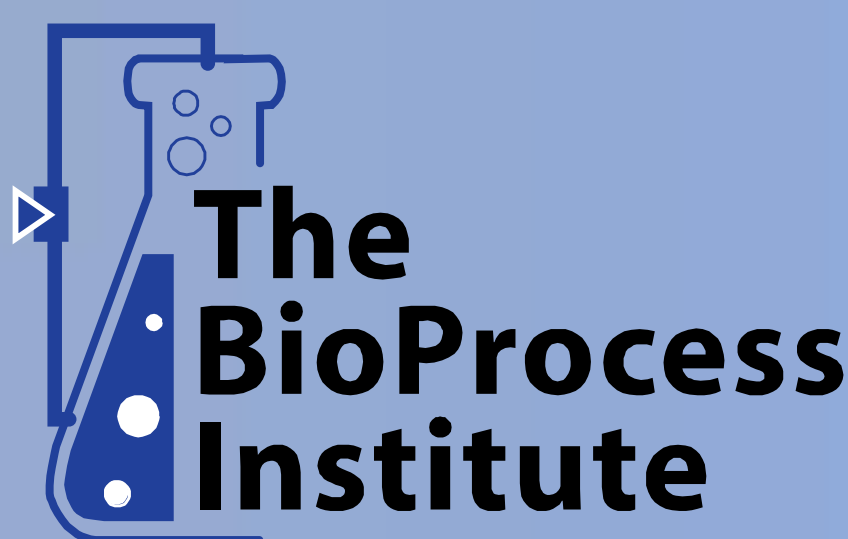


A Comparative Assessment of Diaphragm Valve Service Life

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1 THE SITUATION

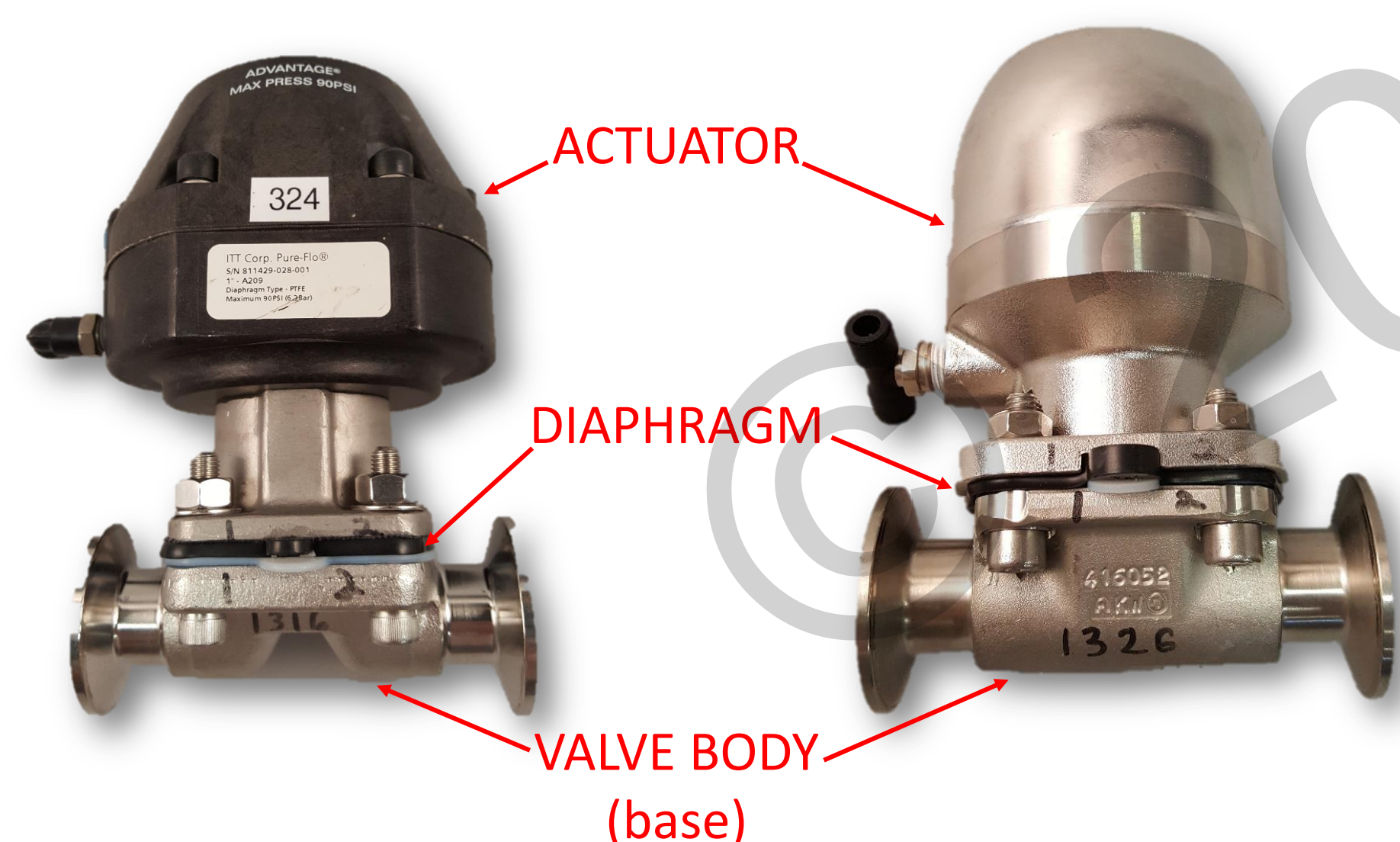
All diaphragm valve diaphragms are not created equal. There is no “perfect” diaphragm valve diaphragm for every application, or for all applications. So how are biopharmaceutical suppliers and end users supposed to operate with process, economic, and regulatory conditions that require a high level of demand for consistent quality in the bioprocessing components they sell and use?

- End users need components which satisfy at least three criteria: (1) they must **meet the requirements of their process application**; (2) they must **comply with industry standards**; and (3) they must provide for a **long service life**.
- Suppliers need to gather as much critical information as possible to **create components which satisfy these requirements**.
- Both must obtain scientific test results to help them **make an informed decision when choosing the right component for each application**.

Before end users select a bioprocess diaphragm valve for an application, they must consider how all commercially-available components compare to each other in terms of service life. This includes categories such as **sealability, entrapment risk/cleanability, and visual condition**. Supply chain and compliance with industry-accepted performance tests (e.g., *ASME BPE-2016 Appendix J*) must also be examined closely. End users must weigh all performance results and then decide which criteria/criterion is most vital to their production process and the safety of the final product. To do this, they must consider each and every union in each of their process lines.

The diaphragm valve consists of three parts: the actuator, the diaphragm, and the body (base). (Figure 1) Each of these parts contributes to the successful performance of the diaphragm valve. History has shown diaphragm valves and gaskets to be the ‘Number One Suspect’ when there is a failure in a process line. However, detailed studies, which can be found in The BioProcess Institute’s *BioProcess Performance Reports®* (BPPRs®), determined that the other components’ limitations may affect performance as much, or more than, the diaphragm valve or gasket. In these major studies, the performance of the most commonly used commercially-available diaphragm valve diaphragms were evaluated. The diaphragms and diaphragm valves were obtained through routine supply chain channels and subjected to side-by-side controlled exposure and performance testing. In those studies, the rigorous testing involved dozens of diaphragm valves diaphragms during the course of many months of exposure and evaluation time, using vast man-years of labor and combined technical experience.

Figure 1: Installed Diaphragm Valves



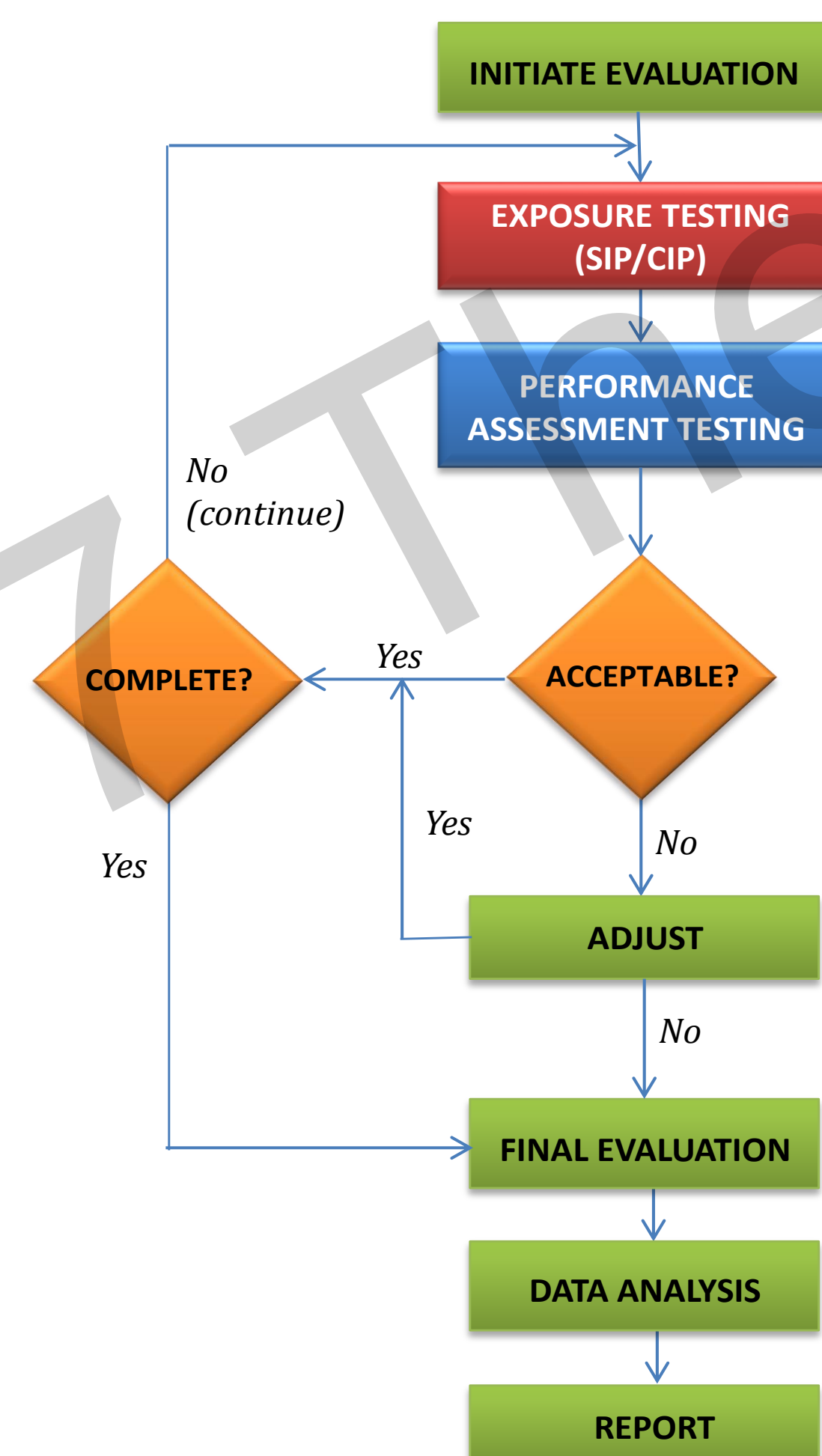
2 THE STUDY

BioProcess Performance Reports® were created to provide the bioprocessing community with independent, side-by-side comparisons of today’s commercially-available bioprocess components. Similar to *Consumer Reports Magazine®*, inside each BPPR® is objective foundational data compiled by assessing and comparing bioprocess components before, during and after subjecting them to simulated process test conditions and trade-secreted testing and evaluation methods. Think of EXPOSURE TESTING like a test track in car racing when the car is exposed to many laps around the track. PERFORMANCE TESTING is where parts of the car are then evaluated in the pit to see how well they withstood the EXPOSURE TESTING (Figure 2).

In those major studies, the performance of the most commonly used commercially-available diaphragm valve diaphragms were evaluated. The rigorous testing involved thousands of diaphragms during the course of many months of exposure and evaluation time, using vast man-years of labor and combined technical experience.

The studies, conducted in a controlled environment, allow suppliers and end users to reference the findings when evaluating the wear and tear of their own components and find a solution.

Figure 2: BPPR® Process Flow for Diaphragm Valve Service Life Testing



3 FINDINGS

The scientific data from this approach provided the information to choose the best diaphragm for an application as well as to help predict diaphragm service life (Figure 3). With the knowledge that this data was based on good, strong science, end users have used it to support their investigations, CAPAs and change controls. While suppliers can see how their component compares to others on the market right now and attain visibility to end users.

Some important findings from the *Diaphragm Valve BPPR®* study included:

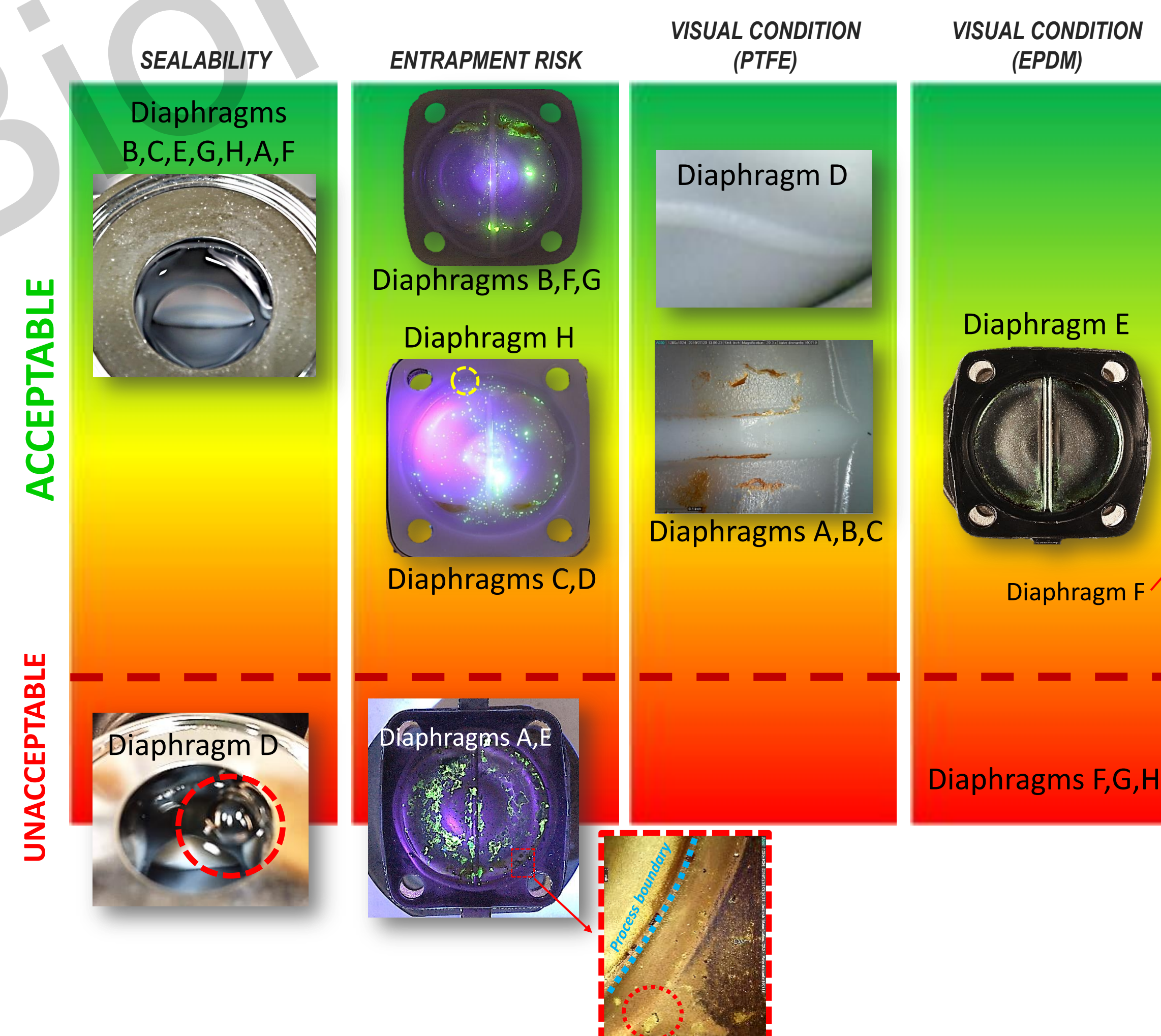
OVERALL

- Most test diaphragms performed well up to 100 SIP.
- Sealing, entrapment risk and visual condition changed thereafter, varying by manufacturer and material.
- Valve manufacturers had different diaphragm tightening limits, % compression, and tightening torque ranges.

SERVICE LIFE

- As expected, wear effects increased with greater exposure.
- The SIP cycle attained before impact to the process varied amongst manufacturers.
- Most types of EPDM and PTFE diaphragm valve diaphragms performed well up to 100 SIP, with the exception of one PTFE diaphragm manufacturer.
- One manufacturer’s PTFE diaphragm required additional tightening to attain shell-side sealing.
- PTFE diaphragms showed fewer signs of wear than EPDM diaphragms.
- EPDM diaphragms’ material changed more significantly with increasing exposure.

Figure 3: Actual Diaphragm Valve Diaphragm BPPR® Results



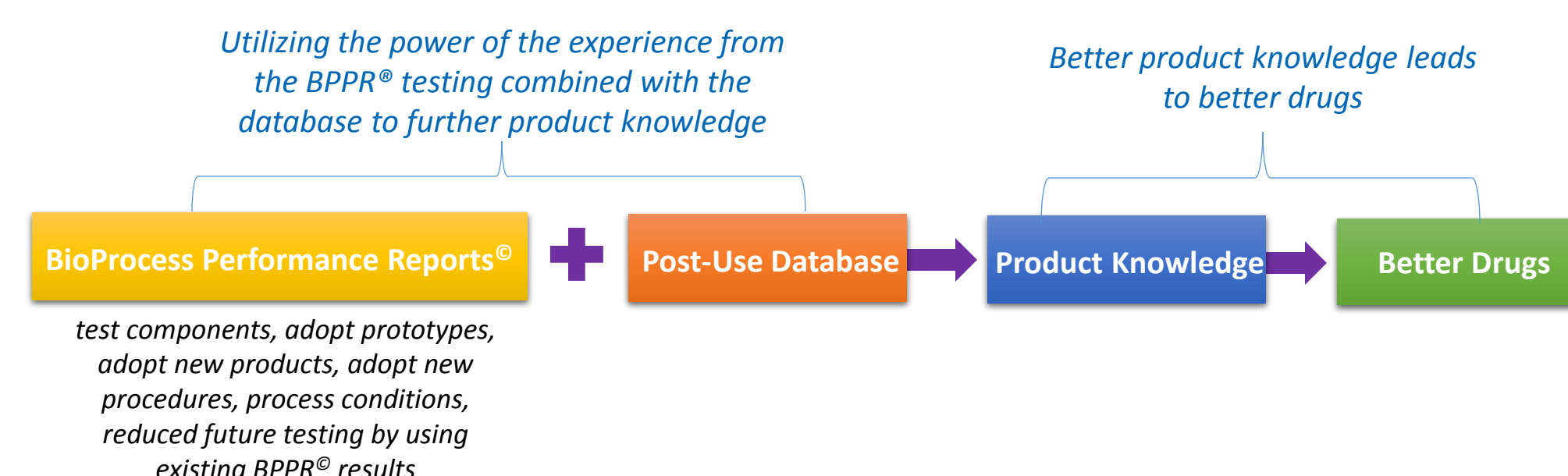
4 LOOKING AHEAD TO THE FUTURE

The **BioProcess Institute** **LOVES bioprocessing components**. We test them every single day! In addition to the important results found in the *BioProcess Performance Reports®*, suppliers and end users share their process performance results from their actual applications by donating their post-use components to BPI for evaluation. Scalable to expand to other component types and process conditions, BPI’s BPPRs® assesses the condition of the component and may also subject it to further forensic diagnosis to determine the root cause of the failure or condition. BPI is developing a post-use testing rationale for reference in future BPPRs®. End users are welcome to send their post-use components to BPI for analysis and inclusion in upcoming *BioProcess Performance Reports®*.

Upcoming *BioProcess Performance Report®* will include hoses, single-use tubing, and other components.

The power of information from the testing, combined with the value of components from actual real life use, leads to product knowledge. This, in turn, leads to better drugs (Figure 4).

Figure 4: Good Science Leads to Better Drugs



“Day in and day out at The BioProcess Institute, we help end users, suppliers, and organizations navigate the industry to make better pharmaceuticals.

--JAMES DEAN VOGEL, P.E.
DIRECTOR

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