

As the use of single-use assemblies matures and becomes an economic and logical necessity, the need for a trusted, approved vendor is critical for success - HPNE offers this service!

Services Offered:

- Assembly, sterilization, inventory, and delivery of single use assemblies
- Manufactured in ISO 7, class 10,000 cleanroom, in a cGMP facility by <u>cGMP-trained</u> workers
- Validation package available for each product
- Sterility Validation / Dose Audits / Protocols
- Fully documented production raw materials, batch records, C of C, irradiation, finished goods records maintained
- Logistical control inventory maintained and managed by HPNE
- Custom assembly designs: Conception, drawing approval, first article, production
- Assemble any commercially available or custom parts
- Biocompatible, traceable, FDA compliant component materials (USP Class VI)





HPNE will help your company integrate single-use assemblies into your facility



- Monitor & provide guidance for extractable and leachable testing
- Reduce cost of building, maintaining inventory & reduce labor cost by outsourcing assembly production
- Reduce costs & downtime for cleaning, cleaning validation, sterilization and process engineering
 - Integrate stainless steel with single-use for hybrid operation
 - ISO 9001:2008 Certified
 - **Send us your sketch!** Download our HPConnexx Assembly Design worksheet



