Quality control for extenders: the key to success

In intensive pig production systems, artificial insemination is used in 100% fecundations. Semen is collected from the boars and diluted in an extender that should preserve spermatozoa in the best conditions.

For this reason, the quality controls applied to extenders (from the raw materials purchased to the final product) is key for product safety and plays an essential role in its efficacy.

Any alteration in the quality of the extender could cause a decrease in the reproductive parameters on farm including returns to heat, reduced litter size or even reproductive failure.

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An extender is a biological medium that maintains correct sperm functionality during a certain period of time, reducing the negative effects of cellular aging and seeking a balance that allows semen survival.

By controlling the medium from a physical-chemical point of view, we obtain a product capable of maintaining the viability of the sperm cell in the best conditions, preventing early cellular deterioration processes and controlling bacterial contamination.

This needs to be achieved while preserving the functional characteristics of the sperm cells so that the appropriate sow fertility rate is maintained.

Spermatozoa are found in the seminal plasma, which supplies them with the necessary nutrients for the high metabolic demands of sperm transport through the female genital tract.

In the ejaculate, this high metabolic activity can only be maintained over a limited period, as has been established in early studies on the preservation of boar semen.

Thus, to preserve spermatozoa for prolonged periods, their metabolic activity needs to be reduced by diluting the ejaculate in an appropriate medium and lowering the temperature.

The extender's powdered format helps to preserve and extend product life, control bacterial growth and ease of transportation, etc.

However, the powdered formulation requires very thorough quality control to prevent alterations in the product and to ensure its highest quality.

For this, a specific program for quality control of extenders which includes several points is absolutely necessary:

- Specialised technical personnel dedicated full time to extender quality control.
- Specific pharmaceutical facilities (clean room).
- Reception and control of raw materials (quarantine).
- Control of the manufacturing process.
- Validation of the finished (in vitro/in vivo) product.
- Continuous monitoring of all batches during lifetime.
- Stability and storage of batches in a sample bank.

Control of raw materials

One of the most important points is to follow the GMP (Good Manufacturing Practice) protocols applied in the pharmaceutical industry.

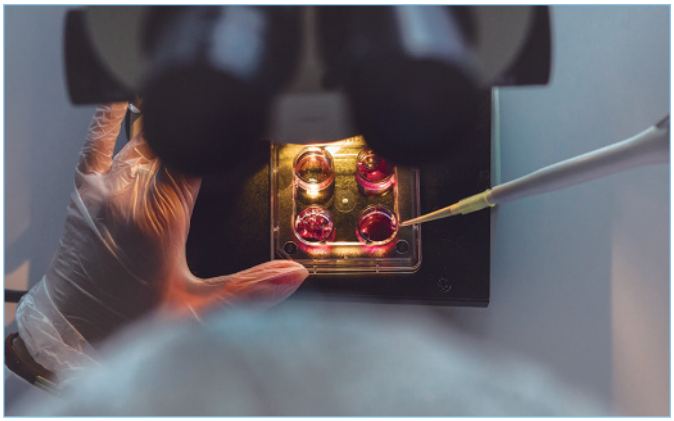
For this reason, the control of the raw materials is the initial and critical point because they will be an active part of the extenders.

The selection of suppliers and grading of raw materials (pharmaceutical or food grade) is decisive for good balance of the medium.

On reception, it is necessary to check the data and analytical sheet as well as making a visual inspection of components (colour, appearance, odour, etc).

After that, a quarantine period is required until all the external analyses (samples under control) are performed.

Another important aspect is to keep a 'sample bank' which should contain samples from all the batches and become a resource for solving any problem detected in the final product.



Raw materials should be in compliance with the technical specifications in every batch. To be sure that raw materials meet the requirements, samples must be subjected to an external analysis with several critical points.

Correct selection of raw materials is crucial in controlling possible alterations in the final extender.

The different raw materials should present a high degree of water solubility, a specific density, a pH that meets the spermatic conservation ranges of the extender, high purity and a specific rotation.

Raw materials that meet the technical specifications should be tested, especially in reference to the levels of heavy metals. Excess of some of them could change the biological and physicochemical qualities of the extender or even be harmful for spermatozoa.

For example, an excess of calcium may lead to an increase in this molecule in the final product and could produce premature sperm capacitation, just the opposite effect we intend to achieve with the conservation of spermatozoa in the extenders.

An excess of iron can also alter the physicochemical properties of extender, reducing the useful life of the product.

With supplier analysis certificates, a correct heavy metal analysis and a sample of each batch in the bank, we can manufacture the extender in a clean room with positive pressure where temperature, humidity and particles in suspension are controlled.

At this point, the metrological control of all the production process is essential.

Validation is crucial

In the final product, validation and control of the semen extenders is crucial.

The approval of the final product passes through the control of heavy metals, which should be below the established limits, and a microbiological analysis to check the quality process and avoid further contamination.

Weight controls of sachets and sealing also play an important role in quality control.

At the end of the manufacturing process of the extender, it is necessary to perform an in vitro and in vivo validation of the product.

To be sure that the entire production process is being carried out correctly, the chemical print (chromatographic profile obtained in extenders) should be obtained as a plus in the safety of the extender.

For each point of the process performed, both in the manufacturing process and in the validation of the extenders, a written record has to be kept for full control of each production batch, providing complete traceability. ■