



U.S. Food and Drug Administration

**Notice: Archived Document**

The content in this document is provided on the FDA's website for reference purposes only. It was current when produced, but is no longer maintained and may be outdated.



## Division of Compliance Risk Management and Surveillance

H. Gregg Claycamp, PhD  
Director, DCRMS  
Anthony Orenca, MD, PhD, FACP  
Deputy Director, DCRMS  
Office of Compliance  
Center for Drug Evaluation and Research

## Promote Public Health through influencing Drug Availability

- Our goal is to advance public health through increasing availability of safe, effective, & quality drugs; and conversely, through limiting exposure to unsafe, ineffective, & poor quality drugs.
- Our focus is on DATA support for decision-making

## DCRMS Focus

---

- Surveillance – Monitor public health impact and drug industry compliance to improve drug quality and safety reporting
- Identify and target compliance problem areas, based upon public health impact
- Enhance coordination and prioritization of inspection processes for both GMP and ADE inspections through data support

## Division Teams

---

- Drug Registration and Listing Team
- Surveillance Programs Team
- Data Analysis & Information Management Team
- Risk Management & Strategic Problem Solving Team

## Drug Registration and Listing Team Functions

---

- Manage Drug Establishment Registration and Drug Product Listing System (DRLS) and the National Drug Code (NDC) Directory
- Lead electronic drug facility registration through FURLS/DFRM and drug product listing through SPL
- Provide data support for Drug Efficacy Study Implementation (DESI) compliance activities
- Monitor marketed unapproved new drugs and provide data support for regulatory activities

## Drug Registration and Listing (DRL Team)

---

- Register all drug establishments with FDA
  - Manufacturers, Packers, Relabelers
  - Assign NDC labeler code & FEI number (FACTS)
- List all marketed drug products with FDA
  - Repository of all drug product NDC numbers
  - Includes all ingredients & each establishment
- DRLS team enters & reviews data
- DRLS accessible to ORA investigators

## Future → electronic registration and listing

---

- Implement electronic submission/updating of registration and drug listing information
- FDA issues (and control) all valid NDC numbers
- Integrate electronic registration and listing with Structured Product Labeling (SPL)
- Provide electronic label access through DailyMEDS at NLM

## Drug Efficacy Study Implementation (DESI)

---

- 1962 Amendments required all marketed drugs to be approved for both safety and effectiveness
- DESI reviews started in 1966; include 3,443 drug products approved between 1938 and 1962, and approximately 15,000 unapproved drugs that were similar to DESI drugs
- DRL Team supports and identifies DESI pending and final drug products for CMS that are not reimbursable under CMS's Drug Reimbursement Program

## Surveillance Program Team Functions

- Monitor postmarketing Adverse Drug Experience (ADE) reporting for complete and timely surveillance, receipt, evaluation, and submission of ADE data to the agency
- Identify potential risks associated with manufacturing, labeling, and packaging of pharmaceuticals through the Drug Quality Reporting System (DQRS) and NDA/ ANDA Field Alert Reporting (FAR) program.
- Monitor the quality of the nation's drug supply through the identification and coordination of drug product sampling and analysis.

## Drug Quality Reporting System

- Central reporting system for marketed drug quality problems to identify areas or trends requiring corrective action.
- Drug quality reports are received from consumers & health professionals – primarily pharmacists.
- Reports are prioritized and forwarded to district offices, other CDER offices, and manufacturers for appropriate follow-up

## NDA/ANDA Field Alerts

---

- Applicant holders submit NDA/ANDA Field Alert Reports on drug labeling, manufacturing, safety, effectiveness, or other quality issues for products on the market.
- Firms must notify District office within three working days of awareness of potential problem
- Districts submit FARs to DCRMS, and follow-up investigational findings

## Biologics Product Deviation Reporting

---

- In 2003 CBER transferred to CDER certain therapeutic biological product oversight responsibilities
- Biologics Product Deviation Reporting for CDER products are now integrated with the DQRS and FARs programs
- CDER Biologics website:  
<http://www.fda.gov/cder/biologics/>

## Drug Product Quality Sample Survey

---

- Monitor the quality of the nation's drug supply through chemical and microbiological analyses of selected marketed drugs
- Include domestic and foreign finished dosage forms and bulk ingredients (APIs)
- Utilize a risk-based sample surveillance approach to select products for analysis that have greatest risk of quality problems and/or health impact

## Drug Product Quality Sample Survey

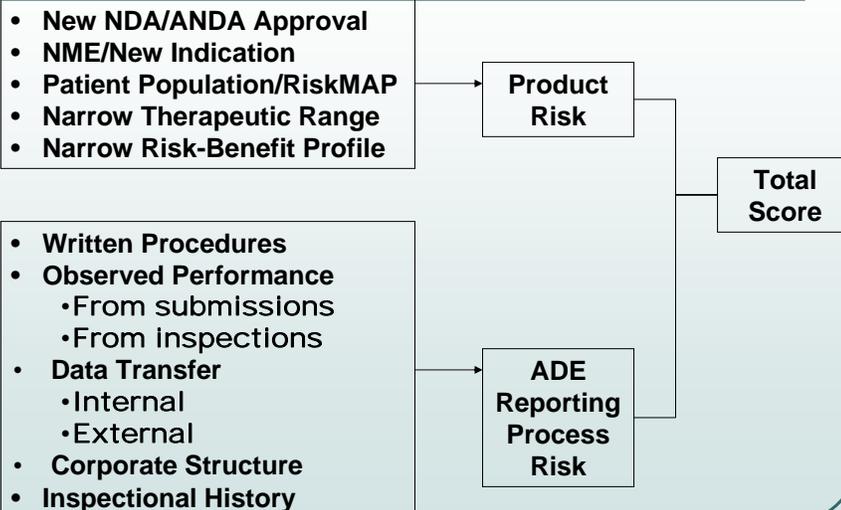
---

- Drug products are selected for sampling each year using a risk-based approach
- Emphasis can change each year
- Survey results are intended for publication and address broad issues in drug quality
- Individual drug quality issues are followed-up by ORA district offices

## ADE Reporting: Compliance Inspections

- Develop and maintain risk profiles associated with drug products and ADE reporting processes
- Manage inventory of establishments responsible for submitting ADE data to FDA
- Issue inspectional assignments using risk-based approach based upon risk profiles
- Review inspectional findings and corrective actions by firms, and support/initiate regulatory actions

## ADE Inspection Site Selection Model (Example Only)



## ADE Reporting: Compliance Education

---

- Public forums and individual interactions to educate industry on regulatory reporting obligations and industry best practices
- Formal on-line and classroom training for ORA field staff, as well as technical support for investigators and compliance personnel
  - Training video available on web at:  
[http://www.fda.gov/cder/learn/ade/ade\\_page.htm](http://www.fda.gov/cder/learn/ade/ade_page.htm)

## Data Analysis & Information Management Team – Functions

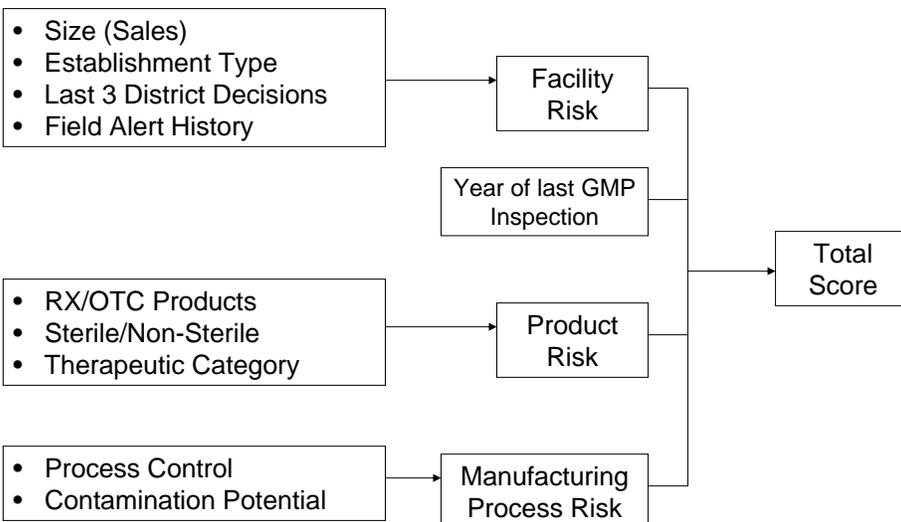
---

- Identify relevant internal and external data and information that supports compliance policy and decision making
- Currency with AERS, EES, DRLS, PDMA, Recalls and Shortages, DQRS, FARs, FACTS, OASIS, Turbo EIR.
- Perform quantitative and qualitative analyses of data collected in and generated from surveillance programs and other relevant databases.
- Work with other DCRMS teams and other FDA organizations to identify patterns of non-compliance to help target specific interventions.

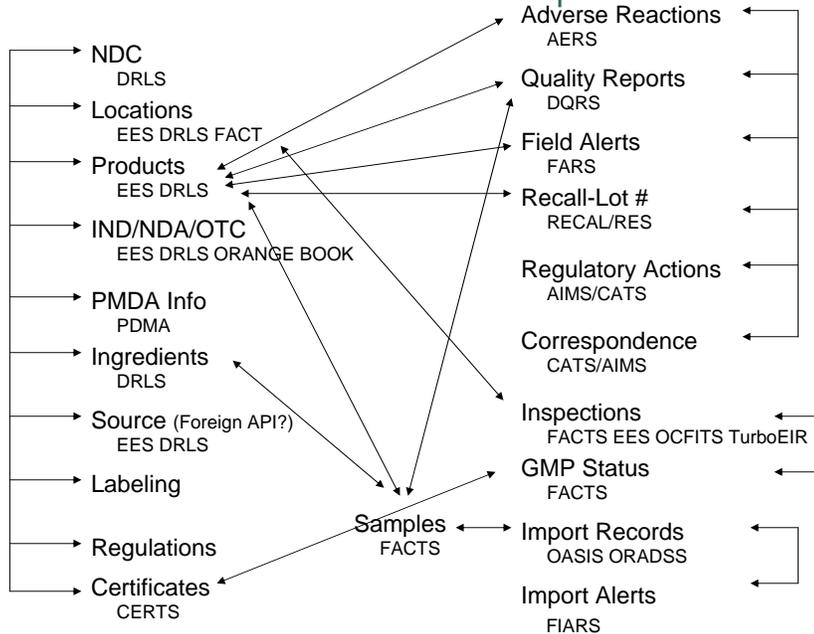
## Surveillance Steps

- Identify universe of source data for assessment of problems related to drug quality, drug safety monitoring, and related well-being of the public and industry
- Select sources to utilize in identifying drug and industry surveillance and establish access
- Develop surveillance systems and approaches
- Assure that public health issues relative to drug safety and quality, and to related public and industry well-being, are monitored

## Risk Management: GMP Inspection Site Selection Model (Example Only)



## Firm Profile Data Relationships



DCRMS

## Risk Management & Strategic Problem Solving Team (Functions)

- Utilize quantitative and qualitative data analysis and strategic problem solving techniques to focus compliance and regulatory activities, and develop innovative compliance strategies for reducing public health risks

## Risk Management & Strategic Problem Solving Team (Functions)

---

- Work with other DCRMS teams and CDER/OC divisions, identifying patterns of non-compliance, assessing public health risk, and developing strategies for risk minimization
- Work closely with other agency units in areas of strategic planning, program targeting, and compliance prioritization

## RiskMAP Compliance

---

- Review Risk Minimization Action Plans for procedural issues, enforceability, and barriers to successful implementation
- Review RiskMAPs for adequate ADE reporting procedures by all involved personnel and firms
- Monitor ADE reporting and RiskMAP implementation, develop strategies for corrective action if RiskMAP variance is noted during inspections or surveillance
- Monitor achievement of risk minimization goals

## Strategic Problem Solving

---

- Utilize surveillance data to identify problem areas
- Analyze surveillance & other data to identify potential risk factors and root causes
- Identify strategies for prevention/protection and develop control measures
- Evaluate potential impact of control programs
- Implement control programs using the best strategies
- Monitor outcomes and assess impact of the implementation programs