INGERSOLL RAND WHITE PAPER | MARCH 2025

How to Produce Consistent, Clean Dry Air for API Applications, whilst Preventing Equipment Issues and Downtime

Ingersoll Rand®

Introduction: A Constantly Growing Industry

API (Active Pharmaceutical Ingredients) is a subsegment of the pharmaceutical industry that is tasked with producing the active ingredients that go into pharmaceutical products. As Active Pharmaceutical Ingredients, they are the specific substances responsible for the desired effect they have on the individuals consuming the medication. These chemical ingredients (API) are then often sent to CMOs (Contract Manufacturing Organisations) or pharmaceutical companies that will mix them with excipient to make the tablets, parenteral liquid or powder. However, in some cases, the API CMO does both the manufacturing of the Active Pharmaceutical Ingredients and the final product.

The API sector represents 60% of the total pharmaceutical market, and this figure is growing by 6% per annum. This is due to a large number of drug patent expirations approaching in the coming years, which is causing big pharmaceutical manufacturers to sub-contract their API needs to CMOs. As a result, the number of API CMOs is growing by over 7.7% per annum. These shifts mean that producing consistent, clean, high-quality compressed air has never been more important to fulfil growing demand, but we've noticed a couple of issues. In conversation with our API and CMO partners, it has been revealed that the major factors plaguing their operations are the prevention of contaminants, costly leaks, the need for predictive maintenance and methods to ensure consistency. This is where we come in! In this White Paper, we aim to put your mind at ease about each one of these concerns

In This White Paper, You Will Learn:

- The uses of compressed air in the Active Pharmaceutical Ingredient (API) sector
- How to produce consistent, clean, dry air for your API applications whilst also preventing equipment issues and downtime
- How to select the right air compressor and the solutions we have available to you
- How to find service and maintenance programs that optimise the total cost of ownership

Compressed Air In The API Sector - Mitigating Contamination Risk

Compressed air plays a vital role in the API subsegment of the pharmaceutical industry for a variety of applications and production processes. Ensuring consumer and product safety is essential in this industry, meaning that air quality is of paramount importance. This is especially important as many API production processes are contact applications, meaning that any air that comes into contact with the final pharmaceutical products must be of the highest purity standard. Typically, this means that most, if not all, API applications will require ISO-certified, Class 0, 100% oil-free air. Therefore, mitigating compressed air contamination risk is a critical consideration at every stage of your facility's production processes.

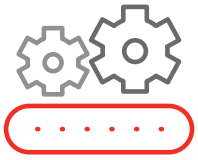
Applications That Rely On Compressed Air In The API Sector

Fermentation:

Fermentation is the production of healthy bacteria and is a process that involves the conversion of organic materials into relatively simple substances by microorganisms. During antibiotic production, as well as in other oxidation processes, compressed air is used during the fermentation process to supply oxygen to the bacteria. Contamination poses a big risk here as even small oil traces will kill the bacteria and spoil the end product, leading to product waste and potential consumer risk. Therefore, an effective downstream system is essential here to ensure the production of 100% oil-free air. Reliable filtration should be carried out to ensure that any oil, dust, or other particulates are removed from your air stream. Dryers and condensate management are also important here to ensure your air is clean, dry and moisture-free.

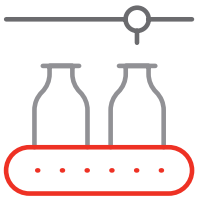
Tablet Production:

Another application in the API sector that requires compressed air is tablet production. Compressed air is used to spray coatings on the tablets. As this is a contact application, and oil in the air would be directly deposited on the tablets, increased purity is vital. Failure to treat your compressed air will lead to product rejections and consumer health risks. To avoid this, as with the above, an effective downstream system is of utmost importance here.



Automated Production Lines:

Automated production lines in the pharmaceutical API sector utilise pneumatic cylinders, control valves and components, all of which are powered by compressed air. If oil is present in your compressed air, then it will contaminate the production space, leading to possible contamination of the end product. Ensuring an efficient filtration system is therefore important to remove any harmful contaminants. An air dryer is also fundamental here to remove excess moisture from your compressed air, as moisture is the known enemy of pneumatic equipment. The presence of it in your air stream can not only lead to product contamination but also accelerated equipment degradation. This is because moisture rusts and corrodes its components and parts, leading to potentially hazardous equipment breakdowns and inefficiencies, thus making its removal essential.



Packaging and Bottling:

Compressed air is also used for the conveying of tablets, as well as for blister packaging and bottling. Despite being one of the last processes, it is still important to stay vigilant and prevent contamination. If any oil is present in your compressed air, even at this stage, contamination will occur, resulting in rejection, product spoilage and compromised labelling. As mentioned above, effective air treatment is uncompromisable here to avoid these issues.

Aseptic Applications:

Compressed air is also vital for a range of aseptic applications. These can have different pressure requirements. However, one thing is certain: they demand Class 0 air quality. '100%' oil-free air in these processes may not actually suffice, as small amounts of hydrocarbons may still be present in the air from the intake of ambient air, which may contain contaminants, e.g. vehicle exhaust or industrial pollution. Therefore, optimal air purity is critical! Implementing an ISO Class 0 certified air treatment system is the most reliable way to ensure the continuous production of air of the required purity for these applications.

Removing The Pain Points

How To Produce Consistent, Clean, Dry Air For API Applications Whilst Also Preventing Equipment Issues And Downtime.

1. AIR AUDITS

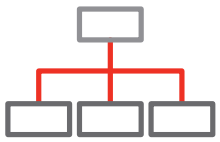
A significant amount of equipment issues and inefficiencies all stem back to the very foundations of your compressed air system. Whether this is due to insufficient or wrongly sized equipment or piping or due to other gaps in your system, these issues will contribute towards costly downtime. A complete air audit can help here by assessing your existing compressed air system, checking for any issues, inefficiencies and leaks, as well as identifying any areas of potential improvement. After this analysis, your system can be adjusted and enhanced to ensure it aligns with the pressure, flow and air demands of your API production applications. This will have a positive impact on the entirety of your operations, specifically for powering any pneumatic production equipment, as these have precise pressure and air flow demands.

2. LEAK ASSESSMENTS

From discussions with our pharmaceutical API partners, waste reduction is an issue that crops up, as having negative impacts on production processes. This is because compressed air is expensive in itself, and compressed air leaks are even more expensive. Not surprisingly, an increase in the leak's diameter is directly matched with an increase in production costs, which can have a significant impact on your facility. As an example, the US Department of Energy concluded that a low to moderate compressed air system leak can waste up to 20-30% of the compressor's output. Say, for example, the leak in question was equivalent to 20% of the total air produced. When calculated using the average number of production hours per year and average power costs, this could result in financial losses equivalent to €16,700 per year! Understanding the signs of a leak, as well as frequent leak assessments, is therefore vital to maximise your uptime and minimise the impacts of leaks and any unnecessary costs. Leaks are typically unavoidable, which is why we offer a full ultrasonic leak detection service to assist your API facility.

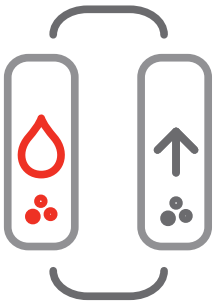
3. CHOOSING THE RIGHT EQUIPMENT

While oil-flooded compressors can technically be used for some less critical API production applications, their oil-free counterparts are typically preferred due to the high standard of air quality required. However, if you do have oil-flooded compressors operating anywhere in your facility, oil sampling assessments are vital to ensure air purity. When considering the right solution for your API applications, aligning your compressed air technology with your purity, pressure, demand and flow needs is important to ensure the consistent production of high-quality air and to prevent equipment issues or downtime. We offer a guide on selecting the right compressor later on in this White Paper to aid your decision.



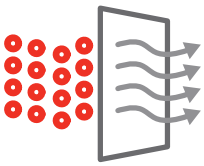
4. AN EFFECTIVE, RELIABLE DOWNSTREAM SYSTEM

Another major concern of API producers is preventing contaminants. As mentioned in the applications section, an effective and reliable downstream system is vital to eliminate contaminants and ensure the continuous production of high-purity ISO-certified compressed air. This consists of 3 major components:



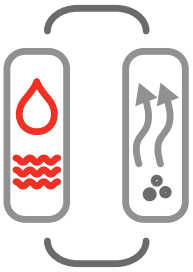
Dryers:

First up are dryers, an essential component for the removal of excess moisture from your compressed air. As mentioned, not only is this vital to ensure air quality, but it also helps to prevent any unexpected, costly downtime due to equipment issues and breakdowns. There are a variety of dryers on the market, but typically, for pharmaceutical API applications, we'd recommend desiccant dryers because of the high standard of air required. Desiccant dryers are renowned for their ability to supply ultra-dry, high-quality air at a low-pressure dew point (typically from -20° C to -40° C or from -4° F to -40° F). Some API applications will require a pressure dew point of 3° C or 38° F, so refrigerant dryers are also used in these circumstances.



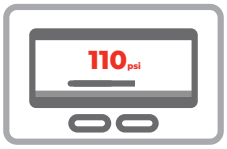
Filtration System:

Next is a reliable filtration system, which is crucial for eliminating contamination and impurities such as oil, dust, and moisture. This is particularly important because most, if not all, pharmaceutical API applications require ISO Class 0 air. By implementing a filtration system, you can mitigate contamination risk and protect the integrity of your compressed air and production line equipment. Effective air filtration is particularly important for any contact applications, such as fermentation and chemical ingredient or tablet production, in your manufacturing facility. This is to ensure that any air that does come into contact with pharmaceutical products meets consumer safety requirements.



Condensate Management & Treatment:

No downstream system is complete without an efficient condensate management and treatment system. Condensate is a natural by-product of compressed air, but due to the mixture of oil and water produced, it is actually classified as a type of hazardous industrial waste. This is something you definitely don't want anywhere near your API applications, making correct and safe condensate management vital! The most effective way to deal with condensate is by implementing a condensate management unit, which often contains timed or zero-loss drains. These drains transport condensate to an oil-water separator, which, as its name suggests, separates out the oil from the water. The condensate or zero-loss drains are typically equipped with set timers, which will then transfer it from the oil-water system out of your compressed air system. An oil-water separator is crucial here to ensure the correct and safe removal and disposal of condensate that aligns with stringent industry requirements.



5. PROACTIVE MONITORING, MANAGEMENT AND CONTROL

We understand that product safety is paramount in the pharmaceutical API sector, which often means that looking after and managing your compressed air system can feel like a bit of a burden. Being able to manage and monitor your system in a simple and easy way is, therefore, an effective way to maximise its reliability and performance without compromising your more important daily operations. Compressor controllers are one way in which you can do this, as they allow you to adjust pressure and flow rates to prevent inefficiency and wasted energy. There are a lot of different pressures involved in API applications; compressor controllers can help you meet these requirements without wasting any energy.

Other solutions involve proactive, remote monitoring and control using IIoT cloud-based technologies. These innovative solutions utilise the latest technology to offer you maximised visibility and connectivity to ensure the efficient monitoring of your system. At Ingersoll Rand, we offer the Helix™ Connected Platform and Ecoplant, two solutions geared towards proactive compressor monitoring and control. You can learn more about these in this White Paper's Service and Maintenance section.

6. PREDICTIVE MAINTENANCE, OEM PARTS, AND WARRANTIES

Another concern noted by our API partners was the unfulfilled need for a predictive maintenance solution that protected their operations and equipment. A predictive approach towards maintenance ensures that your compressed air system is consistently performing to industry standards at a competitive level. It also makes sure your system is protected. It's of vital importance that you understand the warranties, OEM parts and accessories, and maintenance plans that are available to ensure the protection of your compressed air investment. For example, later on in this White Paper, you can discover more about our suite of CARE maintenance plans. With our proactive and predictive approach towards maintenance, we have everything you need to prevent equipment issues and downtime. When discussing our available options with our customers, we place special emphasis on discovering more about their exact needs and requirements. This enables us to correctly align one of our plans with their facility. Whether this may be scheduled maintenance, total asset management, OEM parts and accessories, remote monitoring or a warranty, Ingersoll Rand ensures you are receiving the exact service you need! Correctly managing and maintaining your compressed air system is vital to preventing any downtime or issues that may be disrupting your API production processes.

Sizing Up Your Needs - Ingersoll Rand's Available Solutions

As mentioned, the biggest concern for any pharmaceutical company is product quality and safety. Ingersoll Rand has you covered, offering equipment that can provide 100% oil-free, ISO Class 0-certified compressed air.

Selecting the Right Air Compressor

Various applications in your API production facility will require different air compressors. Choosing the right one for your specific application should be done carefully. The key is to make sure the selected unit is able to meet your desired demands, including air quality, pressure and flow rates, while keeping maintenance and operating costs low.

Things to Consider Before Purchasing:

It's essential to address key questions before making a purchase:

- How much airflow is required?
- What are the pressure requirements?
- How clean does your air need to be for this application?
- Which filters or dryers do you need to ensure air quality?
- How many hours will the compressor operate per day?
- Will the flow demand fluctuate?
- Are you going to raise the scope of your operations in the near future?

Oil-Free Air Compressors

Due to the stringent air quality requirements involved in API production processes, oil-free compressors are the ideal solution. At Ingersoll Rand we offer the E-Series, Nirvana variable speed and Sierra oil-free rotary screw models. All of these compressors guarantee a continuous flow of ISO-certified, Class 0, oil-free compressed air for your mission-critical operations. Reliable by design, these compressors offer unmatched performance, efficiency and quality in a range of configurations and power specifications. They are also all optimised for energy savings. We also offer a portfolio of oil-free centrifugal solutions that are well suited to the demands and challenges of the API sector.

Compressed Air Dryers

We also offer a complete range of compressed air dryers that meet the requirements of the pharmaceutical API subsegment. Our range includes heated and heatless desiccant dryers, cycling and non-cycling refrigerated dryers, subfreezing dryers, and heat-of-compression dryers. This allows you to match your dryer technology to your exact production process and requirements. All of our dryers are reliable by design and guarantee the efficient production of continuous, ISO-certified, clean, and dry compressed air.

Service And Maintenance Programs

There are many applications in which you will require high-quality compressed air in your API production plant. You also now understand how to build a compressed air system that produces consistent, clean, dry air for your API applications whilst also preventing equipment issues and downtime. Now it's time to look at how to service and maintain your equipment to avoid unplanned, unbudgeted downtime and production interruptions.

Lower cost of ownership, quality results, increased uptime, and efficient energy use all add up to peace of mind.

PackageCARE™: We Protect You

- The greatest value for asset management
- Transfer operational risk for up to 10 years
- Includes all scheduled maintenance
- Predictive and analytical tools prevent production interruptions

PlannedCARE™: We Help You

- Predictive, on-time planned maintenance
- Preventative diagnostics to catch potential problems
- Up to five-year coverage on major airend components in new rotary compressors

Performance Services

Our performance services include electronic, air leak, and system assessments. Whether you need to manage costs, increase reliability, or plan for future growth, our portfolio of assessment tools provides you with detailed diagnostics that give you the proper insights to help lower the total cost of ownership.

System Automation

System assessments often identify waste caused by a lack of adequate controls. Our suite of system automation solutions lowers energy costs and stability pressure.

HELIX™

24/7 Remote Monitoring With The Helix™ Connected Platform

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Powered by ECOPLANT

Proactive Control With Ecoplant

Ecoplant is a remote, cloud-based compressed air management solution that integrates seamlessly with your network to reduce downtime and increase efficiency. It combines intuitive maintenance with SAAS proactive analytics and controls to respond to your exact production needs. With Ecoplant's innovative IIoT technology, your system is optimised using dynamic AI to stabilise pressure levels, maintain ISO quality standards, minimise production outages, and detect and isolate leaks.

Reliability For Life

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- Generate air in any environment. We offer solutions that operate indoors and outdoors in compact spaces and extreme temperatures.
- Enjoy increased oversight with controls you can access remotely. Regulate your air use with compressor controls that monitor critical operating parameters and adapt the system to prevent downtime.
- Designed for easy serviceability and maintenance, our compressors minimise the total cost of ownership.
- An extensive catalogue of OEM genuine consumable and replacement parts is available to you to make service and maintenance easy and cost-effective. Genuine OEM parts guarantee a perfect fit and function for the highest quality standards.

Protect Your Investment With Ongoing Preventative Maintenance

When it comes to API and other pharmaceutical production facilities, original equipment manufacturer (OEM) parts are an operator's best choice to maintain maximum reliability and performance. Non-standard parts can expose equipment to unnecessary wear and tear, leading to downtime and higher operating costs.

If you want to protect your investment and the performance and longevity of your equipment, make sure to invest in quality parts to keep it running. Ingersoll Rand has a complete offering of maintenance and OEM-quality compressor parts, including lubricants, maintenance kits, replacement parts, filtration, and condensation management, complemented by the expertise to keep your API production facility running.

CARE SERVICES PROGRAM

Find A Partner You Can Trust… Global Service and Support Network

Renowned for its market-leading reliability, quality, and untroubled performance, Ingersoll Rand brings over 160 years of innovative solutions to the compressed air market. In addition to a comprehensive portfolio of best-in-class air compressors, Ingersoll Rand offers various maintenance programs as well as air compressor repairs that use OEM genuine components.

Depending on your needs, Ingersoll Rand offers a range of service packages, from a comprehensive service program that takes the operational risk away from the customer. We also offer a simple package that includes delivering the right part to you at the right time. Choosing the right package that provides the best, most efficient support to keep your business up and running requires careful consideration. To save our customers' time, our engineers will perform a deep analysis to help determine which maintenance plan is the best for your specific industry and application needs.

There's a lot riding on the quality of your air. Let Ingersoll Rand help you get it right!

Ingersoll Rand's Wide Portfolio of Air Compressors

Ingersoll Rand provides a wide range of high-quality, low-maintenance commercial and industrial air compressors to fit every application. Our engineers can provide you with a bespoke solution and the support you need to keep your API or other pharmaceutical production facility working at maximum efficiency.

About Ingersoll Rand Inc.

Ingersoll Rand Inc. (NYSE:IR), driven by an entrepreneurial spirit and ownership mindset, is dedicated to helping make life better for our employees, customers and communities. Customers lean on us for our technology-driven excellence in mission-critical flow creation and industrial solutions across 40+ respected brands where our products and services excel in the most complex and harsh conditions. Our employees develop customers for life through their daily commitment to expertise, productivity and efficiency. For more information, visit irco.com

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Ingersoll Rand compressors are not designed, intended or approved for breathing air applications. Ingersoll Rand does not approve specialised equipment for breathing air applications and assumes no responsibility or liability for compressors used for breathing air service.

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