Instant results you can trust

THE FUTURE OF MICRO-
BIOLOGICAL MONITORING.

bwt-pharma.com

BWT AQU@Sense MB

FACT:

» YOU CAN SAVE TIME OR WASTE TIME.
» MANY PREFER SAFETY AS OPPOSED TO RISK.
» THERE ARE VISIONARIES AND THOSE WHO KEEP ON DOING THE SAME THING.

BUT WHICH OF THESE ARE YOU?

It's a waste of time if you have to wait five days to determine the microbiological quality of critical utilities, when you can obtain the results within an hour. You can increase safety and minimise risk by avoiding inaccurate measurements and increasing test frequency. Pharmacopoeias see the limits of traditional methods and the opportunities for implementing new processes in the future – do you?


For all those who
provide the best!

Time for something new!

The colony-forming units (CFU) have been the standard for measuring the microbiological quality of PW and WFI for over 100 years. The regular determination with the plate-count method is slow, expensive and error-prone. Pharmacopoeias therefore advocate the use and validation of alternative methods to determine microbiological quality.

By applying rapid microbiological methods (RMM), information about microorganisms is available promptly. Action can be taken as soon as microbial deviations occur – not just five days afterwards, as with the compendial method. The functional advantages also enable improvements in the quality of the test routines, where correct qualification and implementation are crucial. For additional information, see **European Pharmacopeia (Ph. Eur.) 9.2 chapter 5.1.6** and **United States Pharmacopeia (USP) 41, chapter <1223>.**

The USP aims to provide guidance on selection, evaluation and use. Ph. Eur. sees the potential for improving the effectiveness of microbiological monitoring and the quality of pharmaceutical products, and therefore aims to facilitate the implementation and use of alternative rapid microbiological methods.

CFU AS THE YARDSTICK OF MICROBIOLOGY

Colony-forming units (CFU) are still the decisive factor in assessing microbiological quality, but even pharmacopoeias criticise the value of the data generated.

The USP describes the unit of CFU as an estimate rather than a precise quantification as, for example, only 0.1–1% of the existing pathogens in drinking water are counted as CFU. It is therefore proposed that CFU should not be regarded as the exclusive measure for microbiological evaluation.

According to Ph. Eur., the effective limits were set without a quantitative definition. Therefore, while for example the arbitrarily defined 10 CFU/100 ml permitted for WFI has been validated.

It is clear that even pharmacopoeias themselves clearly describe the limits and restrictions of the compendial CFU count. Therefore, it is time to change towards forward-looking, cutting-edge technologies, which offer significant benefits for quality managers and microbiologists.

Expert monitoring

BWT AQU@SENSE MB

The time has come to use more accurate and rapid methods to determine the level of micro-organisms in water. BWT recommends flow cytometry, whereby a laser is used to count the cells of a water sample in the AQU@Sense MB measurement chamber. A fluorescent liquid is used to dye the cells' DNA in the sample to ensure reliable and accurate detection. This prevents extraneous particles from being counted as 'false-positives' and allows for detailed sample analysis Operators can therefore obtain the total microbial cell count (TCC). RMM enable users to accurately assess water quality at any time, ensuring safer and more efficient plant operation.

FOCUS ON ONE ASPECT OR KEEP THE OVERVIEW

The AQU@Sense MB has two operating modes. It can be permanently installed at a measuring point to automatically record the microbiological quality of critical utilities at regular intervals. Alternatively, manual grab samples from multiple sample points can be analysed by a single AQU@Sense MB. Action can be taken immediately, if your set limits are exceeded. Promptly. Not after five days, as before.

FREEDOM TO CHOOSE

The online use of RMM has many interesting features, one of which is the process control in systems that generate PW and WFI. Another advantageous application is the monitoring of the water quality in storage and distribution systems.

Identify the risk of contamination at an early stage. Initiate sanitisation as appropriate and verify its effectiveness right away.

Compelling

IDENTIFY BACTERIA QUICKLY AND ACCURATELY

01 **MEASUREMENT**
Reliable. Counts actual cells, not just colonies

02 **OPERATION**
Easy, intuitive and user-friendly

03 **CONNECTIVITY**
Simply data transfer for system integration

04 **FLEXIBILITY**
Incorporation into the system or manual sampling

05 **SPEED**
Results and reactions < 1 hour

Be informed...

5 FACTS ON CFU AND RMM IN THE USP

01 ACCURACY
More cells are identified with RMM. This does not automatically indicate a higher risk or higher probability of pathogens.

02 DIFFERENT
Microbiological quality is determined indirectly and using different procedures – the values will therefore vary (i.e. CFU and TCC).

03 STATISTICS
It is not anticipated that statistics will help achieve comparability of mean values or variabilities (between CFU and TCC).

04 EQUIVALENCE
The values of conventional and alternative procedures may not correspond. Clear values and prudent judgement are therefore crucial.

05 EXPECTATIONS
False and unrealistic expectations regarding the equivalency of values may hamper the implementation of new procedures.

LIMITATIONS OF CFU

We must understand the strengths and weaknesses of CFU as an indicator of microbiological quality. According to the USP, this knowledge is vitally important for a risk-benefit assessment and the validation of alternative procedures. Likewise, in accordance with Ph. Eur., it is essential to understand and define the objectives of the procedure when validating RMM.

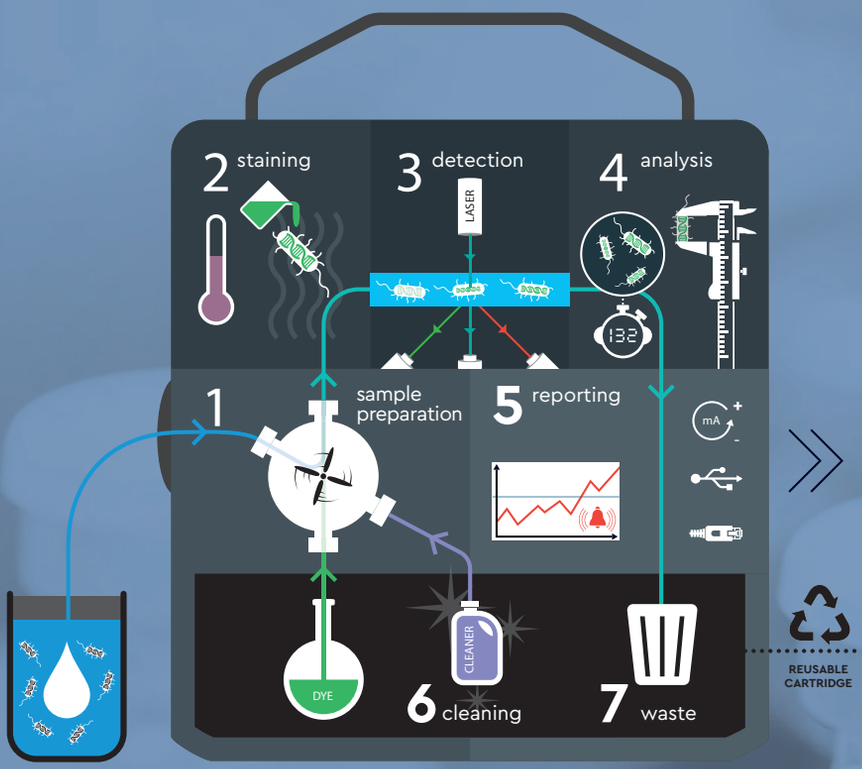
CLEAR VALUES

The USP holds users responsible for proposing values to prove that the method selected is suitable for determining microbiological quality. This can be carried out independently of existing standards, as expressed by CFU. Other meaningful microbiological values are also permitted.

SOUND JUDGMENT

According to the USP it is crucial that microbiologists are able to make consistent and accurate decisions regarding product quality, irrespective of whether such decisions are based on CFU from plate counts or on TCC by RMM.

Operating principle



01 SAMPLING
Integrated automatic sampling and processing saves time in the lab.

02 PREPARATION
The fully automated preparation of the sample includes dyeing, mixing and incubation.

03 MEASUREMENT
A laser induces cell fluorescence. A detector analyses the cells based on their fluorescent response signal. The cell count is as accurate as using lab equipment.

04 ANALYSIS
The results are available in 20 minutes. See total cell count (TCC) and share of HNA/LNA (high and low nucleic acid content).

05 VISUALISATION
The information and values are displayed on the integ-raed HMI. Data export is extreamly user-friendly.

06 CLEANING
The cleaning process is automated. Ready for the next sample.

07 CHEMICALS AND SAMPLE
All generated waste is collected in the sealed cartridge, which contains, at the same time, the chemicals required for ~1.000 measurements.

SIMPLICITY AND SAFETY IN A BOX

1.000 measurements with no handling of chemicals. The practical, environmentally-friendly, reusable cartridge of the pioneering AQU@Sense MB also makes management and disposal a thing of a snap. The user can replace it on site in a matter of minutes. The rest is managed by BWT.

Implementation & Tests

The use of alternative methods can be justified based on the Ph. Eur. The requirements are formulated precisely: the information must provide a scientifically sound benchmark for evaluating microbiological quality. Furthermore, the alternative method should not impose greater limitations than the conventional pharmacopoeial plate-count method.

VALIDATION OF RAPID MICROBIOLOGICAL METHODS

The validation process is described in Ph. Eur.. A distinction is made between the primary validation of the method performed by the manufacturer and the validation for the intended use by the operator. It is the responsibility of the operator to ensure that the method selected is appropriate for the relevant situation or purpose.

The Ph. Eur. demands a risk-benefit analysis for the comparison of conventional and alternative methods. In addition, it is explained which factors influence risk and therefore have to be considered. Analysis tools may help operators to select a suitable method and to justify the implementation and outcomes.

Validation and qualification should include the entire process with URS, DQ_, IQ_, OQ_and PQ_. It starts with the decision to change an aspect of the test procedures for microbiological monitoring and extends all the way to routine use. Verification of the primary validation data, proof of the intended purpose and the suitability test all take place in the PQ_.

The validation criteria for a quantitative method such as the AQU@Sense MB are listed in a table and detailed in Ph. Eur. and the USP.

THE THEORY SOUNDS GOOD. BUT PRACTICE IS CRUCIAL.

USER-FRIENDLY SERVICE PLAN

The AQU@Sense MB is designed to require no more than two scheduled services per annum, which is carried out by qualified BWT personnel as part of the fully documented AQU@Service.

HIGHLIGHTS:

- Maximum uptime: scheduled maintenance
- Transparent, accurate maintenance and operating costs
- Reliability due to verified accuracy

Pioneers shape the future...

The conventional method has disadvantages, but is accepted, while the accuracy and speed of alternative methods offer many advantages. Pharmacopoeias also support the use of systems such as AQU@Sense MB.

There are many reasons from a regulatory and technological point of view to start testing and implementing future technologies.

BWT
BEST WATER TECHNOLOGY

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FOR YOU AND PLANET BLUE.