



MANAGEMENT REVIEW AND ESCALATION IN TIMES OF CRISIS

by Lynne Byers

How a company reacts to a crisis speaks to the culture of the company and reflects the leadership of the company. First, we need to understand the definition of a crisis. This will vary significantly from company to company, depending on the maturity of the company, the size and scale of its operations and its financial viability. Crises come in many forms, e.g. the loss of a site due to a fire, cashflow problems, global patient level recall and global pandemics, to name a few. Some issues are clearly a crisis, e.g. a fire or a global recall, but other potential crises are not as immediately noticeable, e.g. cashflow problems or a new emerging disease. It depends on what signals a company is using to track potential business threats. What mechanisms does your company have to track and respond to potential threats?

WHAT KEY PERFORMANCE INDICATORS (KPIs) DO YOU ROUTINELY TRACK?

Every company should have a clear set of KPIs which it tracks. The KPIs should not be the same at every level in the organization but should be appropriate to the ability of the management of that area to act on the KPI. For example, at a local line/area you will probably track documentation errors per line/area, but at a company with multiple sites a measure such as batches right first time (e.g. combining documentation errors, deviations and so on) by site is more appropriate.

The time frame for each KPI should also be defined, e.g. what needs to be discussed at the daily accountability meetings and what should be discussed monthly or quarterly? Other important parameters include the source of the KPI and who takes ownership to act if it is outside the set targets? It is important not to waste energy in tracking KPIs and then not acting on the information. There is a saying that "What

gets measured gets done," but this only holds true if management takes an interest in the results.

Management reviews are the ideal time for management to show an interest and act upon trends. In pharmaceutical manufacturing sites they typically take place monthly, although some sites only perform the review annually. (NSF would recommend a monthly review.) The EU GMP Guide, EudraLex Volume 4 states that management reviews of the operation of the pharmaceutical quality system should take place periodically to identify opportunities for continual improvement of products, processes and the system itself.

WHAT SHOULD CHANGE IN A CRISIS SITUATION?

The normal KPIs may need to be changed to reflect the crisis. For example, if a site has burned down then the KPIs will switch to day-to-day management of the recovery plan/rebuild of the facility. Daily tracking of available supply of product and rationing product may become a daily metric, compared with the norm. If the site is facing a pandemic, it may be appropriate to track absence rates.

Management should ask themselves:

- > What is the potential impact of the crisis?
- > How will that impact operations of the site/company?
- > Are there any new KPIs that need to be tracked on a daily/weekly basis?

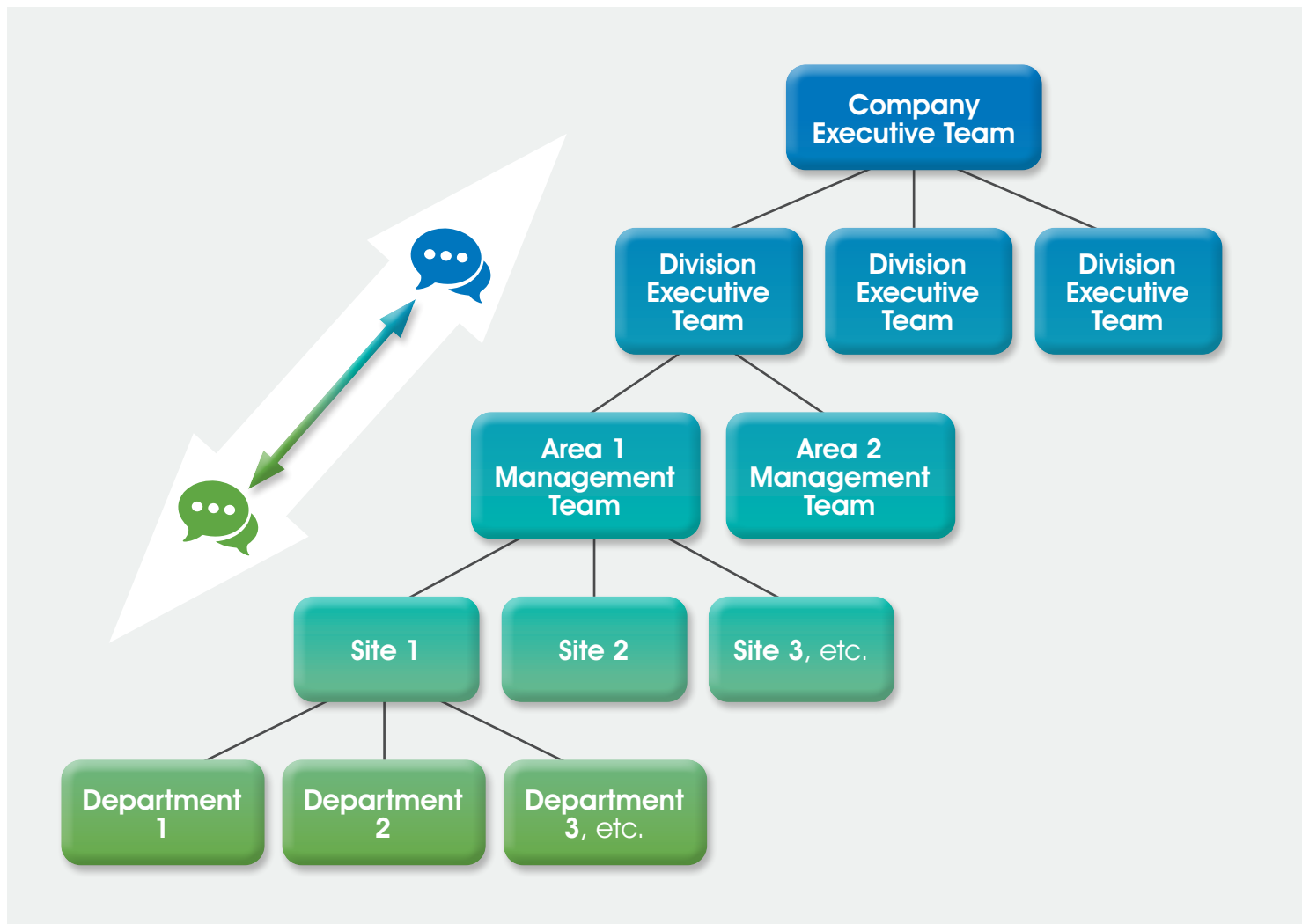
Once a decision has been made about the new KPIs, implement them and consider if all existing KPIs will continue to be tracked. Do not be afraid to make necessary changes.



ESCALATION

In a large company with several divisions, escalation during a crisis can become confused. This will be particularly evident if there is public, press, regulator, government or customer interest in the crisis. In today's world communication via various media is 24/7. This

simplified diagram shows a typical company hierarchy and its communication routes. This works well in normal times, with communication and escalation flowing up and down through the organization, but in a crisis an alternative approach needs to be taken.



When facing a crisis, smart companies set up cross-organizational teams to help manage the crisis. Communication becomes essential, both within the company and with external stakeholders. Ensure staff from the communications department is in the team. The team members should ensure they are clear about what information they require regularly, maybe even daily, from each site. For example, if there is a pandemic then perhaps measuring staff sickness and availability of personnel protective equipment (PPE) would be important KPIs. Shortages of PPE at one site could trigger supplying stocks from a central stock or another site.

Keeping the multitude of stakeholders informed is very important. In many circumstances internal crises need to be escalated outside the company, e.g. to regulators and shareholders. What to communicate, to whom, how frequently and how all need to be decided. Develop a communications strategy answering these questions. Internal communications will be more detailed than external communications. Think about the many communication tools, e.g. Twitter, company website, press releases, press conferences, video conferences, telephone, face to face, email, WhatsApp, etc.

Stakeholder	Website	Group Video or Telephone Conference	1:1 Video or Telephone Conference	Email	Text Message or App, e.g. WhatsApp, WeChat
Internal to Company (Senior management)	No	Preferred	Preferred	To provide written updates	Yes, for quick updates
Internal to Company (All Staff)	Yes	Preferred, periodically	No	Yes	No
Regulator	No	Potentially, if multiple regulators involved	Preferred	To provide written updates	No
Customers	Yes	Potentially, situation dependent		Yes	No
Suppliers	Yes	Potentially, situation dependent		Yes	No
Shareholders	Yes	Yes	Potentially, for major shareholders	Yes	No
General Public	Yes	No	No	No	No
Press	Yes	Yes	Yes	Yes	No

Being transparent in communications is critical in a crisis, even if the news is bad. This will engender trust with stakeholders. Frequent communication may be required, e.g. daily when the situation is evolving.

We hope you do not have to manage too many crises in your career, but in reality, everyone will face several throughout their working lives. Hopefully this white paper has provided some guidance for when you next face a crisis situation.

ABOUT THE AUTHOR



Lynne Byers has gained more than 35 years' of extensive pharmaceutical manufacturing management and QA experience working for three major international pharmaceutical manufacturers, culminating in the role of Global Head (VP) of External Supply Operations QA for Novartis in Switzerland. In addition, she worked as Head of Inspectorate and Licensing for the MHRA from 2004-2006. She joined NSF in 2017.

Ms. Byers has broad experience in manufacturing management and QA of a wide range of sterile and non-sterile dosage forms, and is fully conversant with current EU and FDA GMP regulations and requirements. She has extensive experience in international QA auditing of a wide range of pharmaceutical manufacturers who are suppliers to the pharmaceutical industry worldwide. She also has extensive experience in managing QA teams in country affiliates.

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