SHUTDOWN... A NECESSARY EVIL!
BUT WHAT ELSE?

Summary

"A shutdown in a production facility is an event where an entire process plant or unit has to be put out of operation in order to carry out specific maintenance tasks and/or other work".

A plain and, at first sight, simple description of a necessary evil. But also a situation which, when announced, is often the start of an tense period of time. Usually the shutdown is an event that can keep a senior management awake. All in all, shutting down production often causes problems: no output, high costs for carrying out extra (indirect) work and overall often leading to a logistical problem. In other words: a shutdown often has a negative economic impact on the company!

How can we increase the efficiency of a shutdown and avoid unnecessary waste of time? What are the pitfalls and what do we need to think about in the case of a planned shutdown? This is an interesting issue that we want to highlight in this white paper.

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1. Introduction

A shutdown is a well-known concept within many production facilities of various kinds. In principle, every company is affected by a temporary shutdown of production and there is virtually no possibility of carrying out a planned shutdown without an economic consequence. After all, employees are not able to work normally, so there is no output and the activities that are carried out usually cost a lot of money.

Let us not confuse the planned shutdown with an incident leading to a lockdown of part or all of production. Possibly we will issue a separate White Paper on this in the future.

A recurring shutdown is seen in many industries in order to carry out preventive maintenance and, where appropriate, smaller corrective projects in the facility. However, if we focus on our area of expertise "Controlled Environment" (CE), the objective and content of a shutdown is clearly more complex compared to most general industrial sectors. In contrast to general industry, the shutdown within the CE market is also often an annual operation.

In a CE facility it is primarily about the concept of contamination. This contamination can consist of dust or fibres, airborne micro-organisms, fine dust or chemical vapours. We try to create an environment in which contamination to the product process or to the research that takes place in that environment can be limited, or if possible excluded. In addition, there is often a controlled climate (temperature and RH) in such areas in order to be able to carry out the specifically planned activities..

For the sake of convenience, let us use the umbrella term 'clean room' when we talk about these spaces. Of course, an OR in the hospital, or high-care area in the food industry, is also a facility in which the exclusion of contamination plays an important role, yet you do not say that you will be transported to the 'clean room' if your tonsils need to be removed...

In the following paragraphs, we will try, among other things, to clarify why a shutdown in a production facility with clean rooms differs from other industries.

2. The organisation of a planned shutdown in general

In the case of a shutdown of a somewhat larger production company, of a general nature, a specialised facility manager or maintenance manager will usually make the start-up by putting together an experienced shutdown project team. This project team should first of all freeze the time plan of the shutdown period. Starting time and expected duration, is important for all other stakeholders within the organisation. Needless to say, that clients are not allowed to notice anything or little of this necessary evil. Sales and logistics, among other things, must be and remain well informed about the shutdown organisation and its progress. If external communication to customers is necessary, the sales management will need good and up-to-date input!

The shutdown team will then prepare, plan and coordinate the entire implementation process and record all related information in a comprehensive Shutdown Management Plan (SMP). Obviously, the team will also be responsible for monitoring and evaluating the entire process during and after the shutdown.

They start by determining whether all planned work actually requires a shutdown. If this is not the case, an activity that is not necessary is scheduled for normal maintenance during the operational functioning of the site. They will then usually consult the evaluation of the previous shutdown and learn from experience. This is followed by the collection and study of up-to-date information about the site, normally documented in an updated Site Master File with all attachments that may be relevant in relation to legislation and regulations as well as the possible risk assessment carried out. The Master Validation Plan and the Calibration Plan may of course not be omitted during the preparation.

Ideally, all the files mentioned are included in a Document Management System (DMS software) and the maintenance planning is implemented in the CMMS (Computerized Maintenance Management System) on the basis of an LTMP (Long-term Maintenance Plan). If such software systems are not available, it will have to be manually traced and clearly registered in order to be able to follow the planning flexibly and adjust it where necessary during the execution of all activities.

Possible internal optimisation programmes such as an Overall Equipment Effectiveness (OEE) programme as an important part of a Total Productive Maintenance (TPM) care system can also play a role in the preparation of the SMP.

When talking about a general factory, the shutdown maintenance programme usually concentrates on the following activities:

- the planned maintenance of the equipment;
- the systematic maintenance of the structural interior (floors, doors, etc.);
- planned maintenance of general HVAC equipment (filters, etc.);
- systematic periodic work on the infrastructure of the building;
- planned calibration of equipment, measuring and monitoring equipment, etc.

Of course, the work mentioned above, which is carried out during a shutdown, has been evaluated and it has been established that it is impossible to carry out this maintenance during normal operational functioning of the plant. That should be clear. Never forget that every day without production costs an enormous amount of money!

In addition to maintenance, minor modifications or renovation work will be carried out, which can only be carried out when production has been completely (or partially) halted.

It is useful to establish at the start of the plan who will be responsible for the internal communication of notifications to staff and communication to other external stakeholders.

3. The shutdown in a controlled environment

The CE market can primarily be divided into the High-tech (related) segment on the one hand and the Pharmaceuticals and Life-Science segments on the other hand. In addition to this rough two-part division, the Food sector should be mentioned as the third segment for the time being. Within this sector there are many developments around the theme of food safety and many changes in legislation and guidelines at a global level. More and more one can speak of a CE facility within this market segment.

Independently of the market segment in which one is active, the general shutdown activities mentioned in paragraph 2 will also apply as a basis for production facilities in which

cleanroom spaces are built. The definition of activities will often be regulated on the basis of an existing ISO 9001 quality management system.

In addition to this basic task, there is clearly more being demanded from the shutdown team as a result of the more extensive legislation and regulations within the CE sector.

3.1 High Tech market

These more extensive requirements in relation to maintenance, cleaning and annual validation are often based on the specific ISO 14644 standard as well as sector-specific (VCCN) guidelines. Of course, there are also requirements for the applied cleanroom related to the URS (User Requirements Specification). (VCCN: Dutch national member organization of the ICCCS (International Confederation of Contamination Control Societies)).

The requirements for the design, construction and start-up of a dust- and germ-free room are described in the ISO 14644-4 standard, but this part of the standard also clearly describes what is required for maintenance activities, performance monitoring as well as documenting the whole of the equipment, the construction facility and the complete technical installation, in the broadest sense of the word..

The 14644-3 standard describes the tests that are important for the initial qualification of the cleanroom. However, the standard also requires that, during the use phase, proof is provided that the room continues to meet the initial process qualification as established upon commissioning.

Attention: The standards mentioned often describe what needs to be done, but not how! It is up to the entire management team of an organisation and the EHSQ team (Environment, Health, Safety and Quality) to determine how all internal (policy) matters and tasks as well as Standard Operating Procedures (SOP) are carried out in order to demonstrate that everything that is required is indeed met.

In the high-tech (related) market there is normally a check on compliance with agreements made and compliance with agreed standard standards by means of internal or customer Audits. The government primarily pays attention to municipal or provincial legislation and regulations. (Environmental permits or licences, etc.).

For ISO 14644 standardized cleanrooms within the high-tech (related) cleanrooms, the following repetition cycles apply during the usage period.

External validation as mandatory in ISO 14644-3		
	Class	**Cycle**
Particle count test	< 5	6 months
	> 5	12 months
Airflow velocity	all	12 months
Airflow volume	all	12 months
Pressure difference between rooms	all	12 months
Optional validation in ISO 14644-3		
Filter leakage	all	24 months
Airflow visualization	all	24 months
Recovery time	all	24 months
Containment leakage	all	24 months

Table 1

3.2 GMP related market

Within the Pharmaceutical, Life-Science and Food markets, companies in the United States (US) must comply with Good Manufacturing Practices (GMP). GMP is a quality assurance system aimed at creating a safe production process around products related to human and animal health.

The GMP standards have been framed within the legislation by the Food and Drug Administration, or FDA. The FDA is the agency of the US federal government, which controls the quality of food and medicines in the broadest sense of the word. The FDA also controls the treatment of blood, medical products and cosmetics.

In a where desired slightly modified form, these GMP standards are laid down for Europe in the EudraLex, which stands for the collection of rules and regulations for e.g. medicines in the EU. Incidentally, EU legislation is applied in Europe for the various market segments mentioned above, in which the GMP regulations are often also used as a basis. For exporting food products to the USA, an implemented GMP care system is necessary (CFR Title 21 part 117).

It is clear that the regulations, as mentioned above, are clearly stricter than those that apply to the high-tech market. The licence, which is necessary in order to carry out production activities in the GMP related market segments, can only be issued if the requirements for this quality assurance system are met.

Below is an overview of the validation measurements and repetition cycles during the usage period:

GMP Annex 1 related cleanrooms for manufacture of sterile medicinal products			
	Class A/B	**Class C/D**	**Cycle in months**
Concentration of airborne viable and non-viable particles	x		6
Concentration of airborne viable and non-viable particles		x	12
Integrity test filters	x		6
Integrity test filters		x	12
Airflow Volume	x		6
Airflow Volume		x	12
Pressure differences	x		6
Pressure differences		x	12
Pressure velocity	x		6
Pressure velocity		x	12

Table 2

In the Netherlands, the Health Care and Youth Inspectorate (IGJ = Inspectie Gezondheidszorg en Jeugd) issues a GMP certificate to the manufacturer if it complies with the GMP guidelines. The IGJ carries out periodic inspections of manufacturers in the Netherlands to verify whether they comply with the GMP regulations. If the GMP rules are not met, the GMP certification is withdrawn and the company loses its production licence. The IGJ also inspects manufacturers in and outside Europe on behalf of the European Medicines Agency (EMA) and the Medicines Evaluation Board (MEB).

In addition to the above validation measurements, the GMP standard also refers to a continuous monitoring process to determine that the effective operation of all technical and structural components is adequate. An LTMP is required and the monitoring of the performance should be documented, as well as the documentation of the entire equipment, the structural facility and the complete technical installation, in the broadest sense of the word.

Not only during a shutdown period, but also after the implementation of any change or maintenance activity of a significant nature in the composition of the equipment, the HVAC installation or the structural cleanroom, a full validation of the above requirements, as listed in table 2, should be carried out.

Risk Assessments are performed during cleanroom development and maintenance, to identify, assess, reduce/eliminate (where applicable) and control contamination risks.

It is clear that the planning and timing of a shutdown in cleanrooms with GMP quality assurance clearly differs from that in general production facilities or cleanrooms within the high-tech sector.

4. Cleaning during and upon completion of the shutdown

We may assume that during the shutdown, the active air treatment has been stopped for a longer period of time. Consequently, the air treatment will often have to be readjusted upon start-up. Moreover, after the adjustment, a validation should take place as described in paragraph 3.

This means that validation cleaning will have to take place in accordance with the 10-step plan of the VCCN, which is applied by nearly all cleaning companies. (See 3.1 about VCCN.) This means that steps 6 through 9 will have to be completed. Below is an overview of these steps as described by the VCCN:

- PHASE 6 > Placing the filters (HEPA).
  Purpose: Prior to each filter installation, clean the overlapping edges on all sides. Immediately remove any impurities arising during the fitting of filters (CG fabric). Direct responsibility of filter mounting technicians.
- PHASE 7 > Adjusting the air-conditioning system including filters.
  Purpose: remove suspended particles from the circulating air and create overpressure in the rooms.
- PHASE 8 > Bringing the clean room into the prescribed class.
  Purpose: To rid all surfaces in order ceilings, walls, inventory and floors of sedimented and/or adhered dust.
- PHASE 9 > Checks and measurement procedures (validation).

A cleaning regime must be drawn up based on the various processes, the required classification and the particular market segment in which the cleanroom is to be used. This can be divided into regular cleaning, usually performed by in-house personnel. In addition to this regular cleaning process, periodic cleaning is required in certain cycles in a classified area. Which activities and with which intervals this must take place is described in guideline 4, drawn up by the VCCN. (Vereniging Contaminatie Controle Nederland).*

It should be noted that the periodic cleaning and in particular the disinfection process is often carried out by specialised companies. This is not only because of the qualifications of the trained cleaning staff, but also because of the material and equipment needed to carry out all the work correctly and safely.

Disinfection can be performed manually, using varying disinfectants during the disinfection cycles. However, if there is equipment in the cleanroom and the cleanroom is often visited by external technicians during a shutdown, a risk assessment will often show that a VHP (Vaporized Hydrogen Peroxide) sterilisation might be the best solution to obtain complete certainty that all microbiological contamination (also in seams and cracks of the equipment) will be decontaminated.

* See annex 1 and 2

5. Important starting points for a successful shutdown

In this white paper, a lot of background information is described that can be helpful in the context of a planned shutdown of a production site. As there is a great diversity of cleanrooms, processes and products, as well as just as many requirements described in customer-specific URS (User Requirement Specifications) documents and a great diversity of laws and regulations, it is almost impossible to cover everything in a document like this.

It is therefore good to set out the necessary ground rules for a shutdown that is successful and as short as possible:

1. Start in good time! As shutdown manager of the project, try to determine as early as possible what work needs to be done and who should do it. Only then will you be able to claim the planned effort in time from your implementing partners. They also need time to prepare the work and, in some cases, to ensure that all parts that may be important are also available at the work site on time. Presenting a shutdown to the management only to have to change it later is usually not appreciated and causes many problems.
2. Management support. It is absolutely essential to discuss a shutdown with the management at an early stage and obtain full support for the closure of all or part of the plant. Prepare the discussion well, because often after realising the necessity of the shutdown, negotiations about the length of the shutdown start immediately.
3. After management support has been obtained, the date and duration should be frozen and clearly communicated throughout the organisation. It is important to stick to the agreed dates and not to change them. Only then can the planning be completed and good agreements made internally and externally.
4. Put together an experienced and skilled "lean and mean" Shutdown Team. Try to assemble the team as complete, but also as efficient as possible. The necessary consultations before, during and after the shutdown may and will take time and will demand a number of people, but may not paralyse entire departments or certain processes.
5. Discuss together what tasks everyone in the team has to carry out and demand full commitment. Agree who reports and what must be documented or recorded in the reports. Also determine who will take care of the external communication towards the primary stakeholders. Ensure that these external stakeholders also make the information provided well known at all levels of the organisation.
6. The shutdown team will normally also include the safety coordinator, who will be responsible for carrying out a Task Risk Analysis and drawing up a H&S plan including the Control Measures Plan.
7. Study the evaluation of the last shutdown and go through each planned work in the forthcoming shutdown period with those involved and ask yourself whether a shutdown is necessary for that activity. If this turns out not to be the case, cross every such action off the plan and schedule this work for outside the shutdown period! Only then can you be sure of a well thought-out plan.
8. Take good care of your document flow and the correct instructions. Especially in the pharmaceutical sector, the flow of forms is immense. Of course, more and more things are being processed digitally, but make sure that everything is processed correctly and completely in accordance with GMP requirements when the necessary people are on site. (Evidence)
9. In a small pharmaceutical plant, nevertheless, there are easily 50 people who have at least 15 to 20 different tasks and/or disciplines! Make sure that they are well

supervised and avoid time wasted waiting for support, advice or otherwise. Prevent the technical people from your own organisation from being busy with work themselves, but involve them earlier in the supervision and control of the correct implementation of the work by third parties.

10. After 90% completion, have the shutdown plan assessed by an expert with a fresh and independent view. The cost of having an outside specialist do this is often easily regained through prevention of mistakes or smart advice on how to optimise the process.
11. Also consider the implementation of a pre-shutdown and a post-shutdown schedule! There are often many things to be prepared in production prior to the shutdown to ensure that operations run smoothly during the shutdown. Also, there are often tasks to do after the shutdown to get the entire site up and running again correctly. Plan these actions as well and ensure correct implementation and control.
12. Implement in the SMP a contingency plan for unexpected activities and emergencies. After a machine has been dismantled, it may turn out that a problem which was not planned for must be solved immediately. Make sure there is a procedure for this and that a panic reaction is prevented. Those involved need to know what to do to keep the process going and to anticipate the right way in the event of an unexpected situation.
13. Ensure in good time that the external parties involved have a (possibly technical) workplace available and can safely store their administration as well as technical parts and tools.
14. Have the supervisory and coordinating team prepare a daily report and try to evaluate all activities on a daily basis as well. Try to implement the continuous learning process as much as possible, during and of course after completion of the work. Include all data in the evaluation report.
15. It goes without saying that we want to make use of every hour of the shutdown. Therefore, try to set up a work schedule that allows for working in 2 or 3 shifts, also from a supervisory point of view. Ensure supervision and safety at all times when people are working on the plant.
16. Make sure that all people involved, working for third parties, also have the necessary experience of working in a heavily GMP regulated facility and understand what the codes of conduct are in, for example, a sterile working environment.
17. Ensure proper handover of applied procedures, timeline disclosure, as well as other responsibilities. Also give clear instructions for handover at each stage (Commissioning Cx).
18. Supervise the correct garment regime also during the shutdown period and only allow materials that have been cleaned into the cleanroom. If possible, arrange for access control. Obviously, we do not want people walking around in our cleanroom or other facilities who have no business there!
19. Do not only think about the final cleaning for the validation, but also plan 'daily cleaning' in order to prevent contamination as much as possible. It may be possible to deploy part of the in-house staff for this purpose, working under the guidance of a cleaning expert who can supervise.
20. It may be superfluous to mention this, but develop a good evaluation report during all phases of the SMP. Distribute this evaluation report to the stakeholders upon completion of the SMP.

6. Conclusion

The experienced shutdown manager may well be able to add some advice to the above overview. In fact, it is almost impossible to cover every detail of this topic in depth, especially considering the extensive legislation and regulations for highly classified GMP cleanrooms in the pharmaceutical industry.

In practice, there are (too) few people with the required knowledge and experience to manage such an expensive and complex operation as a shutdown, efficiently and with the achievement of the predefined objectives. It should be clear that many facility or maintenance managers who are confronted with a shutdown for the first time could use the necessary help to approach it correctly and to better understand what is in store for them if the shutdown is to be organised properly. If we have been successful in providing such a helping hand with the information described in this paper, we will be very satisfied and we have achieved our goal!

For the sake of completeness, we would like to mention that various training courses are offered for turnaround and shutdown management; to avoid being incomplete in mentioning training institutes, we refer to the Google website.

Finally, it is worth mentioning that nowadays new sites are designed with modern insights and methods. The building and technical installations are designed in a REVIT Model / BIM environment. Equipment is developed using Industry 4.0 technological capabilities. Digitalisation of production processes and the possibility of connecting and communicating between different systems are therefore new aspects of the current monitoring process.

In addition to these developments, there is increasing interest in the ISIO 55001 care system around Asset Management. This means that when starting a purchase or development of a new physical asset, the Total Cost of Ownership (life cycle) or the total cost of acquiring and owning the asset, including maintenance, energy costs, circularity, etc. is carefully examined.

We will gain a much better understanding of the technical condition of our assets and our machinery in particular. The improved predictability of the production lines will certainly help in the implementation of risk analyses. All in all, these developments will reduce the need for long shutdown periods.

Remember the title of this white paper and the words "necessary evil"!
So those new developments are most welcome.

ORIGIN

PP4CE (Professional Partners for Controlled Environment) is a strategic alliance between a number of specialised companies. They are active in the design, construction and maintenance of cleanrooms and laboratories in a broad range of market segments. PP4CE also operates in medium and high care areas in the food industry.

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For more information, see: https://www.pp4ce.com/

Source reference:

- Various documentation and sites on the subject of maintenance and shutdown operations
- FDA.org website for miscellaneous GMP data
- Understanding GMP in the food industry
- Website eur-lex.europa.eu
- ICT Portal: Documentbeheer farmaceutische industrie (Document management pharmaceutical industry)
- ICT Portal: Overall Equipment Effectiveness (OEE)
- ICT Portal: Total Productive Maintenance (TPM)
- ICT Portal: Een DSM systeem verbetert de documentenstromen (A DSM system improves document flows).
- Bachelor assignment Technical Business Administration written by J.A. ter Harmsel Title: Verminderen van productiestop (Reducing production stoppage)

Annex 1: Periodic cleaning of high-tech clean room:

Work schedule for low-dust areas			
Dust Class according to ISO 14644	**ISO 5**	**ISO 7**	**ISO 8**
Action	**Recommended annual frequency**		
Floors			
• damp wiping of hard floors	520	260	260
• wet cleaning of hard floors	52	24	24
• wet cleaning of mats	520	260	260
• repairing floors (if applicable)	12	12	12
• preservation of floors (if applicable)	1	1	1
• vacuuming	260	260	260
please note: for perforated floors, adapt work programme			
Furniture and equipment			
• emptying paper / waste bins and pedal bins	260	260	260
• damp wiping of any furniture and equipment within reach	260	260	260
• damp wiping of parts with hard finish	260	260	260
• damp wiping of furniture and equipment out of reach	260	52	12
• complete wet cleaning of outer surfaces of furniture and equipment	52	24	12
• damp cleaning of sinks	520	260	260
Walls / ceilings			
• damp wiping of edges / ledges within reach	260	260	260
• damp wiping from edges / ledges out of reach	260	52	12
• removing stains from doors incl. window frames / tracks	260	260	260
• damp cleaning of doors including window frames / tracks	52	24	24
• damp wiping of walls	12	12	12
• damp wiping of complete ceiling	1	1	1
please note. for perforated walls or ceilings, adapt work programme			
Other			
• cleaning of fire-extinguishing equipment	260	260	260
• cleaning of light switches in direct contact areas	260	260	260
• cleaning of communication equipment	260	260	260
• cleaning of technical facilities (traps, etc.)	1	1	1
General			
• damp wiping of surfaces that frequently come into contact with cleanroom staff	520	520	520

The above frequency is recommended by the Dutch Association of Contamination Control Netherlands (VCCN). Of course, frequencies will have to be adjusted if the production process gives cause for this. Complete cleaning, including the entire ceiling, is necessary when the cleanroom has been shut down (whether or not on purpose!)

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Annex 2: Periodic cleaning for low-germ cleanrooms:

Work schedule for low-germ areas			
Dust Class according to ISO 14644	**ISO 5**	**ISO 7**	**ISO 8**
Action	**Recommended annual frequency**		
Floors			
• damp wiping of hard floors	520	260	260
• disinfecting the floor	104	52	52
• wet cleaning of hard floors	52	24	24
• wet cleaning of mats	520	260	260
• repairing floors (if applicable)	12	12	12
please note: for perforated floors, adapt work programme			
Furniture and equipment			
• emptying paper / waste bins and pedal bins	260	260	260
• damp wiping of any furniture and equipment within reach	260	260	260
• damp wiping of parts with hard finish	260	260	260
• damp wiping of furniture and equipment out of reach	260	52	12
• complete wet cleaning of outer surfaces of furniture and equipment	52	24	12
• damp cleaning of sinks	520	260	260
• disinfecting furniture and equipment within reach	104	52	52
• disinfecting furniture and equipment out of reach	24	12	12
Walls / ceilings (excl. filters)			
• damp wiping of edges / ledges within reach	260	260	260
• damp wiping from edges / ledges out of reach	52	52	12
• removing stains from doors incl. window frames / tracks	260	260	260
• damp cleaning of doors including window frames / tracks	52	24	24
• damp wiping of walls	12	12	12
• damp wiping of complete ceiling	1	1	1
• disinfecting edges / ledges within reach	104	52	52
• disinfecting edges / ledges out of reach	24	12	12
please note. for perforated walls or ceilings, adapt work programme			
Other			
• cleaning / disinfecting fire-extinguishing equipment	104	52	52
• cleaning / disinfecting of light switches in direct contact areas	260	260	260
• cleaning / disinfecting of communication equipment	260	260	260
• vacuuming pre-filters of the LAF cabinets	52	52	52
• cleaning of technical facilities (traps, etc.)	1	1	1
General			
• damp wiping of surfaces that frequently come into contact with cleanroom staff	520	260	260
• disinfecting elements that frequently come into contact with cleanroom staff	260	260	260

The above frequency is recommended by the Dutch Association of Contamination Control Netherlands (VCCN). Of course, frequencies will have to be adjusted if the production process gives cause for this. Complete cleaning, including the entire ceiling, is necessary when the cleanroom has been shut down (whether or not on purpose!)