Journey to becoming a Resilient by Design Organization

SPEAKERS

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We Are Vertex

We invest in scientific innovation to create transformative medicines for people with serious diseases.





of everything we do





For the lives we have changed and for those who are still waiting, we will never stop fighting until we discover transformative therapies.

Quick Facts

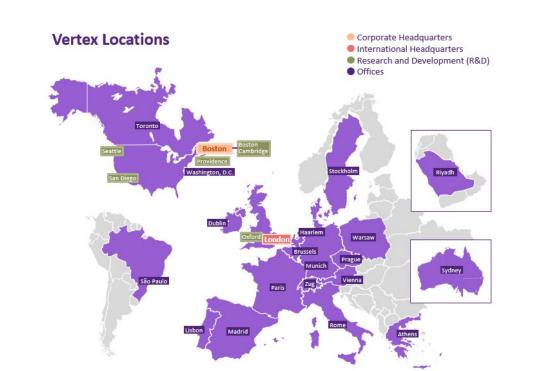


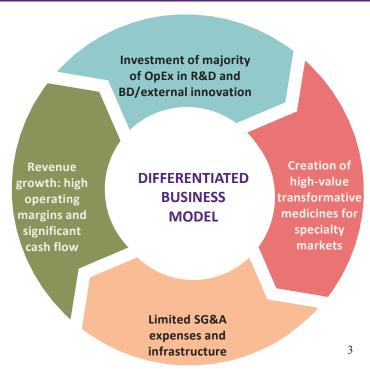












ENTERPRISE RISK MANAGEMENT (ERM) IS A HOLISTIC APPROACH TO IDENTIFYING AND MITIGATING MAJOR ORGANIZATIONAL RISKS

An ERM program helps companies:





affect the business over the next 3 years



Address the associated risks and opportunities that

result from these events



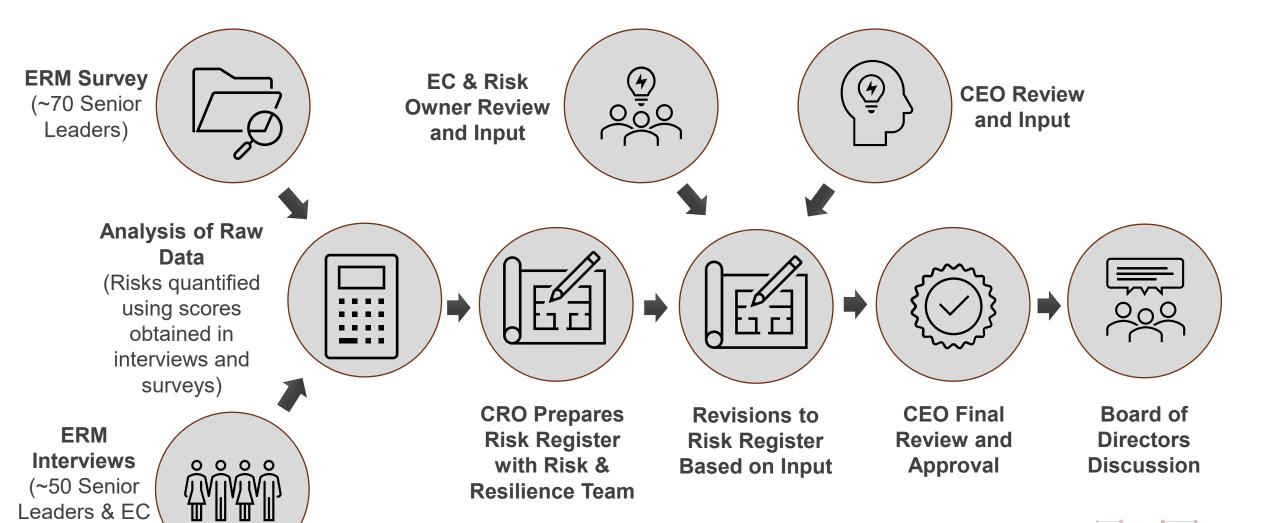
Deliver reasonable assurances that

the company's objectives will be achieved

Effectively deploying an ERM program will help enable an organization to successfully achieve its strategic objectives

BY DESIGN, WE IDENTIFY AND PRIORITIZE KEY ENTERPRISE RISKS THROUGH A COMPREHENSIVE BOTTOM-UP AND TOP-DOWN PROCESS





members)





- Drives annual BC updates
- Informs DR and Infrastructure resourcing
- Focuses TPRM Strategy
- Business area resource planning
- BIA helps to ID areas of operational risk



Our Journey to becoming a *Resilient by Design* Organization

"By failing to prepare, you are preparing to fail." Benjamin Franklin



Our Journey to Resilience by Design

To reach "Resilience by Design" we needed to understand our starting point, and our vision for the program in an ideal yet Fit-for-Purpose future state

MATURITY ASSESMENT KEY FINDINGS*

Diverse Governance Structure

Varying approaches (topdown versus bottom-up) to meetings and escalation pathways

Cross-Functional Collaboration

Cross-program forums contributing to targeted risk discussions and alignment

Reactive Mitigation Actions

Reactive approach to managing emerging / urgent risks across the supply chain

Minimal Data Integration

Various risk registers requiring integration to support a holistic risk view and list



Top-down Bottom-up approach to Risk Management



The top-down approach ensures the strategic "bigger picture" is cascaded throughout risk efforts while the bottom-up approach ensures that the people who work closest to the risks can identify, manage, and escalate those risks up





Playbook Scope

Risk exists across the organization in various forms, and our Playbook focuses on CMSC Risk Management and its interfaces with other parts of the organization. The Playbook offers a consistent yet not rigid approach to managing risks end-to-end.



The Playbook Will Address the Following Questions:

- How is risk consistently managed within CMSC across functions, modalities, and regions?
- How does CMSC Risk Management interface with Quality Risk Management and Third-Party Risk Management to prevent redundancy and ensure consistency?
- How does CMSC Risk Management align with and feed the overall Enterprise Risk Management process?
- How does CMSC Risk management align with and feed the overall Business Continuity and Incident Management process?

CMSC Risk Management Playbook Content Overview



CHAPTER 1: RISK MANAGEMENT OVERVIEW



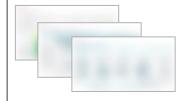
- Risk Management Framework
- •Top Down / Bottom-Up Approach
- Risk Appetite
- Risk Profile
- Risk Categorization Strategy
- Key Risk Indicators
- Success Factors

CHAPTER 2: CMSC RISK MANAGEMENT GOVERNANCE



- Leading Practices
- •Role of Risk Committee
- Meeting Governance
- Meeting Details
- •Role of the Risk Champion

CHAPTER 3: CMSC RISK CLASSIFICATIONS



- •Scope of CMSC Risk Register
- CMSC Risk Categories
- CMSC Heat Maps
- Acceptance & Closed Criteria
- •Risk Levels & Requirements

CHAPTER 4: CMSC RISK MANAGEMENT PROCESS MAPS



- Process Maps
 Depicting Ownership
 & Riskonnect Use for the Following
 Processes:
 - Identify
 - Assess
 - Control
 - Monitor
 - Review

CHAPTER 5: CMSC BUSINESS CONTINUITY



- Detailed Sections on Business Continuity Planning, Supply Chain Disruption & Mitigation, and Incident Management
 - Definitions
 - Governance
 - Thresholds for Plans
 - •RACI / Process Flows
 - Everbridge Capabilities

CHAPTER 6: RISKONNECT PLATFORM



- Riskonnect Overview
- Riskonnect User
 Manual Contents
- Riskonnect Workflow / Instructions
- Integration with Other Systems



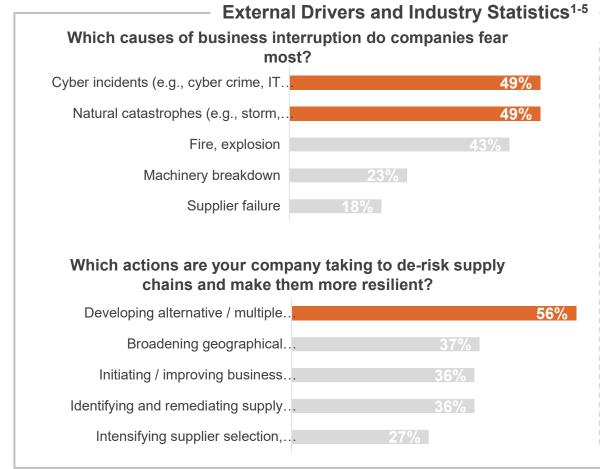
Business and Supply Chain Continuity & Resilience

Our Approach to Resilience in a Polycrisis Era



Connecting the Dots – Instilling a Compelling Sense of Urgency

In a "polycrisis" Era, it is imperative to ensure robust, holistic and cohesive Business and Supply Chain Continuity and Resilience strategies, particularly as Vertex continues to scale and expand their pipeline



9/10

companies experience at least 4 network or system outages per year

~50%

of manufacturers suffered supply chain disruptions in the past year

36%

of surveyed individuals identified supply chain disruptions as one of the top 5 external risks

Internal Drivers

Agile Approaches: corporate programs set expectations while giving flexibility to functions to tailor their approaches to fit specific needs

Growth & Preparedness: need for proactive preparation and documentation to address potential crisis or events associated with scale-up and growth

Evolving Risk Appetite: changes to appetite should be reflected in mitigation efforts, defined thresholds, and resiliency strategies

Cross-Functional Representation: plans require cross-functional representation to ensure the end-to-end supply chain is represented in preparedness strategies

Balancing Efforts: essential to strike a balance between responding to immediate disruptions and investing time in proactive mitigation and day-to-day responsibilities

Risk Management's Influence and Intersection with Business Continuity

The proactive classification and continuous monitoring of risks within the Risk Management framework supports the development and refinement of CMSC Business Continuity and mitigation plans

Business Continuity Planning

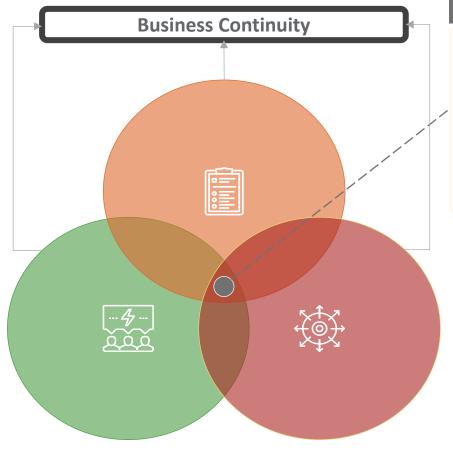
The tactical planning, processes, and procedures that specify how Vertex will overcome interruptions and restore critical operations as defined in a documented plan owned by each function

Critical, high-impact, cross-functional risks identified through the RM process are incorporated into Business Impact Analyses or Business Continuity Plans

Incident Management

The process of responding to real-time urgent events that have significant CMSC or Vertex-wide impacts through clear escalations, cross-functional collaboration, and after-action reviews

Real-time events identified through notifications or escalated risks that are captured in the RM framework for appropriate monitoring or required mitigation plans



Risk Management

Risk Management is the comprehensive process of **identifying, analyzing, and responding to risks** that could impact organizational and CMSC objectives

It forms the backbone for strategies like BCP, supply chain disruption planning, and incident management, ensuring that risks are prioritized, captured, and integrated appropriately across CMSC efforts

Supply Chain Continuity Planning

The strategic process designed to identify, assess, and manage potential disruptions within the supply chain to build flexibility and robustness of the supply chain

Risks with a direct impact on the supply chain network require proactive documentation of dependencies and cross-functional exercises for disruption mitigation plans

2025 Key efforts within the frameworks

CMSC Business Continuity efforts are organized into three key pillars, each with distinct roles and responsibilities, yet have overlapping outcomes that can influence one another

Business	Continuity
Planning	

Supply Chain Continuity Planning

Incident Management

Relationship

Department level Business Continuity Plans sit with CMSC Leadership and are referenced if a crisis occurs

SCCPs and risk details inform critical work to capture in BIA template to inform Continuity Plans

Business Continuity and SCD&M Plans guide the realtime crisis management efforts

- Business Impact Analysis (BIA)
 Function specific risks, critical work,
 processes, vendors, and workarounds
- Plan Development
 Develop plan using BIA outputs and details
 in SCD&M plans
- Plan Refresh
 Refresh and review of plans through various
 exercises on an annual basis or as needed

Risk Identification
Identify disruption risks and document related critical suppliers, impact, and dependencies

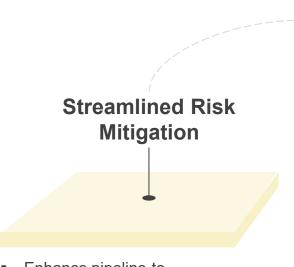
- Plan Development
 Evaluate whether a risk necessitates a SC
 Disruption Mitigation Plan or a BC Plan
- Mitigation Execution
 Execute mitigation actions and milestones to regularly report out on progress and findings
- Plan Refresh
 Review and update plans based on drills,
 updated assessments, or mitigation impacts

- 1 Event Identification
 - Detect real-time or potential crises and assess the scale and impact to determine escalation
- Incident Response
 Define response actions, obtain leadership approval, and notify impacted parties of plan
- Action Coordination
 Identify resources and execute activities according to the defined plan
- After-Action Report / Recovery
 Determine when the crisis is stabilized and evaluate response for improvements

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2025 & BEYOND FOCUS AREAS

The CMSC Risk Management Program continues to focus on opportunities to grow and support the organization, aligning with the Vertex 2030 strategy to enhance patient outcomes and impact



- Enhance pipeline-tocommercial risk transfers and hand-offs
- Increase KPI and KRI reporting capabilities
- Continue to mature the existing risk forums, processes, and systems

Integrated Business Continuity

- Leverage current system(s) to provide valuable alerts across CMSC to drive proactive efforts
- Explore opportunities for future guidance to support Incident Management
- Define materials to support development of Supply Chain Continuity Plans

Cross-Functional Collaborations

- Establish alignment on risk management efforts across thirdparty, quality, and other functions
 - Enable better coordination and integration to manage third-party risks throughout the contract lifecycle, and across disciplines
- Continue to support enterprisewide risk management and business continuity efforts



- 1 Extend leadership in CF
- Prepare for near-term launches
- 3 Advance R&D pipeline
- Scale organization and capabilities

Each effort within CMSC RM serves to strengthen the supply chain, Vertex, and their impact on patients



Questions?

CONNECTING RISKS THAT MATTER

MATRIX

Thank You!



Connect with me.

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