Cleanroom Specification Client Service

Asgard Cleanroom Solutions & CleanSpace Modular, LLC USA are delighted to announce our cGMP / GxP Cleanroom Specification Initiative, which is a free service to all of our clients.

SPECIFICATION INITIATIVE

Asgard & CleanSpace's Cleanroom Specification Initiative uses best practice when considering cGMP cleanrooms or any GxP controlled environment, from project inception through detailed design, frequently considering how a correctly written cleanroom specification will impact a project design and the performance of the built asset at occupation and throughout its life cycle.

We use guidance from the following professional associations when developing design & specifications, including the following:

- ISO 14644, EU EudraLex, Volume 4 EU GMP (Medicinal Products for Human & Veterinary Use)
- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2007
- 21 Code of Federal Regulations Part 210 - Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs
- ASTM Standard E2500, 2007 (Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment)
- ISPE Baseline Guides
- EN10326-1:2016 for mechanical vibration within Laboratories

Asgard & CleanSpace also consider cost management and safety when developing client specifications as well as constructability.

It is our endeavor to assist biopharmaceutical clients and design firms to develop project specifications using the most up to date material technologies as well as disruptive and innovative technologies based on over 20 years of experience of delivering cleanroom projects across Europe. We are also delighted to be in a position to transfer this experience and knowledge base to our colleagues in CleanSpace, LLC in the USA.

We strongly believe our initiative will create continuity throughout our Global Design Community with more consistent and uniform specifications. Ultimately, all facilities should be delivered to the same high quality standards, using globally cleanroom compliant materials and methods. This initiative will enhance our clients' successful operation when manufacturing life saving medicines and therapies.

CONTACT US!

For more information please visit either website:

www.asgardcleanrooms.com
or www.cleanspaceus.com
Or
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