FDA Voluntary Observation Corrective Action Report (OCAR) Industry Portal

For Human and Animal Food Processing Facilities

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

HIGHLIGHTS

- ★ Secure electronic portal for firms to provide corrective actions (CA) and documentation in response to inspectional observations
- ★ Communication with FDA on observations, corrective actions and observation status(es)
- ★ Phased roll-out to human and animal food facilities

BENEFITS

- ✓ Elite groundbreaking project with direct beneficial public health impacts
- ✓ Real-time management of CA activities and documents
- ✓ Increased efficiency/improved CA workflow
- ✓ Intelligent CA activity and document organization/security/control
- ✓ Facilitated/enhanced CA communication with FDA
- ✓ Refined turnaround times intended to improve the CA experience
- ✓ Higher productivity
- ✓ Green business practice
- ✓ Industry Portal Representative (IPR) access as well additional sub-accounts as necessary

SELECTION CONSIDERATIONS

- Documented observations
- Geographic location
- Total number of facilities applying
- Categories/types of products
- Inspection and compliance history
- FDA Division management input
- FDA work plan obligations
- Firm size
- IT capabilities
- IPR involvement

PARTICIPATION CRITERIA

- ❑ Portal participation is VOLUNTARY!
- ❑ Domestic human or animal food firm
- ❑ Inspection with observations presenting opportunities for CAs
  - ❑ FDA inspection with FDA 483 observations, or
  - ❑ Documented Discussion observations
- ❑ IT capabilities
  - ❑ Secure, stable broadband internet services
  - ❑ Familiarity with web-based document upload
- ❑ Must adhere to required User Agreement
- ❑ IPR is identified along with up-to-date contact information

Not all interested firms will be selected for Phase 1!

HOW TO PARTICIPATE

- ❑ Send email expressing interest and addressing inclusion criteria applicability to the FDA post-inspection firm response email address provided by the investigator
- ❑ Emails should include
  - ❑ Firm name and address
  - ❑ Date of qualifying inspection
  - ❑ IPR's name, title, and email address
- ❑ FDA will notify applicants if they have been selected using the contact information provided
- ❑ Communicate interest within 5 business days after the current inspection closes

For additional information or related questions, please email: OCARFAQs@fda.hhs.gov

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products

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