Applying Best Vent Ducting Practices from the Semiconductor Industry to Pharma Facilities

Fluoropolymer Coated Stainless Steel Piping and Ducting Offers Significant Maintenance and Operating Cost Savings

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Given an ever-changing body of rules and regulations, pharmaceutical and biotech facilities must be as flexible as possible, to meet existing mandates and anticipate proposed regulations. A growing number of drug manufacturers are focusing on facility exhaust systems as an area where improvements can be made.

Aiding them in their improvement efforts are innovative materials of construction. This article will focus on the use of fluoropolymer coated stainless steel piping and ducting in both cleanroom and non-cleanroom applications.

Fluoropolymer coated stainless steel was first used by the semiconductor industry in the 1990s, but is now finding increased use in pharmaceutical and biopharmaceutical manufacturing, driven by such regulations as the U.S. Environmental Protection Agency's (EPA) Ruling 40 CFR and the National Fire Protection Association's (NFPA) Standard 318 for cleanrooms.

Enacted in 1998, EPA's ruling 40 CFR imposed strict standards, with the goal of reducing industrial emissions of hazardous air pollutants and toxins by around 65%. To meet these regulations, many drug manufacturers use a regenerative thermal oxidizer (RTO) to incinerate the chemicals, or a caustic scrubber system to remove some emissions. Often the two technologies are used in tandem, so that the scrubber removes hydrochloric acid emissions from the oxidizer.

Coated duct installation on the roof of a California Biopharmaceutical Pilot Plant. (Photo courtesy of Hellwig Plumbing)

Increased use of thermal oxidizers and scrubbers has resulted in the need for materials that can carry these hazardous pollutants to the vent collecting and destruction system without compromising plant safety. As a result, more facilities are specifying the use of high temperature and corrosion-resistant fluoropolymer coated duct and piping.

Coated Ducting in the Manufacturing Suite

Fluoropolymer coated stainless steel ducting can be used in manufacturing suites, the synthesis and formulation areas within pharmaceutical manufacturing, and pilot-plant operations. Such areas typically use specialized materials of construction for reactor vessels, process equipment and process piping, including borosilicate glass, glass-lined steel, exotic alloys, and fluoropolymers.

Reactors, filter-dryers and other process equipment in this category are usually of ASME pressure-rated type, capable of containing process liquids and vapors up to 150 PSIG, and it usually incorporates a vent nozzle or relief device connection.

The manufacturing suite may have a general exhaust system, or snorkel vents at individual equipment stations. However, many facilities today are also incorporating large walk-in reactor enclosures and fume hoods that are tied into the process vent system. In these applications where higher pressures and full vacuum are customary, fluoropolymer coated schedule 10 pipe (150 PSIG rated) would be an appropriate choice for corrosive vent lines.

Ducting for Cleanroom Venting and Exhaust

In pharmaceutical and biopharmaceutical cleanrooms, it is essential that every trace of any hazardous vapor be completely removed from an entire room, or piece of equipment. Fluoropolymer coated stainless steel ducting can be more effective than traditional piping, in these types of facilities. Cleanroom exhaust, fume hoods, snorkels, walk-in reactor enclosures and Biological Safety Cabinets (BSC) used to store chemicals with corrosive fumes, can all benefit from the use of fluoropolymer coated stainless steel duct, rather than pipe.

Coated stainless steel exhaust duct staged for installation at a NY State University research center. (Photo credit V. Rocca, Fab-Tech, Inc.)

These negative and low-pressure systems are governed by Sheet Metal and Air Conditioning Contractor's National Association (SMACNA) HVAC guidelines. In applications where biologic agents are involved, but no corrosive chemicals are present, exhaust is usually passed through a high-efficiency particulate air (HEPA) filter and perhaps even a carbon absorption (CA) filter. In this situation, uncoated stainless steel duct could be used. But if the process is one where corrosive chemical vapors are produced (which can potentially damage HEPA filters) duct material with a higher level of corrosion resistance, such as fluoropolymer coated stainless steel, should be considered.

Additional areas for use of fluoropolymer coated duct include "clean air" supply duct system feeding the biopharmaceutical cleanroom. Hot, corrosive, ultra-pure WFI (water for injection) is used to set incoming air humidity levels. Some biotech/biopharm manufacturing facilities have ex-

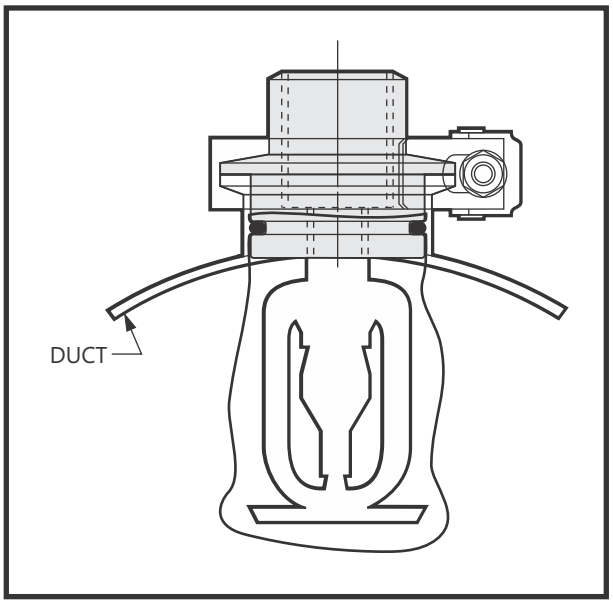
perienced corrosion in the galvanized and even stainless steel supply air ducting from hot WFI vapors. Fluoropolymer coated duct can be used in this application to provide years of maintenance free service. Coated duct is also impervious to harsh chemicals used to disinfect and sterilize cleanrooms and ducting. Chemicals used can range from sodium hypochlorite (bleach) to quaternary ammonia to phenols to formaldehyde-based chemicals. Steam temperatures for sterilization can often exceed 120°C (248°F). All types of chemistry, up to 300°F, can be easily handled by fluoropolymer coated duct.

Potential Hazards

As in the semiconductor industry, hazards in the life sciences industry are ever-present. They include fire or explosion due to the use of solvents, flammable liquids or dust, and the resulting contamination of production, storage, and cleanroom areas by smoke or other substances released by the fire. The role of fluoropolymer coated duct is to contribute to the overall safety of both the facility and its inhabitants by providing a reliable, corrosion resistant conduit for the gaseous by-products of manufacturing, even in the most extreme situations.

Many building codes and insurance companies require ducting made of stainless steel or other noncombustible materials. In some instances, fiberglass and other combustible duct materials may be used but require the use of internal sprinklers.

As stated in the National Fire Protection Association's Standard 318 "3-3.6: Exhaust duct systems shall be constructed of non-combustible materials or protected with internal sprinklers in accordance with 2-1.2.6. Exception: Ducts approved for use without automatic sprinklers." The NFPA standard continues with a hierarchy of material preferences, "3-3.6: Considering fire protection issues only, duct materials listed in descending order of preference are: (a) metallic, (b) approved coated metallic or nonmetallic not requiring fire



Exhaust duct with internal sprinklers will add significant costs to an exhaust duct system as compared to a fluoropolymer coated unsprinkled system.

sprinklers, (c) combustible with internal automatic sprinkler protection."[1] (See illustration) Note: "... although most NFPA standards are not laws, they are widely accepted industry standards with considerable legal standing. Failure to comply with them can potentially put manufacturers in serious liability."[2] Factory Mutual (FM) approved stainless steel duct coated internally with a fluoropolymer satisfies this requirement without the use and costs of an internal sprinkler system.

When selecting pipe or duct for corrosion exhaust applications, it is critical to choose a product that is rated by Factory Mutual, an affiliate of FM Global, an insurance company devoted to reducing commercial and industrial property losses and maintaining the continuity of its policyholders' business operations. The insurer's extensive research is often used to help set new industry standards, develop new products and advance loss-prevention practices.

"In the past, cleanrooms and wet benches (plastic or stainless steel workstations upon which computer chips are manufactured) often need to be protected by sprinklers or more expensive special fire-protection systems like carbon dioxide,

fine-water spray or halon. But, by the time a cleanroom fire propagated and triggered a sprinkler or special fire protection system, damage could already have occurred in the rest of the cleanroom. Due to such factors as potential lost earnings, chip makers are requiring suppliers to use materials in wet-bench fabrication that are less flammable and therefore don't need additional - and costly - fire protection systems installed, so they will be inherently safe when they arrive in the cleanroom."[3]

Manufacturers of fluoropolymer coated stainless steel duct use FM Research's services to earn the FM Approval mark, certifying the reliability of their products. Fluoropolymer coated stainless steel duct is regulated and approved by FM Research Standard Number 4922. With fluoropolymer coated stainless steel duct, structural integrity is maintained in the event of a fire. With extremely low flame and smoke characteristics (flame spread under 10, smoke generation under 15), these systems will not burn or melt or generate large quantities of smoke, an extremely important issue in the life sciences environment. They are inherently safe when they arrive on site.

Coated duct connected to scrubber unit at a California Biopharmaceutical pilot plant. Building was completely renovated from warehouse to cleanroom research facility use. (Photo courtesy of G. Cortes, SMW 104)

Material of Choice: Fluoropolymer coated Pipe and Duct

The choice of materials for the corrosive vent exhaust system is a function of the science and processes employed within the building. It is the role of the design engineering firm, working in conjunction with the architect and client, to choose the highest performing, safest, yet cost-effective materials.

ETFE (Ethylene-Tetrafluoroethylene) and ECTFE (Ethylene-Chlortrifluoroethylene) fluoropolymer coated stainless steel was developed in the early 1990s to address a specific need of the semiconductor industry. Plastic and fiberglass products were just not providing the needed safety and performance. Compared to the more common materials of construction, fiberglass reinforced plastic (FRP), polypropylene (PP) and polyvinylchloride (PVC), stainless steel ducts coated with fluoropolymer offer superior value. Based on published data, fluoropolymer coatings far surpass these other materials in chemical resistance, and the stainless steel tubing does not burn, collapse or leak.

Fluoropolymer coated duct is 300 series stainless steel that is coated with a two-part (primer and top coat) fluoropolymer system, then heated and "baked" to form a chemical and mechanical bond with the stainless substrate. Some manufacturers have developed proprietary primer technology that assures superior adhesion to the stainless steel, resulting in a coating that will not delaminate. The coating is both visually inspected and spark-tested to guarantee a pinhole free surface. Fluoropolymer coatings have been evaluated in over 400 chemical applications, and have been proven superior to both FRP and plastics when tested for corrosion resistance, concen-

ACID	FRP	CPVC	COATED SS
Hydrofluoric	20% @100°F	37% @72°F	35% @275°F
Hydrochloric	37% @180°F	37% @210°F	CONC @300°F
Acetic	50% @180°F	25% @73°F	50% @250°F
Ammonium Hydroxide	10% @150°F	10% @185°F	100% @300°F
Nitric	50% NOT RECOM	50% @73°F	50% @150°F
Sulfuric	80% NOT RECOM	80% @210°F	CONC @300°F

tration and upper temperature limit. (See portion of corrosion resistance table, above.)

In evaluating the level of corrosiveness of a given application, it is vital to consider the entire range of chemicals that the duct system will be exposed to. Even more important is to consider the potential of combinations. "It is also important to evaluate complex systems with several different types of process streams (e.g., reactors, storage tank, relief system) discharging into a common header. Where vents from several sources are combined, it is necessary to carefully consider all possible interactions between the different streams in terms of both chemical reactivity and flammability."[4]

It's reassuring that fluoropolymers have a wide corrosion resistance envelope to handle most chemical situations. Additional reasons for considering coated stainless steel duct include; robust mechanical strength, light weight, ease and speed of installation using rotating van stone flanges or EZ-type clamps, the ability to be field modified (shortened, add nozzles or drain ports) and the fact that the stainless steel exterior will never need painting. Unlike FRP and other "glued" plastic systems, there is no need for grinding, sanding, prep work or the use of malodorous epoxies and heating blankets, especially in the cleanroom setting. Installation time of a fluoropolymer-coated stainless steel system using EZ-type clamps, is the least time and labor consuming high performance duct system available.

With regard to cost, fluoropolymer coated duct is priced competitively against other materials such as FRP, composite materials are PTFE lined pipe. The savings become greater as the duct diameter increases. It is important not only to compare per-foot costs, but also to look at the total installed cost of the system including the mechanical contractor's labor and any related piping and sprinkler costs.

Conclusion

In the past, chemical and pharmaceutical plant operators often specified fiberglass, plastics, stainless steel or even PTFE lined carbon steel to handle corrosive vent applications. Today, many building codes and insurance companies require vent duct made of stainless steel or other non-combustible materials.

The intent of the EPA's Ruling 40 CFR was to reduce harmful emissions and make the air we breathe safer. NFPA Standard 318 is focused on making our work environment safer and less prone to the ravages of fire and smoke. Fluoropolymer coated duct is one step forward in improving the overall safety of both the facility and its inhabitants by providing a reliable corrosion resistant conduit for the gaseous by-products of manufacturing.

Coated Schedule 10 vent pipe installed on the roof of a Pennsylvania Specialty Chemical plant, replaced leaking Schedule 40 stainless steel pipe. Vent streams are from glass-lined steel and Hastelloy reactors and centrifuges. (Photo courtesy of J. Brobson, Design Plastic Systems, Inc.)

Fluoropolymer coated stainless steel duct are materials of construction new to life sciences, but have been successfully used in manufacturing for over 15 years. It meets all the required design and operating criteria for extreme service when applied and installed according to the parameters for its intended use. If corrosive vapors and fire safety are concerns, fluoropolymer coated stainless steel could be the ideal solution. Professionals who design, build or manage life sciences facilities that contend with corrosive and hazardous vapors can benefit by doing additional research into this new type of product.

References

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2. Fire Chief, December 9, 2005
3. Cleanroom Materials Flammability Test Protocol (Class 4910), FM Global
4. Collect and Destroy Emissions Safely, Tony Ennis, Haztech Consultants, Ltd. Chemical Engineering Progress, May 2004

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