CDER Site Selection Model

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CDER's Risk-Based Site Selection Model (SSM)

Purpose

To prioritize manufacturing sites for routine quality-related (current good manufacturing practice (CGMP)) surveillance inspections.

Background

Rank drug manufacturing sites for CGMP surveillance inspections based on risks to public health.

Continual Improvement of the Model

The SSM Work Group reviews the SSM annually and changes are approved by the SSM Steering Committee.

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

Learning Objectives

- Identify the section in the Federal Food, Drug, and Cosmetic Act (FD&C Act) where a risk-based schedule is codified
- List the factors used in the CDER Risk-Based Site Selection Model

CDER's Risk-Based Site Selection Model (SSM) Operation

- The SSM considers risks to drug quality as may arise from violations of CGMP requirements.
- The SSM uses risk factors to generate CDER's Site Surveillance Inspection List (SSIL).
- The SSIL prioritizes sites for routine surveillance inspections

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

Risk Factors Stated in Section 510(H)(4) of the FD&C Act

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.

(G) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

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Risk Factors Used in the SSM

SSM generates a risk-based score for each site.

This site score is based on empirical evidence collected by FDA, subject matter experts' judgment, or a combination of both.

The following are currently identified as risk factors in the SSM:

- Site type
- Time since last surveillance inspection (or if the site was never previously inspected)
- FDA compliance history
- Compliance history of country or region
- Foreign regulatory authority inspectional history (with an authority deemed capable under section 809 of the FD&C Act (21 U.S.C. 384e))
- Patient exposure
- Hazard signals: FAR and BPDR; Recalls
- Inherent product risk

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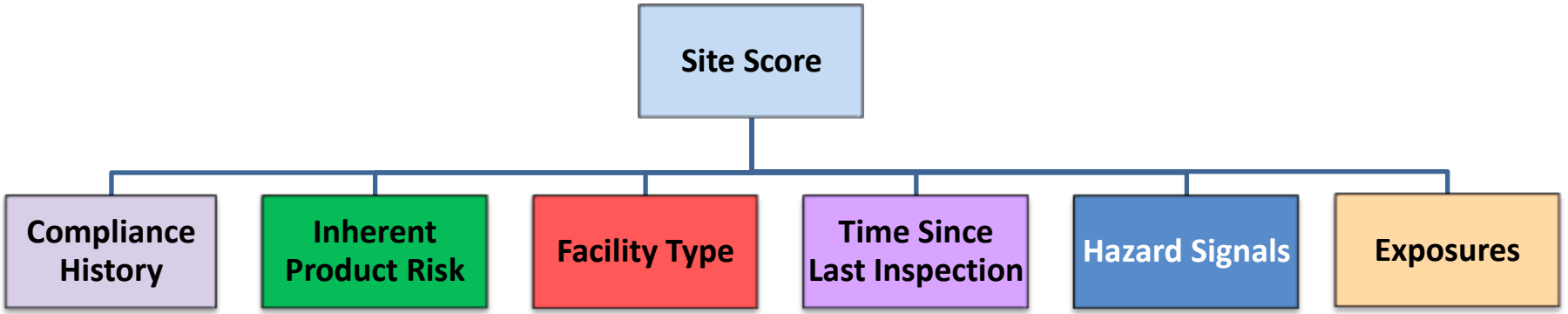
Risk Factors Used in the SSM



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Continuous Improvement

- The current governance structure for the SSM includes a cross-functional, model improvement working group and a steering committee that reviews proposed changes to the model.
- This process encourages continual improvement by assessing the SSM's requirement, risk factors, weights, and methodology and then identifying areas for improvement and modification.

Summary

- CDER Risk-Based Site Selection Model use risk factors consistent with section 510 (H)(4) of the FD&C Act
- SSM calculate a score for each facility using risk-based factors. Factors in the SSM includes, compliance history; inherent product risk; facility type; time since last inspection; hazard signals; and exposure.
- The SSM is governed cross-functionally with annual assessment and review process that encourages continual improvement

U.S. FOOD & DRUG ADMINISTRATION

Thank You

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