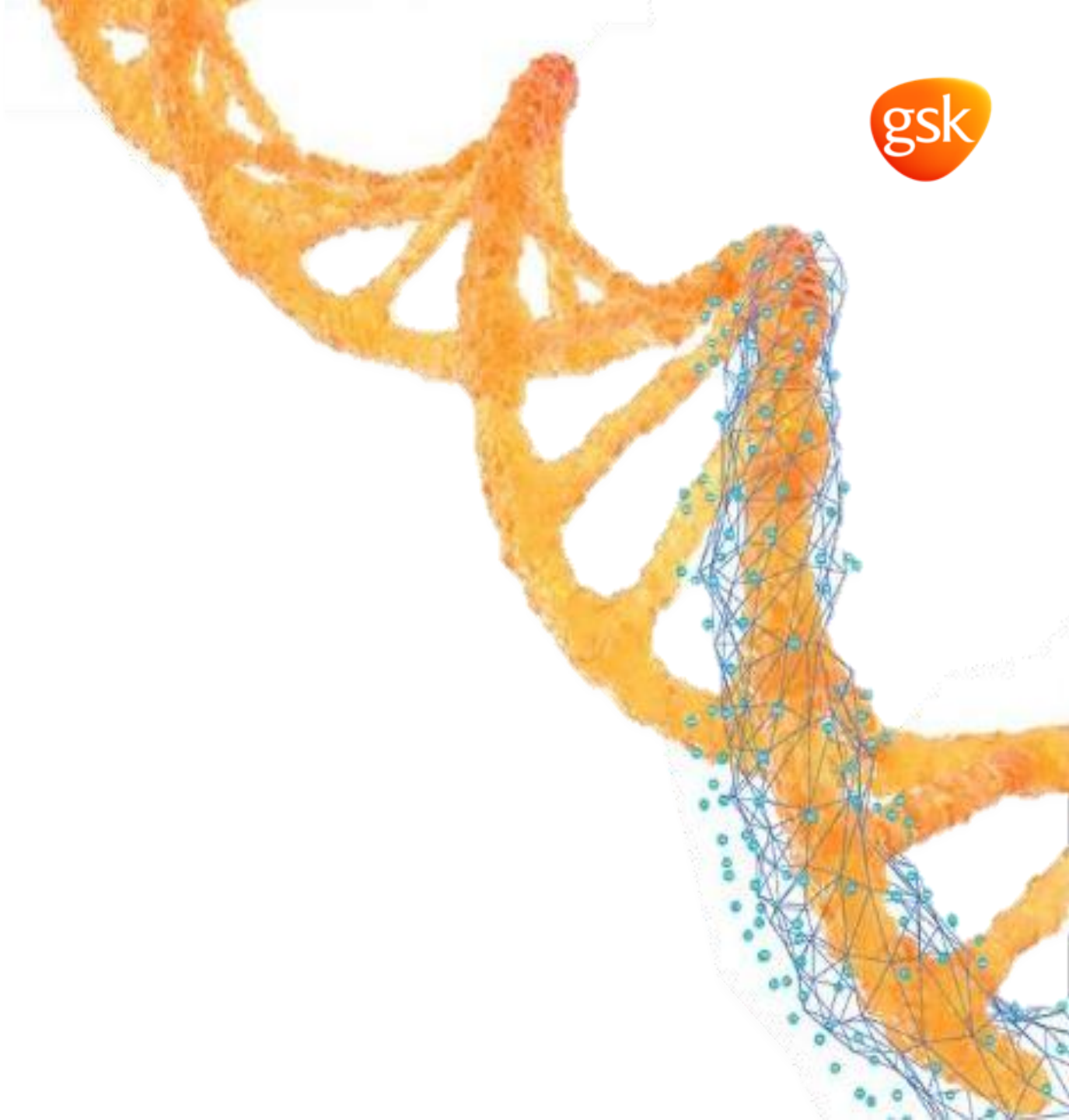
NASEM Dissemination Workshop

Session #2

Sarah Arden

Ben Stevens

Jean Hu-Primmer



- This work was sponsored by GlaxoSmithKline Biologicals SA

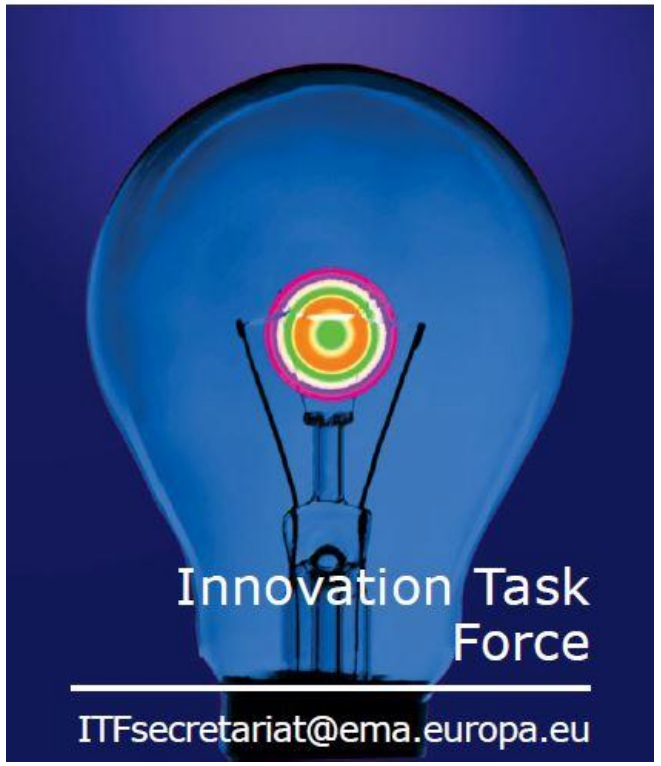
- Jean Hu-Primmer, Sarah Arden and Ben Stevens are employees of the GSK group of companies

Existing Mechanisms 1

Direct Sponsor Interactions

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

gsk



MHRA

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Our innovation office provides free, confidential and expert advice

FDA U.S. FOOD & DRUG ADMINISTRATION

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CBER Advanced Technologies Team (CATT)

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CDRH Innovation

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

Innovative Manufacturing Technology WG (IMT-WG)

Existing Mechanisms 2a

Guidances

Guidance for Industry
PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance

Quality Considerations for Continuous Manufacturing
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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. All comments should be identified with the docket number listed in the notice of availability when published in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Sau L. Lee at 301-796-2905.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2019
Pharmaceutical Quality/CMC
Pharmaceutical Quality/Manufacturing Standards (CGMP)

15276548 Dft

Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

September 2017
Pharmaceutical Quality/CMC

2483881 FNL

ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CONTINUOUS MANUFACTURING OF DRUG SUBSTANCES AND DRUG PRODUCTS
Q13

Draft version
Endorsed on 27 July 2021
Currently under public consultation

Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Core Guideline

Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@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.

Existing Mechanisms 2b

Innovation Initiatives

Comment on Proposed Regulations and Submit Petitions

Share | Tweet | LinkedIn | Email | Print

Making Your Voice Heard at FDA

Submit Comments Online

You can submit your comments on many of FDA's proposed regulations at Regulations.gov

(See Instructions for using Regulations.gov)

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement

A Notice by the Food and Drug Administration on 10/16/2020

Digital Health Center of Excellence

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Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

Our objectives: The Digital Health Center of Excellence aims to:

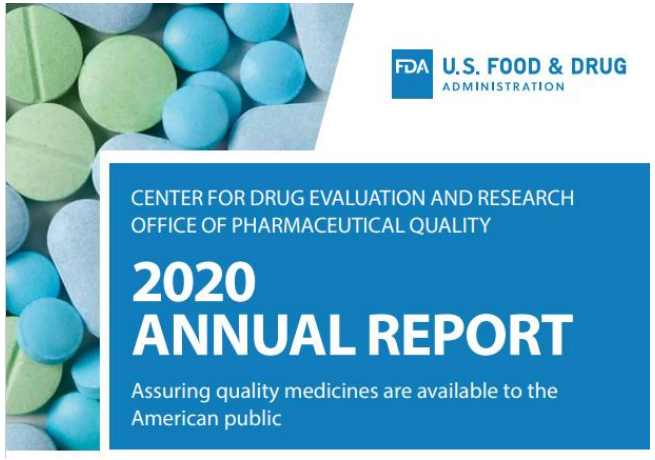
- **Connect and build partnerships** to accelerate digital health advancements.
- **Share knowledge** to increase awareness and understanding, drive synergy, and advance best practices.
- **Innovate regulatory approaches** to provide efficient and least burdensome oversight while meeting the FDA standards for safe and effective products.

Digital Health Center of Excellence | FDA

Duke | MARGOLIS CENTER *for* Health Policy

MEETING

FDA and Duke-Margolis Public Meeting: Establishing a High-Quality Real-World Data Ecosystem



Existing Mechanisms 3

FDA Extramural Funding

Regulatory Science Extramural Research and Development Projects

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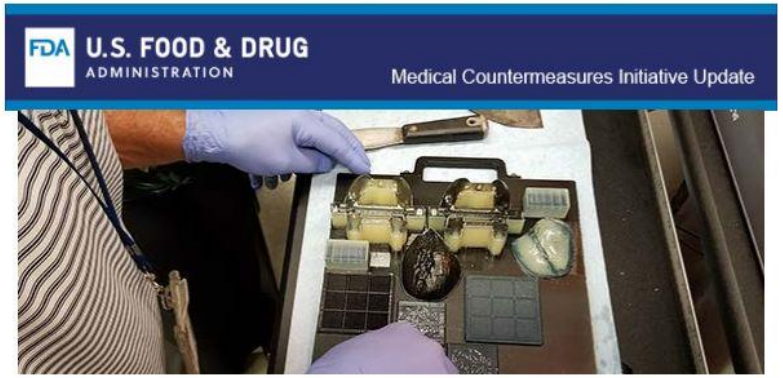
Priority Area 3: *Support New Approaches to Improve Product Manufacturing and Quality*

Priority Area 4: *Ensure FDA Readiness to Evaluate Emerging Technologies*

Emerging Technology

Funding Opportunity Title



July 31, 2019

New agreement to support advanced manufacturing innovations

Research centers: partner with FDA to apply for new funding

In July 2019, FDA entered into a Collaborative Research and Development Agreement (CRADA) with the University of Delaware on behalf of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). This CRADA creates a research partnership, in the pre-competitive space, to support research, development, testing, and training in the field of advanced manufacturing innovations to enhance the biopharmaceutical manufacturing ecosystem.

Funding Opportunity Announcement (FOA) Number RFA-FD-21-033

U.S. Food and Drug Administration (FDA)

NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA.

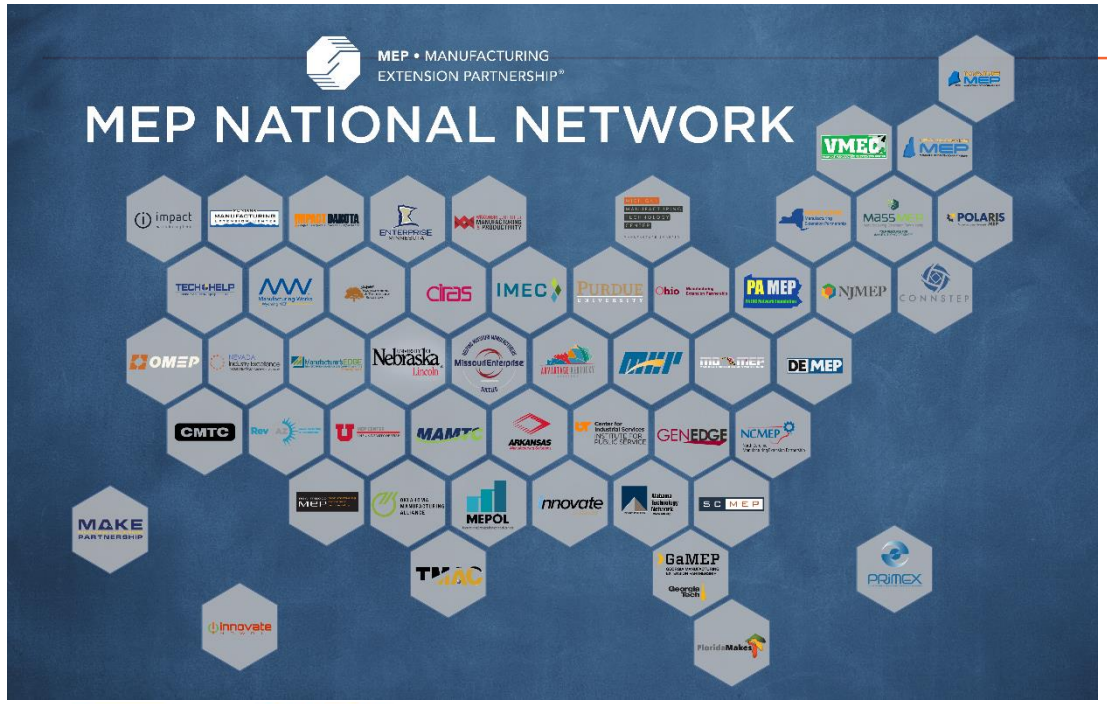
The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.

Center for Biologics Evaluation and Research (CBER)

Enhancing Innovations in Advanced Manufacturing Technologies for Vaccines against Influenza and Emerging Infectious Diseases (R01)

Existing Mechanisms 4

Public-Private Partnerships



MEP National Network™

NIST National Institute of Standards and Technology U.S. Department of Commerce

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

biofabusa Manufacturing the Future of Biofabrication

BioFabUSA

Biofabrication | Robotics | Biotechnology | Materials

Manchester, NH USA

NIIMBL

NIIMBL (The National Institute for Innovation in Manufacturing Biopharmaceuticals)

Metrology | Biotechnology | Materials | Material Processing

Newark, DE USA

ManufacturingUSA℠

BioMADE

BioMADE (Bioindustrial Manufacturing and Design Ecosystem)

Biofabrication | Bioindustrial Manufacturing | Recycling | Reuse | Sustainable Manufacturing | Sensors | Optics and Photonics | Design | Chemical Processing | Materials | Material Processing | Lightweighting

St. Paul, MN USA

Recent GSK Experience with ETT

Useful pathway for integrating novel manufacturing and testing platforms

- Meeting request submitted to discuss novel microbiological testing platforms with ETT.
- Discussions centered on:
  - Leveraging prior knowledge for method validation.
  - Approach for product-specific method validation and verification following method transfer.
  - Sample preparation and bracketing of evaluated species.
  - Comparability to compendial methods.
- Subject matter experts from various FDA divisions were assembled into the meeting package review.
- Robust feedback and discussions. Agency provided actionable responses and encouraged GSK to seek additional interaction as needed.

What Works…

But can be improved…

- Direct Sponsor Interactions
  - Consistency across Centers using formalized pre-preIND/type C process (can type D be used), e.g. informal interactions for CATT not ideal
  - Well-publicized, clear champion (POC) within Centers to facilitate sponsor interactions
  - Technology Master File that can be reviewed in the absence of application cross-reference (can manufacturing equipment vendors use this?)

- Global Alignment
  - MOU(s) between Agency and counterpart innovation task forces at other National Regulatory Authorities to enable parallel scientific advice consultation to achieve alignment on regulatory risk and path forward

- Innovation Centers and Test Beds
  - Agency supports academia, but how impactful are/were these BAA or RFA awards to the private sector?
  - Agency can consider collaboration with private sector R&D in the precompetitive space with CRADAs or using test beds

Thank You