CATEGORY: **PHARMACEUTICAL**

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POWDERS, HANDLED.

WHITEPAPER

BETTER BUILDINGS FOR BETTER PHARMACEUTICAL PRODUCTION

why materials handling matters

Discover how a change in the way materials are handled can give manufacturers of pharmaceutical oral solid dosage (OSD) products an 'edge' over their competitors.

THE POWDER HANDLING EXPERTS

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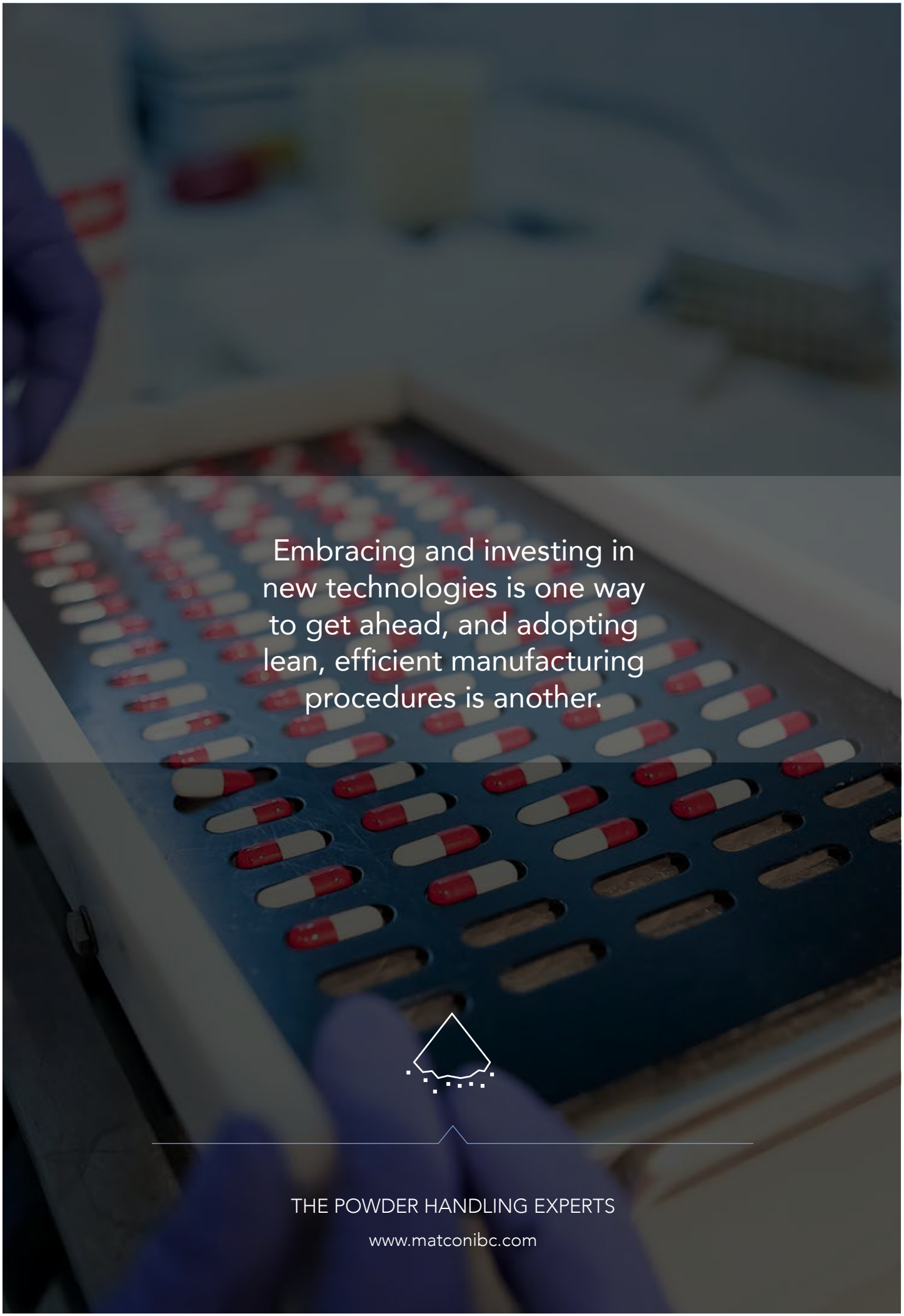

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Introduction

The manufacture of pharmaceutical oral solid dosage (OSD) products is a crowded marketplace in which it can prove challenging to provide an 'edge' over competitors.

This is particularly so in the generic drugs industries of emerging economies, which are characterised by low profit margins and high volume sales.

Embracing and investing in new technologies is one way to get ahead, and adopting lean, efficient manufacturing procedures is another. At a fundamental level, achieving efficiency can start at the outset of a project by considering the very design of a production facility. Careful planning can cut costs and reduce waste at all stages, while at the same time ensuring the production of quality products.

For both new entrants wishing to establish a position in the sector, and for established OSD producers seeking to successfully expand their product ranges, getting the end product consistently right is, of course, crucial. In this article, we take a look beyond the processes involved in drug manufacture itself, and instead turn our attention to an often overlooked and underappreciated factor of the manufacturing process: that of materials handling.

Materials handling matters

Assembling a factory is not simply a question of 'fitting it all in'; a complete understanding of the processes, equipment and space required to manufacture those products is critical.

Careful consideration must also be given to the ways in which powders, granules, tablets and capsules are handled and moved from one stage of the production process to another. Ignoring this element of the project can have a detrimental effect on the production efficiency and capability in the longer term.

Take the example of the compression phase: a tablet press and suitable space to operate it in is required, but so too is thought as to how powdered or granular ingredients will be delivered into the inlet of the machine, and how the compressed tablets will be collected from it. More than the compression process itself, the ways in which input and output materials are handled and moved can dictate the optimal production set-up.

Perhaps you plan to tip material into the press by hand, or maybe deliver powders via a vacuum system? In these cases, a single floor facility with a low ceiling height would suffice. However, if drums or intermediate bulk containers (IBCs) are to be used to feed materials in to the tablet press, a taller room height would be needed to accommodate a gravity feed system. It may even be more efficient to feed materials down from a dedicated materials handling floor above to a compression room below, so a two-floor facility, or a single one with a mezzanine level might be designed instead.

Of course, tablet compression is not the end of the story – how will you move the pressed tablets to the coating machine, or to the bottling area? Can you couple the tablet press outlet directly to the next stage of the pipeline, or do you require tubs, boxes or drums to move tablets from one area to another?

This example considers only one stage of the process, and for only one type of product, yet it illustrates the many decisions that are taken concerning materials handling, and the impact that these decisions can have on overall facility design and efficiency.

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Know the process(es)

"How are the materials moved from one process step to another?"

"What is the best way to do this?"

At the start of any new production line project, you'll need to know what steps are involved in the product's manufacture.

For a pharmaceutical OSD producer, commonly the focus of attention is on the processing stages of granulation, compression, coating and packing.

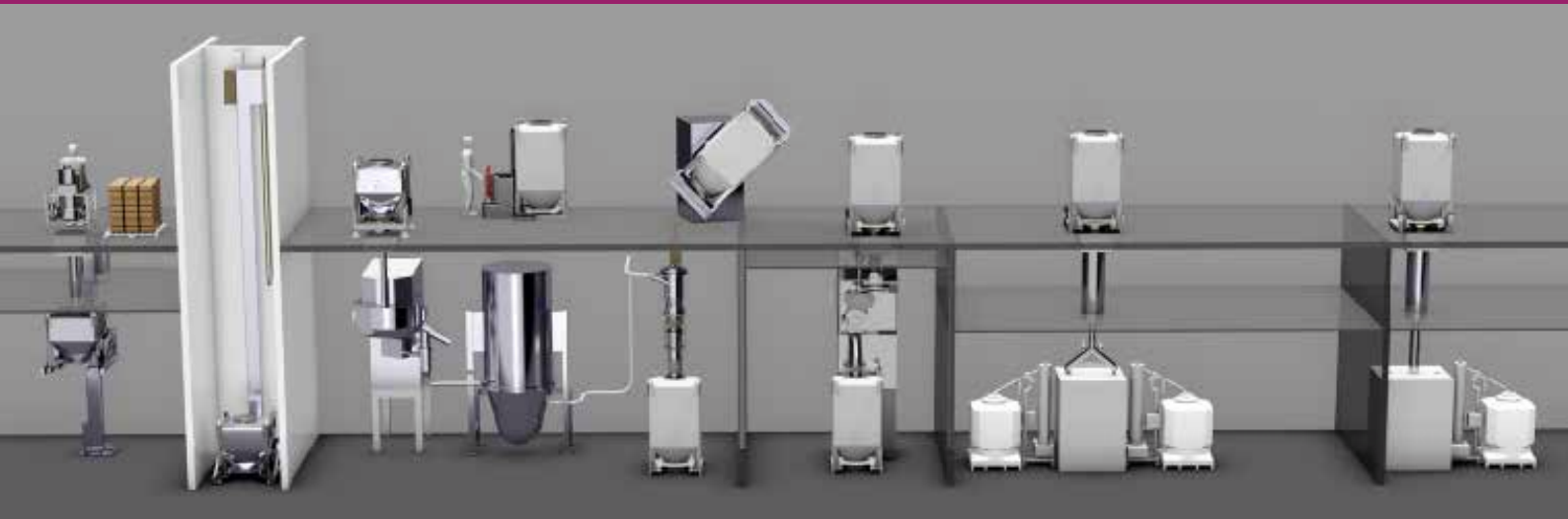
Often overlooked, or not considered early enough in the facility design process, are the questions:

"How are the materials moved from one process step to another?"

"What is the best way to do this?"

Without fully considering these fundamental questions when designing a facility, the manufacturer not only risks compromising the productivity of a given product line, but also limiting future potential for expanding capability and capacity.

Of course, there is not a 'one size fits all' solution to materials handling. Not only do different product lines with different ingredients and formulations have different materials handling requirements, factors such as building space constraints, containment requirements, material characteristics, regulations and budget must also be considered to arrive at the optimum facility design.



Types of materials handling system

Though there are many ways to move materials through the pharmaceutical OSD production line, three of the most commonly used methods are:

1. Continuous processing
2. Manual handling
3. IBC systems

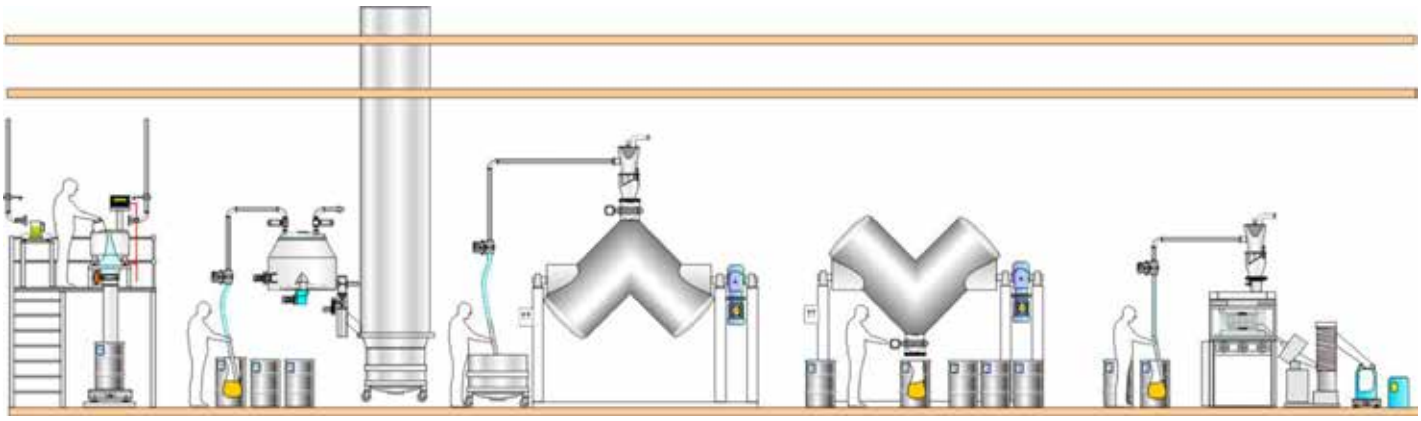
1. CONNECTING THE DOTS: continuous processing

Put simply, continuous processing is a production line in which one stage of the process is directly connected to the next.

Taking our example of the tablet press again, a continuous process here would involve directly coupling the press to a coating machine, and the coating machine to a packing machine, thereby creating a continuous line in which powdered ingredients become tablets that are coated and packaged in one smoothly flowing process.

An obvious advantage of this type of system is that it effectively removes the need for any materials handling at all, thus eliminating some of the risk of waste. Materials moving through this continuous process also have little opportunity to become contaminated, and remain well-contained as there are no connections to be made along the line. Any given batch will be highly consistent, making it a good choice for GMP manufacturers. This type of system also takes up much less space than more complex set-ups, so can be effective in small, single-floor facilities. But it's never that simple; there are some limitations with this approach:

- In practice, it is difficult to establish a completely continuous process from one end of the pipeline to another – batch processes are almost always involved at some stage (e.g. blending), which can introduce variations in the finished product.
- Some parts of a process are inevitably quicker than others – connecting processes together means that overall productivity is limited to the rate of the slowest step.
- Should a fault in the pipeline occur, or if cleaning is necessary, then the entire system must be shut down, creating an unavoidable bottleneck in production.
- It is difficult to expand the capacity of a continuous processing system – for example, if a greater quantity of tablets is required in the same amount of time, the only way round this is to install an entirely new line.



2. MANUAL LABOUR: moving materials in containers

Manual materials handling involves an Operator physically collecting materials at the end of one process and moving them to the start of the next using tubs, boxes or drums. It can work well in single-floor facilities, especially when a vacuum transfer system is added in to the equation.

A major advantage of manual materials handling is that it can be more flexible than continuous processing. By uncoupling the steps from each other, not only can each process operate at its optimum speed without creating rate-limiting bottlenecks, the outputs of that process can also be fed into more than one pipeline. Say, for example, a particular tablet needed to be packaged into blister packs and in bottles – tablets coming from one press could be collected and moved to two different packing machines working in parallel, rather than requiring two entirely separate continuous process lines.

Another advantage of the manual handling method is cost: not only are boxes or drums cheap to purchase, they are also easy to use thus require less technical training. Building costs are also kept low since the factory does not need to be so large or specialised.

Manual handling is not lean

The 'lean' philosophy is all about eliminating waste with a view to increasing productivity, reducing costs, and improving value for customers. Although manual handling is a more flexible approach than continuous processing, it is not necessarily a fully lean approach.

Disconnecting processes means that there are many more steps involved in the overall production line, and at each of these separate steps there is the potential to create waste, for example:

- Physically moving materials from one place to another can limit production capacity as the production batch is handled in many sub-lots and requires numerous manual operations, with transfers being slow and inefficient.

Types of materials handling system (cont..)

- The additional steps involved in loading, unloading and moving materials in lots of small, individual containers wastes time and physical effort. Sometimes these incur needless health and safety hazards as powders are less well contained and some heavy lifting can be involved.

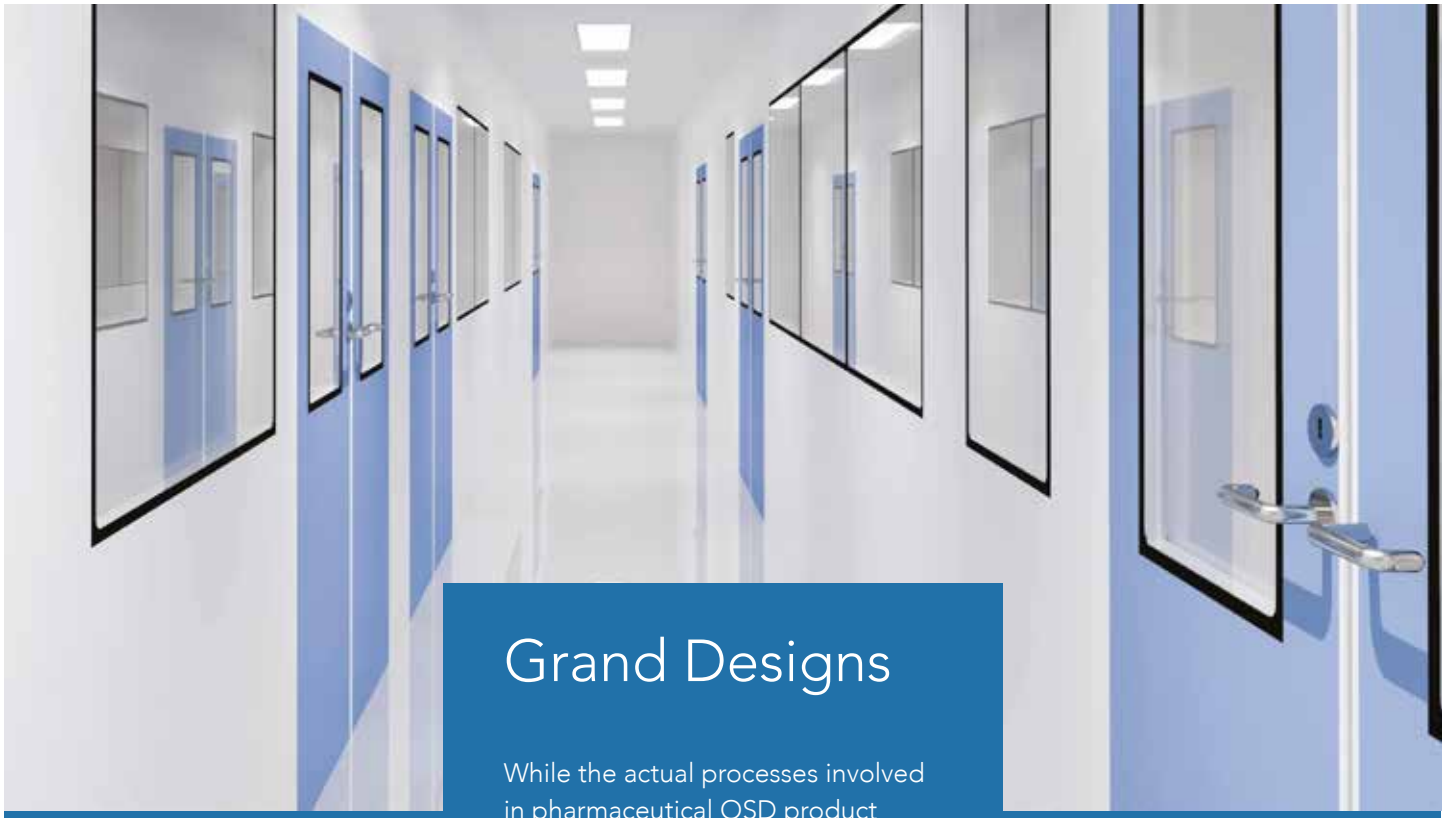
- Although operating parallel processes can be an advantage, it is difficult to track inventory and monitor batch quality. As the batch is split into sub-lots, it requires manual activities to track each container (such as labelling and barcode readings) and results in crowded GMP production areas. As the number of sub-lots increases, the risk of error escalates.

3. IBCs: the best of both worlds

Intermediate Bulk Container (IBC) systems allow pharmaceutical OSD manufacturers to streamline their materials handling procedures by combining the benefits of continuous processing and manual handling.

With an IBC system, the steps in a particular pipeline are 'continuously uncoupled'. Like the manual approach to materials handling, manufacturers using IBCs retain the flexibility to operate parallel processes, and can improve productivity by ensuring that individual steps are operating at their optimal rates. However, compared to manual handling, fewer containers are required to handle the same volume of material, which means fewer container movements, less make/break connections and less floor space to accommodate the containers at each step. What's more, IBCs lend themselves to being automated, both in terms of their discharge but also for movement, if required.

Although processes are disconnected from each other, it is the IBC itself that moves between them, not the materials inside the IBC. So, much like the continuous approach to materials handling, with a well-designed IBC there is little opportunity for material loss or contamination, and the added benefit of much-reduced cleaning requirements.



Grand Designs

While the actual processes involved in pharmaceutical OSD product manufacture are of course crucial, the materials handling methods required to move between these processes are often overlooked during the design phase, and these can introduce time, energy and profit-sapping inefficiencies.

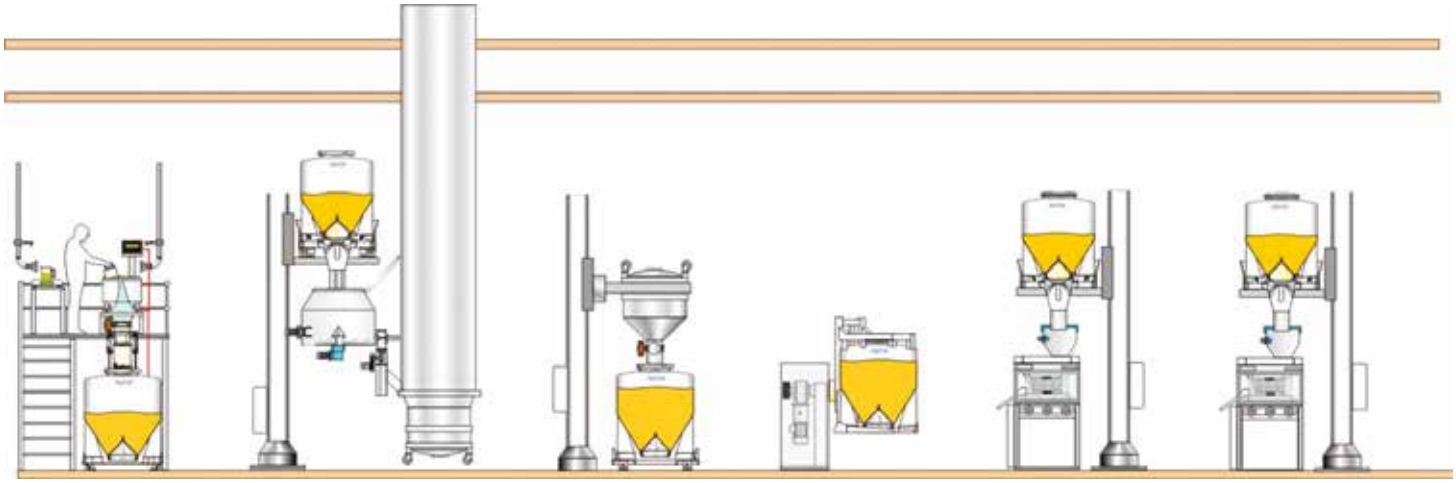
Achieving optimal materials handling efficiency should be a key driver in facility design.

Achieving optimal materials handling efficiency should be a key driver in facility design.

There is no ‘one size fits all’ approach, but whether starting from scratch, or adapting an existing building to establish or expand a factory, getting it right from the outset and creating the ‘leanest’ environment possible will undoubtedly pay dividends.

In the following pages, we explore example manufacturing installations for single, dual and multi-floor facilities.

Grand Designs (cont...)

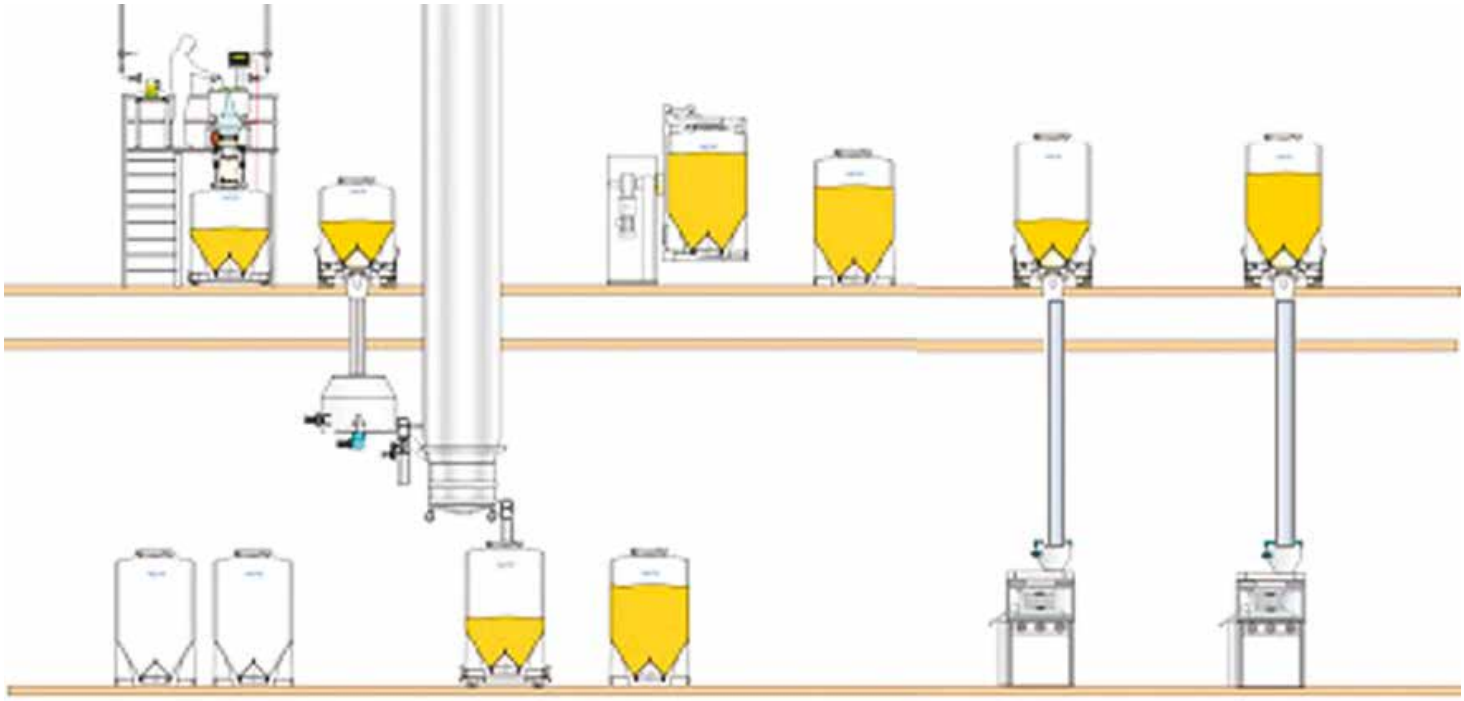


SINGLE-FLOOR FACILITIES

Single floor facilities are among the cheapest to build or lease, but their ceiling height can impose constraints on materials handling solutions. There is no need to 'settle' for the less efficient continuous or manual handling methods; with careful planning it is possible to integrate the use of IBCs in such an environment.

In these single-floor configurations, IBCs can be used to efficiently connect one process to another by matching the volume of the IBC system to the batch volume – in other words, the IBC used should be of a sufficient size to achieve a full batch transfer. Not only will this require only one connection/ disconnection per manufacturing step, it also minimizes effort and waste in transporting containers around the facility.

Vertical materials transfer methods such as gravity-fed systems can be achieved in a single-level facility, provided there is sufficient height to install mezzanine levels or a framework around processing equipment. It is much better to consider this at the outset of the project design, rather than lamenting the fact that if only the ceiling was a couple of millimetres higher you could use bulk containers and automate procedures!



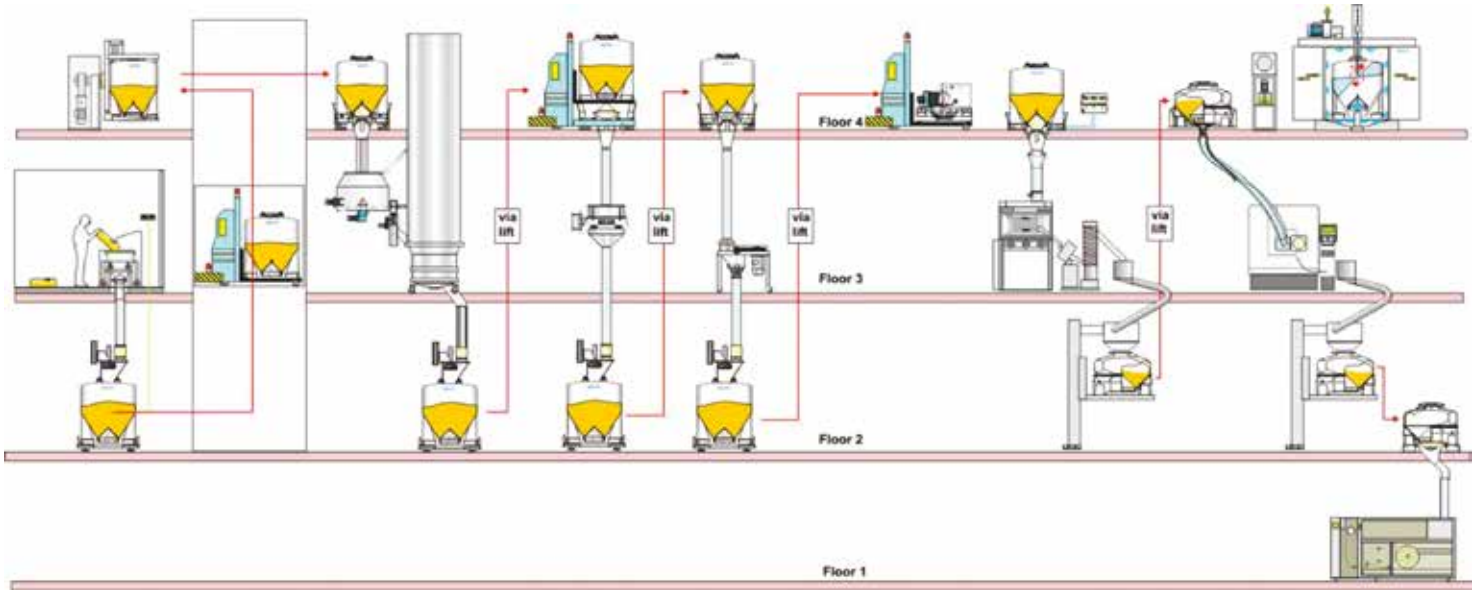
TWO-FLOOR FACILITIES

The major advantage of a two-level manufacturing facility is that it is possible to maintain a top floor that is dedicated to materials handling and blending, while the lower level can be given to tableting and packing procedures. This is particularly important in GMP manufacturing facilities where it is essential to isolate potential sources of contamination, and quality is of the utmost concern.

The top floor can be an open materials handling floor using IBCs, provided that closed connections are used before, during and after IBC discharge to ensure a dust-tight transfer and avoid the risk of contamination and cross-contamination. Through-floor transfer systems require an appropriate solution for handling sensitive materials between levels. Having two floors available also:

- Eliminates the need for pillar lifts to move between levels of a frame or mezzanine;
- Means that smaller rooms are required, with reduced associated construction/rental and cleaning costs;
- Reduces health and safety hazards by minimizing crowding of equipment and personnel;
- Allows the use of larger volume IBCs to manufacture larger batch sizes, thus achieving greater economies of scale, and reducing waste, cleaning and storage space.

Grand Designs (cont...)

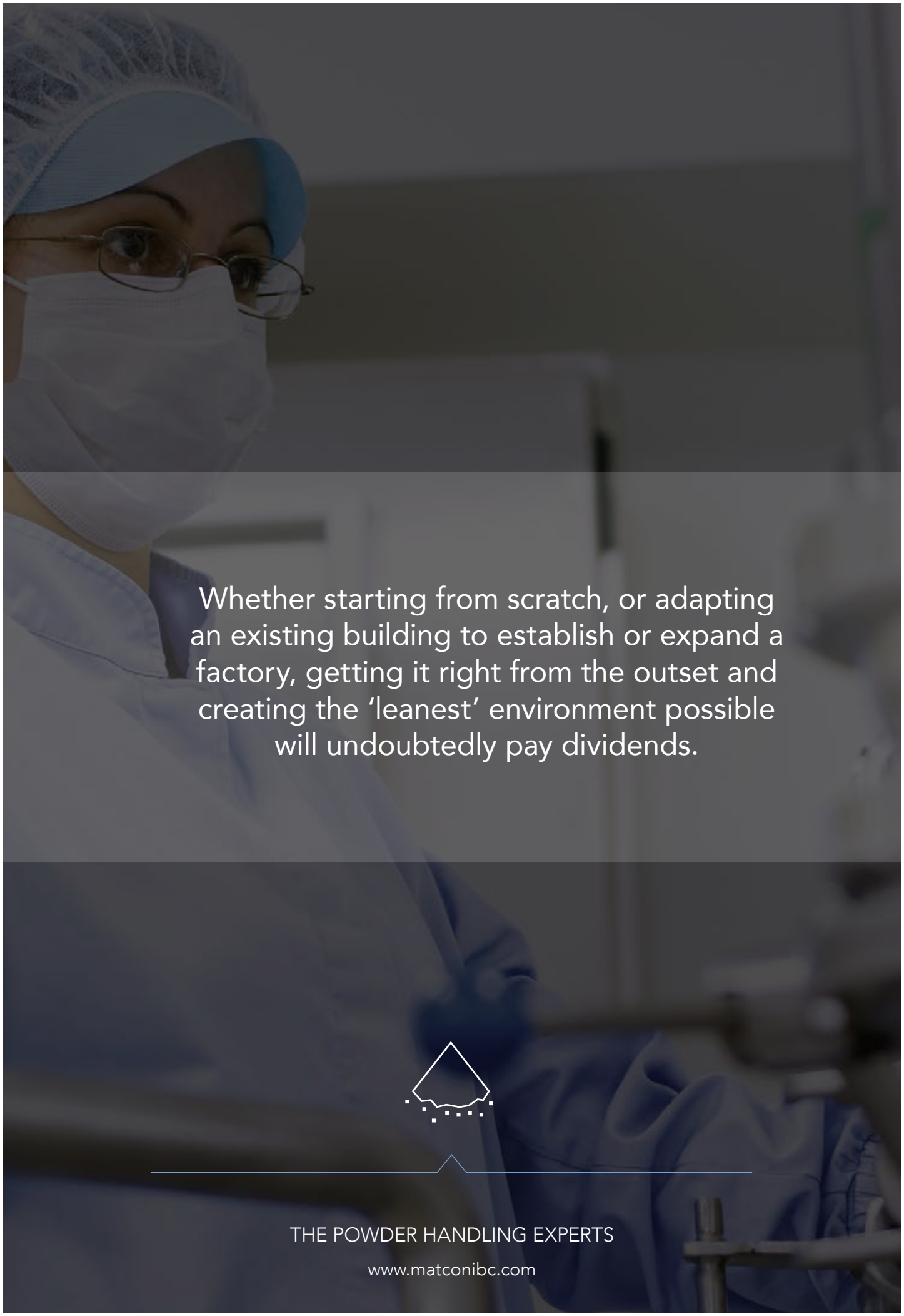


MULTI-FLOOR FACILITIES

With multiple level production facilities, the possibilities are endlessly flexible, but to achieve the leanest facility possible, careful consideration must be given to layout and overall production flow.

Although construction costs are generally much higher than lower level buildings, a major benefit of multi-level facilities is the ability to isolate GMP processes by using IBC discharge systems and filling systems that completely separate the technical materials handling floors.

As with two-floor facilities, larger sized IBCs can also be used to make best use of height and space, and to confer the financial benefits of larger batch size production. Investing in purpose-built or purpose-customized multi-level facilities also provides the opportunity to embrace new technologies, such as automatic guided vehicles, and automated cleaning systems, to further increase the facility's leanness.



Whether starting from scratch, or adapting an existing building to establish or expand a factory, getting it right from the outset and creating the ‘leanest’ environment possible will undoubtedly pay dividends.

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Weighing up the options

Whether considering a new production facility, or upgrading an existing one, the way that powders, granules, tablets and capsules are moved, stored, fed to and collected from processes has a fundamental impact on how the facility operates: its capacity, flexibility, expandability and cost of production.

WE RECOMMEND:

- Careful consideration of the materials handling options available to you at the earliest stage of facility design – there is no 'one size fits all' approach, but getting it right from the outset can maximise efficiencies later.
- Taking a 'lean' approach to materials handling not only opens up new possibilities in efficient building design, it can also drastically increase efficiency and reduce waste for maximum returns.
- Even existing facilities can find ways to reduce or even eliminate waste by improving materials handling processes.
- Careful planning of factory design at an early stage can increase efficiency, improve quality and consistency, reduce waste and increase profits.

Don't leave it to the last minute, when it will be too late and the budget for the right materials handling system will be gone.

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Why choose Matcon

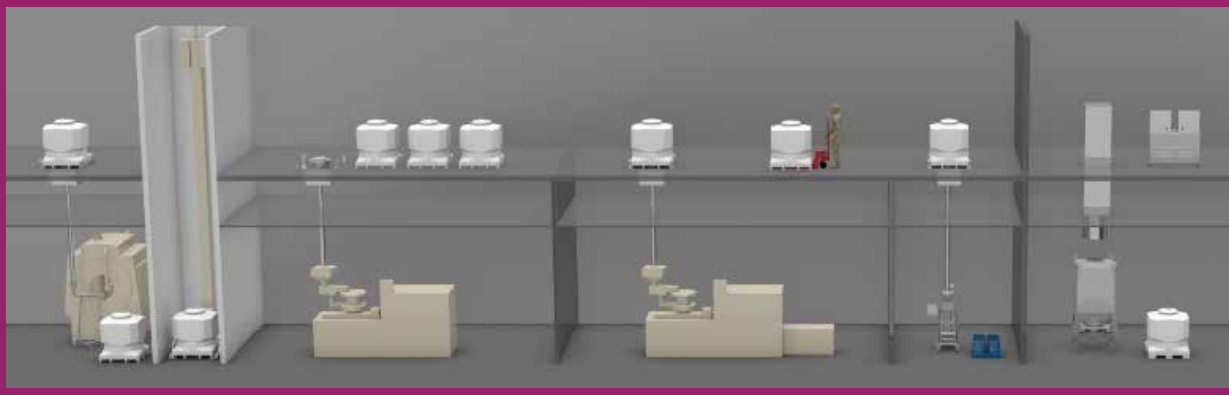
We understand the challenges faced by manufacturers of specialist pharmaceutical products.

We specialise in providing complete materials handling solutions for OSD and API pharmaceutical manufacturers.

YOUR CHALLENGES

How to improve productivity and quality to meet the competitive marketplace demands whilst adhering to strict regulations.

Overcoming materials handling issues such as powder flow problems and blend segregation.



HOW WE CAN HELP

We size the IBCs to match throughput demands so that handling of IBCs is reduced to a minimum. We optimise your materials handling system to meet the needs of the process and facility throughput objectives.

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We specialise in providing complete materials handling solutions for OSD and API pharmaceutical manufacturers.

We're not just an IBC provider, but a true partner helping you accomplish the right system for your needs.

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IDEX