White Paper

PENDOTECH
Leading Process Analytics

Why a Service Program Matters

Productivity, Profitability, and More

When it comes to your process analytics equipment, proactive planning for maintenance and service can ensure optimum performance. This paper addresses how adopting a well-designed service program can help ensure that you:

1. **Reduce downtime**
2. **Regulate maintenance budgets**
3. **Extend the lifetime of process analytics equipment**

Content:

METTLER TOLEDO

1 Why is a Service Program Important?

A good service program will bring valuable benefits to analytics processes in chemical, discrete manufacturing, food and beverage, pharmaceutical, biotech, raw materials and other manufacturing operations. A service program based on your application and process risks is the key to decreasing the total cost of ownership for your process analytics equipment and improving your return on investment (ROI) by helping you to meet your production goals in three distinct areas:

1. Reducing downtime
2. Regulating maintenance budgets
3. Extending the lifetime of process analytics equipment

As in every business decision, ROI is the ultimate guide when evaluating and selecting services. In the following paragraphs, we look at each of these three areas in detail and see how a robust service program can help you enhance productivity and, ultimately, ensure better profitability.

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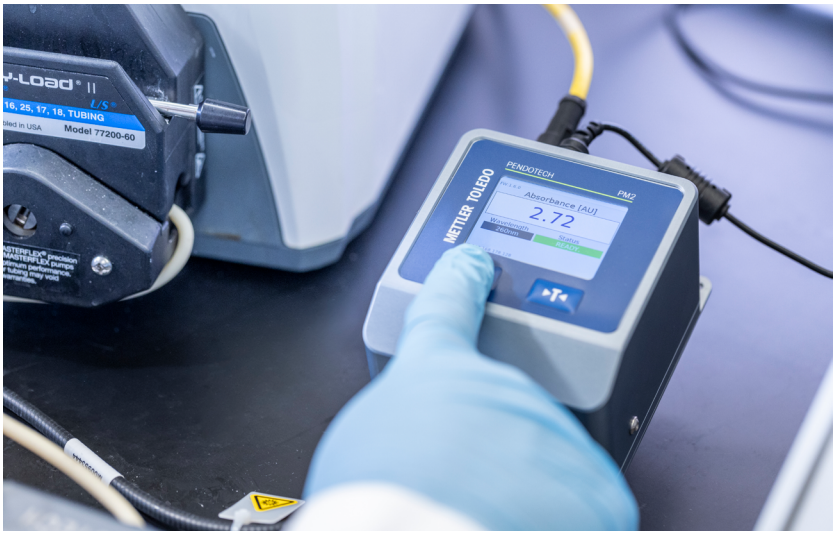

1.1 Reducing downtime

A good service program is among the best available options to avoid unplanned downtime. Proactive service can identify potential reliability issues before they stop production.

The investment in a service program should always be compared to the potential financial costs of lost productivity. That could mean the cost of losing a few hours or days of production, or in some operations, the loss of a high-value batch. (Costs of proactive vs. reactive maintenance are covered in detail in section 5.)

A service program that reduces the risk of production losses offers high financial value as well as protection for your hard-earned reputation of meeting customer delivery commitments. A service program also means that your needs are prioritized in emergency service situations. These situations would be minimized through the preventive maintenance service provided by your program.

1.2 Regulating maintenance budgets

Service programs typically include preventive maintenance, periodic calibrations, inspections, and adjustments. All of these steps help keep your operation running at maximum productivity levels. Planning in advance for these important services at appropriate frequencies allows you to regulate your maintenance budget by eliminating or reducing unplanned costs.

In the event of a needed repair, labor and replacement part costs can also be wrapped into a service program to help create comprehensive protection for your maintenance budget. Additionally, a well-designed service program is outsourced to experts with specialized skills, procedures, tools and parts which allows you to dedicate valuable in-house resources to other pressing opportunities.

1.3 Extending the lifetime of your process analytics equipment

You have a substantial investment in your process analytics equipment assets, and nothing extends the life of these assets as effectively as a well-designed service program. When you combine services and products designed by the equipment manufacturer, they align to provide maximum value in longevity, accuracy and reliable performance.

A key to generating the greatest possible return on your equipment investment is to incorporate a service program that extends its useful life while maximizing productivity. The following sections include additional details about how to make sure your service program provides the highest equipment protection and meets your accuracy and quality goals.

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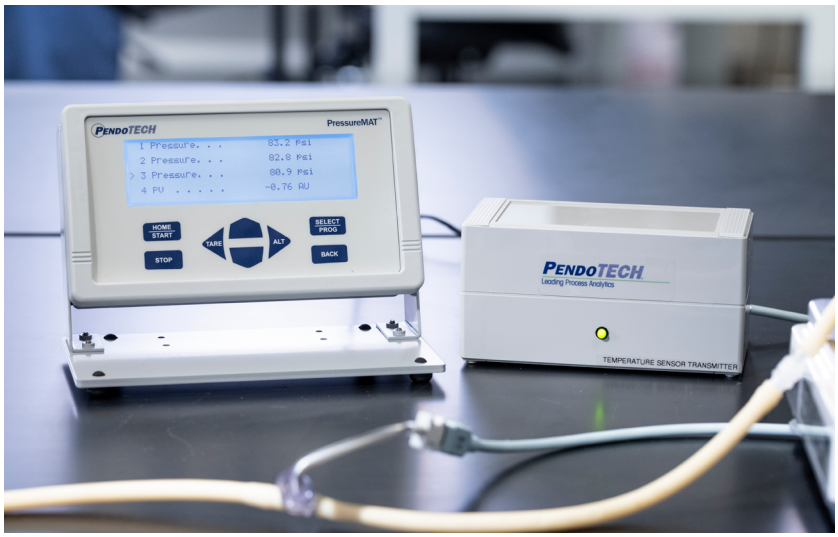

2 Is It Necessary to Partner with My Equipment Manufacturer?

In a word, yes. Most companies select the original equipment manufacturer (OEM) as the service provider for their process analytics assets. These companies typically experience the many benefits of using the manufacturer's services, which include:

- Expert service engineers trained and equipped by the manufacturer
- Factory-designed service procedures
- Spare parts that meet manufacturer specifications and third-party approvals
- Fast turnaround times due to easy access to parts and support

When your process depends on compliance to quality and regulatory requirements, you help to ensure ongoing success by designing an effective plan with the OEM. If you choose a do-it-yourself (DIY) route or use a general service provider, you accept greater risk and must typically absorb higher short and long-term costs. These costs can include, but are not limited to, production loss due to downtime and premature equipment replacement.

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3 How Do I Benefit from Setup & Configuration Services?

The initial integration of new process analytics equipment into your process is a critically important task that generally includes:

- Setup of analytics parameters to meet process and compliance requirements
- Interfacing to data acquisition and automation systems
- Tailoring of workflows to maximize operator productivity
- Configuring of input and output behavior
- Documentation of installation activities and initial performance

Successful integration requires that the service provider work closely with your process and quality managers, engineers and operators. The service provider should have deep expertise with the equipment and familiarity with processes that are similar to yours. Installation and setup activities ideally focus on realizing the highest return on your investment through process optimization.

General equipment documentation from the OEM can help with setup, but successful integration ensures that measurement results meet all applicable quality and regulatory requirements in your specific situation. Particularly in highly regulated applications, you must ensure you have equipment qualification documentation to certify that your equipment is suitable for your process. Relying on OEM service engineers for this customized documentation provides a safe, easy solution to ensure proper setup and configuration.

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4 Are Professional Calibration Services Necessary?

In a regulated environment, you must ensure that measurements are in compliance and that you have the documentation to prove this compliance in an audit. However, even in unregulated applications, the costs to your business created by measurements that are less accurate can cost you in poor quality and product that does not meet requirements.

Your tolerances should be established to optimize outcomes, such as maintaining quality, protecting your profits or as guided by regulations. However, even the most robust and reliable process analytics equipment is subject to influences that can cause out-of-tolerance results.

4.1 Reducing downtime

Out-of-tolerance measurements can produce outcomes that threaten your business objectives, such as:

- Errors in batch concentration or volume
- Inaccurate bioreactor media and filtration buffer properties
- Incorrect product amino acid or nucleic acid sequence
- Out-of-specification liposome or protein formation
- Rejected batches or batch contamination
- Invalid quality control checks

Every measurement system must be periodically tested to determine its accuracy and to confirm that it is capable of performing within required tolerances. In process analytics, some procedures are dictated by drug or medical device regulations, while others follow widely accepted national or international guidelines; the appropriate procedure should be selected in consultation with an expert.

Other important calibration considerations are: the expertise of the service engineer performing the testing, the traceability of the reference devices, the legibility and usability of the calibration certificates, the software used to guide the testing and to calculate, print and archive test results, and the frequency of calibration itself.

Enjoy the flexibility of depot and field OEM maintenance options.

4.2 Setting your risk-based calibration schedule

Some companies arbitrarily choose the lowest acceptable frequency to satisfy their compliance or quality department, regulations or the one consistent with their historical practice. However, frequency of calibration should be guided by pertinent regulations but determined by assessing the risks of inaccurate results in your specific process.

Depending on these risks, an annual, semi-annual, quarterly, or even monthly calibration may be warranted to ensure that you are using process analytics equipment within established tolerances. The best-in-class approach to determining calibration frequency uses analysis of historical test results for a particular process analytics application combined with the criticality of the results. It then adjusts the frequency lower when test results are consistently in tolerance or there is less risk.

Environmental and liquid velocity parameters are a good example of typically consistent, low-risk parameters because those are managed by calibration-dependent systems. Temperature is often controlled by the bioreactor or lab environmental monitoring systems, and flow is often dependent upon pumps and valves which usually have their own service programs.

More frequent calibration becomes necessary when there is an out-of-tolerance trend or more risk to the process. Typically process and product stability parameters like conductivity, pH, pressure, turbidity, and UV are good examples of variable, high-risk parameters due to their association with critical quality attributes and product specifications. Exceptions always exist as bioprocess applications vary widely, but generally all parameters command at least some need for reliable attention.

Because of the risks of measuring inaccurately and the many influences that may cause inaccuracy, a consultation with your service engineer will help determine a suitable calibration procedure, appropriate tolerances, and a frequency for calibration. This will help mitigate your risk, guard your quality and profitability, and audit-proof your process.

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5 Can I Reduce Maintenance Costs While Enhancing ROI?

Prior planning prevents poor performance, and maintenance of process analytics equipment is no exception. Preventive maintenance helps you to identify small issues and prevent them from becoming big problems that cost you time, money and reputation. Building preventive maintenance into your service program also helps ensure that wear parts are replaced before they cause an issue, but not so soon as to be wasteful.

When the manufacturer's service personnel perform preventive maintenance activities, the value is even higher. These service professionals are trained according to procedures designed by the equipment developers and are always the first to know about firmware and software updates. This gives them unique insights to address issues in a timely and cost-effective way.

The opposite of preventive maintenance is reactive maintenance. Waiting until something happens before requesting service can disrupt production schedules, cause product loss, and inflate service costs. Planning ahead to minimize costly downtime can help you to maximize production efficiency and gain the highest return on investment for your process analytics equipment. (See "Which Costs More: DIY, or a Service program," page 10.)

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6 Conclusion

Service programs are the key to maximizing the value of your process analytics assets and minimizing expensive downtime and quality issues. A proactive service program can help improve productivity, reduce operating costs, and improve your bottom line through five critical steps:

1. **Develop a comprehensive and proactive service program** with a professional service provider that covers all of your process analytics equipment to reduce downtime, maximize cost controls, and extend the life of all your process analytics equipment.

2. **Build your service program with the original equipment manufacturer** to utilize their product expertise, factory designed service procedures, and benefit from their access to spare parts that no other service provider can offer.

3. **Plan professional Setup and Configuration services** for new process analytics equipment as this is the critical first step of process optimization by aligning the new equipment with your process and securing equipment qualification documents that satisfy quality and regulatory requirements.

4. **Utilize a professional service provider for calibrations** to minimize the chance of out-of-tolerance measurements that can cost you in waste, rework, and even brand reputation in the case of a recall.

5. **Include preventive maintenance services into your service program** to pro-actively reduce the chances of experiencing the dual expense impact of unplanned downtime; emergency repair costs plus lost production.

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7 Supporting Documentation

Which Costs More: DIY, or a Service program?

Maintenance managers choose one of two approaches for servicing their process analytics equipment: a do-it-yourself (DIY) or reactive approach that typically only involves service experts when issues arise, or a proactive service program approach that includes planned proactive maintenance. While either approach can provide some level of setup, configuration, calibration, and preventive maintenance activities, we will see in the following paragraphs and figures exactly how a proactive service program with a professional service provider can pay off in terms of both present and future cost-savings.

Some managers believe that doing it themselves offers a cost savings. However, a closer look at the lifespan of a typical process analytics asset reveals many hidden surprise costs associated with operating the equipment in the absence of a service provider with deep knowledge about the equipment and compliance. This reactive DIY approach tends to increase total cost of equipment ownership by increasing the likelihood of downtime and quality failures. These costs can exponentially increase costs to the business while also stretching maintenance budgets as well as internal personnel and resources to their breaking point. Nobody wants deadlines compromised because the asset needs service before it is usable.

Let's look at the two scenarios.

Fig 1. Likely Process Analytics Equipment Experience with a "Do-It-Yourself" Approach

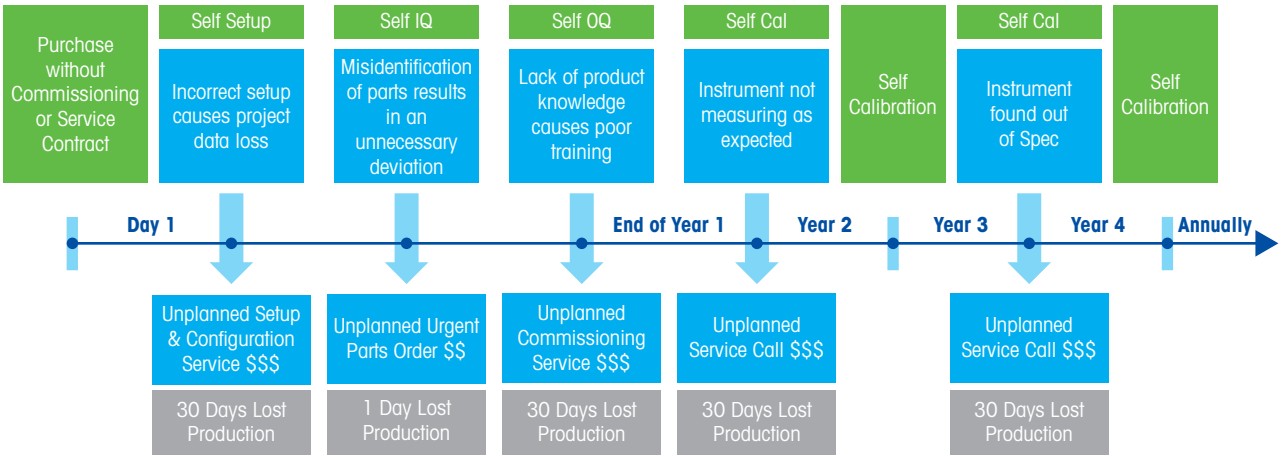
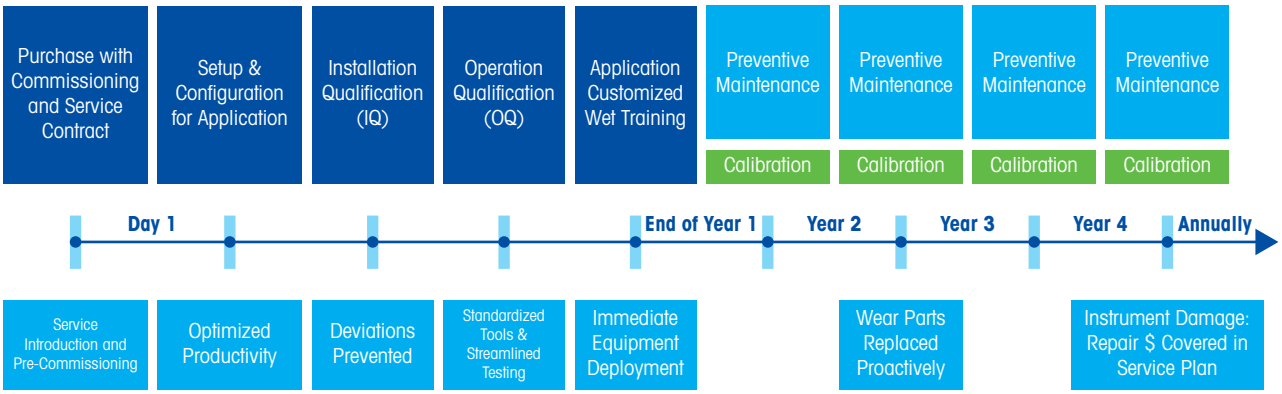


Fig 2. Likely Process Analytics Equipment Experience with a Proactive Service Program



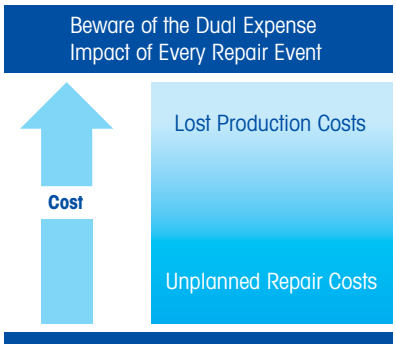
The DIY Approach

With the typically more reactive DIY approach in Fig. 1, there is a substantial risk of process disruption due to the lack of effective preventive maintenance and calibrations. Each process disruption creates a dual expense impact:

- The unplanned costs of an escalated service call and urgent parts order
- The cost of lost production

The unplanned service call can push your maintenance spend over budget. The cost of lost production is highly dependent on your process but can be enormous: thousands of dollars, tens of thousands of dollars, or more. Typically, in modern manufacturing environments, companies cannot afford the steep cost of lost production or the damage to brand reputation due to a recall.

In addition to these higher ongoing costs, the DIY approach also puts a business at greater risk of crossing the point of diminishing returns where the cost of continuing to operate the equipment is greater than its contribution to your productivity. This scenario is best avoided through regular preventive maintenance services provided by a service professional who can identify the end of useful life and recommend actions to maintain high productivity before diminishing returns affect your business.



The Service Program Approach

When you prearrange a service program with the equipment manufacturer (Fig. 2), process disruption and quality risks are drastically reduced while maintenance budgets are predictably controlled. You are able to leverage the expertise of the equipment manufacturer to reduce the risk of costly downtime and maximize the life of your process analytics equipment.

A service program also ensures use of the highest-quality calibration procedures and tools to ensure compliance to quality and regulatory standards. Service programs can typically be tailored to your needs in terms of duration, billing frequency, and parts & labor. Often, they will also provide remote support and priority service response. Each of these features can help to ensure your budgets are managed and greatly reduces the risk of financial surprises.

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