FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

AAM
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Office of Regulatory Affairs U.S. Food and Drug Administration

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November 5, 2019

ORA's Priorities

- Managing a World-Class Workforce and Promote a Culture of Excellence

- Advance ORA's Core Operations

- Leverage and Expand ORA's Public Health Partnerships

ORA - OMPTO Update and Operational Initiatives

- Office of Biological Products Operations
  - Specialized workforce responsible for inspections, investigations, compliance and enforcement activities
  - Growing technological complexity both in the products that are being manufactured, and in the methods used for their manufacture
  - Increase in outreach to industry though participation in conferences and trade meetings
- Office of Bioresearch Monitoring Operations
  - Dedicated Foreign Cadre
  - Adoption of Risk-Based Monitoring Approaches
  - Public workshop: “Improving the Implementation of Risk-Based Monitoring (RBM) Approaches of Clinical Investigations”

ORA - OMPTO Update and Operational Initiatives

- Office of Pharmaceutical Quality Operations
  - Pharmacy Compounding
  - Concept of Operations
    - ORA/CDER Collaboration
      - Responsibilities
      - Transparency
      - Timeliness

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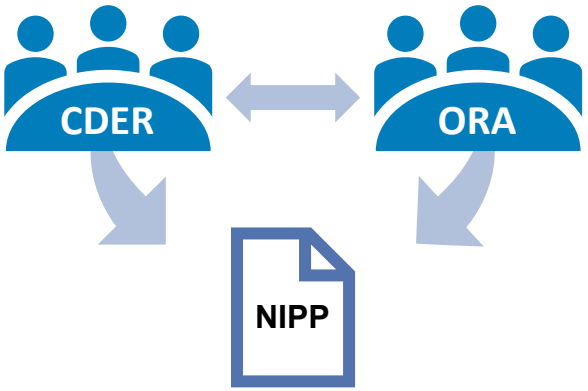
New Inspection Protocol Project (NIPP)

Overview

October 2018

NIPP History and Background

- In February 2014, the Office of Regulatory Affairs (ORA) and the Center for Drug Evaluation and Research (CDER) began working together to support the advancement of pharmaceutical quality by developing a structured, consistent, efficient inspection and reporting paradigm.
- The sterile Pre-Approval and Surveillance Inspection protocols have each been piloted three times over the past four years.
  - Each new protocol version underwent extensive revision and refinement.
- The New Inspection Protocol Project (NIPP) inspections will not change the role of the investigator – which continues to be to collect and evaluate objective facts to assess the state of quality control and assurance practices of a site.



Why Are We Doing This?

The new inspection protocols aim to –

- Enhance consistent and comprehensive coverage of critical areas. The result of these inspections are structured data-rich reports that assess the state of quality of drug manufacturers.

The Goal of the program is to modernize inspections through collecting structured data that can be analyzed; this approach will enable FDA to efficiently analyze this data in order to –

- Better characterize and trend the state of pharmaceutical quality.
- Accelerate the pace of making informed/data-driven decisions.
- Lead to more targeted inspections in the future.

NIPP – Next Steps

Protocol development, IT implementation, piloting & refinement, training and operational implementation will continue and expand to include:

- Sterile dosage form
- Solid oral (non-sterile) dosage form
- Transdermal products
- Creams ointments & solutions
- Metered dose inhalers
- API's
- Terminally sterilized products

Mutual Recognition Agreement

- MRA between FDA and the European Union allows drug inspectors to rely upon information from drug inspections conducted within each other's borders.

- Evaluations and Negotiations started May 2014
- Implemented November 1, 2017
- July 2019 -28 EU countries capability
- Ongoing evaluations to include Vet oversight

- https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

- Vision – To lead the international development & maintenance of harmonized GMP standards & quality systems of inspectorates in the field of medicinal products.
- Goals –
  - Mutual recognition of inspections
  - Harmonization of GMP requirements
  - Uniform inspection systems
  - Training of inspectors
  - Exchange of information
  - Mutual confidence

- PIC/S Inspectors Academy – 2014 Professional Inspectors Academy

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Thank You