RAPID-C+

Real-time Air Microbial Detector for Aseptic Filling Lines

Dr. Svetlana Kiseleva, CPO at Plair SA

safonina@plair.ch

Monday, April 7, 2025

PLAIR
Identify invisible threats | swiss

ENVIRONMENTAL MONITORING IN STERILE MANUFACTURING

Environmental monitoring (EM) determines the quality of a controlled environment via microbial data collection. Data comes from samples of air, surfaces, and personnel in a clean space.

Production lines like RABS (left) or Isolators (right) are designed to keep the process into a grade A environment while the line is situated into a lower grade environment (grade B for RABS, grade C for Isolator).

Total Particle counting

Active air sampling

Settling plates

PLAIR

TRADITIONAL GROWTH BASED METHODS

Vable particle monitoring is traditionally performed with:

Active air samplers

Settle plates
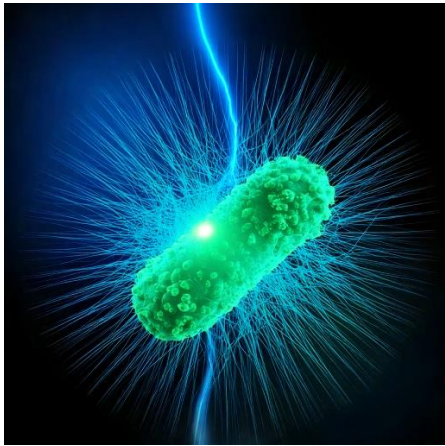

Benefits	Challenges
• Established method • Compendial description • Accepted by authorities • Simple methods • No validation needed anymore • Current GMP / Pharmacopeial limits are in CFU	• Labor intensive, human intervention creates risks of contamination • Slow, requires growth of the microorganisms, identification may take days to weeks • Only culturable microorganisms are detected • Elaborate handling • In certain cases, recovery rate is low

PLAIR

BFPC – OPPORTUNITY OF AN ALTERNATIVE METHOD

Viable particle monitoring in real-time using Laser-Induced Fluorescence (LIF)

Benefits

- In line monitoring
- Real-time detection
- Continuous monitoring

Initial challenges

- High rate of false positives
- Lack of equivalency with traditional methods
- Not possible to decontaminate instrument

*BFPC – bio-fluorescent particle counter

ENVIRONMENTAL MONITORING AS REFLECTED IN EU GMP ANNEX 1

As part of the contamination control strategy (CCS), environmental monitoring should now ensure:

Continuous sampling (9.24)

Microbial identification (9.31)

Rapid and automated methods are encourged to improve the established ones

"The adoption of suitable alternative monitoring systems such as rapid methods should be considered by manufacturers in order to expedite the detection of microbiological contamination issues and to reduce the risk to product. These rapid and automated microbial monitoring methods may be adopted after validation has demonstrated their equivalency or superiority to the established methods." (9.28)

PLAIR

OUR FLAGSHIP PRODUCT RAPID-C+

A real-time air microbial detector for environmental monitoring in sterile production

Viable Particle Counts

Total Particle Counts
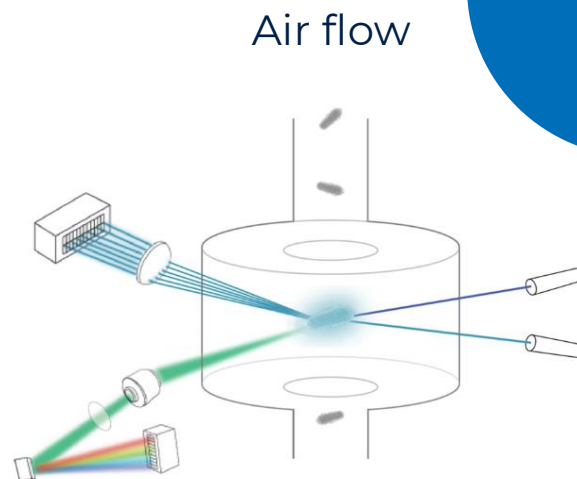
Continuous active sampling

All you need for grade A, outside of grade A

PLAIR

OPTICAL STAGE

Air flow

Advanced BFPC

Viable Particle Counts

(0.5-100 µm)

Total Particle Counts

In accordance with ISO 21501-4

RAPID-C+
PLAIR

PLAIR

SAMPLING STAGE

RAPID-C⁺
PLAIR

Advanced BFPC

Aseptic air sampler C-Catch

Air flow

Viable Particle Counts

(0.5-100 µm)

Total Particle Counts

In accordance with ISO 21501-4

Continuous active sampling

Certified air sampler following EN 17141:2020, Annex E
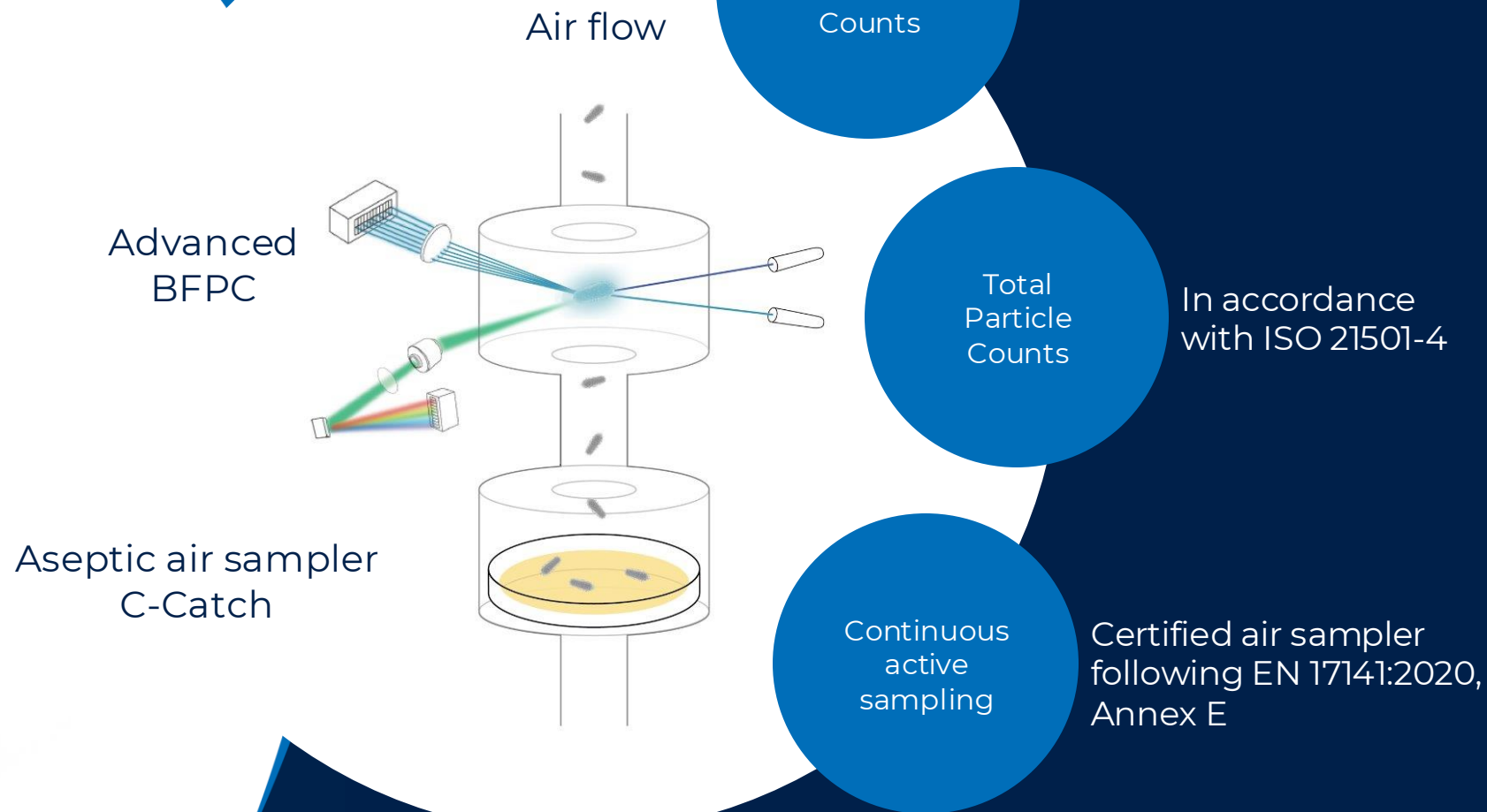
No air concentrator, all particles monitored and impacted

PLAIR

C-CATCH ACTIVE SAMPLER

• C-Catch is a patented aseptic container to protect agar plate (AP)

• C-Catch is a certified active sampler (EN 17141:2020)

• Outside of grade A for quick and easy replacement of APs

• Direct compliance with CFUs

• Direct correlation with viable particles count possible
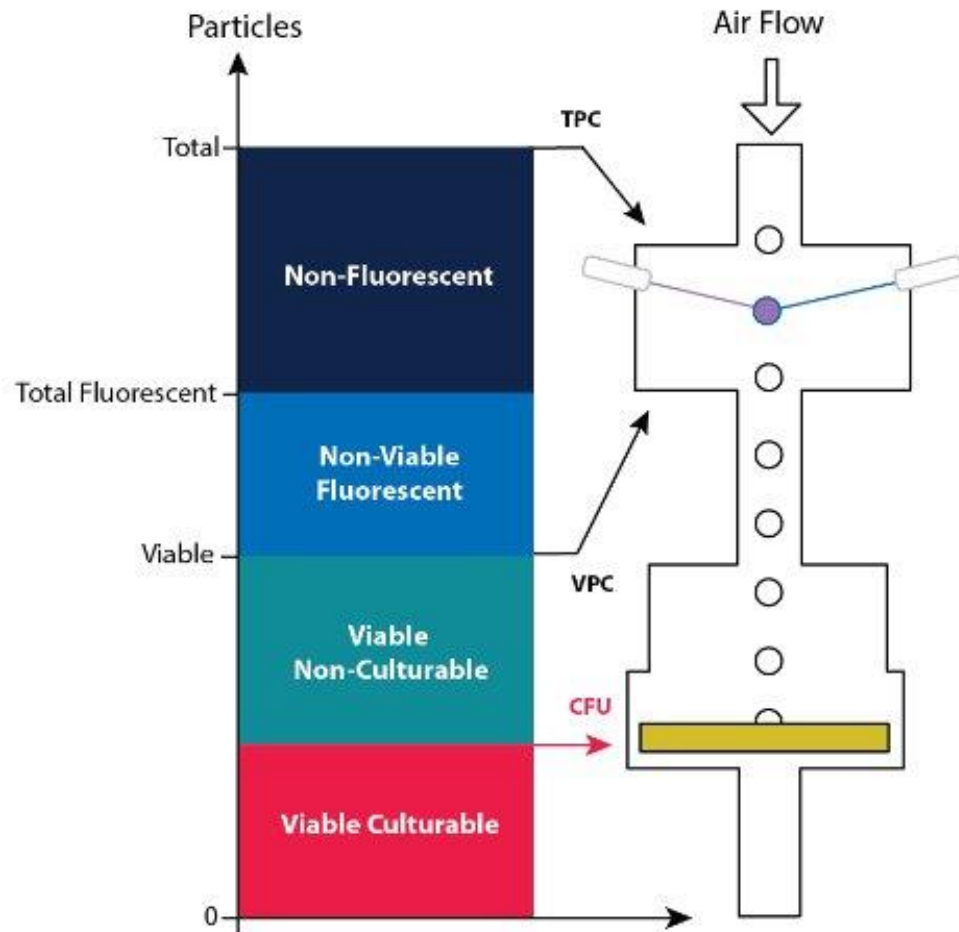

Sieve

AP ⌀90 mm

C-Catch

THE VERSATILITY OF RAPID-C+

TPC – Total particle count
Real-time and quantified

VPC – Viable particle count
Real-time and quantified

CFU – Colony Forming Unit
Continuous and quantified
(external incubation required)

All monitoring done on the same m³ of air

INTEGRATION INTO FILLING LINES

- Ready for integration into fill finish lines

- One exhaust for operation (internal pump)

- Second exhaust for decontamination (external pump)

- Active sampling qualified with complete tubing

- Easy access to replace AP

Isokinetic probe

Aera to monitor

Baseframe

Tubing

Rapid-C+

Easy access to place and remove the C-Clean or the C-Catch

C-Catch

Digital interface to HMI or EM Software platform

Decontamination exhaust

Operations exhaust

PLAIR
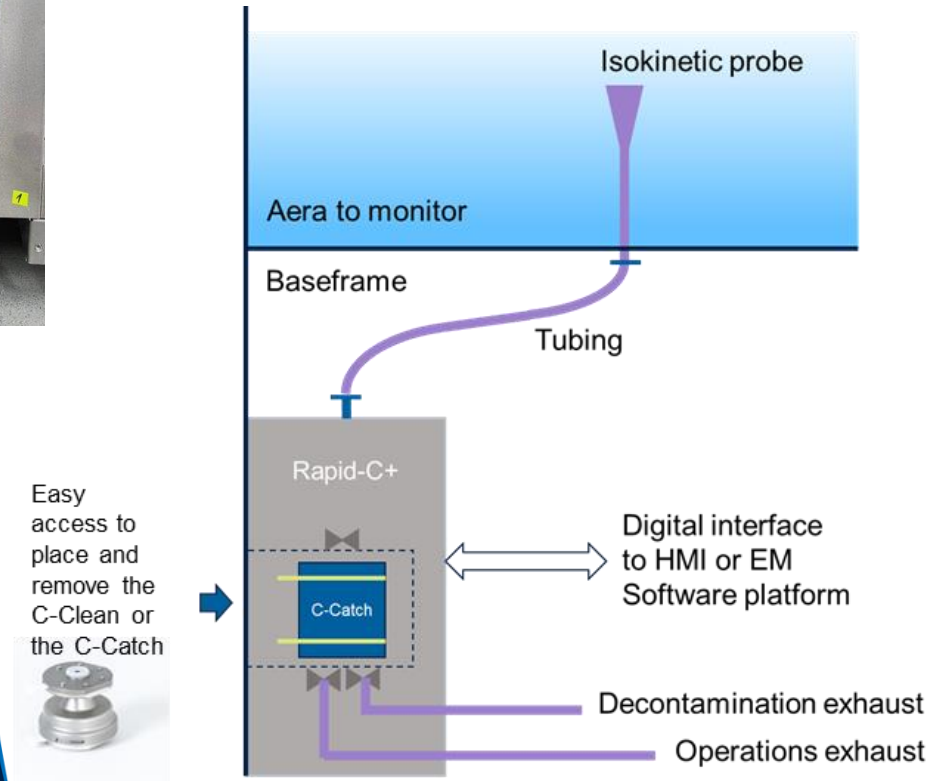
RAPID-C+ INTEGRATION INTO FILLING LINES

Drug

Rapid-C+

Drug packed
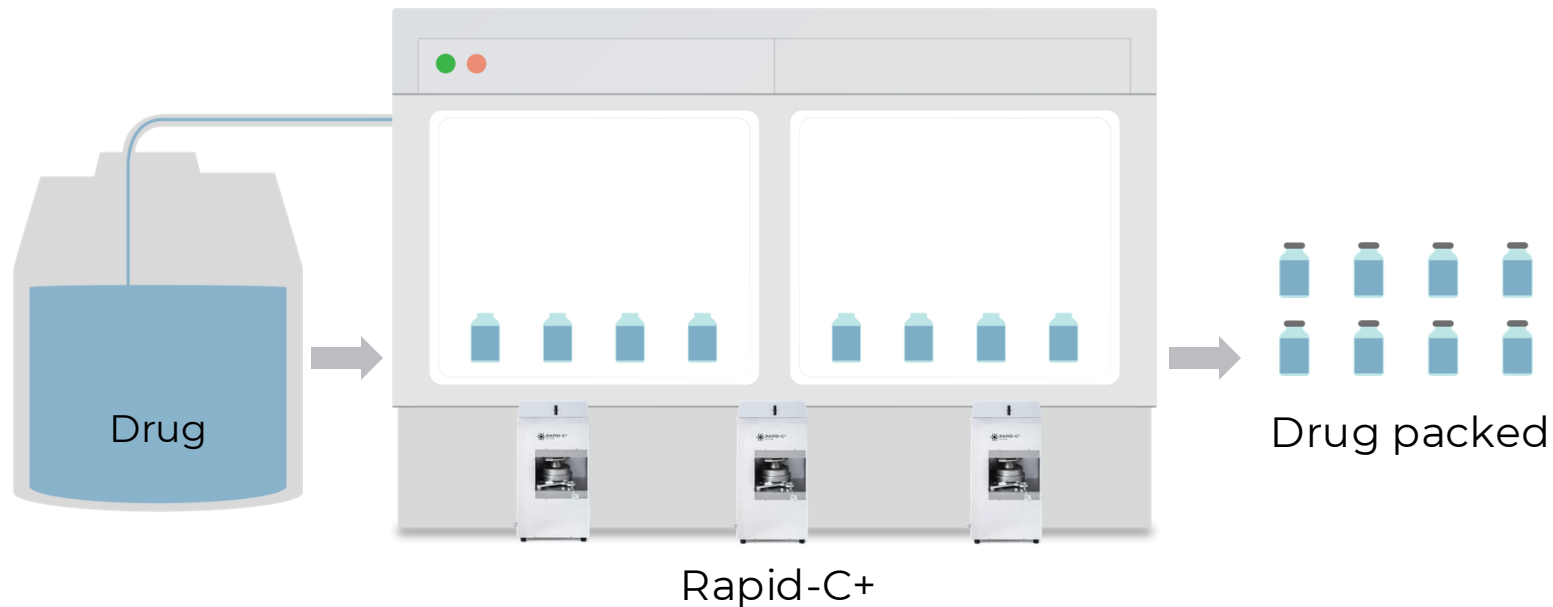
FEATURES

- Continuous viable and total particle monitoring
- Real-time and digitalized data

BENEFITS

- Faster batch release
- More sustainable production with less waste

PLAIR

COMMUNICATION INTERFACE

Rapid-C+ is a "probe" that can be interrogated via REST API (user, admin, service access levels)

Rapid-C+ REST API specification enables the coding of drivers in HMI / EM SW Platform

Plair Dashboard is a diagnostic tool with data/status-control/display

Request

/mode
GET /mode, 9
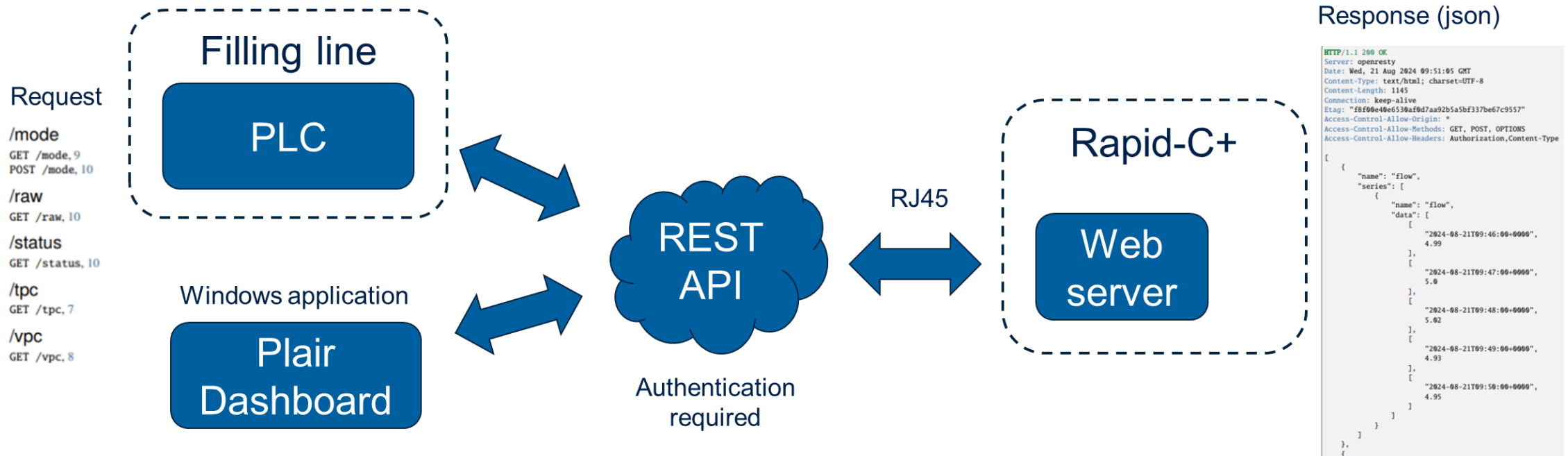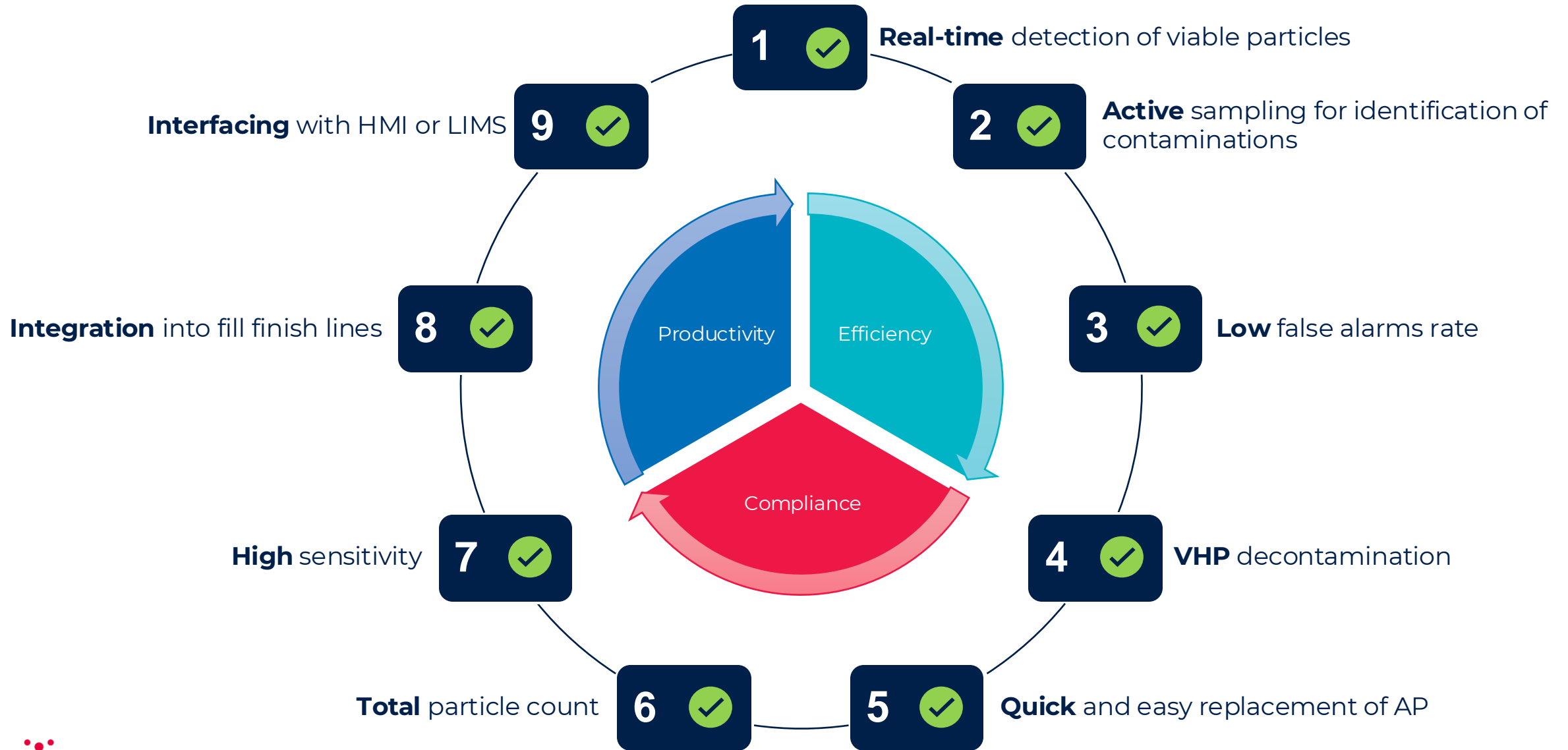POST /mode, 10

/raw
GET /raw, 10

/status
GET /status, 10

/tpc
GET /tpc, 7

/vpc
GET /vpc, 8

Filling line

PLC

Windows application

Plair Dashboard

REST API

Authentication required

RJ45

Rapid-C+

Web server

Response (json)

HTTP/1.1 200 OK
Server: openresty
Date: Wed, 21 Aug 2024 09:51:05 GMT
Content-Type: text/html; charset=UTF-8
Content-Length: 1145
Connection: keep-alive
Etag: "f8f00e40e6530af0d7aa92b5a5bf337be67c9557"
Access-Control-Allow-Origin: *
Access-Control-Allow-Methods: GET, POST, OPTIONS
Access-Control-Allow-Headers: Authorization,Content-Type
[
  {
    "name": "flow",
    "series": [
      {
        "name": "flow",
        "data": [
          [
            "2024-08-21T09:46:00+0000",
            4.99
          ],
          [
            "2024-08-21T09:47:00+0000",
            5.0
          ],
          [
            "2024-08-21T09:48:00+0000",
            5.02
          ],
          [
            "2024-08-21T09:49:00+0000",
            4.93
          ],
          [
            "2024-08-21T09:50:00+0000",
            4.95
          ]
        ]
      }
    ]
  },
  {

RAPID-C+ ANSWERS

1 ✅ **Real-time** detection of viable particles

2 ✅ **Active** sampling for identification of contaminations

3 ✅ **Low** false alarms rate

4 ✅ **VHP** decontamination

5 ✅ **Quick** and easy replacement of AP

6 ✅ **Total** particle count

7 ✅ **High** sensitivity

8 ✅ **Integration** into fill finish lines

9 ✅ **Interfacing** with HMI or LIMS

Productivity

Efficiency

Compliance

PLAIR

THE BENEFITS OF USING RAPID-C+

Productivity

Real-time monitoring
(viable and total particles)

No manipulation inside grade A
(agar plates in C-Catch)

Efficiency

Save batches when excursion
(only a small portion is discarded)

No false positives
(save value with less alert errors)

Compliance

Legacy methods integrated
(CFUs and setting plate)

All monitoring over the same m^3
(simplifies data analysis)

Thank you !

PLAIR
Identify invisible threats | swiss

Route de Saint-Julien 275,
1258 Perly-Certoux (Geneva), Switzerland
info@plair.ch / +41 (22) 552-3830

www.plair.ch