FDA Global Strategic Framework for SSFFC Medical Products

(SSFFC = Spurious, Substandard, Falsified, Falsely-labeled, and Counterfeit)

Global Product Safety Net for SSFFC Medical Products

To protect consumers by reducing public health risks caused by SSFFC medical products

Analytics and Informed Decision Making

Result 1: Better Prevention of Market Entry of SSFFC Products
- Result 1.1: Reduced Manufacture of SSFFC Products
- Result 1.2: Improved Supply Chain Integrity
- Result 1.3: Reduced Market Vulnerability
- Result 1.4: Increased Industry Responsibility
- Result 1.5: Strengthened Oversight by Regulators (Practice & Product)

Result 2: Better Detection of SSFFC Products
- Result 2.1: Improved Surveillance
- Result 2.2: More Effective Investigation of Suspect Incidents
- Result 2.3: More Efficient Confirmation that Products are SSFFC
- Result 2.4: Improved Vigilance Systems
- Result 2.5: More Advanced Technology
- Result 2.6: Strengthened Lab Capacity

Result 3: More Effective Response to SSFFC Products
- Result 3.1: More Effective Notification of Confirmed Incidents
- Result 3.2: More Efficient Removal of SSFFC Products from Market
- Result 3.3: Improved Containment of SSFFC Products
- Result 3.4: Improved Enforcement
- Result 3.5: More Effective Investigation of Confirmed Incidents
- Result 3.6: Enhanced Legal/Regulatory Tools and Actions

Foundational Results

F.1: Effective Leveraging, Collaborating and Strategic Information & Intelligence Sharing among Regulatory and Enforcement Agencies
F.2: Increased Knowledge, Public Awareness or Vigilance of Stakeholders
F.3: Established Policy, Legal and Regulatory Framework
F.4: Strong Regulatory Infrastructure
F.5: Knowledgeable Skilled Personnel

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Analytics and Informed Decision Making

Result 1: Better Prevention of Market Entry of SSFFC Products
  Result 1.1: Reduced Manufacture of SSFFC Products
  Result 1.2: Improved Supply Chain Integrity
  Result 1.3: Reduced Market Vulnerability
    R 1.3.1: Increased Global Investment to Upgrade Product Manufacturing to High Quality Standards
    R 1.3.2: Strengthened Private Sector Distribution Channels
    R 1.3.3: Increased Use of MQAS Procurement Standards
    R 1.3.4: Increased Support for Public Awareness

Result 1.4: Increased Industry Responsibility
  R 1.4.1: Increased Use of GxPs
  R 1.4.2: Increased Compliance
  R 1.4.3: More Effective Disposition of Product and Equipment
  R 1.4.4 & 1.5.4: Increased Collaboration with Industry, Regulators and Law Enforcement

Result 1.5: Strengthened Oversight by Regulators (Practice & Product)
  R 1.5.1: Improved Development of Practices/Guidelines/Regulations
  R 1.5.2: Increased Promotion of Practices/Guidelines/Regulations
  R 1.5.3: Improved Compliance with Practices/Guidelines/Regulations

Result 2: Better Detection of SSFFC Products
  (Etc.)

Result 3: More Effective Response to SSFFC Products
  (Etc.)