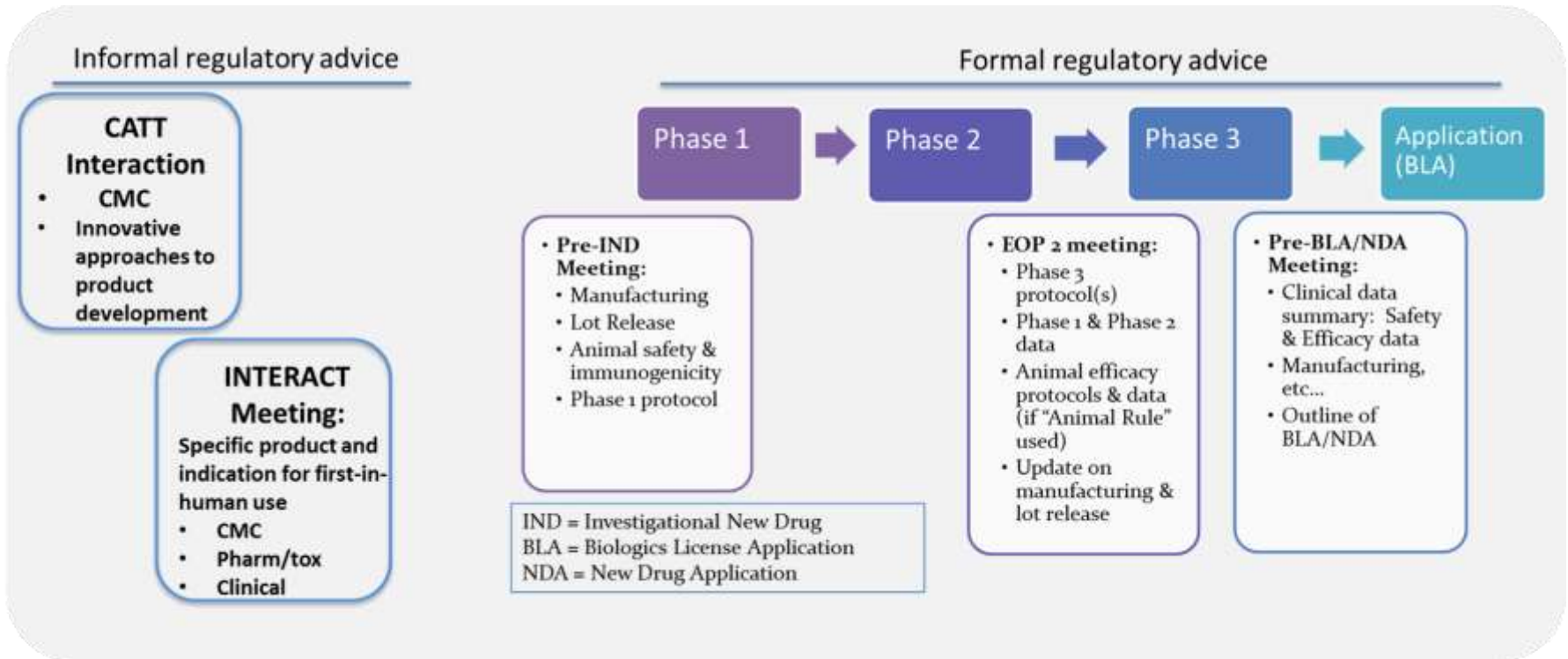


CBER Advanced Technologies Team (CATT)



- **Purpose:**
 - Promote dialog, education, and input on advanced manufacturing technologies
 - Provide interactive mechanism with technology developers at an early stage of development (**prior to regulatory submission**)
- **Scope:**
 - **Novel** technologies (manufacturing and control strategies)
 - Manufacturing and analytical methods for which CBER has **limited experience**
 - **Not for product-specific**, highly technical discussions

Early Engagement with CBER



The Team



- CATT consists of a small cross-functional group representing CBER leadership, relevant policy, review and inspection programs
- Represented CBER Offices:
 - Office of the Director
 - Office of Compliance and Biologics Quality
 - Office Tissues and Advanced Therapies
 - Office of Vaccines Research and Review
 - Office of Blood Research and Review



Submitting CATT Meeting Requests

<https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-team-catt>

- A 2-page (including figures and tables) backgrounder that provides the following information:
 - Description of **technology**
 - Why technology/product class is **novel and unique**
 - **Impact** of technology/product class
 - Summary of **manufacturing or development plan**
 - **Questions** regarding perceived regulatory, technical, or other challenges for implementation

Review Process



Evaluation:

- Initial triage by CATT coordinators
- Assignment to relevant Review Office(s)
- Discussion at recurrent internal CATT meetings

Review Process



Outcomes:

- CATT meeting granted
- Provide responses to submitted questions via email
- Recommendation to request meeting for product-specific discussions

Examples of Technologies Discussed



- Continuous Manufacturing (vaccines, AAV vectors, exosomes)
- Fully closed, automated, scalable and remote-controlled systems for manufacturing cell therapy products
- Innovative tools for assessing vaccine immune responses
- Improved cell lines for vaccine antigen production and AAV vector manufacturing
- Use of AI and advanced imaging technologies for real time product quality assessment
- Multi-product manufacturing facility design
- Continuous processing of blood-derived products

Experience with the CATT



- High interest from technology developers/manufacturers
 - Over 60 CATT requests received
 - 11 meetings granted (face-to-face meetings before pandemic)
- Some growing pains (mainly due to the Covid pandemic)
 - Original turn-around window was 6 weeks
 - Experienced delays, sometimes significant
- The future looks bright
 - Availability of subject matter experts slowly increasing

CATT-related collaborative activities to promote the adoption of advanced manufacturing

CENTER FOR THE ADVANCEMENT OF MANUFACTURING PHARMACEUTICALS AND BIOPHARMACEUTICALS (CAMPB)



CAMPB Mission:

- Accelerate the development, implementation, and evaluation of advanced manufacturing by establishing science- and risk-based standards and policies
- Advance drug product development science
- Train a world-leading regulatory workforce, through strategic partnership, engagement and communication



ICHQ13: Continuous Manufacturing of Drug Substances and Drug Products

Objective

Provide harmonized guidance for the development, implementation, and assessment of continuous manufacturing (CM) technologies used in the manufacture of drug substances and drug products

Scope

Applies to CM of chemical entities and therapeutic proteins, and the conversion of batch manufacturing to CM for existing products. ICH Q13 principles may also apply to other biological/biotechnological entities.

Summary



- Advanced manufacturing can improve pharmaceutical manufacturing and ensure the availability of good quality medicines
- CBER is committed to supporting the **development** and **adoption** of advanced manufacturing technologies for CBER-regulated products
- CBER is collaborating internally and internationally to build the scientific expertise and regulatory framework necessary to evaluate emerging technologies

Challenge Question #1



Which of the following statements is not true?

- A. CBER discourages the implementation of advanced manufacturing technologies for biologics because there is no regulatory framework for their evaluation
- B. CBER encourages the development and adoption of advanced manufacturing technologies for biologics
- C. Advanced manufacturing technologies can improve the quality and availability of needed medicines
- D. Advanced manufacturing technologies can improve emergency preparedness

Challenge Question #2



Which of the following statements about CATT interactions is true?

- A. CATT meetings are formal meetings and therefore, any advice provided is binding
- B. CATT meetings are for discussing product-specific regulatory issues related to CMC, toxicology, and clinical study design
- C. CATT meetings are required before filing an IND submission
- D. CATT meetings are informal and therefore, any advice provided is non-binding

Thank you!

Manuel Osorio
Lead, CBER Advanced Technologies Program
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Manuel.Osorio@fda.hhs.gov

<https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-program>