## HFP LSMV Implementation Overview

### Background

Challenge: HFP operates through fragmented systems (PRIMO, manual processes) that create inefficiencies, limit analytics, and complicate regulatory reporting.

Solution: LSMV provides end-to-end automation with integrated workflows, standardized coding, and advanced analytics capabilities.

### Technical Components

#### Input Sources:

* Safety Reporting Portal (SRP), MedWatch Online, OII CMS, manual entry

#### Core Integrations:

* Food Track API: Real-time product coding and ingredient data
* FMS ETL: Nightly manufacturer/facility data sync
* ThinkTrends Document AI: Automated document processing
* RxLogix: Advanced analytics and signal detection

#### Output Systems:

Open FDA publishing, EBO reporting, FDA TRAK Dashboard

### HFP Workflow

Automated Workflow: Intake → Triage → Data Entry → Coding → Quality Assurance → Review → Case Closure

#### Role-Based Access:

* Records Management: External routing, FOIA processing
* Complaint Coordinators: Internal routing, data management, routine/acute classification
* Program Office Reviewers: Technical assessment, safety issue identification

#### HFP-Specific Modules:

* Custom review tab for abuse/misuse/relatedness assessment
* Safety issues and product problems tracking
* Enhanced contact management for complex reporter hierarchies
* Automated notifications for follow-ups and special case types

### Open Questions and Items

#### Technical Requirements

* FMS Integration Details: Clarify data source, API specifications, and food-specific manufacturer filtering criteria
* Dictionary Management: Finalize requirements for dietary supplement database and cannabis product dictionary loading
* OII CMS Integration: Define API specifications and timeline for work activity creation functionality
* Product Code Builder Integration: Determine implementation timeline and technical requirements

#### **Data Migration and Mapping**

* **SRP Contact Hierarchy**: Finalize mapping strategy for complex contact relationships from XML to LSMV structure
* **Historical Data**: Determine scope and timeline for migrating existing PRIMO cases
* **Code List Validation**: Review and approve all HFP-specific code lists and field configurations

#### Foia

* FOIA Process Adoption: Decision on implementing Cedar's redaction capabilities vs. maintaining current bulk download approach
* Quarterly Extract Format: Confirm output specifications and any modifications needed from current SQL-based process
* Field-Level Redaction: Provide list of fields requiring redaction if shadow field functionality is needed

#### Business Process Clarification

* Whistleblower Designation: Confirm field placement and special handling requirements for anonymous reporters
* RFR Report Scope: Final confirmation that Reportable Food Registry reports remain out of scope for Phase 1
* Special Case Notifications: Verify email recipients and trigger points for cannabis, food additive, and other special case type
* Routine vs. Acute Classification: Define specific data elements and validation rules for coordinator completion

FDA Finder

1. Extract Data from Primo DB
2. Push the data in CSV and XL formats manually and quarterly
3. Clean Data Manually via SQL
4. Upload CSV with a specific name on a given shared folder