Linesight

Exploring the Synergies and Adaptability in Human Health and Animal Health Pharmaceutical Manufacturing Facilities

April 2025

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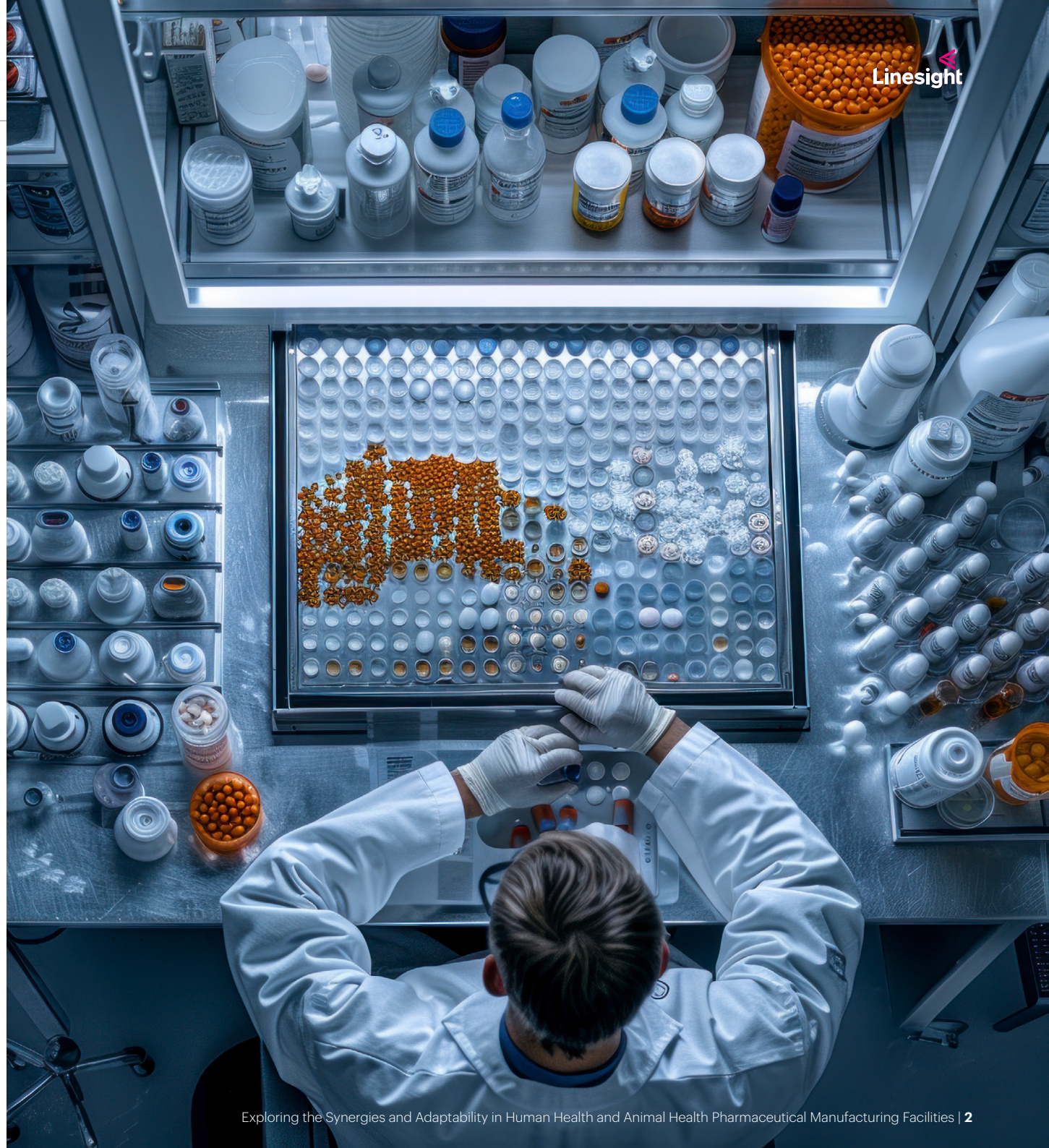


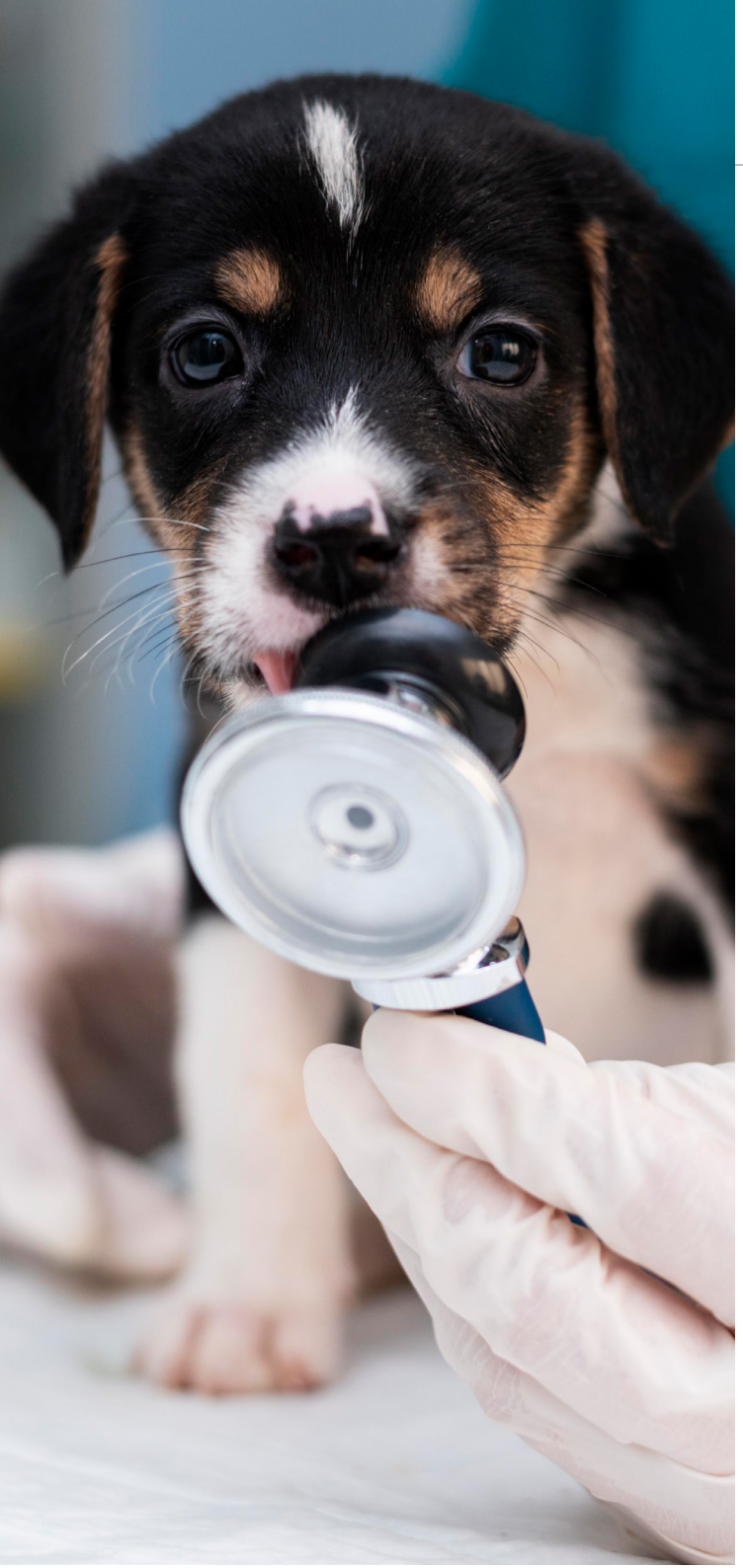
Foreword

The global pharmaceutical industry is constantly growing and changing, driven by the increasing demand for medicines for both **humans and animals**.

While human and animal pharmaceutical plants operate under similar regulatory frameworks and share common design principles, they also cater to distinct requirements due to the differing target populations: humans or animals.

This report dives into the dynamics of both human health and animal health pharmaceutical manufacturing, examining the similarities and differences in facility design, manufacturing processes, operational processes and cost considerations.

Despite the unique challenges of developing medications for animals, both sectors benefit from the same commitment to quality, safety, and efficiency. Furthermore, the modularity of these facilities offers a remarkable potential for adaptability. With minimal adjustments, these plants could be repurposed to meet the needs of either target market, offering pharmaceutical companies greater flexibility and responsiveness to market shifts.



Trends and market dynamics in animal healthcare

Animal health is gaining significant importance globally due to:

- Growing animal population trends
- Increased pet adoption
- Higher pet care standards
- Higher incidence of animal diseases.

These factors, combined with the economic benefits of a healthy animal population highlight the need for continued innovation and investment in the animal health sector.

In 2023, the global market for animal healthcare was valued at US$186.1bn and is projected to grow at a compound annual growth rate (CAGR) of 6% between 2024 and 2032[1]. The pharmaceutical market is experiencing a similar trend, with the global market size at US$1,573.20bn in 2023, and expected to rise to US$2,120.23bn by 2028[2].

The animal healthcare market is divided into two main categories based on the type of animal companion animals and livestock, each with distinct needs, products, and market dynamics.

In 2023, the companion animals segment generated the largest revenue in terms of products at a global level, reaching US$113.2bn and capturing a market share of 60.8%. This segment is further broken down into subcategories, including dogs, cats, horses, and other types of companion animals. In Europe, a similar trend was observed, with companion animals accounting for the largest share of animal medicine sales at 47.3%[3]. This was followed by livestock at 26.8%, poultry and avian species at 10.2%, horses at 2.8%, and non-pet aquatics at 2%.

The largest share of sales in Europe for 2022 comes from vaccines, accounting for 32.5% of total sales, followed closely by parasiticides at 29.2%.

With 346 million pets[4] and 742 million livestock reportedly across Europe, it may seem logical to assume that livestock dominates the animal healthcare market. Yet, companion animals generate significantly higher sales. Pet owners are more willing to invest in premium healthcare, specialized treatments, and advanced

Sources and notes:
[1] gminsights.com/industry-analysis/animal-healthcare-market
[2] towardshealthcare.com/insights/pharmaceutical-market-sizing
[3] animalhealtheurope.eu/Facts-and-figures-brochure
[4] Includes only dogs and cats

vaccines and parasiticides, driving demand for high-value products.

While livestock healthcare remains crucial for large-scale farming, the emotional and economic value of pet care far exceeds its population size.

In 2022, Europe led with about 166m homes[5] (approximately 50% of households), owning pets[6]; followed by the US with around 126m[7].

S.No.	Animal healthcare segment	Population[8] (in millions)	Sales[8] (in €m)	Sales per population[8] (in €)
1	Pets[6]	346	3,736.7	10.80
2	Livestock	742	2,117.2	2.85

Pets

Cats

Dogs

Small mammals

Birds

Aquaria

Terraria

Livestock

Poultry

Goats

Sheep

Pigs

Bovines

Sources and notes:
[5] europeanpetfood.org/FEDIAF-Facts-Figures-2022
[6] Includes only dogs and cats
[7] americanpetproducts.org/industry-trends-and-stats
[8] animalhealtheurope.eu/Facts-and-figures-brochure; data is as of 2022

Presence of animal medicines industry across Europe: Production, R&D, logistics

The table below depicts the geographic presence of the animal medicines industry across Europe, highlighting key areas of production, research and development (R&D), and logistics. As of 2022, the industry has a notable presence in 28 European countries[9].

S.No.	Country	Production	R&D	Logistics
1	Croatia			●
2	Greece			●
3	Latvia			●
4	Lithuania			●
5	Luxembourg			●
6	Portugal			●
7	Romania			●
8	Slovakia			●
9	Ireland	●		●
10	Poland	●		●
11	Sweden	●		●
12	UK	●		●
13	Switzerland		●	●
14	Ukraine		●	●
15	Austria	●	●	●
16	Belgium	●	●	●
17	Bulgaria	●	●	●
18	Czech Republic	●	●	●
19	Denmark	●	●	●
20	Finland	●	●	●
21	France	●	●	●
22	Germany	●	●	●
23	Hungary	●	●	●
24	Iceland	●	●	●
25	Italy	●	●	●
26	Netherlands	●	●	●
27	Norway	●	●	●
28	Spain	●	●	●

Source: [9] *The European animal medicines industry in figures: 2022*, AnimalhealthEurope

Exploring dynamics – human and animal pharmaceutical manufacturing process

As the animal healthcare market continues to grow and evolve, the demand for safe, effective, and species-specific medications increases, highlighting the need for rigorous manufacturing processes. This section explores the dynamics of human and animal pharmaceutical manufacturing, where both sectors share common principles but also face unique challenges due to the distinct needs of their target population.

Animal health and human health pharmaceutical production facilities must comply with Good Manufacturing Practice (GMP) standards outlined by the World Health Organisation and the European Medical Agency which states the minimum requirements for manufacturing processes. Key components of GMP include:

- Adherence to regulatory standards
- Proper facility design and layout
- Robust quality control system
- Suitable equipment and well-trained personnel
- Effective packaging and storage procedures
- Thorough documentation and record-keeping

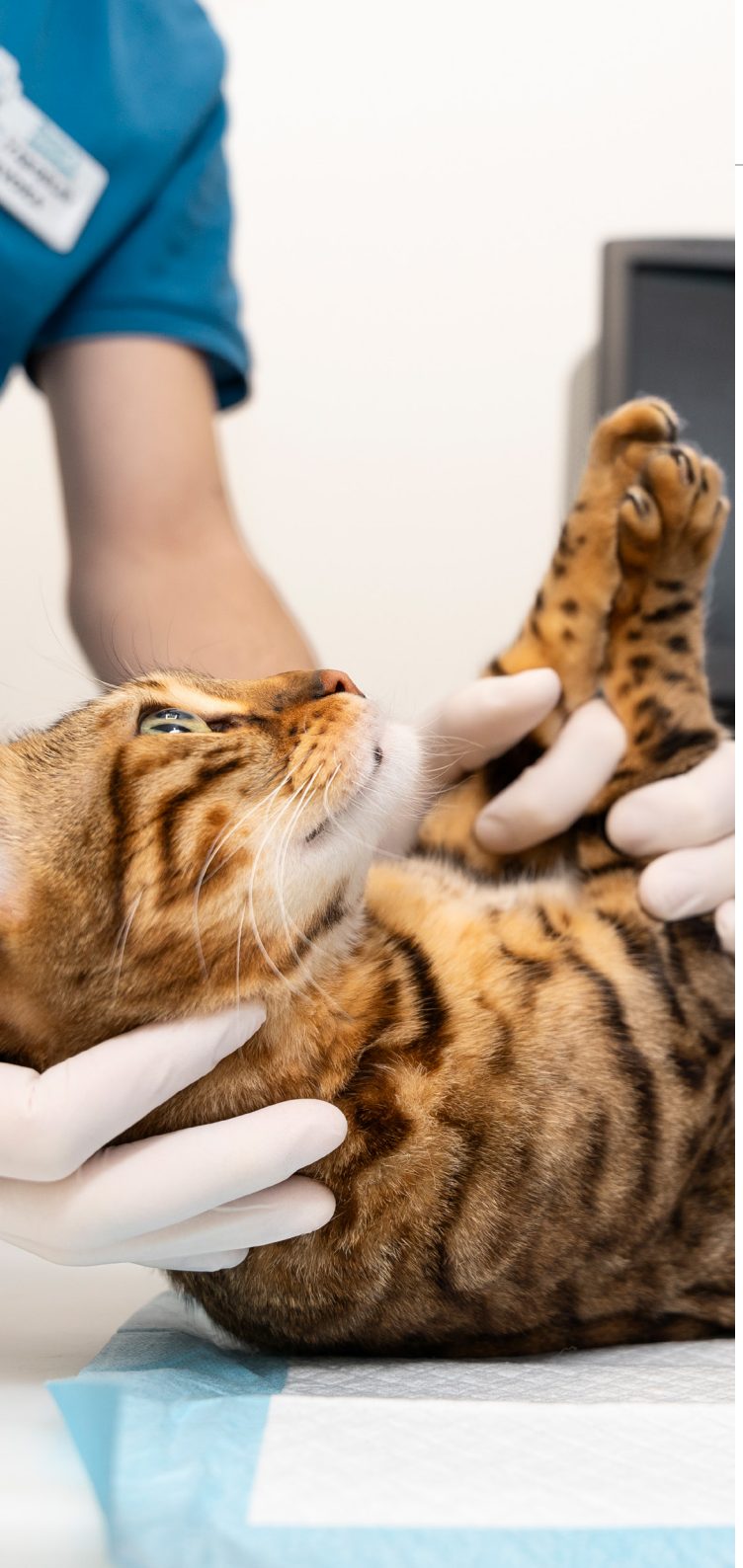
Both the facility types share similar core principles due to the need for quality, safety and regulatory compliance. However, differences might arise from the specific requirements of animal medicines such as species-specific formulations.

The production of pharmaceuticals for animals is governed by strict regulations, aseptic processes, and testing protocols that are comparable to those required for human products along with supplementary research required to ensure the safety of consumers in relation to animals used for food production.

As the demand for pet healthcare products surges, this overlap presents opportunities for adaptive reuse, innovation, cross-industry advancements, and streamlined production processes.

The notable similarities between these two facilities are as follows:

- **Facility Design:** The key elements – such as operational flow, cleanroom design, contamination prevention, production efficiency optimization, adequate storage facilities, spacious workspaces, adaptable layouts for future expansion, versatile production capabilities, and controlled sterile environmental conditions – are fundamentally the same for both human health and animal health pharmaceutical manufacturing plants. In addition to the core facility design, other provisions like parking, administrative facilities, and safety and security systems are integral to both types of facilities.

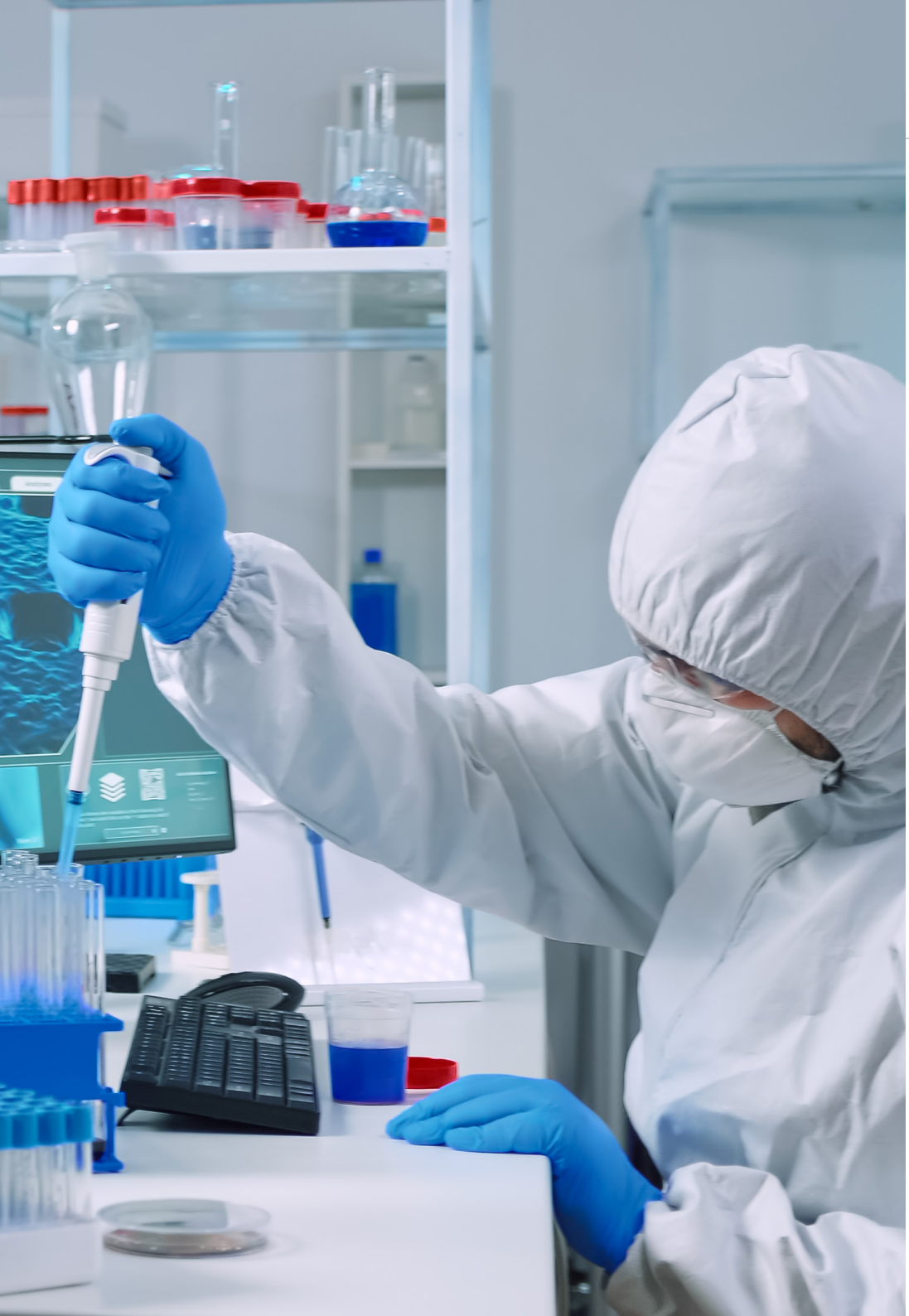


- **Manufacturing process:** The core manufacturing steps which can include synthesis, crystallization, blending, granulation and tableting remains similar for both. However, there are differences tailored to the specific needs of human and veterinary pharmaceuticals.
- **Environmental and personnel monitoring:** Similar environmental monitoring standards such as temperature, humidity, and air filtration, as well as, cleaning, and disinfecting practices, and personnel monitoring protocols, to include gloves, and gowns apply in both cases.
- **Equipment:** Advanced equipment such as autoclaves, depyrogenation ovens, and aseptic filling machines are integral to both animal health and human health pharmaceutical manufacturing. Both the facilities follow similar procedures for cleaning, sanitizing, and maintaining equipment, as well as routine calibration and inspection to prevent contamination.
- **Commissioning and qualification:** The facilities also share similar commissioning and qualification activities. Precommissioning activities for equipment include Factory Acceptance Test (FAT) and Site Acceptance Test (SAT); while qualification activities include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

Given the parallels between animal and human health projects, the elemental costs for both types of facilities will be similar. However, the total cost will be determined by several critical factors, including project scale, production capacity for specific drugs or vaccines, facility complexity, specialized equipment requirements, regional economic conditions, and land costs. Both types of plants require substantial investment in specialized infrastructure and equipment to meet industry standards.

While the fundamental principles of human health and animal health pharmaceutical manufacturing facilities are similar, they encounter differences on certain aspects:

- **Drug formulation:** In veterinary pharmaceutical development, formulating medications that are both effective and acceptable to a wide range of animal species presents unique challenges. Unlike human medicine, which focuses on a single species, veterinary formulations must be tailored to meet the diverse physiological and behavioral characteristics of various animals. Few animal health companies offer a diverse range of products tailored to various animal species, including companion animals and livestock.
- **Operational cost:** An animal health pharmaceutical plant usually has a more scaled-back operations team than a human health pharmaceutical plant. The automation is also more scaled-back, which helps in reducing the cost of goods.



Conclusion

Although human health and animal health pharmaceutical manufacturing facilities are designed to meet the unique needs of their respective sectors, the underlying principles governing their design and operations are fundamentally similar.

This shared foundation – ranging from GMP compliance and cleanroom standards to equipment usage and facility layout – makes it possible to repurpose these facilities for each other's use.

With relatively minimal modifications, such as adjusting for species-specific formulations or slightly altering production lines, an animal health pharmaceutical plant can be adapted for human health pharmaceutical manufacturing, and vice versa.

This adaptability highlights the potential for cost-effective facility management and allows pharmaceutical companies to respond more swiftly to changing market demands. Therefore, these manufacturing plants may present an opportunity for future adaptability, enabling them to serve both human health and animal health pharmaceutical needs as required.

About Linesight

over **50 years'** experience

38 offices globally

1,600+ employees

Who we are

Delivering professional construction consultancy services and strategic support to multiple sectors globally.

Global reach

Established in Ireland in 1974, Linesight now has extensive global reach. With offices across four continents, we have delivered projects in over 45 countries.

Local expertise

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Trusted partner

Our bold ambition, honesty and confidence to deliver, together with our commitment to build meaningful relationships is what sets us apart.

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