TERRA UNIVERSAL.COM
Critical Environment Solutions

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100+ Years of Cleanroom History

Introduction

Throughout history, deliberate environmental control has been used for a number of applications. Consider Egyptian mummies: by observing the natural desiccation that occurs to corpses in the arid desert, people of the 4th Dynasty (2613 BC) began to perfect burial methods, thereby preserving the dead bodies of their revered monarchs. Another centuries-old example of controlling an environment involves the art of Asian lacquer ware, in which a dust-free, humid environment was needed to successfully apply the multiple layers of lacquer.

Fast-forward to the more modern efforts of the Nineteenth Century when, in 1865, Joseph Lister applied carbolic acid (phenol) to operating room instruments, patient incisions and dressings in an attempt to reduce post-surgical infection. He conceived of this antisepsis idea due to a paper on micro-organisms published by Louis Pasteur. Operating rooms, however, continued to be contaminated by microbes and particulates, with practices like hand washing, gloving and gowning only becoming standard protocol in the early Twentieth Century. Nonetheless, the mission to control contaminants and infectious agents was underway.

Figure 1. *Joseph Lister used carbolic acid to reduce infection after surgical procedures. This innovation is seen as the beginning of surgical and biopharmaceutical cleanrooms as well as antiseptic surgery.*

Cleanrooms at War

During World War II, cleanrooms, as they existed, were developed for the assembly of high precision bombsights, including the famous Norden bombsight that is often credited with the success of U.S. bombing later in the war. During this time period, the first HEPA (High Efficiency Particle Air) filters were developed for removing airborne particles, including those generated by atomic research. Postwar, HEPA filter technology helped make possible the manufacture of gyroscopes, astro-inertial guidance systems, and electronics used in many NASA projects and Cold War-era weapons systems.

Figure 2. *The Norden bombsight was designed in the 1930s, and went on to be used by most bombers in the U.S. Army Air Force during World War II. It was a complex analog computer, requiring unprecedented precision manufacturing. This drove the development of early cleanroom facilities and cleanroom techniques for micro-manufacturing.*

Emerging High-Tech Industries

As with many technologies, advances developed by or for the military soon found their way into industry, research and medicine. A number of cleanroom innovations occurred mid-century, including the 1946 hypothesis by Bourdillon and Colebrook that poorly ventilated rooms promoted infection. They showed that contamination was reduced by forcing filtered air into a room under positive pressure.

The concept of laminar flow to reduce particulates, as well as evolutions in reducing particulate production through specialized clothing and careful control of cleanroom practices, was the focus of significant research and development in cleanroom technologies during the postwar period until the early 1960s. Blowers and Crew advanced this research in 1960 by proving that downward displacement (uni-directional) air was more effective in controlling contaminants than turbulent air. Ceiling plenums with HEPA filters, along with smoke tests to trace air movement, were used in their studies.

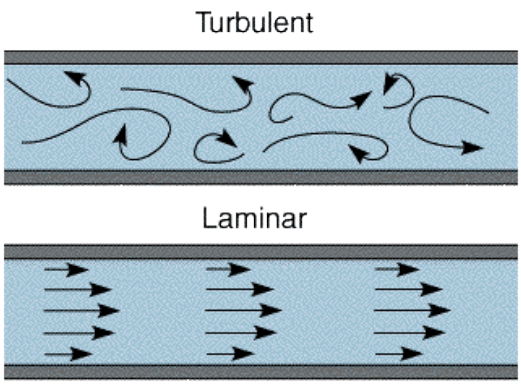

Figure 3. *Uncontrolled turbulent air can disturb contaminants and deposit them onto clean surfaces. Uni-directional laminar flow is consistent and predictable.*

Laminar Flow Innovations

In 1961, John Charnley MD, later awarded the Lister Medal for his efforts, and Hugh Howorth created a zone of near-laminar flow inside a small operating room, in the area surrounding the patient. This environment significantly increased the rate of success, and decreased use of antibiotics, for the pioneering hip-replacement surgeries performed by Dr. Charnley.

Figure 4. *Advances in hip-replacement surgery in Britain using laminar air flow to prevent infection led to this even more advanced approach at St. Luke's Hospital in Denver, CO, in 1972. Both the room and the clothing were based on space program experience and developed under a NASA contract.*

In 1962, a team at Sandia National Laboratories led by physicist Willis Whitfield, perfected this airflow to create the first cleanroom that incorporated multiple air changes, leading to what have today become standard practices – laminar flow, makeup air replacement and filtration, and careful control of surfaces and processes to minimize both particulate production and accumulation.

In 1966, another patent was issued to Whitfield for laminar flow hoods, and by the early 1970s laminar flow cleanrooms became well established as a critical manufacturing technology for the semiconductor, electronics, medical, pharmaceutical and food industries.

Figure 5. *In the 1950s, cleanrooms became increasingly important for a variety of industries, including aerospace and electronics. Application in nuclear science also prompted the development of the first patented cleanroom system based on HEPA filtration, by Sandia Labs. Here, Mercury spacecraft are built in a cleanroom environment.*

More than Semiconductors

In the early 1980s, STERIS, an Ohio company specializing in infection prevention, applied their innovation of using hydrogen peroxide gas for cleanroom decontamination. The effectiveness and safety of this approach for both users and most processes soon led to its widespread acceptance.

The multi-zone cleanroom, first elucidated by Hugh Howorth in a 1978 patent for clean air zones, was commercially introduced in 1987, incorporating chambers or rooms with cascading air pressure that achieve ever-more effective particulate removal. This zone separation, for example, makes pass-throughs and gowning antechambers an effective space for preparing materials or people to enter a more strictly controlled work environment.

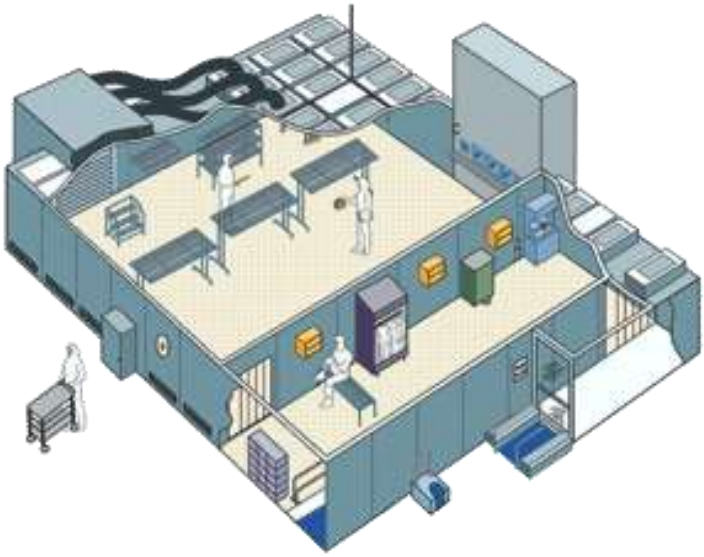

Figure 6. *Multi-room cleanroom schematic shown here: starting at the bottom, you see shoe cleaning stations, leading into an ISO 7 gowning room for hand-washing and garment application. Moving upward, some workers are already at work in the ISO 5 cleanroom.*

In 1991, a self-contained helmet system was introduced for use in medical clean rooms, protecting both the user and the cleanroom from contamination. During the late 1980s and 1990s, modular cleanrooms also became increasingly popular, allowing very cost-effective and rapid building and expansion of cleanroom facilities. Critical to this trend was the 1985 patent for the first large-scale production of the Fan/Filter Unit (FFU), an integrated fan, filter and housing unit.

Modular Cleanrooms Drive Industry

With the introduction of the self-contained FFU, a new kind of cleanroom had emerged, offering rapid construction and more economic cost; performance levels matching dedicated cleanroom buildings with custom HVAC/filtration facilities became possible. Customized modular cleanrooms born from the widespread use of smaller, more efficient, lower-vibration FFUs were soon incorporated in growing industries. Often requiring no additional building permits, modular cleanrooms have become increasingly sophisticated, while retaining some measure of flexibility for reconfiguring production or increasing performance. For these reasons, in all but the largest dedicated cleanroom operations, modular cleanrooms are now the norm.

Figures 7. *Modular cleanroom: this version is a multi-zone BioSafe room made of stainless steel and static-dissipative PVC. Designed to fit in existing warehouse or manufacturing space, modular cleanrooms allow development of just the right cleanroom capabilities to meet specific process needs. They can be easily expanded as production increases.*

New Cleanroom Standards

As cleanrooms became critical to a variety of industries, additional standardization became an important part of designing and managing these controlled environments. These regulatory benchmarks were first created under U.S. Federal Standard 209, then internationally harmonized under ISO 14644-1 in 2001. It used a grading system from ISO Class 1 to ISO Class 9, based on increasingly rigid standards for particulate filtration, particulate presence and air replacement.

Similar FDA and European Union rules for food and pharmaceutical production were also adopted at this time. In 2006, an additional international standard was created for cleanrooms with airborne chemical contamination, ISO 14644-8. These trends have been accompanied by the availability of cleanroom filters with increasing particulate removal performance, such as ULPA (Ultra Low Particulate Air) and Super-ULPA.

Cleanroom in the 21st Century

Lab Manager Magazine, published "Evolution of the Clean Room" in their January, 2011 issue, and stated that cleanrooms will continue their growth, reaching an impressive 180 million square feet by 2015. Others have noted that cleanroom growth has not been as noticeably affected by economic downturns as other industries, perhaps due to the fundamental role they play in so many critical applications used in medical devices, electronics, food and pharmaceuticals.

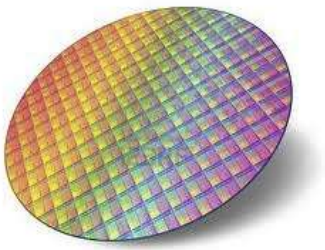

Figure 8. *Semiconductor manufacturing becomes widespread across the world in the 1970s and 80s. Cleanroom advances played a key role in increasing wafer sizes and decreasing component sizes. Advances in the semi-conductor industry continue today as electronic products continue to be developed.*

100+ Year History Timeline Summary

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100+ Years of Innovation in Cleanroom Technology