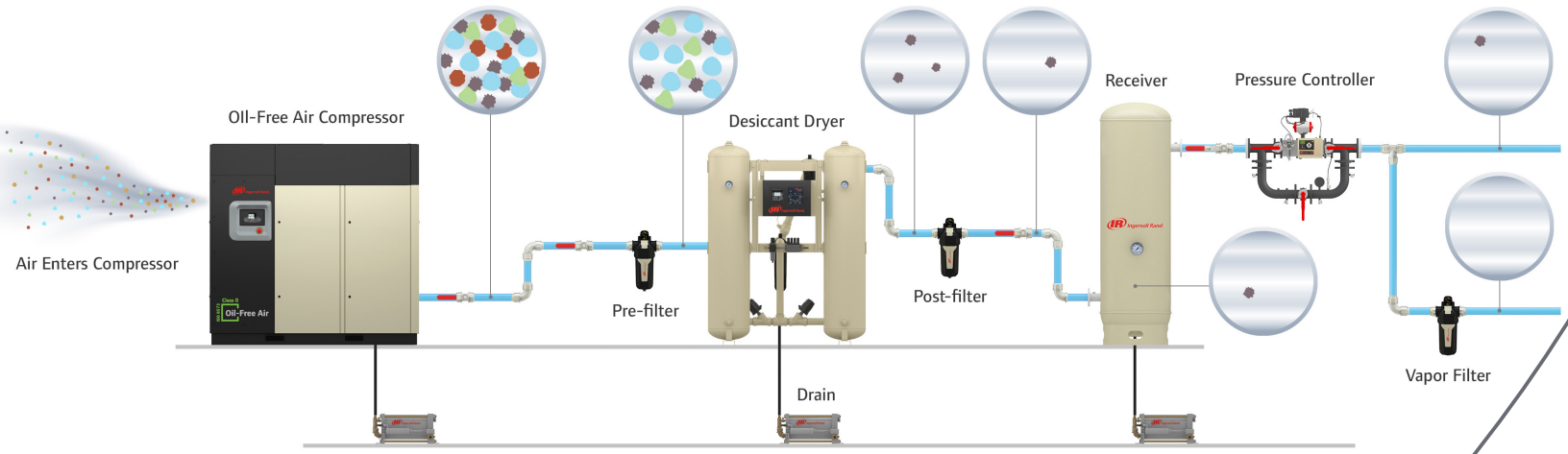
Maintaining Quality Compressed Air in the Pharmaceutical Industry



Maintaining Quality Compressed Air in the Pharmaceutical Industry

This paper is part one of a four-part collection of white papers created to address four crucial aspects of the pharmaceutical industry. Because success in the pharmaceutical industry requires attention to detail on a microscopic level, this paper provides readers with practical strategies for maintaining industry-standard compressed air in pharmaceutical production plants. Even a trace of contaminant can lead to wasted product, unnecessary downtime and exposure to liability. So, understanding the risks and the types of compressed air solutions available will help you match your unique processes with the right equipment. Here are some steps you should consider.

PRODUCTION AREA RISK ASSESSMENT

Many experts start by evaluating the production process and the facility itself for potential risks. Where will the compressed air impact product quality? What potential contaminants are present in the facility or could be introduced from outside sources entering the space, such as hydrocarbons from loading dock exhaust near the intake of the compressor. The more complex the production process, the more complex the evaluation. An OEM supplier familiar with Good Manufacturing Practices can help you conduct a thorough and accurate assessment.

Follow up the production process and facility evaluation with an evaluation of allowable contaminants, based on the specific pharmaceutical application. Possible variables in this discussion are air-borne particulates which include living and non-living microorganisms. These contaminants can ultimately find their way into the final product via the air ingested into your air compressor. Additionally, water is introduced into the compressed air system from the humidified intake air that is heated then cooled, creating condensed moisture. Such moisture can be problematic. Finally, many compressed air systems discharge the oil used to cool and lubricate the compressor into the air system. For pharmaceuticals, since oil can be entrained in the discharge air stream, an oil-injected compressor is often eliminated as a viable compressor alternative. Oil-free compressors specifically designed for pharmaceutical production, whether centrifugal or rotary screw, are most often the choice in pharmaceutical manufacturing. Ultimately, a clear understanding of which contaminants, and at what level, are allowed for your unique production environment will be critical for deciding the proper components and design of your air compression systems.

EVALUATING SYSTEM NEEDS

There are some key considerations when evaluating your air compression needs. The supply side of an air compression system is responsible for providing clean, dry air at the correct pressure, optimal air purity, and best flow rate for the pharmaceutical application. Implementing pressure/flow controllers can dramatically improve the performance of your systems and assist in regulating the optimal pressure rate needed for the application.

The exacting standards of the pharmaceutical industry can be overwhelming when human health is on the line, but know that there are practical steps manufacturers can take to minimize the harsh realities of safe drug manufacturing. Determine what type of equipment will provide the air quality needed to accomplish

the task within industry regulations and safety standards. Air compressors intended for pharmaceutical applications should be designed and constructed with oil-free capabilities. Additional considerations include air dryers and filters. Since unwanted moisture can harbor unwanted viable particulates, the driest compressed air possible is often specified, so an adsorption-type twin tower desiccant dryer or subfreezing dryer, both of which can reach lower dew points, may be better suited than a refrigerated dryer. Then, consider how the compressed air will be distributed utilizing hygienic piping, such as medical gas grade copper, aluminum, or stainless, to ensure a clean, final delivery at the air's intended use. In addition, pharmaceutical air distribution systems may utilize a final filter at the point of use rated at 0.1 µm or smaller to protect the product from airborne contaminants.

Quality air is essential for effective production in pharmaceutical applications. Yet, insuring that your operation has the quality air you need at the correct purity, flow, and dew point for the best price can be complex. Partnering with a knowledgeable air compression solution provider, like Ingersoll Rand, who has your company's success as its inspiration can be a good option. Ingersoll Rand is a global total solutions provider for compressed air, offering everything from oil-free compression technology, clean and smooth extruded aluminum piping, and optimal dryer solutions. Ingersoll Rand's wide range of compression solution options work together to ensure all aspects of your production line remain contaminant-free and your air quality meets industry regulations and your risk assessment requirements. The next paper in this series will focus on waste reduction, another crucial aspect to address shrinking profits in the pharmaceutical industry.

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