Chapter

Dealing with Unforeseen Circumstances. Implication of Risk Management in the COVID-19 Public Health Emergency

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Abstract

Any production plant can be affected by a disaster. Emergency management plans are the best ally to overcome disasters in an adequate way. The present COVID-19 public health emergency can be assimilated to a disaster because of its effects on production and, thus, it requires a contingency plan too. The purpose of this study is to develop a model of contingency plan based on Risk Management (RM) concepts. The methods and analysis used in this development are based on those proposed in international pharmaceutical guidelines. The author, a consultant of the pharmaceutical industry, uses RM tools to provide a practical roadmap to detect problems and implement consistent palliative solutions in any type of manufacturing plant.

Keywords: Absenteeism, confinement, emergency management plan, FMEA, monitoring, PHA, supply

1. Introduction

1.1 Handling a disaster: "the remedy can be worse than the disease"

Any manufacturing site can be affected by a disaster, caused either by natural phenomena (flood, earthquake, fire, landslide, typhoon, tsunami, etc.) or by people (theft, arson, terrorism, vandalism, etc.).

Experience demonstrates that in the situation of stress, which follows a disaster, people are prone to take wrong decisions that could even aggravate the consequences of the incident.

Mismanagement can be avoided if a site has previously developed an "emergency management plan", intended as a roadmap for the satisfactory treatment of a given incident and for preventing the implementation of arbitrary measures.

This study develops a model of rationale to prepare a hands-on plan based on risk management.

1.2 COVID-19, another kind of disaster

A new single-strain positive (+) RNE virus, belonging to the Coronaviridae family, was detected in 2019. It was called SARS-CoV-2 and the respiratory disease that it causes became known as COVID-19 (Coronavirus Disease 2019) [1].

The dissemination of this virus on a planetary scale has created a global situation of "Public Health Emergency by COVID-19", which we will shorten in PHEC-19 [2].

Although we cannot anticipate the evolution and the final consequences of this pandemic, we already know that it has dramatically upset human activities in a completely unexpected way and we can consider it another type of disaster for many manufacturing plants that were forced to manage a problem for which they were not prepared.

We are going to analyze how PHEC-19 can affect the functionality of manufacturing plants and propose a management model derived from the general model proposed for disaster handling.

2. Methodology, the risk management model

When taking decisions, our aim is to take the right ones. However, because of human limitations in terms of information, knowledge, skills, etc., this is easier said than done and, thus, we are obliged to be pragmatic and "take as little risk of being wrong as possible". To meet this end we use risk management (RM), which is defined as the process of assessing, controlling, communicating and reviewing risks affecting the object of study [3].

We speak of quality risk management (QRM) when risk management focuses on protecting the quality of the products.

As shown in **Figure 1**, any RM process starts by defining the object of study or "action field" (item, procedure, unit) and then, getting as much as possible

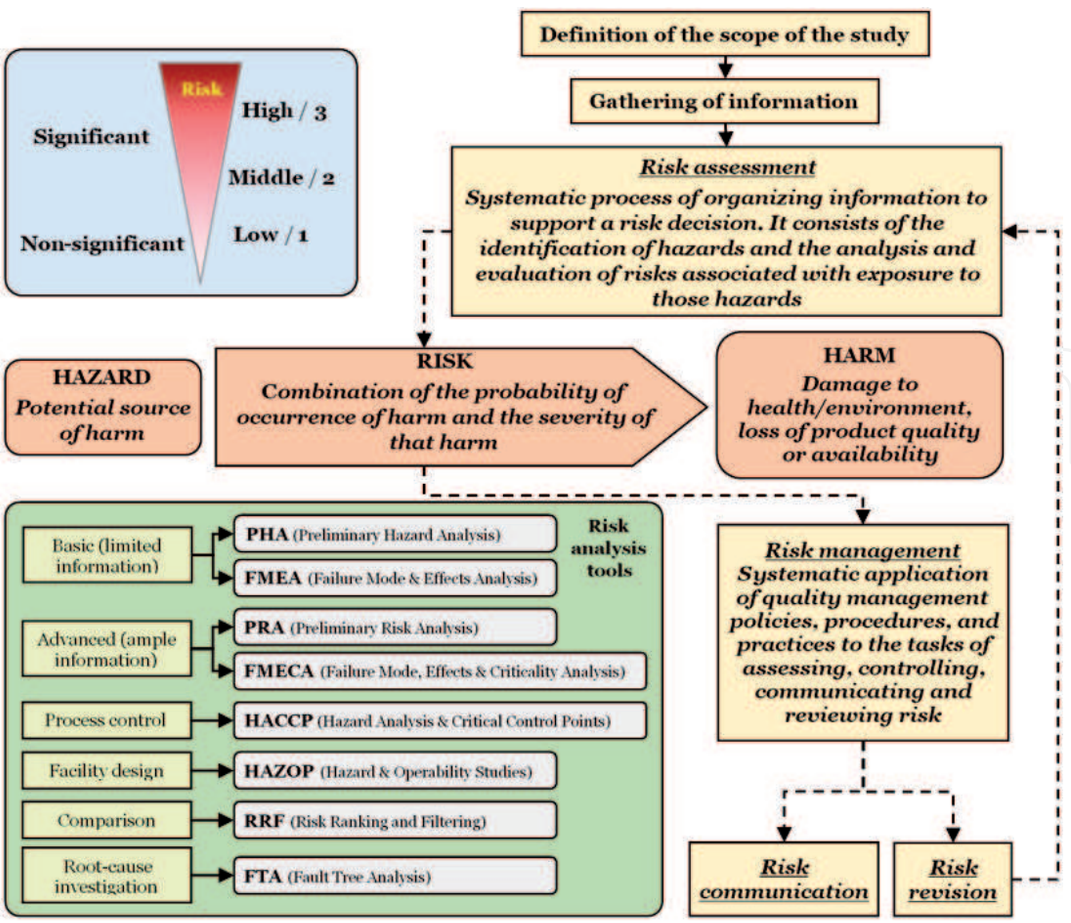

Figure 1.
RM: concepts and organization.

information on it. With this information and some amount of experience, it is possible to detect potential problems (hazards or failure modes) and assess their respective level of significance or criticality.

Risk analysis tools facilitate the organization and assessment of the existing data. The objective is to be able to list the critical hazards or failure modes that require control actions. Those considered non-critical, because of their low level of significance, can be left aside and, thus, we can concentrate our resources and efforts to manage the critical ones.

This process is a cyclical one, because the objects of study can be subjected to technological and methodological improvements or regulatory amendments, which can modify our risk assessment and, thus, affect risk management. In the lower part of **Figure 1** are shown different tools that we can use in risk analysis. All are perfectly valid, although they provide the best performance when used in the most appropriate manner. It is important to keep in mind that they are not miraculous weapons that reveal to us what we do not know. They only organize the information we already have [3].

The level of knowledge and experience determines, in general, the worth of the risk assessment and, in particular, the accuracy of the determination of risk. As it is well known, this can be done either qualitatively or quantitatively. If there are enough data, a quantitative risk estimation is, evidently, preferable, but if this is not the case, a qualitative estimate will do. We should bear in mind that "inventive determination" of risk values does not help and can mislead. It is also possible that as our analysis progresses we get more information, allowing more accurate risk assessments. In all this process, common sense is a very valuable ally.

Regarding risk analysis tools, there is a certain tendency to assimilate risk analysis to Failure Mode, Effects & Criticality Analysis (FMECA) and to privilege this tool in an abusive way. FMECA is an excellent tool for well-known processes and items, because it allows quantifying the risk, and this is a powerful ally in case of continual improvement, where it visualizes the evolution, which is achieved. However, it is easy to come to too subjective risk assessments when applying FMECA to situations for which there is little knowledge and experience [4, 5].

In emergency situations, which are by definition little known, we propose to analyze risk by using simpler tools such as Primary Hazard Analysis (PHA) or Failure mode and effects analysis (FMEA) and to appraise it qualitatively at two levels: "low" (insignificant or non-critical) and "high" (significant or critical).

Table 1 shows a model of chart for PHA. As we can see, the first column serves to indicate the item that is studied. Then, in the second column are listed all the possible hazards that loom on the item. In the following columns are described the possible causes and effects of the identified hazards. With the information written in the former four columns, it is possible to assess the importance of the hazards. If they are deemed significant, it is necessary to take actions, which are described in the last column.

Item	Hazard	Cause	Effect	Assessment	Actions

Table 1.
Example of PHA table.

Process stage	Failure mode	Cause	Effect	Assessment	Actions

Table 2.
Example of FMEA table.

Table 2 shows a model of chart for FMEA. The first column serves to indicate the process stage that is studied. Then, in the second column are enumerated all the possible modes of failure. The following columns are the same that we described above for PHA.

As one can see, both tools are similar, although FMEA focusses on processes, whereas PHA is more general and centers on items.

The main obstacle to overcome while using these tools is to be able to detect all existing hazards or failure modes.

When using PHA, there is no general rule for determining the possible hazards. Each case has a particular approach and it is necessary to use a comprehensive rationale to determine hazards and not to leave aside any of them. Below, are given some practical examples of how to tackle this issue.

Instead, it is possible to say that FMEA is more straightforward, because the key-element for the analysis of a process is its flowchart, which decomposes the process in stages. Then, each stage is studied in order to identify possible failure modes.

PHA and FMEA contain columns intended for the examination of "causes" and "effects". However, they are not always necessary, as shown in the examples that we provide below. When you are assessing, for instance, a disaster, the cause is obvious (the same disaster or an evident consequence of it) and the effect is manifest too (the damage). In these cases, when it is clear that the information contained in one or in both of the columns is worthless, they can be set aside.

3. Application of RM to draft an emergency management plan

It is impossible to draft a detailed contingency plan for incidents that might disrupt normality in a manufacturing plant without taking into account the particular characteristics of the unit, which can be very varied. This is why we just provide an example of the kind of rationale that can be applied to these situations.

In the present example, our object of study will be the effect of a disaster on the production of a manufacturing plant. We are not going to focus on the incident itself but on its effects on manufacturing. Consequently, the factors or elements that we will take into account are the following:

- Documentation: The incident can affect or destroy both paper and computer files.
- Premises and equipment: Here, we include utilities produced in the plant (HVAC, demineralized/purified water, steam, vacuum and compressed air).
- Utilities coming from outside: Electricity, gas and mains water.
- Supplies. Materials, products, chemicals, consumables, etc., which are necessary for manufacturing.

- Personnel
- Production: Processes used for the manufacture of products.
- Quality control (QC)
- Distribution: Shipping and transportation of products.
- Pollution: The disaster can lead to the accidental and uncontrolled liberation of substances to the environment

Next, as we previously said, we detect the hazards that are associated with each factor/element, we assess their significance and finally, we determine the necessary actions.

Table 3 develops these ideas. It goes without saying that real cases require real data and that corrective actions should be carefully described in reports ad hoc.

Factor/ Element	**Hazard**	**Assessment**	**Actions**
Documentation	Loss of data	No effect on production	---
		The loss affects production	If it is possible to recover the missing information, go ahead taking the necessary precautions
			If it is not possible, analyze how to reconstruct necessary information. Draft an action plan regarding data and production recovery
Premises and equipment	Loss of functionality	Evaluate the situation of the site	Develop a recovery plan taking into account affected areas, needed/ existing resources, product priorities, feasibility of outsourcing, etc.
			Try to restart production in the unaffected areas considering possibilities/priorities and outsourcing
Utilities	Lack of supply	Assess delay and consider alternative solutions	Electricity: Restore transmission line or install a generator Water: Restore piping or us a tanker truck for transportation of water Gas: Restore piping. Consider alternative systems or use of cylinders
Supplies	Loss of stock of supplies	Is it possible to restart production with the existing supply stock?	Study the situation and act accordingly. Consider the need of repeating quality controls of the existing supply stock
		Consider delivery time and get new supplies	Draft accordingly a new production schedule
		Will the new supplies suppose a change with respect of those previously received?	In case of change, consider the need of increased analysis and monitoring. If necessary ask for change authorization

Personnel	Has the situation affected the existing personnel?	No	---
		Yes. There is lack of staff	Hire new staff considering training needs and use old trained personnel as supervisors
Production	Does the resumption of production mean changes in methods, monitoring, or data recording?	Can these changes be made acceptable by increased control, monitoring and "concurrent validation"?	Establish a plan to cope with these changes. If necessary ask for change authorization
Quality control			
Distribution	Stock of products affected by the incident	Inspect state of products	Discard products out of specification
			Contact purchasers to evaluate the situation and define production priorities
Pollution	Stocked materials, chemicals or products accidentally liberated to the environment	See the situation and assess severity on a case by case basis	Put in practice control measures (recovery or inactivation and, if required, inform authorities)

Table 3.
Study of effects on products of incidents that disrupt normality.

4. Application of RM to cope with PHEC-19

4.1 An unexpected health emergency

Manufacturing plants were not prepared to face a problem like PHEC-19. The effects of PHEC-19 are less evident that those of a "typical disaster" and this means that problems might pass undetected. We must keep in mind that to have problems is not good, but not to be aware of them is even worst!

Still, the situation created by the COVID-19 is far from being an "unimaginable surprise". In fact, both science and history show that this is a "normal" event.

On the one hand, we know that living beings are constantly evolving and that mutations are the engine of this evolution. A new organism, caused by a mutation, may challenge its environment until the necessary adaptation occurs. Either it loses virulence or the other beings develop defenses against it.

On the other hand, the arrival of a novel infectious agent is nothing new. We can easily remember, for example, what happened several centuries ago when the black plague arrived in Europe. Then, it was an unknown disease, for which there was no treatment, and it caused a very high mortality. This "unforeseen health emergency" came from the Asian steppes, where the causal agent, *Yersinia pestis*, is endemic among groundhogs. The initial diffusers of this bacillus were the Mongol hordes that invaded large areas of the Eurasian continent. Afterwards, however, diffusion took place along trade routes [6].

It is interesting to recall that, in the absence of effective medicines or vaccines, black plague was fought, and finally controlled, by applying confinement and separation measures.

Black plague is just an example but we could mention many other. The human immunodeficiency virus (HIV), which causes acquired immunodeficiency

syndrome (AIDS), was also a newcomer in the last years of the 20th century. We also know that in past centuries many people from outside Europe died because of "new" (for them) pathogenic agents diffused by European explorers and colonizers.

4.2 SARS-CoV-2 diffusion

As far as we know, the basic system of SARS-CoV-2 infection is transmission from person to person by air (aerosols) or by direct person-to-person contact. This is why the main preventive action is keeping distance between people, a measure that has a relevant impact on society.

Because of the limited viability of the virus on surfaces, the risk of contamination by coming into contact with an infected surface and then running your hand over your mouth, nose, and possibly eyes is restricted primarily to those surfaces and objects that are very frequently touched by people (e.g. handles, counters, push buttons, etc.).

The incubation period of COVID-19 is estimated between 2 and 14 days [1, 7].

4.3 Practical effects of PHEC-19 on the industry

So far, no case of contamination by the virus of raw materials or products is known [1, 7].

Outside from the first and more evident direct effect of SARS-CoV-2, disease and death of many people, there are other important side effects, which can be grouped in three areas:

- Absenteeism, both because of illness or because people cannot move freely (confinement, travel restrictions, curfew, etc.).

- Breaks of stock, because of absenteeism, which can affect any stage of the supply chain.

- Behavior deviances, for the reason that people are afraid and do not want to be contaminated by the virus. This type of changes can be very varied and have different kinds of effects: shunning of public transportation, staying longer at home, diminishing consumption, etc. [7].

4.4 COVID-19 prevention

Presently, waiting for the practical results of vaccination, we cannot control the virus itself. Thus, the first and paramount defense measure, as far as it is applicable, is the detection and separation of infected people.

Unfortunately, as it is difficult to detect all infected people, because of the lack of testing or symptoms, our basic preventive measures possess passive character [1, 7]:

- Social distancing (minimum approx. 2 m).

- Use of masks.

- Restriction as much as possible on the number of people.

- Frequent disinfection of hands, washing or alcohol-based disinfectants (at least 60%).

- Proper behavior, covering coughing and sneezing.

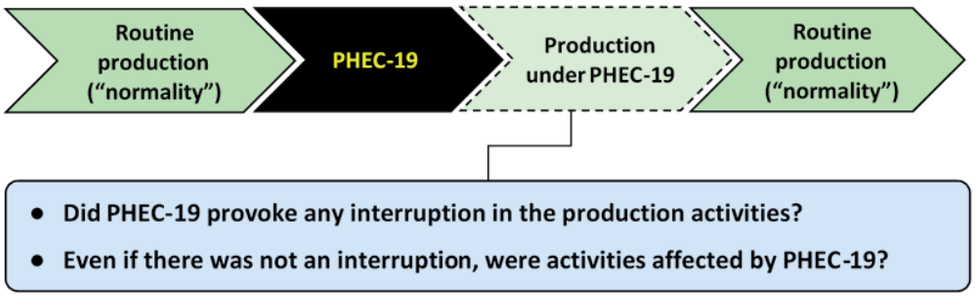

Figure 2.
Effect of PHEC-19 on manufacture.

- Prevent people from sharing objects and surfaces as much as possible.
- Increase cleaning and disinfection practices.
- Apply technical measures where appropriate and possible (increased air renewal rate in rooms, HEPA air filtration, installation of separation screens, etc.).

4.5 PHEC-19 and RM

During this emergency, the industry has two main objectives. On one side, ensuring normal market supply and, on the other, at the same time impede the contamination of personnel and products by SARS-Cov-2.

As shown in **Figure 2**, the objective of the RM process that we are describing is determining if PHEC-19 has led to an interruption or a disturbance of the manufacturing activities and, if this occurred, assess its importance and, accordingly, apply the appropriate corrective actions in order to ensure product quality. Following is described a practical approach to this process.

As, in principle, we can suppose (and hope) that PHEC-19 will be time-limited, the need for revisions can be deemed as restricted. However, any change in the data used for the risk assessment has to be known and evaluated.

5. Practical example of RM for PHEC-19 in a manufacturing unit

The present object of analysis is a manufacturing unit. The situation that we consider is PHEC-19, for which we do not have much information. Thus, PHA is our risk analysis tool of choice.

Here, we are going to use the same approach discussed above for establishing an emergency management plan, as shown in **Figure 3**.

The effect of PHEC-19 in a plant is exerted at two levels. The main one is the lack of staff produced because of increased absenteeism. The second one is the effect of preventive measures to impede virus diffusion.

A manufacturing unit should be seen in terms of a supplying chain. Supplies (materials, products, chemicals, consumables, electricity, drinking water, etc.) arrive and are used in manufacture. Production takes place within premises provided with facilities. Manufacturing processes are monitored. A specific QC department analyzes product samples. Finished products are distributed.

PHEC-19, in principle, should not affect Documentation and this is why here it is not considered. However, some operating procedures might require a review to introduce preventive measures.

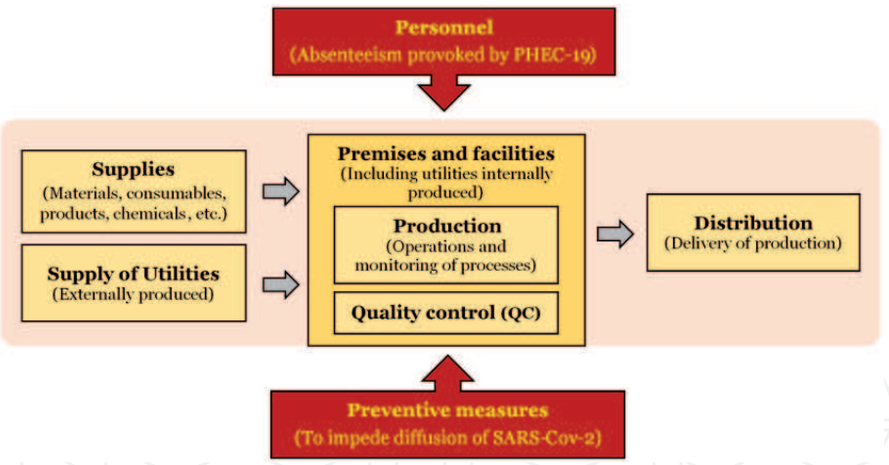

Figure 3.
Possible effects of PHEC-19 in a manufacturing plant.

It is necessary to point out that in the following example we are not interested in production itself but on the effects of PHEC-19 on it.

5.1 Personnel

We should not forget that the PHEC-19 focuses on people because persons diffuse the virus. Neither diseased nor infected persons should be allowed into the manufacturing premises [1].

This means that absenteeism can increase and diminish without prior notice the work force at disposal. It is necessary to ensure that this will not affect the quality standard of production.

5.2 Preventive measures

They can have an indirect effect on manufacturing. On one side the need to limit personnel and to isolate them, can provoke a shortage of personnel, as discussed in the previous bullet. On the other, preventive measures might affect production processes in terms of increased duration (because supplementary sanitization requirements or personnel controls) or modified schedules (e.g. because of lack of catering services).

5.3 Supply of materials, reagents and consumables

Items and utilities supplied to a manufacturing plant can be affected by PHEC-19 and be unavailable or suffer losses of quality.

In fact, as shown in **Table 4**, the problems derived from PHEC-19 can belong to three categories:

- Lack of supply or irregular and delayed arrival of supplies.
- Modification of the attributes of the materials and products supplied. This can be the consequence of using alternative raw materials, of manufacturing under nonstandard conditions, or of diminishing monitoring or controls
- Loss of control on the suppliers (e.g. delayed auditing, reduction of monitoring and analysis)

Hazard	Cause	Effect	Evaluation	Actions
Shortage of supplies	Supplier stopped or reduced production	Production in the plant is disturbed	Study on a case by case basis	Depending on each case: • Stop production if there is enough stock • Reduce production • Establish priorities • Look for another supplier • ...
Delayed supply	Transport unavailable or hindered			
Changes in materials	Supplier switched to other sources of raw materials	Quality of products is jeopardized	Study on a case by case basis	Depending on each case: • Skip the material • Increase monitoring • Increase QC • Look for another supplier • ...
	Supplier unable to meet all requirements			
Unqualified supplier	Supplier could not be adequately approved/ qualified	Materials might be out of specification	Study on a case by case basis	• Well known suppliers could be considered accepted (maybe with additional controls) • Ask for more information and increase controls

Table 4.
PHA of supply of materials, chemicals, products, consumables, etc.

Thus, it is necessary to evaluate in detail each one of these situations to see if they could really affect the quality of the products manufactured in the plant. Changes in attributes could require additional controls to understand their possible effects in properties, stability, etc. The lack of supplies could unleash a chain of shortages.

A regular exchange of information between supplier and manufacturer is essential. The former should understand that changes are likely to affect the manufactured products. The latter should be informed about changes and be aware to detect changes.

5.4 Supply of utilities

We should also consider the possible effect of PHEC-19 on the supply of utilities such as electricity, water or gas, even if this is unlikely (**Table 5**).

5.5 Premises and facilities

In manufacturing plants where sanitization was already a product requirement, the new measures introduced by PHEC-19 do not purport sensible changes. They knew very well that persons are sources of contamination and acted accordingly (use of special attire, sanitization, health control, separation, training, etc.). They also had HVAC systems that controlled the quality of air by ventilation and filtration.

However, in other industrial branches the preventive measures can be more difficult to implement, because personnel is neither familiar nor trained in these procedures. They also do not have HVAC systems prepared for an adequate control of the air quality (**Table 6**).

Have the changes performed in the plant to implement preventive measures affected the approved operational procedures? If the answer is yes, are these changes likely to affect the quality of the products? Logically, the aim is to detect all

Hazard	Cause	Effect	Evaluation	Actions
Power supply cuts	PHEC-19	Production stop	How long will they last?	• Consider alternative supply (if this is feasible) • Use electric generators • Protect equipment from likely voltage changes
Mains water supply cuts	PHEC-19	Depending on water requirements, capacity of storage and alternative sources	How long will they last?	• Consider using other water supplies (wells, streams, tanker trucks, etc.)
Gas supply cuts	PHEC-19	Stoppage of equipment using gas	How long will the restrictions last?	• Consider using gas cylinders or alternative equipment.

Table 5.
PHA of supply of utilities.

Hazard	Cause	Effect	Evaluation	Actions
Uncontrolled changes	Preventive measures to cope with SARS-Cov-2	Is production disturbed?	Yes, if changes affect the approved working procedures	Discover deviations from procedures and evaluate if actions are required
Skipping commissioning/ qualification programs	Lack of staff Technicians cannot travel to the plant	Reliability of equipment under suspicion	Old equipment can be deemed safe based on history and monitoring, but this is not the case with new equipment	Look for alternative ways to ensure the performance of old equipment. For new equipment either wait for the availability of the expected technicians or look for alternative solutions (e.g. on-line communication)
Maintenance program not respected	Lack of staff Technicians cannot travel to the plant	Reliability of equipment under suspicion	Depending on experience	Increase monitoring Skip affected equipment
Calibration program not respected	Lack of staff Technicians cannot travel to the plant	Reliability of equipment under suspicion	Depending on experience	Increase monitoring Skip affected equipment

Table 6.
PHA of premises and facilities.

changes, determine their effects and, if necessary, apply the necessary corrective and preventive measures.

In addition to operational changes, absenteeism and confinement measures may have altered the scheduled maintenance, calibration, commissioning, and qualification/validation programs. Here, cases can be very varied. Usually old equipment is well known and the effect of these alterations can be better assessed. This is not the case with newer equipment, which might require production under increased monitoring or simply, be left aside until situation improves.

5.6 Production

Absenteeism has a direct influence on the manufacturing processes. The lack of personnel and the protective measures for personnel and products can affect production in several modes:

- Modification of the established operating procedures (e.g. to include preventive measures).
- Diminution of the level of in-process control (reduction in the number of samples and in the frequency of sampling).
- Decrease of process monitoring (less intensive surveillance)
- Curtailing the recording of data during the processes.
- Inability of detecting problems in due time.
- Delayed response to problems and deferred application of solutions.

Hazard	Cause	Effect	Evaluation	Actions
Uncontrolled operational changes	Lack of staff Preventive measures to cope with SARS-Cov-2	Approved operational procedures are not faithfully followed	In principle they should be considered significant	Detect deviations from procedures, evaluate their importance and evaluate if actions are required
In process control reduction Decrease of monitoring	Lack of staff	Product quality endangered	In principle it should be considered significant	See if increased QC controls can compensate these deficiencies
Uncomplete process data recording	Lack of staff	Lack of traceability	In principle it should be considered significant	Determine if the missing data affect the procedure used for the approval of the batch of product and/or can be compensated by other means (e.g. QC)
Delayed detection/solution of deviations	Lack of staff	Increased importance of the problems	In principle it should be considered significant	Detect the problem and apply risk analysis to assess its importance and the need of remedial solutions

Table 7.
PHA of production.

Any change affecting operations and its related monitoring has to be detected and assessed (**Table 7**).

Consider the need to inform customers and, if appropriate, authorities, on product supply shortages and quality problems in products.

Revision of production programs and schedules might be inevitable and then it is necessary to establish priorities using RM too, as seen in **Table 5**.

5.7 Quality control (QC)

The QC laboratory is a unit and as such, it shares, in small scale, almost all the problems that we have mentioned for the plant as a whole. The unit needs supplies (reactives, culture media, standards, etc.) and develops operations. Thus, it is necessary to assess all these aspects.

Here absenteeism has a direct influence on quality control products. The lack of personnel and the protective measures for personnel and products can affect analysis in several modes (**Table 8**):

Hazard	Cause	Effect	Evaluation	Actions
Lack of /delayed supplies	Suppliers affected by PHEC-19	Analysis are disturbed	Study on a case by case basis	Depending on each case: • Delay analysis, if possible • Look for another supplier • Look for an alternative method, if there is one
Uncontrolled changes in supplies	Preventive measures to cope with SARS-Cov-2	Production is disturbed	See if they affect the approved analytical procedures	Detect deviations from procedures and evaluate if actions are required
Validation, qualification, maintenance and calibration programs	Lack of staff Technicians cannot travel to the plant	Reliability of equipment and procedures under suspicion	Depending on experience	If analysis cannot be delayed, consider control systems like repeated analyses on the same sample or use of reference standards
Uncontrolled changes in analytical procedures	Lack of staff Preventive measures to cope with SARS-Cov-2	Approved analytical procedures are not faithfully followed	In principle, they are significant	Detect deviations from procedures, evaluate their importance and evaluate if actions are required
Uncomplete analytical data recording	Lack of staff	Lack of traceability	In principle, it is significant	Determine if the missing data affect the procedure used for issuing the analysis certificate and/or if data can be compensated by other means
Delayed detection/ solution of deviations	Lack of staff	Increased importance of the problems	In principle, it is significant	Detect the problem and apply risk analysis

Table 8.
PHA of quality control.

Hazard	Cause	Effect	Evaluation	Actions
Disturbance of distribution logistics	Lack of staff Preventive measures	Delayed delivery	It depends on the product	Increase control on distribution Look for other distributors
Loss of control on the distribution	Lack of staff Preventive measures	Loss of quality	It has to be considered significant	Increase control on distribution Inform clients

Table 9.
PHA of distribution.

- Modification of the established analytical procedures
- Diminution of the level of control (reduction in the number of samples and in the assays)
- Restricting the recording of data during the processes
- Inability of detecting problems in due time
- Delayed response to problems and deferred application of solutions

5.8 Distribution

The objective of a manufacturing plant is not simply releasing production but delivering these products or materials to those who require them. Thus, products and materials should arrive timely and without loss of quality to the intended destinations.

During PHEC-19, absenteeism and, above all, preventive measures (e.g. confinement, curfew, movement limitations) are likely to affect the logistics of distribution and the control on the distribution process. Products that require special conditions during transport (e.g. cold chain) are particularly vulnerable to the distortions caused by PHEC-19 (**Table 9**).

5.9 Pollution

Contamination incidents because of PHEC-19 are very unlikely. However, it is possible that the emergency disrupts services like waste collection and recycling. It is necessary to determine how to increase storage capacity and, maybe, to look for alternative companies.

6. Discussion

Disasters affecting a manufacturing plant can be very varied in both characteristics and effects. This is why they have to be handled at two levels. On one side, it is necessary to detect the damages and understand the problems that they pose. On the other, it is essential to provide solutions to them.

It is evident that concrete actions depend on each type of plant and require specialized knowledge. RM tools, such as those described above, do not increase knowledge but allow for a logical and systematic organization of data.

Manufacturing plants should all possess emergency management plans for emergencies like fire and, if located in accident-prone areas (e.g. seismic activity), for the likely disaster.

As an extension of these plans, any plant should have an agenda to manage unforeseen disasters. RM tools are very useful in these tasks.

Unfortunately, PHEC-19 is a kind of unforeseen disaster, which presents particular characteristics because it has direct and indirect effects on manufacturing production. These effects are not always evident and thus, they require careful analysis.

Emergency management plans based on RM tools can be readily adapted to cope with PHEC-19.

7. Conclusions

In view of what has been written above, it is possible to form the following conclusions:

1. All manufacturing units should prepare an emergency management plan. In the best of cases, they will never use it, but in the event of an emergency, it will facilitate recovery establishing a roadmap and averting disproportionate measures.

2. Risk management (RM) allows for the creation of a rationale to control unknown situations.

3. Risk can only be managed if it has been previously assessed. Risk assessment requires good knowledge of the "object" affected by the emergency and some amount of experience.

4. We have several tools that can facilitate our risk assessment. Anyway, in cases with little experience, such as emergencies, it is preferable to use simpler tools, such as PHA or FMEA.

5. PHA is the tool of choice for items or units, but it requires identifying all existing hazards and this is not an easy task. This is why it is recommended to use a systematic and comprehensive approach.

6. FMEA is the tool of choice for processes. It necessitates an updated flowchart, in order to determine failure modes in each of its steps.

7. Risks can be assessed as significant or critical, which require actions, and non-significant or non-critical, which do not require them.

8. Emergency management plans are a good base to establish a PHEC-19 management plan, but they have to be adapted to the very particular characteristics of it (absenteeism, changes in behavior, social distancing, etc.).

9. The effects of disasters are so evident that to overlook them is very unlikely. However, in the PHEC-19 this is not the case and, thus, it is necessary to analyze accurately the situation.

10. A very important component of PHEC-19 management is to understand how it has affected your manufacturing plant.

Conflict of interest

The author declares no conflict of interest.

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