

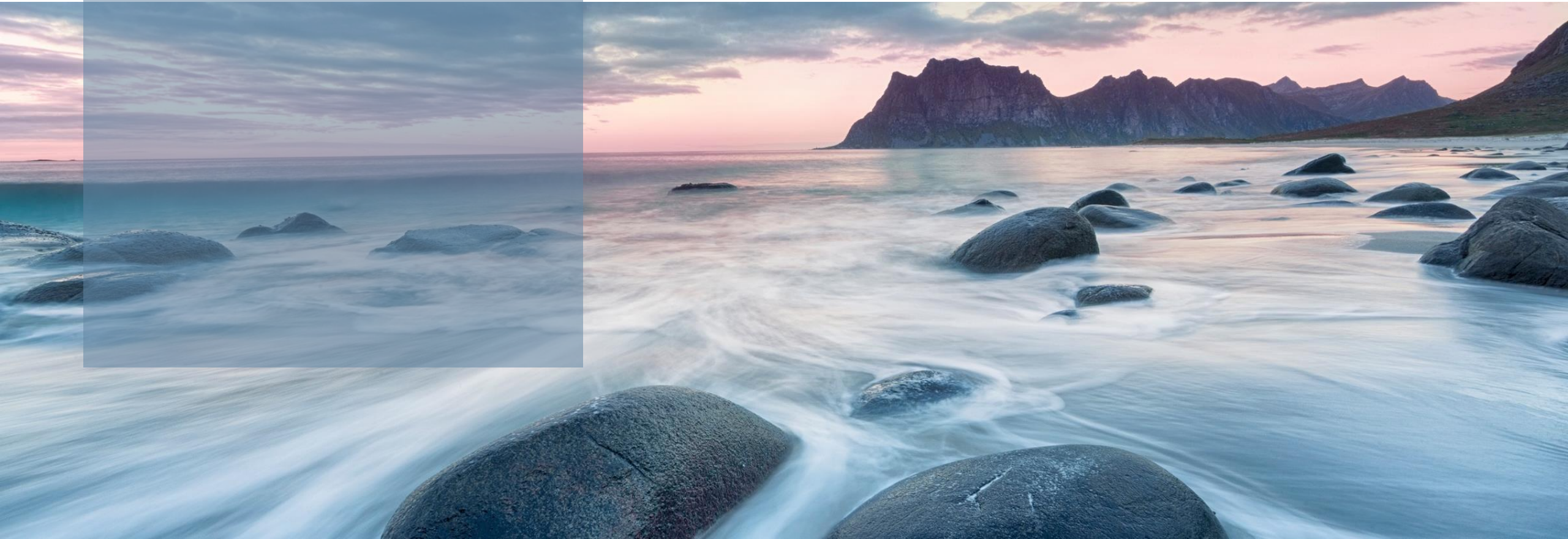
AQU@Sense MB

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22.06.2020



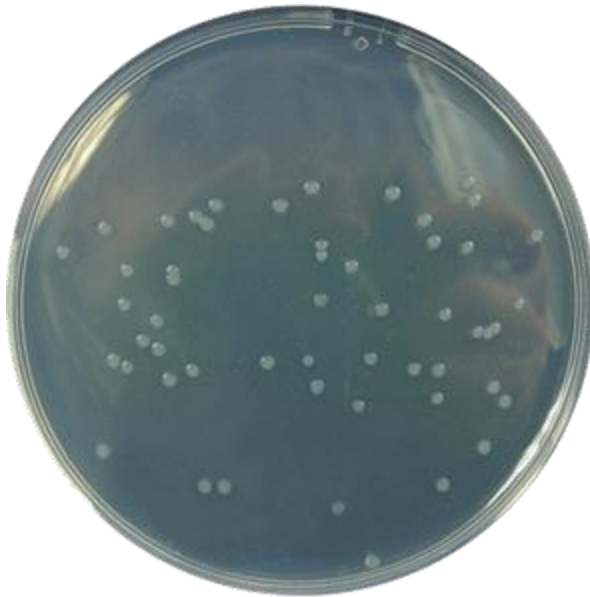
Compendial Method



Compendial Method

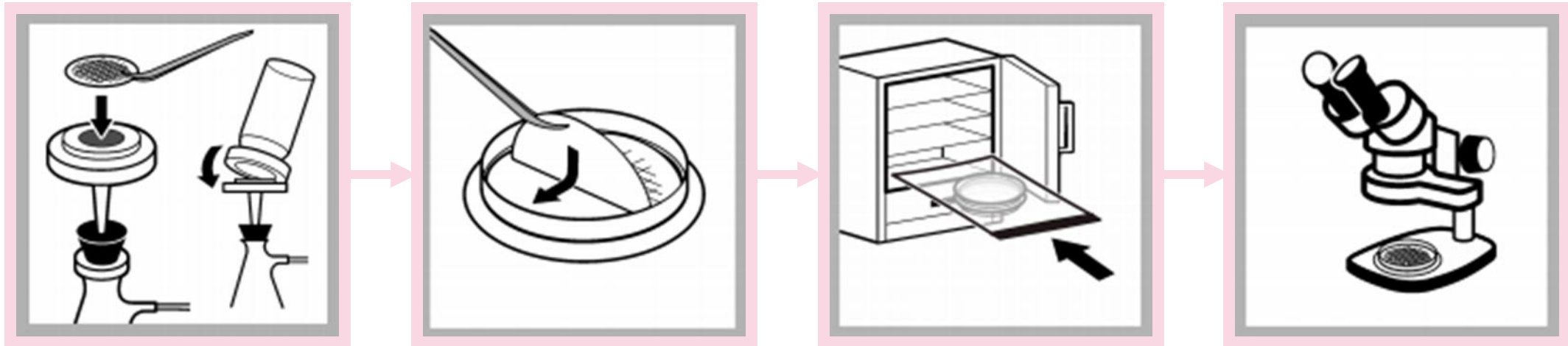
HPC = Heterotrophic Plate Counts

↳ Counting of colonies on an agar medium



- Method 130 years old
- Recognized by the Pharmacopoeias
- Result in CFU: estimate of the bacterial concentration

Compendial Method



1. Filtration of
sample through
0.45µm filter

2. Place filter on
R2A agar medium

3. Incubation for at
least 5 days at
30 - 35°C

4. Counting of
colonies

Compendial Method

➔ **Inaccurate**

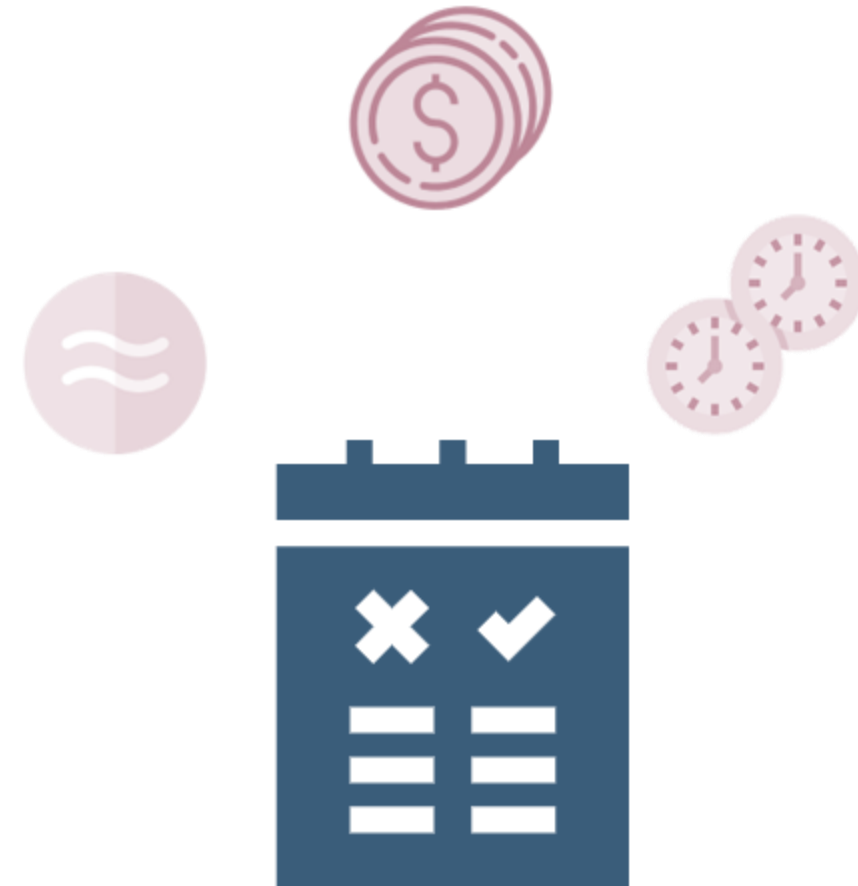
only 0,1 - 1% of bacteria are counted

➔ **Time-consuming**

5 days until results are available

➔ **Expensive**

60 - 105 CHF per sample



BWT's Solution



Customer Needs

**Process
optimization**



**Continuous monitoring of
bacterial count**



**Verify the effectiveness
of sanitization**



**Identify contamination
sources**

Instantly know the microbial
state of your water system

BWT's Solution



Automated flow cytometer for the **continuous and rapid monitoring** of bacteria in pharmaceutical grade water.



The background of the slide features a close-up photograph of a water droplet hanging from the tip of a dark, possibly metallic, object. The background is a soft-focus mix of blue and pinkish-purple hues, creating a bokeh effect. On the left side, there is a large, semi-transparent grey rectangle that partially covers the background image.

The New Method: RMM

RMM Technology: Flow Cytometry

RMM = **R**apid **M**icrobiological **M**ethod

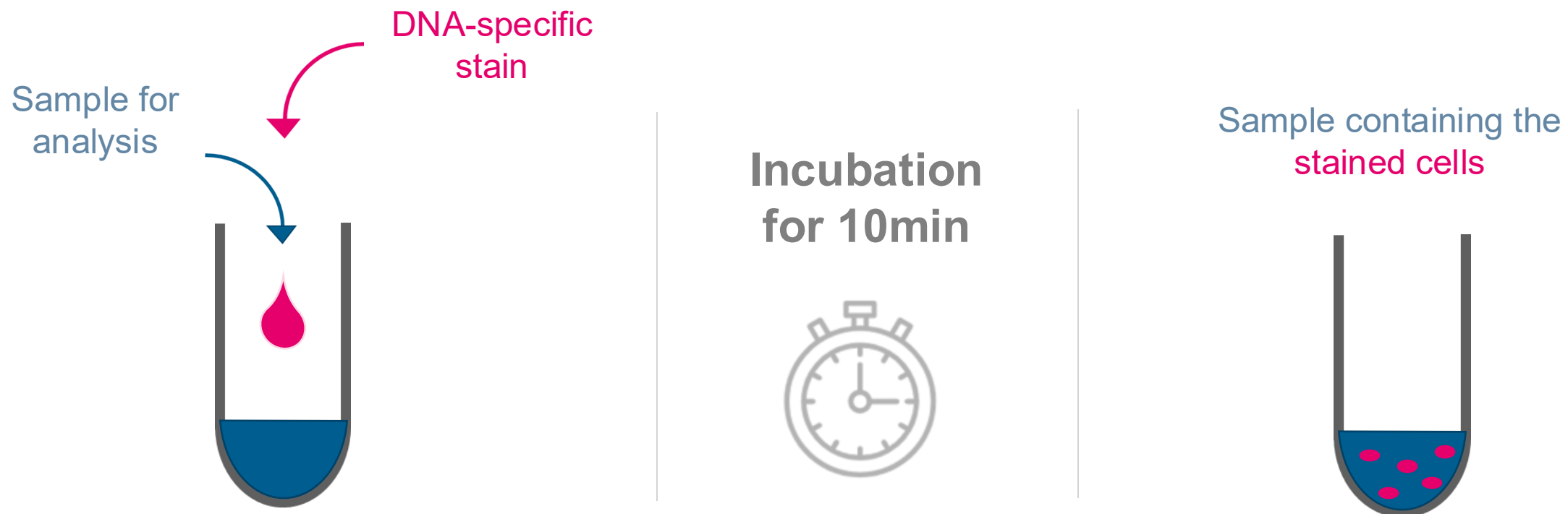
Exact cell count of bacteria
present in the sample



- ✓ Automatization
- ✓ Time-to-result
- ✓ Continuous monitoring
- ✓ Higher precision

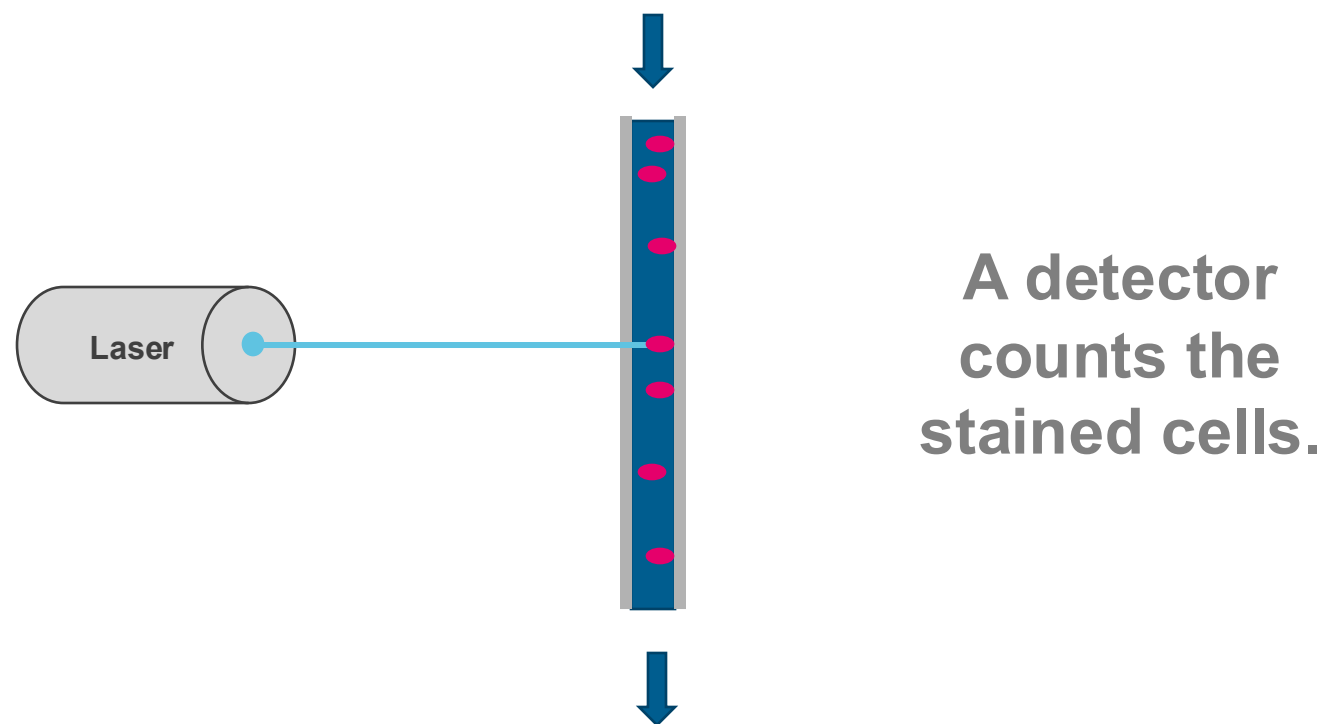
RMM Technology: Flow Cytometry

Step 1: Staining of cells present in sample. The stain binds specifically to DNA



RMM Technology: Flow Cytometry

Step 2: Sample flows through a capillary and passes a laser beam: counting of stained cells



RMM Technology: Flow Cytometry

Step 3: Counting of cells in the sample

The result provides information about the number and the size of viable cells in the sample



Clear understanding of microbial contamination



Results and Export

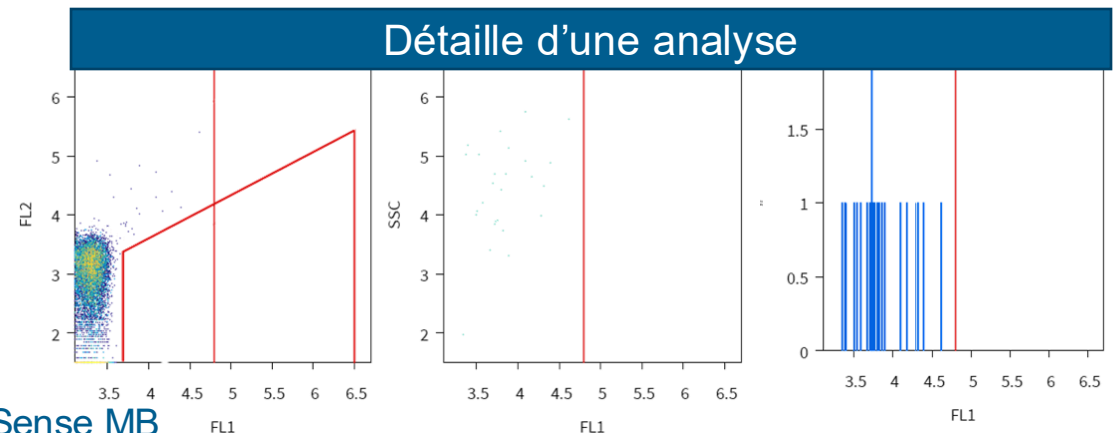


Results and Export

- Numerical results in HMI and exportable as .xlsx and .csv

➡ Data export via USB or Ethernet

➡ Applicable to all levels of knowledge



Validation of RMM



A Supported Method

These organizations promote the implementation and validation of RMMs:

- The United States of America Pharmacopeia – Chapter <1223> :
Validation of alternative microbiological methods
- European Pharmacopoeia – Chapter 5.1.6 :
Alternative Methods for Control of Microbiological Quality
- Parenteral Drug Association – Technical report No 33 :
Statistical Testing Recommendations for a RMM Case Study
- European Medicines Agency – Question and answer



AQU@Sense MB



How to validate a RMM

Validation process

1. Primary validation by BWT (according to USP/Ph. Eur.)

- Documented evidence of functionality

2. Validation for the intended purpose by customer (PQ)

- Verify part of primary validation
- Define alarm and action limits
- (ultimately: define specification limit)

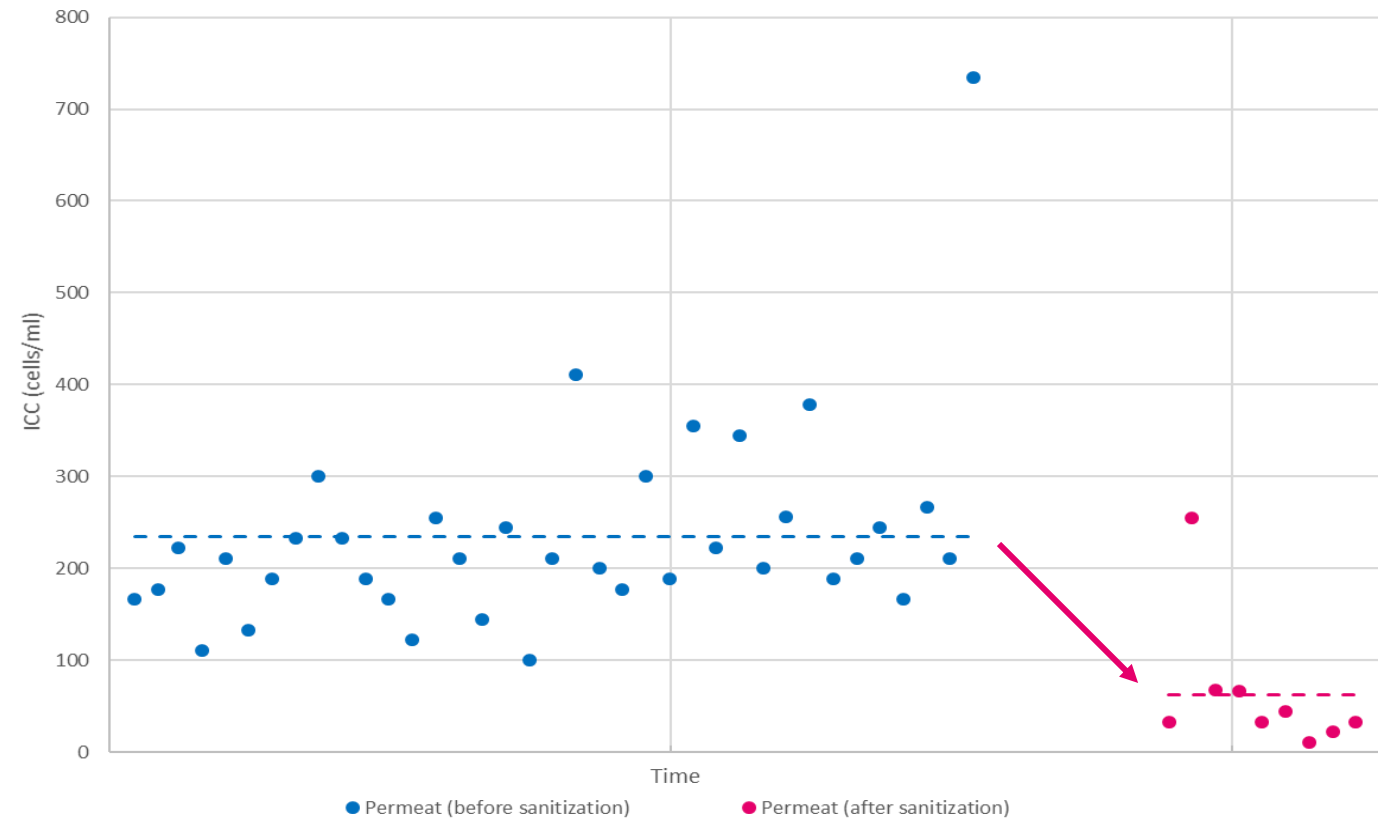


Applications and Benefits



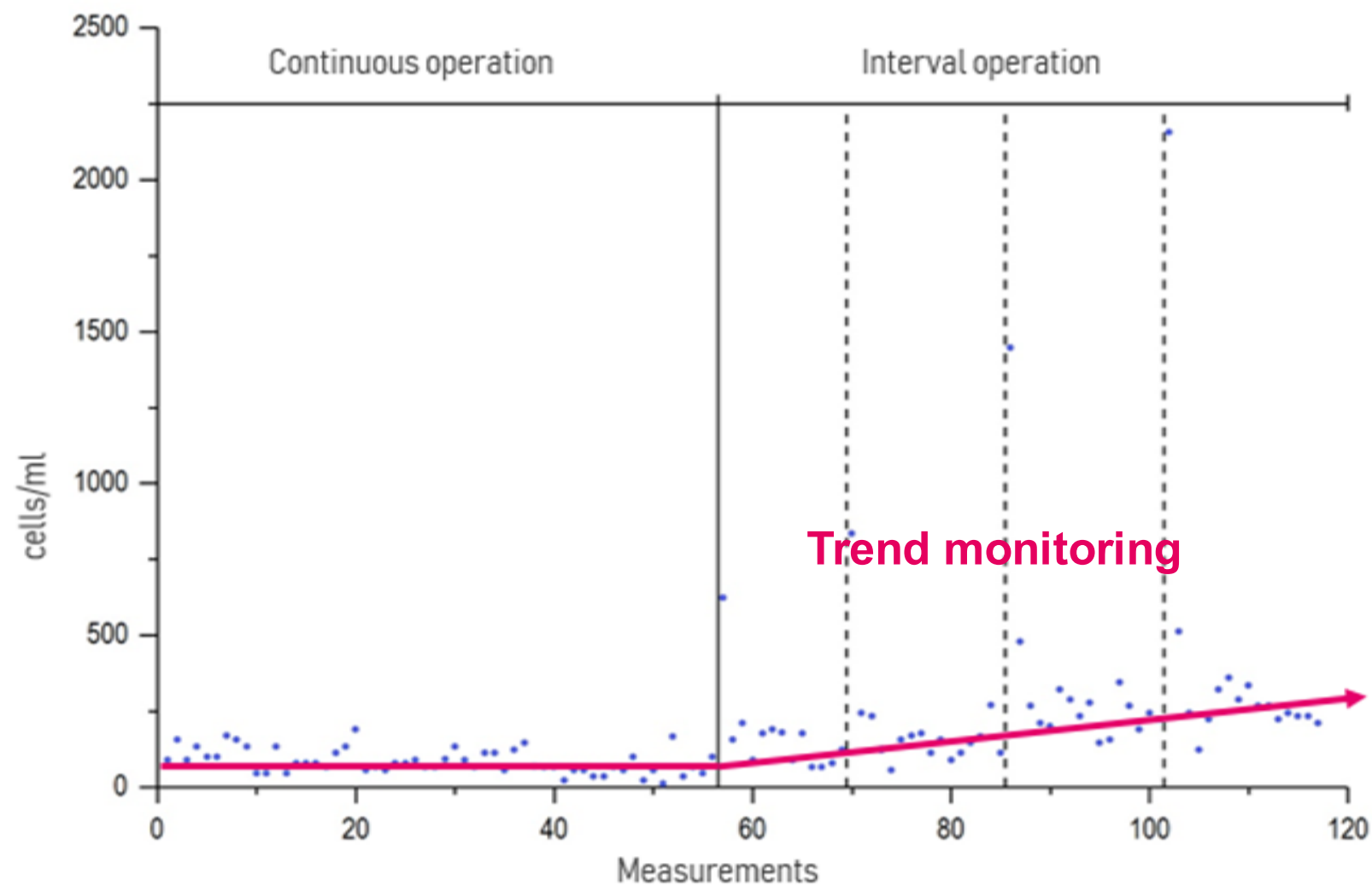
Save time and energy

Quickly verify the effectiveness of your sanitization



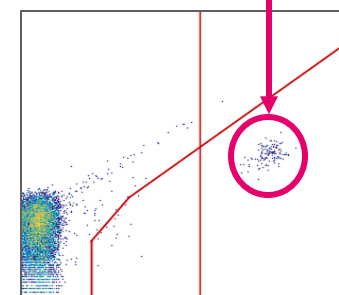
Fast reaction

Detect biofouling early-on
and react promptly



Reduce risk

Detect contamination sources



Robust scientific method

Confidently monitor your
system to get reliable and
fast results



Unaffected by fluctuations of
pressure, temperature or flow rate



Widely used in research and
drinking water industry



Clear distinction between
particles and bacteria

The Benefits of the AQU@Sense MB

Self-explaining and highly user-friendly HMI and data export function



Integration into all points of the system



Can be controlled by BWT's PLC or stand-alone



DNA-specific stain and counting of viable bacteria



Measure quickly grab samples with sterilized sample tubes



Can be sanitized by heat or ozone

Ask for a Test!

BWT proposes a test phase which allows to:

- Integrate the device with the help of our technicians
- Understand how it works and optimize the settings
- Be accompanied by a specialist at every step
- Train your employees in using the AQU@Sense MB



Thank you for your
attention!

