# SOMS Project Evolution
## IT Governance Meeting
## 4.5.12

# SOMS

A system designed and operated to disclose to the registrant suspicious orders of controlled substances

- Orders of unusual size, frequency & pattern
- SOMS is comprised of:
  - New Account Set-up Process
  - Automated Monitoring System
  - Investigation

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# Regulatory Requirement

## 21 CFR 1301.74 (b)

*"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious Orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."*

## Further Guidance: "December Letter of 2007"

*"Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total number exceeds the previous month by a certain percentage or more is insufficient."*

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# Current Automated Model

## Designed and Implemented Within SAP

- Primary user is Customer Relations
  - Order intake process

- Based on a "Threshold"

  - Customer groupings

    - "Class of Trade"
      - Wholesaler, Retail Chain, Distributor, Mail Order, etc.
      - Monthly avg. based on rolling 12 month period
      - Multiplied by static "multiplier" = Monthly allowable

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# Current Automated System (continued)

- ## Customer Groupings
  - Individual Customer "Ship-To" Location
  - Monthly avg. based on rolling 12 month period
  - Multiplied by static "multiplier" = Monthly allowable

- ## Order "Pending"
  - Order will "pend" for disposition if monthly allowable is exceeded
  - Customer inquiry and/or investigation

- ## "Multiplier" Table is populated manually based on estimation

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# Current Automated System Evaluation

– **Based on Compliance Concerns**

  - Increased enforcement action by DEA in the area of SOM audits

    – Most recently, Cardinal & CVS "failing to maintain systems to detect diversion"

  - Expectation that we "know our customer's customers"

    – Cross Functional Team Established in 2010

  - Security & DEA Affairs, IT, & Customer Relations

  - Established Goals: Compliance & Efficiency

  - Budgeted for third-party evaluation in 2011

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# Automated System Evaluation

- ## Cegedim-Dendrite (Buzzeo)

  - Regulatory SME & PhD Statistician
  - Full-Day Working Session with Stakeholders
  - GS & DEAA, Customer Relations, IT, Marketing
  - Reviewed entire process holistically

- ## Consultant Produced Written Report

  - Foundation for Project

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# Findings

- ## Use of Multiplier to Create Monthly Threshold

  - Not consistent with specific requirements noted within regulations and guidance

  - Current system will detect a certain percentage of suspicious orders, but not all

- ## Current Model Evaluates at SKU level

  - Possibility of distributing orders across multiple SKUs without detection

- ## System Does Not Evaluate Listed Chemicals

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# Recommendations

- ## Re-visit  Approach to SOM to Fully Address Specific Regulatory Requirements

  - Develop SOM that is a "non-threshold based adaptive" system trained to identify suspicious orders by utilizing a set of historical markers, to include:

    - Statistical Scoring of:
      - Active ingredient order volume vs. history
      - Active ingredient order vs. short & long term trend
      - Identification of hi/low frequency ordering behavior

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# Recommendations (continued)

- Base system on Milligram Strength Rather than SKU

- Include Listed Chemical Within System

- Based on Recommendations
  - GS & DEAA Requested a Proposal & Quote
  - Established Meeting with IT & Consultant
    - Understand Scope
    - Confirmed that solution was appropriate and achievable

- Budgeted for 2012 Implementation

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# Project Overview

- Consultant will Build, Train, Evaluate, and Deliver Non-Threshold Based System Based on Historical Data Provided By Watson IT

- Consultant & Watson IT will Integrate within SAP and Perform Parallel Testing of System Performance

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# Desired Outcome

- # Implementation of Non-Threshold Based System

  - ## Ensure Regulatory Compliance

    - ### Statistically Defensible System

  - ## Mitigate Risk to the CS Business

    - ### Increased DEA Scrutiny

  - ## Drive process efficiency

    - ### Trained system will eventually reduce "false positives"

    - ### Reduce the manual evaluation aspect within the process

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# Conclusion

- Questions

- Thank you

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