

82nd Annual TPHA Conference

Lessons Learned

Foreign Country Donations of Food & Drugs

Hurricanes Katrina & Rita

&

ORA's Transformation

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And Then The Storm Came...

- Hurricanes Katrina and Rita - 'Caused A Whole Lot of Harm; And, For Many Months, Nothing Was Easy.'

Highway 90 - Mississippi Gulf Coast - Post Katrina

Lessons Learned



- When Disasters Strike
 - Chain of Command for Response
 - Priorities Change
 - Resources Shift
 - Communication Technology
- Procedures & Policies - Donated Goods And Government-to-Government Shipments
 - The Act (It's The Law)
- Transformation
 - Revisit
 - Revise
 - Renew

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When Disasters Strike



- Chain of Command for Response
- Priorities Change
- Resources Shift
- Communication Technology

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When Disasters Strike (cont)

- Priorities
 - Employee Safety
 - Consumer Safety
 - Refocusing Investigations In The Disaster Areas
- Resources
 - Deployments
 - Travel Dollars



Cameron, LA Aerial View

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When Disasters Strike (cont)

- Resources
 - Deployments
 - Travel Dollars
- What did we learn:
 - That communication is key in deployments
 - The heart of the employee to extend themselves to make things work is what often times makes us successful



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When Disasters Strike (cont)

- Tent City - Housing/Sleeping Quarters
- We Learned/Reinforced What We Knew:
 - We Have A Great Dedicated Staff, Willing To Live & Work Under Adverse Conditions To Get The Job Done!
 - It's Not Always Easy!!



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When Disasters Strike (cont)

- Staff Shortages Created in Critical Areas Due to Deployments
 - Lesson Learned: Have A Plan In Place To Stagger Deployment of Personnel

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When Disasters Strike (cont)

- Communication Technology
 - Communication between Agency Organizational Components Was Highly Effective
 - Data Was Shared Routinely & Quickly
 - Needed Guidance from Headquarters To Field Was Received
- Recommended Improvements
 - Alternate Forms of Communication Equipment

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When Disasters Strike (cont)

- Interaction with Other Agencies
 - We Performed Well with HHS Agencies
 - Probably Due to Common Aspects of Agency Missions
 - Communications on Deployment Was Somewhat Lacking
- Recommendations:
 - Up-to-Date Database Lists of Volunteers And Their Skill Sets
 - Inoculation Policy
 - Training for Disasters

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Procedures & Policies



- Procedures & Policies - Donated Goods And Government-to-Government Shipments
 - The Act (It's The Law)
 - 801(a) Entry Data
 - 801(m) Prior Notice Information

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Procedures & Policies (cont)

- Government-to-Government Shipments
 - FEMA/DOS/USAID Taskforce Is Addressing This Issue
 - Even In A Disaster, We Must Continue To Protect The Consumer Through Well Designed Procedures That Emphasize Safety As Well As Compassion & Humanitarian Relief
 - Have FDA At The Table Prior to Any Temporary Wavier of Filing of Import Entry Documents

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Transformation



- Transformation
 - Revisit
 - Revise
 - Renew
- As The World In Which We Live And Work Changes, We Must Change

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Transformation (cont)



- Imports
 - Consider How Best To Implement FDA's Import Strategy, Including Aligning ORA's Organizational Structure And Funding Priorities with This Strategy
 - Risk Based Targeting – Life Cycle of The Product
 - Identify Structure And Function To Achieve Goals of the Import Strategy

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Transformation (cont)

- Import Strategy – Five Workgroups
 - Foreign Operations
 - Border Operations and Entry Admissibility
 - Imported Goods In Domestic Commerce
 - Information Technology
 - Applied Science and Technology



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To Summarize...

- We Have Learned To:
 - Seize The Moment and Act
 - Review What We Did
 - How We Did It
 - Acknowledge Our Successes
 - Recommend Needed Changes
 - Implement Needed Changes
 - Prepare and Plan for the Next Big One!



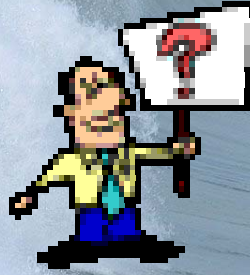
AND

Never Forget It Takes A Team To Sustain Us, and Make Us Successful In Our Mission!

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Questions

- Q & A



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