



The many applications of cleanrooms From medical cannabis to space pharmaceuticals

Frankfurt am Main, 16 05 2024. Be it cannabis cultivation, pharmaceuticals production or laboratories in space – cleanrooms protect all manner of applications against two hazards: particulate and microbiological contamination. Cleanrooms are the only way to ensure the quality of numerous products and research projects. Cleanroom technology creates the conditions needed for innovation in a wide range of fields.

Medical cannabis – another beneficiary of cleanrooms

The partial legalisation of cannabis took effect in Germany on April 1, 2024 – making this a good opportunity to take a closer look at medical cannabis. This has been a therapeutic option for patients in Germany ever since its medical use was first allowed seven years ago. For certified cultivation, however, cleanrooms are required.

The many properties of cannabis have been appreciated since ancient times, with a history stretching back to the Egyptians, Greeks and Romans. In the twelfth century it found its way into the writings of Hildegard von Bingen, where it was recommended for use against various ailments, including pain, nausea and rheumatism. Cannabis enjoyed particular success in the 19th century, when it became the most commonly sold substance in the chemists and pharmacies of the Americas and Europe [1]. However, no one really understood what it contained, how it worked, or what the best way to cultivate it was.

Medical cannabis offers an excellent example of why the best way to cultivate cannabis today is in a cleanroom. It goes without saying that cannabis is subject to the same requirements as are all other medications: the amount of active ingredient must be controlled and painstakingly documented so that the dosage can be precisely calibrated. Various rules and regulations must be observed here, in particular the monograph for cannabis flowers in the German Pharmacopoeia (DAB), Good Manufacturing Practice (GMP), and Good Agricultural and Collection Practice (GACP).

One of the objectives of these regulations is to prevent contamination with pests, mould spores or heavy metals throughout the cultivation process – from the cell culture until the plants bloom. According to GMP, this requires a special form of documentation that includes tests for various heavy metals, determination of the total bacteria count of aerobic micro-organisms, additional qualitative (and in some cases quantitative) proofs of specific micro-organisms, and the determination of the total bacteria count of yeasts and moulds. The control measures extend beyond the cultivation phase to encompass subsequent processing (e.g. drying processes).

These strict tests give rise to very particular requirements for climate control technology. In order to ensure that the active ingredient content remains constant, it is necessary to strictly control a whole range of factors – especially temperature, humidity, light, fresh air supply and airflow. This offers an additional advantage for cannabis growers, as it also maximises the yield. Even the water used to irrigate the plants is specially cleansed and filtered.

Standard-compliant components ensure quality

Many of these conditions are also characteristic of cleanroom technology, so it should be no surprise that satisfying the full range of regulations is best accomplished by working under cleanroom conditions, from the cultivation of the plants through to their packaging. That is why cleanrooms are an ideal location for the cultivation of “cannabis fields”, with the use of special environmental chambers that can be controlled through a platform using certified software, including the recording and archiving of data. An example is helpful here to illustrate the scale: two years ago, a cannabis producer in Switzerland commissioned a 1,100-square-metre production facility for the cultivation and processing of plants under controlled cleanroom conditions. This is equivalent to one-seventh of a football pitch.

The entire production process is subject to strict regulations. Everything must take place in accordance with GMP and/or the cleanroom standard DIN EN ISO-14644 (usually GMP D/ISO 9) and in compliance with the applicable VDI 2083 guidelines issued by the Association of German Engineers (VDI). That is why it is advantageous when building a cleanroom to make use of components that have already been certified according to the standards and other applicable guidelines (e.g. entire environmental chambers, software, microwave extractors).

The reward for these efforts lies in standardised tetrahydrocannabinol preparations suitable for pharmaceutical use. It is also possible to obtain cannabidiol (CBD) preparations in this way. Among this substance's properties are an ability to aid sleep, relieve anxiety and reduce inflammation – and it does not have any intoxicating effects. As a result, it can also be found in nutritional supplements and cosmetic oils.



Visual inspection in the greenhouse and chemical analysis in the laboratory ensure the quality of medical cannabis. - Photo: Shutterstock

Space pharmaceuticals are a focus of research

Cleanrooms are also playing an increasingly important role in many other production and research applications – including space medicine and pharmaceuticals. Pharmaceutical substances, nutritional supplements and cosmetics can often be developed more quickly in weightless environments – in space, in other words. Zero-gravity increases the virulence of bacteria, and biological processes are generally accelerated. The result: experiments can be accelerated and vaccines developed more quickly.

Space medicine is also benefiting osteoporosis medications, because astronauts experience faster bone loss during their missions to space. This, too, is leading to more rapid innovation.

Even the field of agriculture can benefit from experiments conducted in zero-gravity, as these have the potential to increase our understanding of fundamental growth processes. This can lead to the development of improved plant strains with higher yields, increased resistance to pests and diseases, and many other desirable properties (possibly even for cannabis!).

Visitors to the cleanroom trade fair Cleanzone on 25 and 26 September 2024 in Frankfurt am Main will find out first hand about the opportunities being created by the latest developments and pioneering products in the industry.

Literature

1. Barbara Segger: Harmloses Hanfprodukt? (Harmless hemp product?) PTA heute 23 (2023): 88-90
2. <https://swisscanntec.ch/marihuana-anbau-produktion>, retrieved 28 April 2024

Cleanzone

Cleanzone, international trade fair for cleanroom and cleanliness technology, hygiene and contamination control. The event Cleanzone will be held on 25 and 26 September 2024.

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