Fraunhofer Certification of the Modular BCPS Cleanroom System

Summary

When Brecon decided at the start of 2016 to develop a new wall and ceiling system for the international GMP-related market segments, it was clear that we had begun a challenging and innovative process that would be coupled with some sizable investments in energy, time and capital. A long road that also involved researching materials, developing the right profiles and a constructive composition of the building system, evaluating the right parts for the windows and doors, searching for innovative solutions for air transport and a list of hundreds of activities ultimately led to the current BCPS (Brecon Cassette Panel System). But how were we ultimately going to convince the international market that our system was actually certified for ISO 14644, GMP and EHEDG classified facilities?

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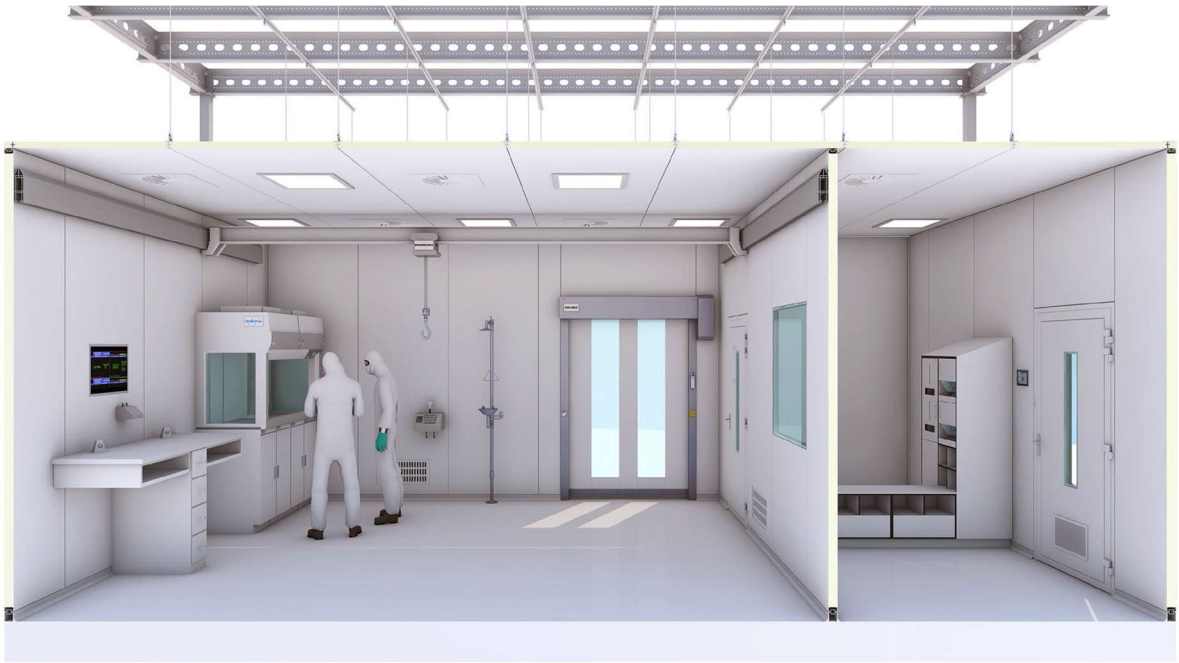
Introduction

First, a brief summary of all the activities at Brecon in order to clarify everything that has occurred during the last few years...

In 2014, the entire Board of Directors decided to change the course of direction of Brecon Cleanroom Systems B.V. Until then, we were rather singularly focused on the semi-conductor sector and especially on one relation, ASML in Veldhoven, and now we would profile ourselves on new markets and work with new products. The mission, on one hand, was to improve where possible, the already outstanding and decades-long relationship with ASML. By expanding our knowledge, product development and scale of organisation, the aim, on the other hand, was to approach new market segments in order to enter into long-term, healthy relationships with a much broader client base in the various industrial sectors.

Smart marketing and sales concepts were developed and resulted in successful activities. The Turnkey approach with the aid the successful PP4C concept is a clear example of this. Also the international version of this, PP4CE, is currently positioning itself on the global market.
The organisation expanded to include more disciplines and is now therefore called the Brecon Group, which has Cleanroom Furniture, Cleanroom cleaning, and also, for example, the Brecon Academy for training as part of its total provision of services.

Although in the history of the Brecon organisation we had earlier realised projects with Steel or HPL wall systems in the pharmaceutical (GMP) sector, it was clear that an important product was missing form our product range. The modular building system for the entire GMP market!



An overview of the various rooms we have built with the modular system

Modular building

In a general sense, we already see modular building systems in the housing and industrial building sectors.
These are often complete modules that make it possible to expand facilities as desired and such building elements can usually be disassembled and used elsewhere. On balance, these kinds of modules are always produced as prefab.

Modular building systems have been discussed in the controlled environment / cleanroom market for years. In practice, this means that, in most cases, however, a system of a certain fixed format is placed in sections (to be customised on site or not) and after a certain amount of time, it is disassembled and can subsequently be re-used again. This includes a framework with a certain fixed pattern that comes with sheet materials in a clamp system which makes disassembly possible. The frame, however, is a structure that cannot be re-used when renovations occur. The wall systems are also assembled and disassembled on the construction site. Nevertheless, as cleanroom builders, we all use the term “modular building” in such cases.

In the controlled environment market, modular building also means, however, that the panels are ready made and prefab in the factory and are put together like Lego pieces at the construction site. This means there are considerably less work activities in the future cleanroom and significantly faster throughput times at the project itself. Also when making changes to the facility, it is clearly better to remove certain elements while doing little damage and re-using these elsewhere!

The doors and walls featuring an air flow grid at MJN (Food)

Fraunhofer Institute Certification

The Fraunhofer Institute, briefly described elsewhere in this white paper, has a special department that focuses on Production and Automation, the so-called IPA. The IPA is internationally recognised, and is the renowned, competency centre for the “Controlled Environment” (CE) industry. For over 15 years, the IPA has tested products and materials that are used in CE environments. These tests are carried out according to international standards and norms.

The term “cleanroom suitability” indicates the behaviour of the particles emission of a device or material. As we know, this does not concern large particles but rather contamination at the level of 0.3 to 1 Micron. Such particles are usually generated by friction or vibration processes. When two parts of engine are in motion and make contact with each other, for example, particles will be released into the air environment. A cleanroom offers a clean and controlled space. This is important in many industries, including the semiconductor industry, the health care industry and the pharmaceutical industry. Contamination by dust particles can lead to loss of quality, or in the case of microbiological contamination, concrete dangers to our health.
As a result of this contamination potential, all devices and materials that are used in a cleanroom must, in principle, be examined on particle emission. The result of this assessment is the utility of equipment for a certain air purity class (an air purity class is defined by the maximum number of particles allowed within the ISO 14644-1 or GMP environment).

In 2018, the GMP compounding pharmacy was realised in Utrecht

The term suitability for equipment contains the assessment of all process-specific purification factors. These factors may have electro-static characteristics, outgassing (resulting in impurity in the air), cleanability of the surfaces and the chemical resistance of the surfaces (acids, bases, etc.). Especially for Life Science applications, the hygienic design must be assessed according to GMP (Good Manufacturing Practice) guidelines.

All of the products that are IPA tested and certified at Fraunhofer have been listed in a file made available on the Internet (www.tested-device.com). The most important aspect, of course, is the research report that describes all of the results and test methods of the certified products / systems concerned. Upon certification, the client is allowed to apply the IPA logo for the products/systems concerned.

The Fraunhofer Institute

The Fraunhofer Institute in Germany is Europe's leading organisation for applied research. 72 institutes and research facilities at locations throughout Germany carry out the research activities. The Fraunhofer Institute has over 25,000 employees who work with an annual research budget of EUR 2.3 billion in total. Of this amount, nearly EUR 2 billion is generated by contract research.

International collaboration with excellent research partners and innovative companies all over the world result in immediate access to regions that are of vital importance for current and future scientific progress and economic development.

Fraunhofer is the largest research organisation for applied research in Europe. The areas of research are focused on the needs of man: health, safety, communication, mobility, energy and the environment. The Fraunhofer IPA (Institute for Production and Automation) has several work areas within various industries. One of those focuses primarily on the testing and certification of products and devices that are applied in a controlled environment, also known as the cleanroom.

With nearly 1,000 employees, the IPA is one of the biggest institutes within the Fraunhofer organisation. It has an annual budget of EUR 63 million, of which more than a third is derived from industrial projects.

Research results

The wall and ceiling system is specifically designed for the GMP-related market. It was an added challenge to include all of the variants in the test procedure of the various processes. Here, it should be stated that the wall and ceiling system is available in steel as well as in an HPL variant.

The cassettes can also be equipped with 100 kg of pressed Rockwool or an aluminium honeycomb material. The table below shows the different variations.

BCPS TECHNICAL DATA

	Steel 0.6 mm Rockwool	Steel 0.6 mm Honeycomb	HPL 3 mm Rockwool	HPL 3 mm Honeycomb	HPL / Steel Rockwool	HPL / Steel Honeycomb	Steel 0.6 mm Rockwool	Steel 0.6 mm Honeycomb
	WALL	**WALL**	**WALL**	**WALL**	**CEILING**	**CEILING**	**CEILING**	**CEILING**
MaximumSize	1200x6000	1200x6000	1200x6000	1200x6000	1200x2400	1200x2400	1200x2400	1200x2400
Thickness	70 mm	70 mm	70 mm	70 mm	53 mm	53 mm	50 mm	50 mm
Density m³	100 kg	x	100 kg	x	100 kg	x	100 kg	x
Weight m²	18.4 kg	14.3 kg	15.8 kg	12.3 kg	15.6 kg	12.7 kg	16.2 kg	13.3 kg
Standard Coil Coating*	25 Micron	25 Micron	x	x	x	x	25 Micron	25 Micron
Food Safe Coating**	110 Micron	110 Micron	x	x	x	x	110 Micron	110 Micron
Silver Ion HPL	x	x	optional	optional	optional	x	x	x
Colour	RAL 9010	RAL 9010	Off white	Off white	Off white	Off white	RAL 9010	RAL 9010

All of these materials have been tested in Stuttgart on a number factors, including:

- Chemical resistance according to ISO 4628-1 AND VDI 2083 PART 17
- Absorption test of Hydrogen Peroxide (VHP process) according to VDI 2083 PART 20
- Particle emission according to ISO 14644-14
- Assessment of the hygienic design according to the following legislation and standards:
  - EU GMP Annex I
  - EHEDG Doc.8
  - DIN EN 1672-2
  - ISO 14159

The final assessment subsequently led to a classification according to:

- ISO 14644-1 class 3
- GMP starting from class A and lower classification

When we look at the result in the GMP classification, Brecon has achieved its prime objective: a cleanroom wall and ceiling system that can be used in the pharmaceutical, cosmetic, health care, food and medical device markets at the highest levels! It goes without saying that this result was met with great satisfaction and enthusiasm by the market.

IPA
Fraunhofer
TESTED® DEVICE
Brecon Group
Brecon Cassette Panel System
Report No. BR 1804-1024

Conclusion

By using the modular building systems in Controlled Environment facilities, rebuilding turns into ‘moving’ and destruction becomes ‘disassembly’...

Experienced users know that cleanrooms or hygienic rooms are not built with the same lifespan as the building itself. The changed market circumstances often demand an adjustment to the cleanroom areas and this often leads to a longer shutdown period due to large-scale rebuilding activities. When the cleanroom has been realised with a real modular system, a new wall or room can be produced prefab. Disassembly is much faster than rebuilding and causes much less damage and the rebuilding process can begin almost immediately. All wall and ceiling parts can be disassembled straight away.

These systems are available in various designs on the European market. The systems are primarily made of steel and are occasionally also available in HPL. What is truly unique in Europe is that the BCPS (Brecon Cassette Panel System) is fully certified by the Fraunhofer Institute and has a classification up to and including ISO 14644-1 class 3 and can be implemented in GMP rooms, in the highest A classification. In addition, based on internal testing and a computational evaluation, we have a confirmation from TNO that the maximum load the ceiling panels can handle for maintenance activities by a person is a maximum weight of 150 kg.

The question of how we can convince the market has clearly been answered...
By having research done by a highly specialised and internationally recognised institute and by really making these research results count!

Origin:

PP4C (Professional Partners for Cleanrooms) is a strategic alliance between a number of specialised firms. These firms are active in the design, construction and maintenance of cleanrooms and laboratories in a broad spectrum of market segments. PP4C is also active in the medium and high care areas in the food industry.

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Geerd is the initiator of the PP4C organisation and as also the General Manager of Brecon International B.V., and as such, is strategically involved in the PP4C alliance. For more information, please visit: http: /www.pp4c.nl

Sources:

- Report BR 1804-1024 Fraunhofer Institute, Stuttgart - Aug. 2018
- Mechanical test report INVESS Dec. - 2017
- Internal correspondence TNO Innovation Centre “BOUW” - Aug. 2018