



Contamination problems

We solve the

Personalized medicine for your bioprocesses

Contents 1 | About us 2| Bacterial fermentations 4 Eucaryotic cell cultures 6 | Fungal fermentations 7| Anti-bacterial phage 8 | Consulting Personnel training 9| **Support for CMOs** 10 | 11 | New facility development

12 |

Research



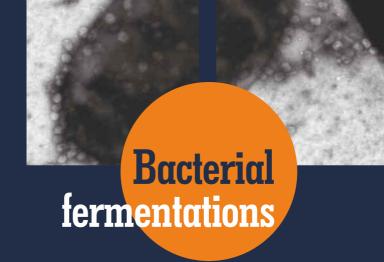
Mission

Contaminations are one of the major threats that may occur in bioprocesses. If contamination occurs, it may result in a complete paralysis of a given facility and its productivity. Although even the best protection cannot guarantee that no contamination problems will occur, a better prepared facility will recover faster, and chances are good that the contamination will not turn into an outbreak. The Phage Consultants company was created to help companies whose production is based on microbial activities to fight with and prevent bacteriophage and other contaminations. Based on our research and experience we offer different ways of assistance: from personnel training, through consulting and process optimization, to help with development of new facilities. Phage Consultants can help you avoid contaminations, as well as help in recovery from contaminations which had already occurred.

Due to frequent inquiries, we introduced a contract research service in all aspects of bacteriophage use in various fields of biotechnology, medicine, food, and crop protection, etc. Our extensive expertise in phage biology research allows us to deliver high quality results to our clients in a relatively short time and at a competitive price.

Our customers

We provide our experience and help to a wide range of companies that want to protect their bioprocesses against contaminations or which are experiencing problems caused by contaminants. Our customers come from a pharmaceutical sector, industrial biotechnology, research laboratories and a dairy industry sector. As the type of problems they are experiencing might be of interest to their competitors, we guarantee full protection of the customers' identity.



Bacterial fermentations are prone to several types of contaminations:

Phage contamination

Bacteriophages cause the most devastating contaminations, usually resulting in destruction of the bacterial culture with subsequent contamination of the facility, due to sampling or leakage caused by equipment failure. In this type of contamination, equipment failure is likely to occur in some equipment set-ups due to extensive foaming and possible clotting of the exhaust filter with subsequent pressure build-up.

Bacterial contaminations

This is the most common type of contaminant in bacterial cultures. Depending on the type of bacterium contaminating the process, the effects that are brought about are different. In all cases, one may expect a reduced product yield and a possible contamination by metabolites produced by the contaminating bacteria. In some cases toxins may be produced by the contaminants. The probability of occurrence of a particular type of contamination caused by bacteria may differ, depending on the process itself and the organism used in the process.

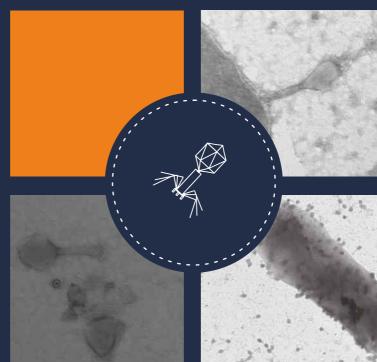
One of the most frequently occurring contaminants are lactic acid bacteria and sporulating bacteria. Clean-up and re-occurrence prevention, especially in the case of the latter organisms, presents a considerable challenge.itself and the organism used in the process.

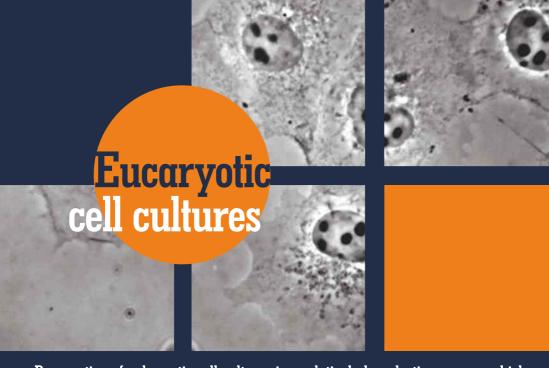
Fungal contamination

Due to a relatively low growth rate of fungi when compared to bacteria, this problem may occur mainly in processes based on continuous bacterial fermentation. However, once it had occurred, fungal contamination requires a very cumbersome and often expensive restart of the whole production line.

How we can help:

- consulting,
- contamination detection,
- cell bank tests for phage and prophage presence,
- research,
- · rapid detection methods,
- · help with facility development,
- help with the choice of proper equipment,
- personnel training.





Propagation of eukaryotic cell cultures is a relatively long-lasting process which makes it sensitive to a greater number of possible contaminants. Among them are:

Virus contamination

Viruses are the most dangerous contaminants in this type of fermentation. Due to their small size, they are the toughest enemy to beat when preventing their entrance into the production process, and their occurrence may result in a very long paralysis of the whole facility's productivity, which can even last several months. Due to the fact that eukaryotic cell cultures are usually used for production of highly valuable products, the risk of running a fermentation process without optimal protection is something which in the end could incur very high costs for a given company.

Bacterial contamination

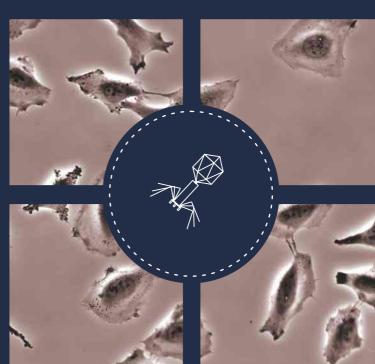
Bacterial contamination of eukaryotic cell cultures is a problem which occurs relatively frequently. Mycoplasmas are especially well known for contaminating this type of fermentation process, but other types of bacteria can also be causative agents of this problem.

Fungal contamination

Fungal contamination, due to a relatively long fermentation process, can be also a problem. When fungi spread in the culture, they may cause many adverse effects like e.g. production of toxins. They are also relatively hard to get rid of, due to the high resistance of fungal spores to different cleaning agents and procedures.

How we can help:

- · consulting,
- contamination detection,
- research,
- rapid detection methods,
- help with facility development,
- help with the choice of proper equipment,
- personnel training.





Fungal fermentations are considered to be the safest ones and the least prone to contaminations. However, they also suffer from contamination problems. The most frequent are bacterial and fungal contaminations.

Bacterial contamination

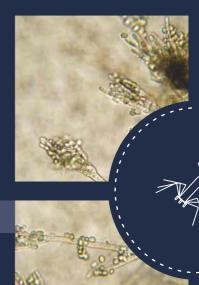
Due to a relatively long development cycle of fungi, even single bacterial cell can relatively easy multiply to high numbers during fungal fermentation. This may result in reduction in product or biomass yield. One of the most common contaminants are lactic acid bacteria.

Fungal contamination

Fungal cultures could be also contaminated by other fungi. As this type of contamination may be relatively hard to detect, good precaution measures should be undertaken to prevent it.

How we can help:

- · consulting,
- contamination detection,
- research,
- rapid detection methods,
- · help with facility development,
- · help with the choice of proper equipment,
- personnel training.





Anti-bacterial phage

Every production process is different. Each one may suffer from different re-occurring bacterial contaminations. Phages are sworn enemies of bacteria, but they kill only selected bacterial species, not interfering with others. A carefully selected custom bacteriophage mix can suppress bacterial contaminations in any process, no matter if it is based on bacteria, fungi or eukaryotic cells, or if it should contain no bacteria at all. Such a mix works very efficiently in minimal concentrations, which makes it a very economical and eco-friendly solution.





Good decisions are made on the basis of complete information.

We would like to share with you our experience to help prevent contamination in your facilities in the future or fight against them in the existing facilities. Our experts will help you plan on rational basis the recovery steps in your production process, as well as help with proper SOPs and emergency procedure development which should be used if contamination occurs. We have broader experience, so why should you re-invent the wheel in a field where every detail matters?

If you want to run a phage-related research, we can help you with designing the proper research streamline or even provide a project leadership if necessary. Among our consultants there are highly qualified and experienced project leaders with excellent portfolios.

Skilled personnel is a key factor in the safety of fermentation processes.

This is your first and last line of defense against contaminations occurring in bioprocesses. Even the best protection may be ineffective when skilled personnel is lacking. Scientists employed by Phage Consultants are willing to share with you their knowledge about phage and other contaminants' biology – knowing your enemy is the first step to beat it. The knowledge of proper sample handling, good laboratory practice with special emphasis on avoiding contamination, as well as knowledge of possible sources of infection will help protect your facility. When contamination happens, such skills as recognizing the infected processes, contaminant spread prevention and the ability to decontaminate the facility may help to minimize the possible losses. A personnel training is also highly recommended for companies that currently do not have problems with contaminations, just to make such problems even more unlikely in the future.





We offer to estimate the safety of your bioprocess after an audit made by one of our consultants. Companies which meet our contamination safety requirements may obtain a certificate and may be listed on our webpage as a contamination-unfriendly CMOs. Such a certificate would be a guarantee for your potential customers that any contamination-related problem is highly unlikely to occur in a given facility.

We can help CMOs in improving the safety of the fermentation processes.

Companies looking for a CMO can use our skills to select the most appropriate contractor that offers the best process protection.

While designing a new facility, why not

minimize any problems that might occur in the future?

Building a new fermentation facility is a huge investment. It is also an opportunity to avoid some problems in the future e.g. by the elimination of in-build errors that can facilitate the spread of contaminations. We offer our huge expertise to help you in avoiding any problems related to facility design. It is the best way to save you the hassle and the money, as in a badly designed facility you may experience unforeseen contamination problems.





We can perform R&D for you in all aspects of contamination problems.

Our strong points include designing strategies which minimize a chance of fermentation process contamination, curing bacterial strains from bacteriophages and designing strategies which minimize phage development after infection.

Virtually we are able to handle every type of research. A vast part of our experience is related to bacteriophages, so in this field especially we can be considered as a prime choice of CRO for your project. We can provide phage isolation, production and purification services on demand.

The most common research services that we perform for our customers are:

- contaminant detection,
- contaminant identification,
- production of phage resistant strains,
- design of contaminant detection methods,
- design of rapid contaminant detection methods suitable for process monitoring,
- determination of effectiveness of different cleaning agents against a specific bioprocess contaminant.



"Aldevron manufactures plasmid DNA for research, clinical, and commercial applications. It is essential that our processes remain free of bacteriophage contamination. We rely on Marcin and his team at Phage Consultants to prevent such infections. Phage Consultants is by far the world's most qualified consulting group in this area. Their expertise is unsurpassed and their dedication to customer service is outstanding. They have helped Aldevron with host cell selection, new facility design, and the development of screening methods to test incoming plasmid samples. This allows us to provide a higher level of service and security to our clients.

Bacteriophage contamination is a very important issue to the field of biological manufacturing. It is important for life science CMOs to have a partner like Phage Consultants to ensure product

and process integrity."

Michael Chambers
CEO, Aldevron

"I had the opportunity to work with Phage Consultants on a project that my company had in Bazancourt, France. The project consisted in the manufacturing of bio-based succinic acid using an E.coli production system. With the help of Phage Consultants, we conduced an audit of the production facility to identify potential issues related to bacteriphage contamination, and from that audit we developed a phage prevention plan. Phage Consultants did a remarkable job and we were able to prevent phage contamination. They are very professional, efficient and most importantly trustworthy. I highly recommend them for any problems related to phage contamination.

Laurent Bernier, Ph.D., P.Ag. Senior Vice President, BioAmber



"MetGen can highly recommend Phage Consultants as reliable and highly efficient consultants. The project was performed smoothly, within agreed budget and resulted in significant improvement in the way how our pilot fermentation facility operates."

> Alex Michine CEO, MetGen



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