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How Site Surveys With Coatings Experts Help Facilities Prioritize Repairs and Breathe Easier

SHARON LEE
Pharmaceutical Market Segment Manager,
Sherwin-Williams Protective & Marine

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By Sharon Lee, Pharmaceutical Market Segment Manager, Sherwin-Williams Protective & Marine

Audit Calm is a state of mind. It's the confidence you feel knowing your pharmaceutical manufacturing facility is totally prepared for a Food and Drug Administration (FDA) inspection at any time. That confidence comes, in part, from having a preventive maintenance and repair program in place for your floors, walls, ceilings and other surfaces. It remains in place by keeping up with that program and by having the appropriate documentation on hand.

Audit Calm is accompanied by visually pleasing results. The coated surfaces throughout your plant look intentional and uniform. Finishes are aging predictably and can be cleaned reliably. Across all rooms, areas, corridors and entryways, there is consistency in quality and design. In sum, nothing exists to attract the inspector's eye, create a cause for inquiry or upset the tone of the inspection.

Audit Calm is the antithesis of rushed, makeshift repairs in the hours before an inspection. Instead, coated surfaces that need attention are identified months in advance, prioritized and scheduled, and assigned sufficient budgets for maintenance.

While 90% of plants pass their inspections, that doesn't necessarily mean the personnel at these plants are operating with Audit Calm. In some cases, they may just be getting by, locked in a cycle of reactive maintenance, as they address this emergency need, and then the next one. In today's world of budget and staffing constraints, it's not difficult to imagine how best practices can erode. One project is deferred in favor of another that appears more urgent. The preventive maintenance plan falls behind or becomes out of date. Internal inspections lapse, and plant personnel who see the same walls and floors every day become blind to small problems, which become larger problems. And the cycle of last-minute repairs and fixes continues.

But Audit Calm is not purely aspirational. It really is attainable. However, it often requires a reset in the form of a self-audit, with a revised set of prioritized projects and manageable costs. The self-audit stands a much better chance of leading to a sustainable maintenance plan – and a state of Audit Calm – if it involves, or is led by, an expert from your coatings supplier who can perform a site survey side by side with your team. You are best served by having an individual with deep knowledge of the life cycle for each type of coating system in your plant walk alongside your review team. That expert will have insight into what underlying problems may be leading to coatings deterioration and frequent repair needs. Their experience with coatings and pharmaceutical manufacturing plants will help you set the appropriate priorities for both proactive and reactive repairs.

A SEMINAL STEP TOWARD AUDIT CALM

A self-audit looks closely and systematically at all coated surfaces, including walls, floors and seams between these surfaces, as well as steel surfaces, handrails, piping and more. The audit proceeds through all locations in the plant, from processing areas to labs and cleanrooms, hallways and entryways, storage areas and warehouses, mechanical equipment rooms, vivariums and employee welfare areas. The internal audit team usually consists of personnel from engineering, sanitation and maintenance teams. While this team could conduct the audit on their own, there are good reasons to involve an expert from your coatings supplier.

The chief reason to involve an outside coatings expert is specification expertise. The supplier's representative will know which coating systems will hold up and perform best in which locations and yield the best return on your dollar over time. This expertise is particularly important because every area of your plant creates a unique set of conditions and demands, relative to:

- Cleaning protocols, chemical exposure and drainage
- Impacts and traffic
- Cleanliness, antimicrobial capacity, scratch resistance, moisture vapor mitigation, non-outgassing and non-particle shedding
- Static electricity resistance
- Visual appeal and design
- Slip resistance versus cleanability

In addition, in each area of a plant, there are different substrates to consider. For example, walls may consist of concrete masonry units, fiberglass reinforced plastic panels, insulated metal panels or sheetrock. Coatings experts can match the appropriate coatings system to the unique set of requirements, conditions and type of substrate material, with longevity of service always top of mind.



Figure 1. *Resinous flooring is one area a coatings expert will review to ensure a facility is considering the optimal solutions for each space. For example, they may recommend a durable, flake-filled option for corridors to accommodate cleaning protocols and aesthetic goals.*

Flooring is an excellent case in point for relying on specification expertise from an outside provider **(Figure 1)**. Various resinous flooring systems can be used to achieve your desired performance results in pharmaceutical manufacturing plants, with the right choice depending on the needs of the area, the available timing for repairs or installation and your budget.

The nuances among systems are best relayed by a coatings expert to help you arrive at reliable, low-maintenance solutions that match your operations **(Figure 2)**.



Figure 2*. A coatings expert will help facilities choose reliable, low-maintenance flooring solutions that match their operations.*

Such resinous flooring systems fall into mainly three categories:

1. **Thin-Film Coatings**: 2 to 40 mils thick
2. **Slurries:** 1/16″ to 3/16″ thick (solid colored or decorative)
3. **Mortars:** 3/16″ to 3/8″ thick (solid colored or decorative)

A coatings expert can help you understand that thin-film coatings are economical and quick to install, but they're also prone to damage from impact or thermal shock and develop wear patterns in high-traffic areas. So, they may only be the right solution for certain areas. That expert may suggest slurries or mortars instead for better impact resistance, chemical resistance and thermal shock resistance, as well as chemical resistance. A facility or maintenance manager likely won't have much or any of this knowledge, so the coatings expert can be an invaluable resource in identifying the optimal flooring system for a situation and support the development of an appropriate specification that favors long-term performance.

A coatings expert joining plant personnel on a self-audit will also likely draw their attention to the transition between floors and walls. A seamless transition is required to prevent the possibility of bacterial growth at the point where the floor and wall meet and to facilitate easy cleaning. The coatings expert may suggest one of several ways to create a seamless transition – such as installing a cove base **(Figure 3)** – while recommending an approach that will perform best in your plant and be the most economical to install and maintain. He or she can also recommend the right application team.



Figure 3. *During a site survey, a coatings expert may point out the need for installing cove bases (shown) at wall-to-floor transitions to eliminate the otherwise 90-degree interface, which can be a bacteria harborage point.*

A coatings expert can also assist with recommendations to overcome the challenges of insulated piping, including corrosion and condensation potential, which can each be addressed via high-performance coatings. See the sidebar "Insulated Hot or Cold Piping – A Special Case" to learn why.

SELF-AUDIT GOALS AND EXPECTATIONS

The expert from your coatings supplier will ensure, at the outset of the self-audit, that everyone on your team understands the criteria for evaluation. What is the ideal state in terms of the condition of floors, walls, ceilings and other coated surfaces? Per 21 CFR 211.42 of the FDA's GMP:

1. Floors must be smooth, hard and easily cleanable.

2. Surfaces must support contamination prevention.

3. Surfaces must be designed to facilitate routine maintenance, proper facility operations and environmental control.

Conversely, your coatings expert will ensure the audit team understands what visual signs FDA inspectors are looking for as evidence that surfaces are past their useful life, not being maintained properly or not holding up under the particular conditions. For example, they'll be looking for:

- Blistering coatings
- Discoloration or other signs of degradation from cleaning protocols
- Cracking or shadowing
- Mismatched or patchwork repairs

A surface does not need to be in failure mode to create concern with an inspector. It only needs to look inconsistent or be repaired in a manner that is incongruous with the surface around it. Inspectors are looking at these areas with fresh eyes and may target even barely noticeable flaws. So, they want to see evidence that the plant's maintenance is intentional and methodological. Random repairs are blaring signifiers that the opposite is true.

More obvious signs of problems would include rusty equipment, peeling or flaking paint, porous surfaces that could harbor bacteria, seams or crevices (especially where floors meet walls), improperly sloped drains, wet floors or standing water, or other slip-fall hazards.

SITE SURVEY DOCUMENTATION

Your existing documentation is an integral part of a site survey. Your coatings expert will review this documentation in advance of the walk-through, and your internal audit team can do the same. You will want to note the age of each coating system in the plant; whether repair and maintenance schedules have been maintained; and whether there are any coatings in the plant that are requiring frequent repairs, suggesting the specified coating system may be incompatible with the conditions in that area. By reviewing the documentation in advance, you will be approaching the walk-through with an understanding of which areas deserve special scrutiny.

SITE SURVEY WALK-THROUGHS

The walk-through is an opportunity for the coatings expert to model how a self-audit should proceed, observing and recording the condition of all coatings in the plant. With all members of the internal team present, everyone can be sure they are seeing the same signs of problems or issues. Since the internal team sees many of these surfaces every day, they may be surprised by what the outside coatings expert observes from the point of view of someone new to the location. The walk-through can also be an occasion to raise questions or provide explanations or history about coatings and surfaces in the plant and the conditions they may be subject to.

SITE SURVEY SPECIFICATIONS, ESTIMATES AND PRIORITIES

When you invite a coatings expert to participate in your self-audit, you will receive a comprehensive, detailed audit report following the walkt-hrough. It contains recommendations for each area of the facility in terms of urgency and priority. They can also provide a list of qualified contractors to apply the coatings (which can be used for bidding purposes). The detailed report is intended to identify all risk areas that would require attention in a six- to 12-month time frame.

ALL THE WAY TO AUDIT CALM

Audit Calm is a function of organization. If you know the condition of the coatings in each area of the plant, what it will cost to address the repairs, and in what time frame they should be addressed, you are a long way toward Audit Calm. By conducting a thorough self-audit in collaboration with an expert from your coatings supplier, you will have achieved all this in a short period of time. The expert from your coatings supplier will ensure the specifications in the audit report are precise and that the repairs will be efficient and cost-effective over the long term. Further, going forward, you will have an expert on hand who understands each repair or replacement project in your maintenance plan and can assist you with any questions relating to application, specification changes, cost or timing. By maintaining your new maintenance schedule month-to-month and year-to-year, your team will be able to reduce or eliminate unexpected downtime relating to coatings issues and save money through more efficient repairs and longer-lasting coating systems. Your team will also feel more confident and ready for an FDA inspection at any time.

SIDEBAR: INSULATED HOT OR COLD PIPING – A SPECIAL CASE

In a pharmaceutical manufacturing plant, piping, tanks and related assets that need to stay hot or cold relative to ambient temperatures present several risks. There are safety issues: the assets need some form of outer protection to prevent workers from being burned if they bump into them. The assets may also cause condensation, which may lead to corrosion. Condensation can also pool on the floor, creating a slip-fall hazard or an occasion for bacteria to grow. Finally, these assets need to be insulated; otherwise, they would be exceedingly costly to maintain at temperature.

The traditional solution for protecting and insulating hot and cold assets is mineral wool insulation covered in steel cladding, but this approach introduces the possibility of the formation of corrosion under insulation (CUI), which can degrade the assets without any visual signs **(Figure 4)**. While mineral wool insulation is very effective when it is first installed, it loses up to 85% of its R-value when the mineral wool reaches just 10% water volume, which often occurs because of condensation. Mineral wool and cladding is also costly to install, monitor and maintain. Inspection and repair of these systems can be a common reason for plant downtime.



Figure 4. *An example of the damage that corrosion under insulation (CUI) can cause on insulated piping.*

Fortunately, the latest generation of thermal insulative coatings (TICs) provide the same benefits at much lower costs, with minimal maintenance and no risk of CUI. For example, the TIC Heat-Flex® Advanced Energy Barrier (AEB) from Sherwin-Williams Protective & Marine can maintain operating temperatures up to 177°C (350°F), with excursions to 204°C (400°F). In these temperature ranges, the insulating properties of Heat-Flex AEB are comparable to a traditional system when newly applied (before it becomes wet).

Heat-Flex AEB also protects against burns. Once a single coat of the TIC is applied, the surface temperature of the asset is reduced instantly.

TICs are also significantly easier, faster and safer to apply than installing bulky mineral wool systems. Like any coating, Heat-Flex AEB requires a clean substrate so it can adhere properly and deliver long-term service. Usually, some type of blasting is required to remove old coatings and any contaminants from the pipe and tank surfaces. After a primer coat, Heat-Flex AEB is applied on top and can serve as the functional topcoat **(Figure 5)**, or another product can be applied on top to improve aesthetics and durability. With Heat-Flex AEB, plant assets can also be maintained at a temperature of up to 148°C (300°F) during the coating application, which, in many cases, enables plant processes to continue running while the coating is being applied.



Figure 5. *An example of a thermal insulative coating applied to a pipe (before an optional topcoat is applied).*

TICs represent one example of how a coatings expert, in connection with your self-audit, can introduce new solutions that greatly reduce labor, downtime and maintenance, enabling plant personnel to move forward with the projects on their maintenance schedules, rather than having to double back to address unplanned work for high-maintenance systems like mineral wool insulation and cladding.

ABOUT THE AUTHOR

Sharon Lee is Pharmaceutical Market Segment Manager for Sherwin-Williams Protective & Marine. She has more than 20 years of experience in the coatings market and is active in local ISPE and AMPP chapters. She focuses on helping facility teams reduce uncertainty through stable, long-term coating solutions. Contact: Sharon.L.Lee@sherwin.com

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North America
sherwin-williams.com/protective
swprotective@sherwin.com

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