

# TOP TIPS

## for environmental monitoring of pharmaceutical clean rooms



Environmental monitoring should promptly identify potential routes of contamination, allowing for implementation of corrections before product contamination occurs.

US FDA- 21CFR 211.42 & 211.113

### 1 Define your environmental control plan and methodology

Environmental monitoring evaluates the quality of air, surfaces, and personnel through testing and sample analysis. Meeting appropriate hygiene standards is essential to the safety and efficacy of a finished pharmaceutical product.

According to American Pharmaceutical Review, all programs should use a combination of the following methods:

#### Viable



- Active and passive air sampling**
  - Volumetric air sampling instruments
  - Settling plates, and BD RODAC™ plates
- Surface sampling**
  - Settling plates, BD RODAC™ plates, swabs
- PPE - Personnel glove, gown, and garb sampling**
  - Settling plates, BD RODAC™ plates



#### Non-viable

- Particle counters

### 2 Help ensure compliance with regulatory agencies

Regulatory agencies like the FDA and the European Medicines Agency (EMA) require pharmaceutical manufacturers to have an environmental monitoring program in place to ensure that aseptic processing is possible.

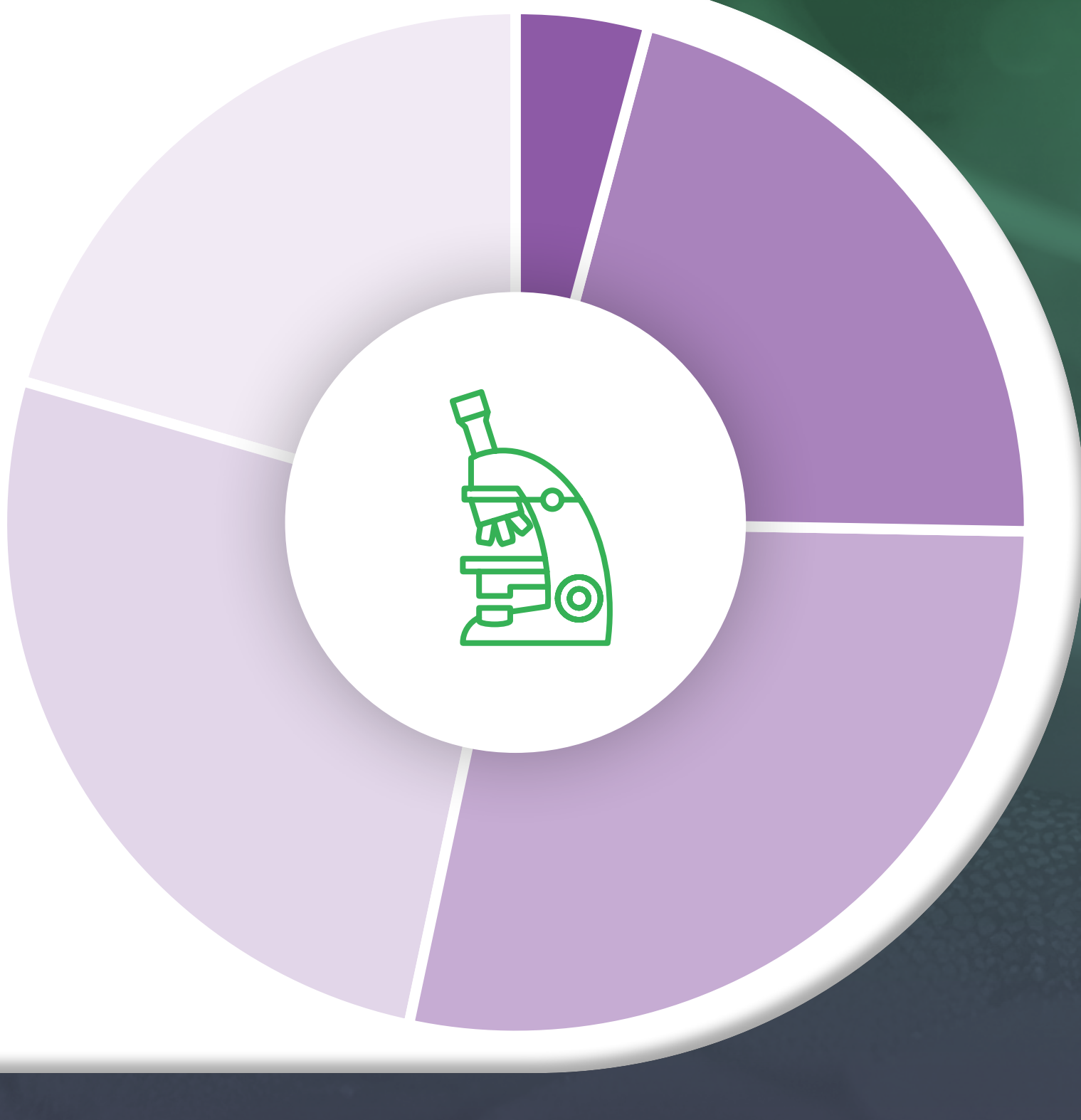
Sterility is of the utmost importance when it comes to Environmental Monitoring. BD offers a complete line of top-quality products to support your compliance with USP <1116>, or Media Solutions for USP <1116>.



### 3 Choose dependable plated media and storage solutions

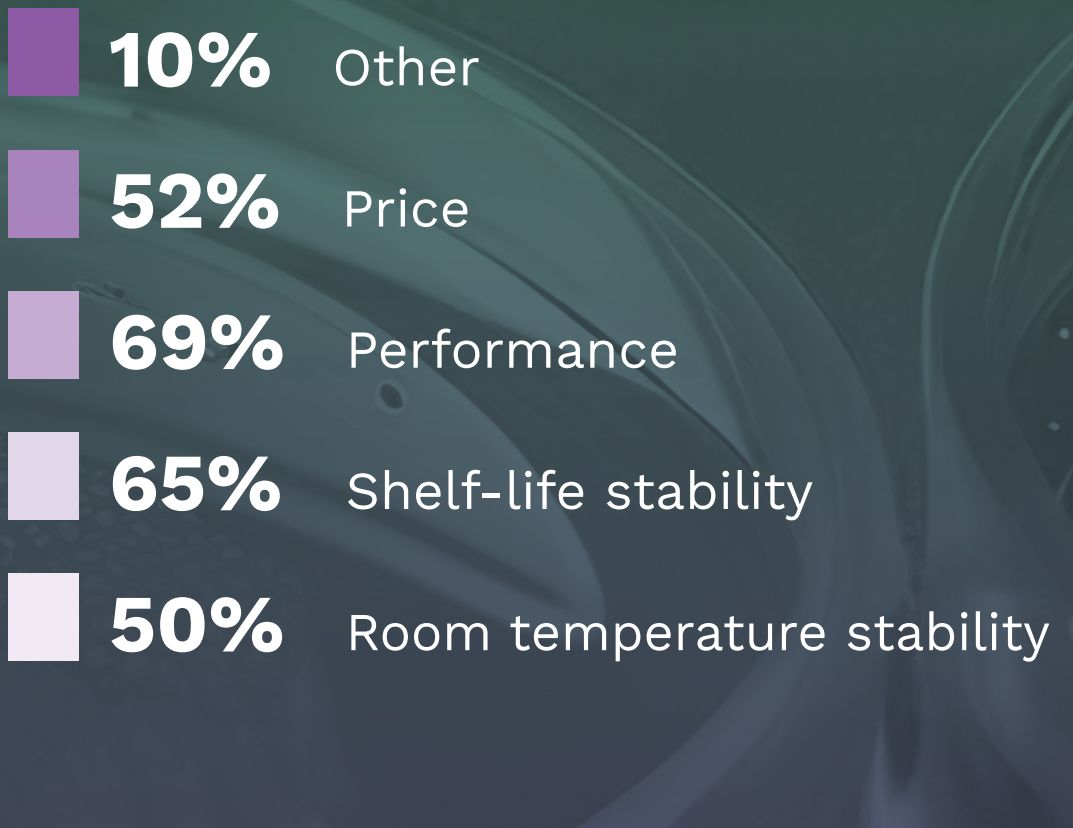
When choosing plated media for environmental monitoring of pharmaceutical clean rooms, it is important to consider the specific requirements of the room and the types of microorganisms that are of particular concern. It is essential to select media that can support the growth of a wide range of commonly found microorganisms such as bacteria, yeast, and mold.

It is also important to consider factors such as shelf life, storage requirements, and ease of use when selecting plated media for environmental monitoring. Conducting thorough research and consulting with experts in the field can help ensure that the most appropriate plated media is chosen for monitoring the clean room environment effectively.



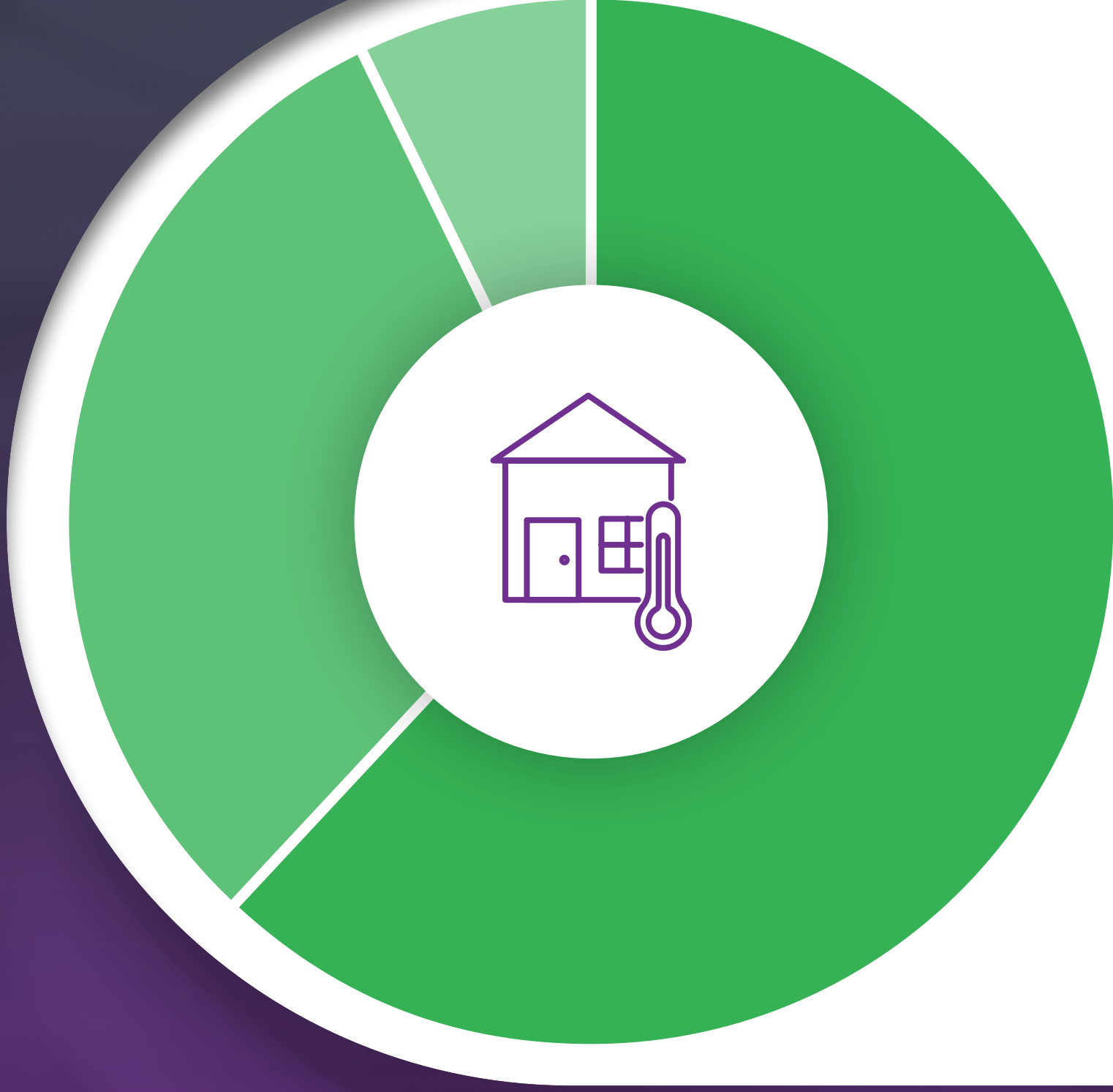
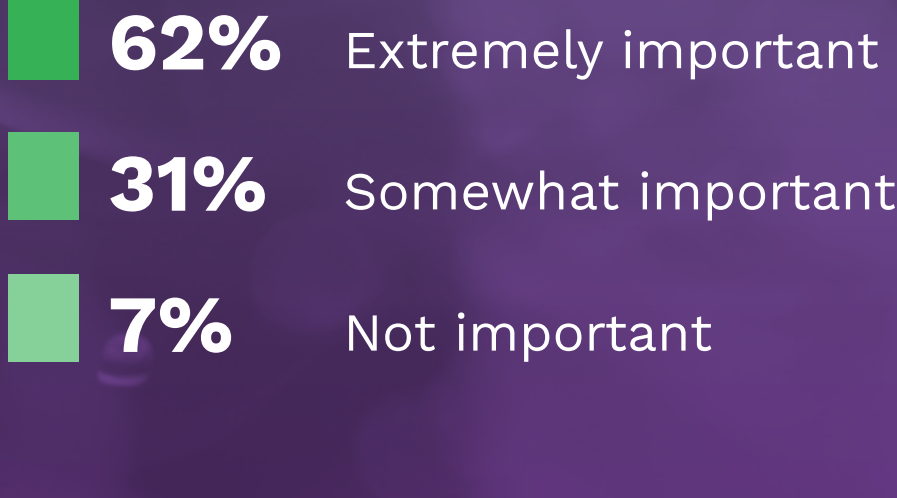
#### Q What factors influence your choice of microbiological monitoring plates for your laboratory?

Respondents favored shelf life and performance over cost in an industry survey.\*



#### Q How important is it for you that your microbiological monitoring plates are room temperature stable?

Over 60% of respondents stated it is extremely important that plates are room temperature stable.\*



### Discover BD BBL™ IC-XT sterile plated media

More information can be found at [bd.com/ic-xt](http://bd.com/ic-xt)

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Triple bag packaging maintains sterility assurance
- Product traceability**  
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- Storage flexibility**  
Room temperature storage media with a range of 2-25°C
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Compatible with many types of commercial air samplers
- Sample integrity**  
With BD RODAC™ SNAP LID and LOCKING LID Settling Plates
- Multiple applications**  
For both contact and air sampling
- Vaporized Hydrogen Peroxide (VHP®) resistant**  
Isolator and clean room compatible
- Resource efficiency**  
Large batch sizes with extended shelf life

[Learn more](#)

Environmental Monitoring starts with a quality media plate from a trusted partner, discover pharmaceutical microbiology with BD

\*The advice highlighted in this resource is based on the results of a survey conducted by SelectScience® with its members in partnership with BD Life Sciences.  
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