

Factoring the uncertainties out of cleanroom design

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The pharmaceuticals industry is rife with acronyms so let's start with two that should be at the forefront of your mind when you're designing a cleanroom, GMP and SOP. When planning for GMP, your SOP must be in place and in line with contamination prevention and control standards as dictated by the MHRA – and that's before you even consider purchasing anything.

Grand designs... or not?

The SOP must also align to your company culture. If it doesn't, at worst you'll be left with a costly white elephant and/or a situation in which the total cost of ownership (TCO) is way beyond what was originally envisaged.

If a business has a very clear outlook on the lifetime use of the cleanroom, then a fixed design can be used. This is an opportunity to make the area a showpiece for your operation. While aesthetics cannot take precedence over function in this arena, a cleanroom that wouldn't look out of place in a science fiction film is worth considering if you need to wow customers or investors.

However, other than being hugely expensive, a showroom finish may be limiting. A bespoke approach will usually incorporate fully integrated equipment and see fittings permanently fixed to the wall or floor. Certainly, there's little doubt it will look great, but it does reduce the options to change the the layout or swap out kit if required without undergoing a full and very costly refit.

Known unknowns, and just the unknowns

If a business can afford to take this approach, it's a statement of confidence in itself, but there is also some ~~it does carry with it~~ (financial) risk. A word that we've kept seeing over the past months and years is 'uncertainty'. The current geo-political situation suggests it would very reasonable to leave your options open. The same could be said of technology-led disruption within the sector: while it's understandable you might want your cleanroom to *look* space age, you don't want the functionality to be stuck in the jet age!

By its very nature, this isn't an industry where change can happen particularly quickly. However, it is worth bearing in mind trends in other sectors that are led by science and tech, in recent years it has typically been those businesses that are most agile that come to dominate their markets.

Not even the biggest players can be entirely confident that the use scenario for a cleanroom won't change over time. Companies must be prepared to pivot in line with how the market develops. As such, the use case for cleanrooms, changing and packing areas can all change in line with how the business evolves.

While you can't cost out peace of mind, it's a precious commodity and in the current climate any organisation will want to be sure that any expenditure will offer a good return. A cleanroom will be one of the biggest single investments a business is likely to make, other than perhaps M&A. As such, you want to be sure it will remain fit for purpose over its entire lifespan and meet the needs of all that will use it.

Reflecting on flex

Unless you can afford to operate multiple cleanrooms, it makes sense to make the most of what you do have, so in most cases function will take precedence over form.

This is where the benefits of a modular approach become clear. This takes a core standard – such as using a common working height or designs to support air flow – but offers flexibility on where items are placed. The use of lightweight, free-standing furniture allows a space to be reconfigured as required to support growth, align to new processes, or integrate new equipment should there be changes in product development.

The strategy also facilitates ‘hoteling’ – an increasingly popular approach by which communal working spaces are shared between teams. This ensures cleanrooms can flex as required and be updated with minimal downtime. A modular approach makes it much easier to address any immediate issues and to implement continuous improvement cycles.

Power to the people

Regardless of whether or not you are intending to support multiple teams, it’s still good practice to consult with all stakeholders at the planning stage. Cleanroom design is simply too important to leave in the hands of just the senior management and consultants, rather than those that will use it on a daily basis.

Getting it right means bowing to the wisdom of the crowd, everyone’s perspective is valuable, from the project leads, to the compliance and cleaning staff. This is a really useful way to identify issues that could be missed at a purely conceptual level and to factor out previous problems.

Once you have analysed the feedback the next step is to integrate the findings in to the SOP. A close consideration of the practicalities of the clean down should lie at the heart of the planning process when considering the lifetime cost of ownership. This means taking into account both the most obvious factors such as the chosen sterilisation option, to the minutiae such as the positioning and even the height of the furniture.

Start with the SOP

Working backwards from the SOP, conduct a time analysis on cleaning to identify what’s eating up the most minutes every day. Next look for simple solutions to reduce that expenditure without incurring risk.

Teknomek’s mantra is ‘the devil is in the detail’ and it should be yours’ too. Generally speaking, it’s not complicated but many factors are all too easy to overlook. Most businesses remember to purchase furniture that is suited to their given sterilisation option, but it’s well worth conducting a risk assessment to ascertain how often you really need to sterilise.

This isn’t the only factor that will take a toll on how long furniture lasts – over specifying on the strength of cleaning products can end up being just as costly as under specifying. It’s worthwhile considering using non-corrosive cleaning sprays and bleach for the daily routine. This can save you money in the longer term and won’t compromise hygiene standards.

Also, bear in mind the physical space around the furniture. Contaminants can be found in any part of the cleanroom so it’s vital that teams are able to clean all the floors and the walls. Something as simple as a desk blocking access to a wall can present a significant risk.

Tables, cupboards and trolleys aren't the most exciting things to consider when planning a cleanroom, but the most innocuous items can become the greatest time stealers. When you're spending so much time and money on a project it really does pay to look out for the finer points. As such, your SOP is the most important tool at your disposal in guiding the procurement process.

Proper planning

The reality is root cause analysis of swab testing almost always reveals design flaws in furniture as posing the most significant risk for microbial contamination. Therefore, buying in haste should be avoided at all costs. When possible, it really is worth spending as much time as necessary to be sure every item meets your hygiene requirements and fits into your SOP.

Pay particular attention to harbourage points, such as gaps, ledges and even raised welds, where bacteria could gain a hold. Don't be afraid to ask difficult questions, request photographs, and closely examine individual samples before committing to buying. In short, be awkward. It's good business sense to get it right first time because making the right choices allows you to clean smarter and without compromising on hygiene.

Lifetime value

Furniture can also have a significant role to play. In terms of total cost of ownership, think practically about how easy it is to clean. In the most basic terms, each item that is fiddly or each area that is hard to access not only increases risk, it also adds to the running costs week by week and year by year. Specialist furniture will pay for itself in terms of TCO by factoring out trap points and unnecessary design features that will extend cleaning times.

Regardless of how the cleanroom will be used and by how many different teams over the course of its lifetime, the furniture and equipment you install will have a major impact on TCO. A substantial part of your team's daily routine will be spent on risk management, swab testing and maintaining hygiene standards. Your procurement choices will dictate how much time will be spent on reworking or conducting further investigation. As we know, time is money.