



# CAN YOU TAKE THE HITS AND BOUNCE BACK STRONGER?

## HOW TO THRIVE WHEN THE GOING GETS TOUGH – YOUR ORGANIZATIONAL RESILIENCE HEALTH CHECK

by Martin Lush

At NSF we're really passionate about two things.

- > We do our best to our best to ensure our clients continue to supply patients with the products they need.
- > We help you to prepare for the future, not for a world that no longer exists.

We specialize in helping you become resilient so you can prepare for disruptions, recover from shocks and stresses, and bounce back, revitalized from unplanned disruptive events.

We all live in an uncertain world. To protect your licences, your market share and profitability, you **must build in ORGANIZATIONAL RESILIENCE**. That is the ability to bounce back quickly and stronger following a surprise event.

### THE KEY QUESTION:

**Will your people, processes, systems and procedures bounce back no matter what hits them?**

## ORGANIZATIONAL RESILIENCE SELF-ASSESSMENT: YOUR TASK (15 MINUTES TOTAL)

### STEP ONE: AWARENESS (5 MINUTES)

Accepting reality and being aware of the challenges on the horizon is vital. Once acknowledged you can put plans in place for dealing with them. Look at the "predictable surprises" listed under Step One: Awareness below. These events are going to happen and you need to be ready and waiting.

- > Discuss these challenges with your colleagues.
- > Which one do you think you are most vulnerable to?
- > Would you add others, unique to your situation, location or circumstances?

### STEP TWO: SELF-ASSESSMENT (10 MINUTES)

To succeed in a turbulent, unpredictable world you must know your strengths, vulnerabilities and the associated risks you face.

- > Take this questionnaire along to your next team meeting or shift handover.
- > Discuss each best practice carefully and give yourself a score where 5 means you're doing everything described and 1 means the opposite! To keep it simple, we've focused on the top five to six points for each, the "must haves."
- > Be honest. Explore areas of disagreement; don't defend them.

### STEP THREE: REFLECTION AND ACTION PLANNING (5 MINUTES)

- > What are your top three vulnerabilities?
- > What actions must you take to become more resilient?
- > Please don't reinvent the wheel. If you would like a free copy of best industry practices for each area, please let me know ([martinlush@nsf.org](mailto:martinlush@nsf.org)). We will give you practical guidance on how to improve your organizational resilience in each of the areas covered.



## STEP ONE: AWARENESS

### Task:

Consider the following predictable surprises. These are just a sample of the key challenges that you will face. It's not a question of if, but when. Each will have a profound ripple effect on every company, big or small. Discuss each one. Are there challenges unique to your location, market, products and processes that you could add?

### **Environmental, political and socioeconomic instability:**

The world is a turbulent place. Any one of these alone would be challenging. The fact that all three are happening at the same time means that the pharma world will continue to change radically. Every aspect of the product lifecycle from research to distribution will face new challenges. New threats will surface requiring different decisions. Disruption to your complex supply chain is inevitable. How will you bounce back?

### **Scarcity of an educated workforce and the talent war**

The growth in the global labor force will fall by nearly one-third by 2030. By 2020 it is predicted that business will be short of 85 million workers with college degrees or vocational training. The shortage of scientists, engineers, biologists, pharmacists and the like will become acute. Companies must attract and retain the best people – those capable of making the right decisions across your organization. Are you ready?

### **Lower prices and lower profit margins**

With the population aging and an obesity pandemic to deal with, governments will be forced to restructure healthcare and health insurance systems. Medicines will be seen as commodity items. The pressure to reduce price will be acute. How will you cope?

### **New low-cost centers of manufacture**

As India and China become more expensive, the manufacture of low-tech medicines will move; further driving down prices and profit margins. How will you react?

### **More regulations to absorb and implement... only with fewer resources**

Enough said! Do you know what's coming? Do you have plans in place?

### **Shortage of raw materials, including water**

With everyone chasing the same limited resources, shortages (and increased cost) are inevitable. Many regions of the world are suffering from chronic drought. Since the pharma industry uses a lot of water, the impact will be profound. California (a center for biologics manufacture) as well as manufacturing hubs in southern Europe, India and China are all suffering from the longest droughts in living memory. The flip side of this is too much of the wet stuff. Plants built on low-lying flood plains will be challenged by keeping water out. Are you ready? How will you adapt?



## SO, IN SUMMARY

- > You will be asked to do more with less
- > You will have to simplify systems, dismantle bureaucracies, remove hierarchies and speed up decision making
- > You will have to fight hard to attract and retain the best people
- > You must invest in education and excel at doing the basics exceptionally well (such as risk-based decision making, intelligent risk and change management and problem solving)
- > You will face disruption to your supply chains
- > You will have to dramatically improve efficiencies without compromising product safety, quality and efficacy

### **What other challenges do you foresee?**

## STEP TWO: SELF-ASSESSMENT

Despite these predictable surprises, we're very optimistic about the future, as are many of the clients we've helped to get back to basics. They are now prepared and resilient. If you're complacent, you won't be. The key question is how do you compare with your resilient competitors?

### Task:

Discuss the following openly with colleagues and give yourself a score of 1 to 5 (where 5 is the best possible score).

#### Do you have a resilient quality culture? SCORE

- > Very high levels of trust/respect across all sites, departments and business units?
- > Total transparency. Good and bad news is shared, not restricted or manipulated?
- > Very high levels of collaboration throughout. Silos non-existent?
- > Passionate about people (education and development) and patients?
- > QA totally integrated and on the shop floor?
- > Focus on prevention and improvement, not firefighting and crisis management?


#### Do you have resilient leadership at every level?

- > Everyone has in-depth knowledge of products and processes?
- > Supervisors (first line managers) spend at least 80 percent of time on the shop floor?
- > Blame free culture from top to bottom, at all times?
- > Leadership understands the product lifecycle from start to finish?


- > Leadership possesses excellent risk-based decision making skills?
- > Leadership ALWAYS keeps the patient and their people at the heart of everything they do?
- > **Do you have resilient people?**
- > Low levels of staff turnover (less than 5 percent)?
- > Low levels of contract workers (less than 5 percent)?
- > Key activities/functions (QPs, HR, engineering, validation, etc.) not contracted out?
- > Training seen as a profit generator, not a cost center?
- > Cross-functional development of people at every level?
- > Training takes the 10/20/70 approach. If you don't understand this question, give yourself a 1!


#### Do you have resilient manufacturing processes?

- > Reliable and robust with very low levels of reprocessing, rework and work in progress?
- > Quality by design and continuous process verification to ensure consistency?
- > Plant/equipment utilization in excess of 80 percent?
- > Stock levels (materials, components, etc.) that provide some redundancy/cover?


#### Do you have resilient management of third parties?

- > Third parties selected based on quality and professionalism, not price alone?

--



- > Treated as partners, not contractors (genuine win:win)?
- > Clear technical agreements in place describing the who, what, why and how?
- > Level of your management support and oversight based on risk?
- > Information shared via knowledge management system (KMS)?


- > Customized impact assessment form used to review and approve/reject changes?
- > Every change formally followed up to confirm successful implementation?
- > 80 percent of changes confirmed as successful with demonstrable return on investment?
- > Information shared via knowledge management system (KMS)?


### Do you have resilient management deviations?

- > All incidents reported within 60 minutes?
- > Every incident risk-ranked, using risk-based impact assessment criteria within 4 hours?
- > Investigations investigated proportionate to risk?
- > Investigations take place where the incident happened, not from behind a desk?
- > Do you have less than 5 percent of repeat incidents per year?
- > CAPAs focus on prevention. Ratio of two preventive to every one corrective action?
- > Human error considered as the starting point of investigation, rarely its conclusion?
- > Information shared via knowledge management system (KMS)?


### Do you have a resilient documentation system?

- > Policy documents that describe the why in less than five pages?
- > SOPs written by the user, for the user (not the inspector)?
- > SOPs that use more pictures, schematics and process flows than words?
- > Instructions start on page ONE?
- > Road tested and practiced before implementation, not rushed in?
- > Key policies and procedures reviewed annually, not every two to three years?


### Do you have a resilient audit and self-inspection system?

- > Audit program based upon risk?
- > Audits completed by certified and fully trained auditors to ensure consistency?
- > Audits focus on prevention (fixing root cause), not short-term actions?
- > Escalation process for critical observations (within 24 hours)?
- > Formal review and close out of CAPAs?


### Do you have resilient management of change?

- > Change requests approved in less than 60 minutes?
- > Change control system rejects at least 40 percent of change requests?




- > Ratio of three self-inspections for every audit?
- > Results and findings trended and shared via KMS?


#### Do you have resilient risk management?

- > RM fully integrated into every aspect of your business?
- > People fully trained in risk-based decision making and not using "gut feel"?
- > Customized, objective impact assessment forms used for all decisions?
- > Simple risk register to provide management with overview of business risks?
- > Results and findings trended and shared via KMS?


TOTAL

--

## STEP THREE: REFLECTION AND ACTION PLANNING

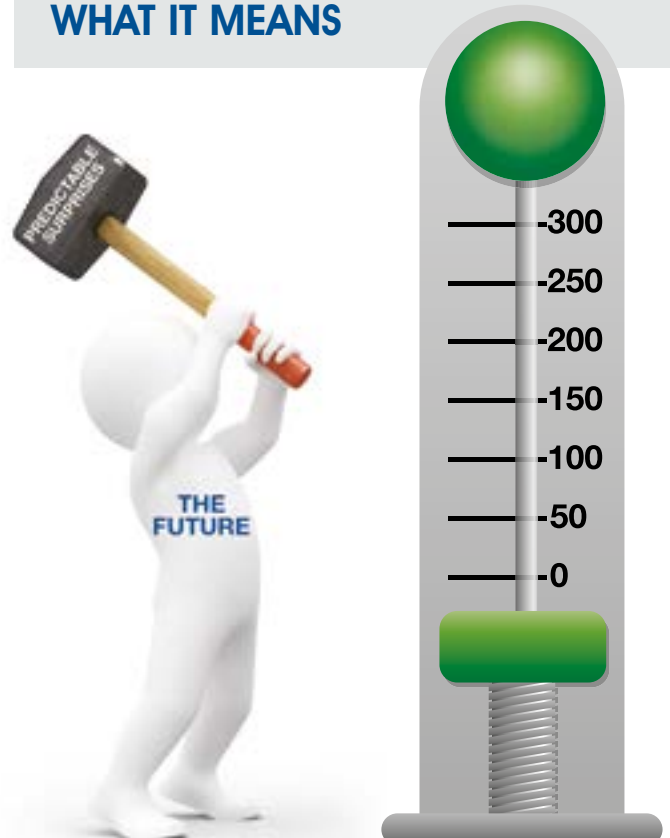
- > Add up your scores and see how you fare on the resilience gauge below
- > What are your top three vulnerabilities?
- > What actions must you take to become more resilient?

#### Remember

*"Victory awaits those who have everything in order; luck, people call it. Defeat is certain for those who have neglected to take the necessary precautions in time; this is called bad luck."*

Amundson

## YOUR RESILIENCE SCORE AND WHAT IT MEANS



**300 = Market Leader – just keep it up**

**250 = You're in the top 10%**

**200 = You're in the top 15%**

**150 = You're competitive, but only just**

**100 = There is hope, ACT NOW!**

**50 = Your days are numbered!**

How we can help you prosper and succeed:

- > We believe that **complex, rigid structures and systems will not work**. Simple, adaptable and flexible ones will. If you want to simplify your systems to improve their resilience, we can help
- > We believe that **your success depends on what you STOP doing**. We can help you to focus
- > We believe that your **success depends on just doing the basics very well** and ignoring everything else. If you want to know more about the basics, we can help



- > We believe that it's **better to spend \$100 preventing** rather than \$100,000 reacting. It's also a lot less painful. If you want to focus on prevention, we can help
- > We believe that **Warning Letters and the like are a great opportunity to get back to basics** and build in resilience. If you're involved in remediation activities, we can help. We will leave you with systems and practices that will work. We don't believe in adding complexity
- > We believe your success depends on having **people who are educated, not trained**. If you want to know the difference, we can help

We hope this resilience health check has helped to gain a perspective on how to negotiate the changing landscape. Remember success awaits those who have everything in order. For more detailed information on more predictable surprises and some solutions, please contact me at [martinlush@nsf.org](mailto:martinlush@nsf.org)

#### Please remember:

- > The world today is one of turbulence, volatility, change and unpredictability
- > In times of uncertainty, what worked yesterday may not work today
- > Resilient companies are those with the ability to bounce back stronger when hit by a predictable surprise. Not through luck, but by meticulous planning and preparation
- > If you have a resilience score above 200 you will turn uncertainty into commercial advantage
- > Anything below, please give us a call

With thanks to references provided by Richard Dobbs, James Manyika and Jonathan Woetzel of the McKinsey Global Institute and authors of No Ordinary Distraction: The Four Global Forces Breaking all the Trends.

## ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

Copyright © 2017 NSF International.

This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

Cite as: NSF International. October 2017. Can You Take the Hits and Bounce Back Stronger? NSF: York, UK.

## NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF

**T** +44 (0) 1751 432 999 | **E** [pharmamail@nsf.org](mailto:pharmamail@nsf.org)

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA

**T** +1 (202) 822 1850 | **E** [USpharma@nsf.org](mailto:USpharma@nsf.org)

[www.nsf.org](http://www.nsf.org) | [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)