



Discussion Document

Is My Organization Prepared for a Disaster?





Biotech Operational Resilience

Best Practices in Business Continuity Planning (BCP) Threat Risk & Solutions

*Join us to discuss this document and your questions about
BCP online, in a BioChat Event*

Presented by

The UMB Center for Health and Homeland
Security (CHHS)

&

Vigilant Bioservices

Participate Live: Wednesday, December 6th, 2017: 1PM ET

Hosted by the Capitol Region BioBuzz BioHive.

[Link Directly To BioChat](#)

After the event date, use this link to see the Discussion Q&A (BioChat) archived online.





Table of Contents



Introduction to CHHS & Vigilant Bioservices	4-6
Risk Considerations	7–14
Biotech Resilience Resources	16-22
Bios & More Resources	23-26





Your BioChat Hosts*



UMB Center for Health and Homeland Security

- Eric Oddo, MPA, CHHS Continuity Program Director
- Megan Timmins, JD, CHHS Associate Director

Vigilant Bioservices – cGMP Biostorage

- Jeff Lange – Partner, Vigilant Bioservices; Quality Consultant
- Teresa O’Keefe – VP Sales & Marketing



*See bios and contact info starting on page 24



University of Maryland Baltimore (UMB) Center for Health and Homeland Security (CHHS) MDCHHS.com

- ❖ Founded in 2002; non-profit academic and consulting group based out of Baltimore
- ❖ Areas of expertise: emergency planning, crisis management, cybersecurity, training and exercise, public health
- ❖ Extensive client list within continuity planning: international, federal, state, county, municipal government entities, academic institutions, and the private sector
- ❖ Cost-Effective Solutions for all-sized organizations



“We are here to help”



Vigilant Bioservices

cGMP commercial biostorage solutions

vigilantbioservices.com



- ❖ Founded in 2009 by Biotech Quality Industry consultants, Quality Solutions, Inc., located in UMB Biopark in Baltimore
- ❖ Areas of expertise: biostorage in all ranges (e.g. LN2, -80C, -20C, 2-8C, etc.), ICH stability testing storage, photostability
- ❖ Facility Redundancy Include: Hospital Feed Electric with Dedicated Natural Gas Generator and Chiller, HVAC System, Unit Monitoring, cGMP standard operating procedures
- ❖ Solutions Include: Business Continuity, Archival, ICH Stability and Photostability, Biologic Distribution and Tissue Management





Risk Considerations

The Reality of Disasters



FACTS:

- ❖ 43% of US companies experiencing disasters never re-open, and 29% close within 2 years

Source: Contingency Planning Research & Strategic Research Corporation)

- ❖ 70% of companies go out of business after a major data loss

Source: UK DTI

Your insurance will not cover the soft costs of recovery from a disaster. It may not even cover the hard costs. Regardless of insurance, a disaster can put you out of business.

You can't avoid all disasters, you can only recover from them. Resilience is achieved by Risk Mitigation through Best Practices.

Unless you have completed a business continuity plan (BCP) and trained your entire staff in the last year, or update/revise your plan with re-training/awareness bi-annually, ***you are probably not adequately prepared for current disaster risk.***

New Cyber Attack Threats



2017 AIG Cybersecurity Report

CONSIDERATION: INCREASED POWER GRID THREAT RISK

Areas of Greatest Concern

Cyber cat-and-mouse war games, retaliation, and escalation

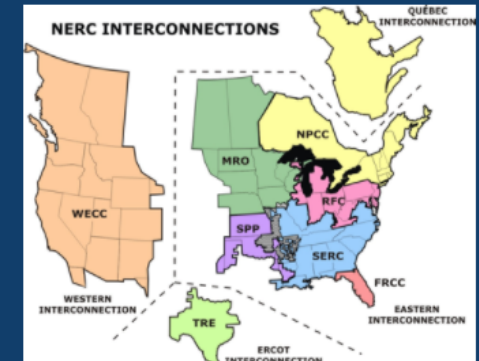


A power grid attack during times of system stress with widespread impact on the population

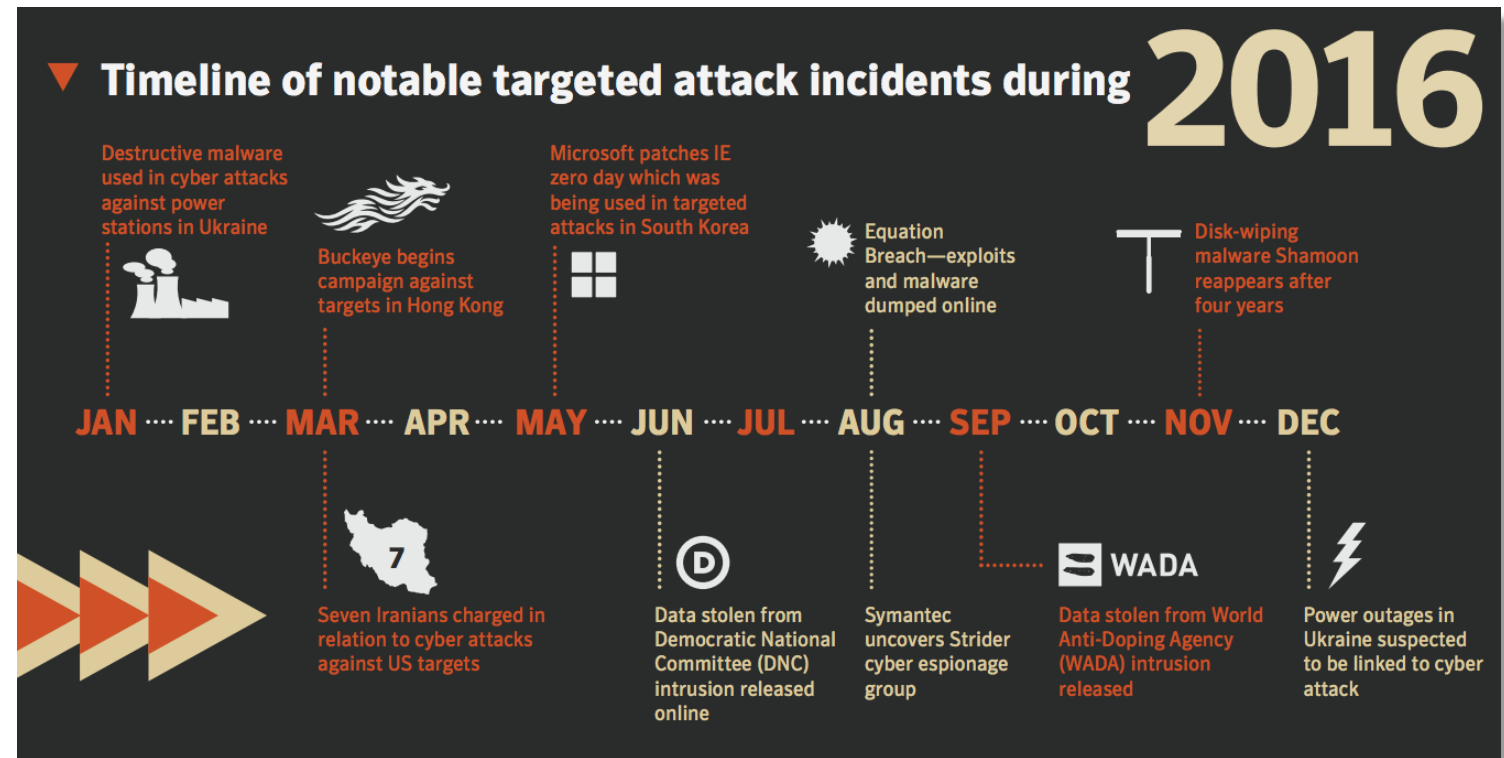
A significant attack on telecommunications and utilities infrastructure that has a widespread impact on essential services



The US/Canadian Continental Power Grid



Symantec's 2017 Internet Security Threat Report



Some Biotech Hubs are High Risk for Natural Disasters



Rank	State	H.R.S.*
1	Florida	94.51
...		
4	California	75.56
5	Massachusetts	72.12
...		
12	New Jersey	61.54
.		
14	Texas	60.89
15	North Carolina	59.72

CONSIDERATION: TOP BIOTECH STATES RANKED IN TOP 1/3 OF NATURAL HAZARD RISK RANKINGS



For every geo-coded location across the US, data represents composite score for nine natural hazards: **flood, wildfire, tornado, storm surge, earthquake, straight-line wind, hurricane wind, hail and sinkhole.**



U.S. Natural Hazard Risk by State
Source: 2014 CoreLogic Hazard Risk Score* (HRS)

Human Error and Maintenance Lapses are a Constant Challenge



CONSIDERATION: ULTRA LOW FREEZER MAINTENANCE

Are you counting on your freezers to not fail?

Ambient Temperature

If not maintained in ambient temperature, freezers lose their ability to maintain a set point; compressors run hot, shortening service life.

Proper Voltage

When voltage drops to below 170V, compressors become overworked trying to maintain target temp. Power must be conditioned.



Ice Build Up

Routine removal of snow from around the top inner door is an absolute must. If not removed, it will eventually interfere with door closure.

Positioning

Freezers should be positioned away from the walls to allow proper ventilation. Poor heat dissipation is the leading cause of component failure.

Filter Maintenance

Similar to the filters found in air conditioners, they must be cleaned every 6 months.



What is Your Most Valuable Biologic Intellectual Property?



ASSESS THE COST TO YOUR BUSINESS



Material Lost

Pre-Clinical Samples

Cell Lines

Product/API

Clinical Samples



Recovery Timeline

Months



Years



Cost

\$ 100,000s

\$ 1,000,000s

Priceless

High Profile Scientific Freezer Failures

In cold storage facilities with some of the most important material stored in the world, major human and mechanical failures lead to disaster. These make it into the news, many others don't....

❖ 2012 - Harvard Brain Bank

150 harvested brains lost "...the setback to neurological research and, specifically, Autism, is priceless."

❖ 2017 – Arctic Core Ice Loss

13% of samples lost "22,000 years of years of history melted."





Imagine the Disaster. Assess Your Risk.



- ❖ Cyber Attack
- ❖ Localized Power Outage – Human Error, Backhoe/Utility
- ❖ Localized Natural Disaster - Flood, Fire, Hurricane
- ❖ Pandemic Affecting Your Employees
- ❖ Localized Human Error/Sabotage – (ex. Unplugging a Freezer)
- ❖ Non-localized Disruption in Your Supply/Distribution Chain (ex. Liquid Nitrogen (LN2) Shortage)





Biotech Resilience Resources





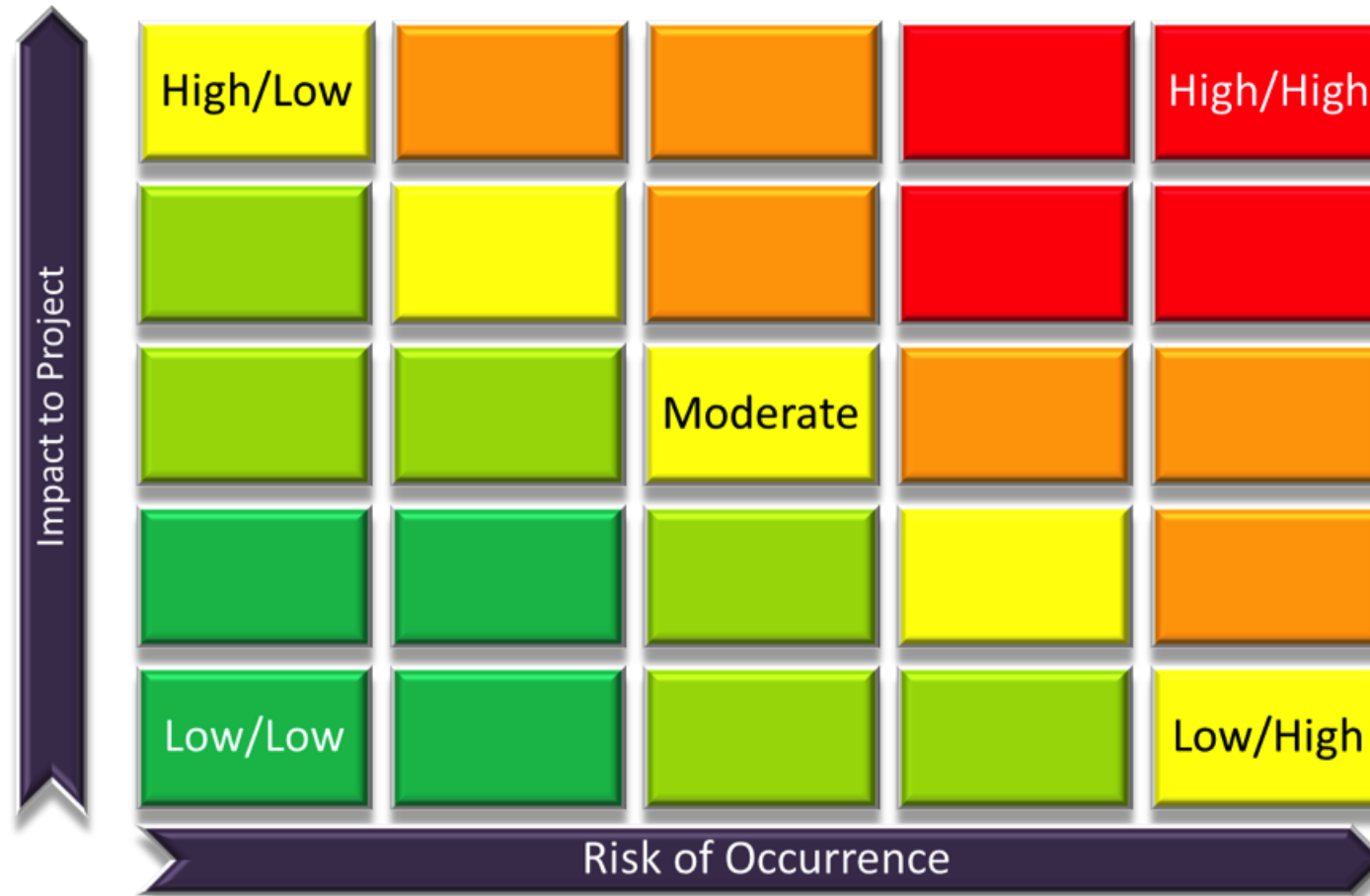
Biotech Resilience: Risk Mitigation Best Practices

	Practice	Detail
1	BCP is a Board-level Priority	The Business Continuity Plan (BCP) is implemented and <i>Revisited Bi-Annually</i> as part of Enterprise Risk Management.
2	Multiple Level Plans for Various Scenarios	Included in your comprehensive BCP: cyber attack, fire, flood, temporary power outage, personnel on call, temporary work space, etc.
3	Valuable IP and Work Product is Regularly “Backed Up”	<ul style="list-style-type: none">❖ Periodic assessments identify and move valuable biologic materials and/or stability studies to a <i>hardened</i>* offsite biostorage facility❖ All IT resources are backed up either to a cloud-based service automatically or appropriately backed up and system tested regularly.
4	Employees are Trained on Cyber Security Best Practices	Training includes contingency plans for localized disasters. If you cannot dedicate internal resources, a third party facilitates training your employees to ensure the completion and robustness of the BCP.
5	A Temporary Power Outage Plan Addresses Auxiliary Power Sources and Procedures to Secure Cold Storage	<ul style="list-style-type: none">❖ Plan includes resources for re-locating high value biologics❖ Dry ice and validated shippers are accessible if move is necessary❖ LN2 cold storage is monitored and LN2 supply is maintained at an adequate level to accommodate a temporary outage.
6	Remote Workforce Technologies and Temporary Workspaces are on Standby	Resources are identified and are ready for deployment. Employees are aware and trained on policy and procedures.

* Biostorage facility has multiple redundancies for core utilities such as power, HVAC components and utilizes cGMP standard operating procedures



Heat Maps Can Provide the Framework for Defining Unique Challenges and Cost-Effective Risk Mitigation Strategies

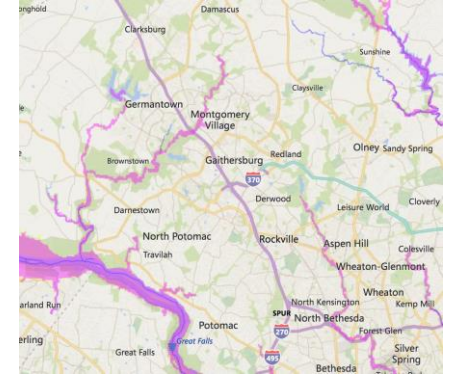




Resources for Risk

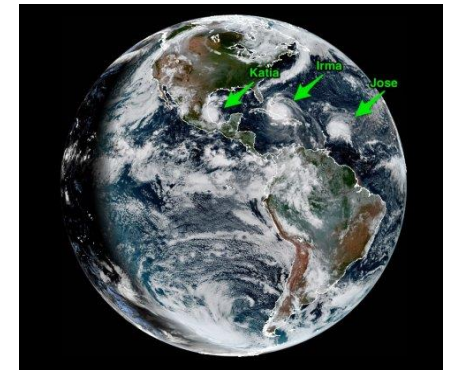
Are You in a Flood Zone?

[FM Global Interactive Flood Hazard Map](#)



Comprehensive Risk Determination

[Core Logic Research](#)





CHHS BCP Packaged Services

Three Levels of Continuity Of Operations (COOP)



- Level 1:** High-level assessment of current COOP gaps and capabilities
- Level 2:** Includes Level 1, and comprehensive COOP plan development and implementation
- Level 3:** Includes Level 1 and 2, and the planning, facilitation and evaluation of a discussion-based or operations-based exercise, and training for all personnel





COOP Class Available to the Public

CHHS' nationally-recognized, FEMA-accredited Continuity Planning course

- ❖ Celebrating its 10th year, having taught over 2,000 people in over 30 states and US territories -- “Maximizing Organizational Resiliency: COOP for Public Entities.” (highly applicable to private businesses, as well)
- ❖ Provides participants with the knowledge and skills necessary to develop, implement and exercise a comprehensive Continuity Plan which will enable their organization to seamlessly respond to disasters
- ❖ Next Delivery: December 7-8, 2017 in Baltimore, MD (\$200)



[Register Online](#)



Vigilant Bioservices Case Studies



- ❖ Vigilant Bioservices (VB) Saves the Day for Biotech that Loses Working Cell Bank Due to Freezer Failure
- ❖ A CDMO expands offerings with robust Stability and Photostability storage using VB resources
- ❖ Biotech Frees Up Valuable Working Freezer Space, Safeguarding Most Valuable Biologics offsite with VB
- ❖ Florida-Based Tissue Bank Stores Materials with VB During Hurricane Season



[Read More](#)



Bios of Presenters





Megan Timmins
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Megan Timmins, JD, joined CHHS in September 2007. Ms. Timmins graduated *magna cum laude* from St. Mary's College of Maryland in 2004, with a BA in Economics and pursued her law degree at the University of Maryland, Francis King Carey School of Law. Ms. Timmins received her JD in 2007 and is admitted to practice law in Maryland.

- During law school, Ms. Timmins served as a member of the Moot Court Executive Board, completed an Asper Fellowship at the Maryland Office of the Attorney General, studied comparative law in Aberdeen, Scotland, and worked as a law clerk for Rosenberg, Martin, Greenberg, LLP in Baltimore.
- As a Senior Law and Policy Analyst at CHHS, Ms. Timmins wrote continuity of operations plans for the University of Maryland, Baltimore, aided in fatality management planning for the State of Maryland, assisted the District of Columbia in planning for the 56th Presidential Inauguration, contributed to the Maryland Energy Assurance Plan, and lead regional resource management planning efforts for the Federal Emergency Management Agency's (FEMA) Region III.
- As an Associate Director, Ms. Timmins manages CHHS' Exercise and Training, Continuity of Operations, and Public Health Programs. Additionally, Ms. Timmins works closely with Maryland Carey Law in the administration and oversight of CHHS' academic work within the J.D. and Master of Science in Law programs.

Projects

- As an Associate Director for CHHS, Ms. Timmins has a hand in all projects coming into the Center. Areas of expertise include: Exercise and Training, Continuity Planning, Public Health, and Academic Program Management.





Eric Oddo
Continuity Program Director
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Eric Oddo joined CHHS in September 2008. He is a graduate of the Maxwell School of Citizenship and Public Affairs at Syracuse University, where he earned a Master of Public Administration with a concentration in National and International Security Policy, and a Certificate of Advanced Study in Security Studies through the Syracuse College of Law.

- Eric specializes in the development, implementation, and exercising of Continuity of Operations (COOP) Plans for governmental and institutional entities. He currently serves the District of Columbia Homeland Security and Emergency Management Agency (HSEMA) in a contractor role as the principal COOP planner in the District. Eric is responsible for ensuring that all cabinet-level District agencies develop their COOP programs in compliance with District and federal standards.
- In addition to his work with DC government, Eric has managed the implementation of multi-year COOP programs for federal, state, local, non-profit and institutional entities. During his time at CHHS, he has taught COOP to government personnel in Bangalore, India, to Department of Defense personnel in the Pentagon, and to local Washington business leaders via the Golden Triangle Business Improvement District. Eric has also performed live in-studio local television interviews to speak on recent emergency events.
- Eric is a Department of Homeland Security-certified Instructor. He is part of a team at CHHS that travels nationwide to deliver "Maximizing Organizational Resiliency: COOP for Public Entities," a two-day management-level training course designed to provide state, local, territorial, and tribal entities with the knowledge and tools necessary to design effective, all-hazards COOP Plans. As of 2017, Eric has conducted over 75 trainings comprising over 2000 total students cumulatively.
- While at the Maxwell School, in May 2008, Eric was part of a six-student team that consulted the U.S. House Homeland Security Committee on the current state of security screening effectiveness on mass transit systems. Shortly after, in July 2008, he earned Executive Certificates in Counter-terrorism Studies and Arab Culture and Environment from the Interdisciplinary Center at Herzliya, Israel.
- Eric completed his undergraduate coursework at SUNY-Oswego in 2004, earning BAs in Political Science and Criminal Justice. His professional experience includes three years at the Bank of New York-Mellon, where he served as a Client Management Administrator for corporate defined-benefit and defined-contribution plans.

Examples of Projects include COOP Training, Planning and Holistic Campus Security

US Department of Homeland Security
Howard County, MD government
Maryland Public Service Commission
University of Maryland-Baltimore
Sam Houston State University

Illinois Association of Community Action Agencies
Montgomery County, MD government
District of Columbia government
US Department of Agriculture Animal and Plant Health Inspection Service
College of Southern Maryland





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Jeff Lange joined Quality Solutions, Inc. as a consultant in 2005. Vigilant Bioservices was formed in 2009 with partners from Quality Solutions partners representing facility design, validation, compliance, quality assurance and tissue management disciplines. Vigilant Bioservices fills a need for high-end GMP biostorage services in the mid-Atlantic.

- As a Managing Partner for Vigilant Bioservices, Jeff is responsible for the daily operations in the facility and works with clients to accommodate specialized biostorage solutions.
- As a consultant for Quality Solutions, Jeff provides Biotech, Pharma and Sterile Compounding Pharmacies with the testing, certification, cleanroom environmental monitoring, validation and consulting services to support their facility, equipment, utilities, processes and Quality Systems. Services are performed in accordance with cGMP, 21CFR Part 11, FDA, EU, USP<797> and USP<800> regulatory requirements.

Please visit www.vigilantbioservices.com/solutions-ppt for more information.





We Look Forward to Your Questions and Participation on December 6th, 2017, at 1pm ET.

The “chat”, in the form of typed Questions & Answers, will remain online indefinitely, so feel free to check it out anytime after December 6th and forward this document to interested colleagues.

