Figure 14-6 Exterior view of sterile manufacturing facility comprised of modular units. *Source*: Courtesy of Baxter Healthcare Corporation.

Many sterile facilities today are put together as modular units where each room is built separately, then the entire set of modules put together. Materials of construction are the same as a normal production facility. Modules include process equipment, critical utilities, HVAC (heating, ventilating, and air conditioning), piping, ducting, and electrical installations. The modules are assembled, then tested to ensure that everything is prequalified according to customer approval. The modules are dissembled although equipment and utilities remain within each module. The modules are shipped to the permanent building site, reassembled, and requalified. From start of design until final assembly and qualification, the time required is relatively quick (12–18 months).

Modular construction involves design, construction, testing, and qualification of each module independently. If complexity exists, it should be contained within a module, not between modules. Each module, being independent, has its own supports for utilities, power, instrumentation, piping, and other components. Modules are interconnected at the final site via piping and wall connections.

There are many benefits to modular construction (Table 14-6). Normal delivery time from the modular construction site (e.g., Pharmadule's site is in Nacka, Sweden) to the site for final commissioning is 6 to 12 months from the time the contract is signed. Although costs for modular construction are higher compared with convention construction, the shorter implementation time means faster market introduction of a new product and likely overall greater profitability.

There is so much more that is involved in facility construction that is not covered in this chapter, for example, specifics of the exterior building, specially the roof, fireproofing, caulking, partitions, piping, drains (in lower classified areas), pressurization, temperature and humidity

Table 14-6 Benefits of Modular Construction

- Construction at a single site (e.g., Pharmadule, Sweden) enables better control of weather conditions, labor, and finding building materials in compliance with GMP
- Shorter validation time
- Quicker start-up of production
- Ability to incrementally add to module
- Ability to move modular plants to other locations
- Substantially reduces time to bring new product to market
- Reduced costs overall although initial costs are higher, but time savings from start to completion of installation much faster than traditional construction
- Expansion can occur with minimal interruption to existing production