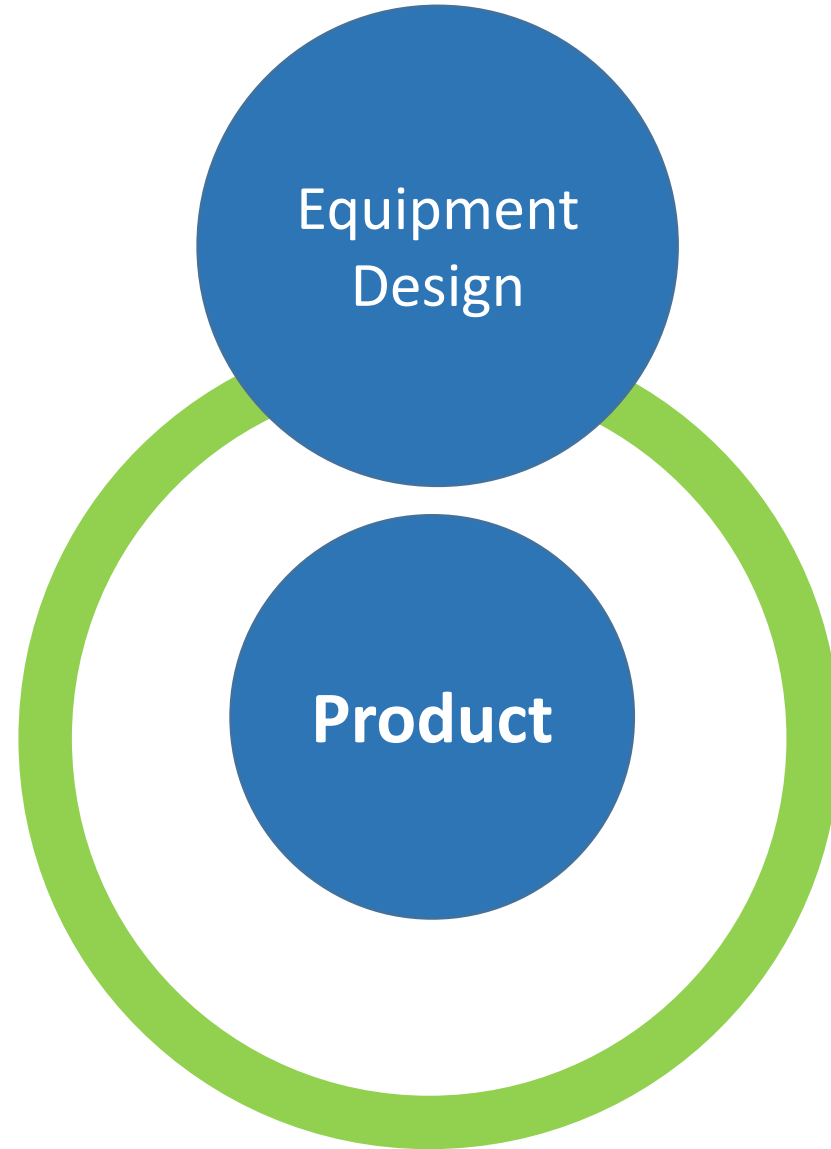


# Holistic Approach to Hygienic Design

**The Symbol  
of Assurance**



# Holistic Approach to Hygienic Design



# Key Steps in Hygienic Design Process

- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria

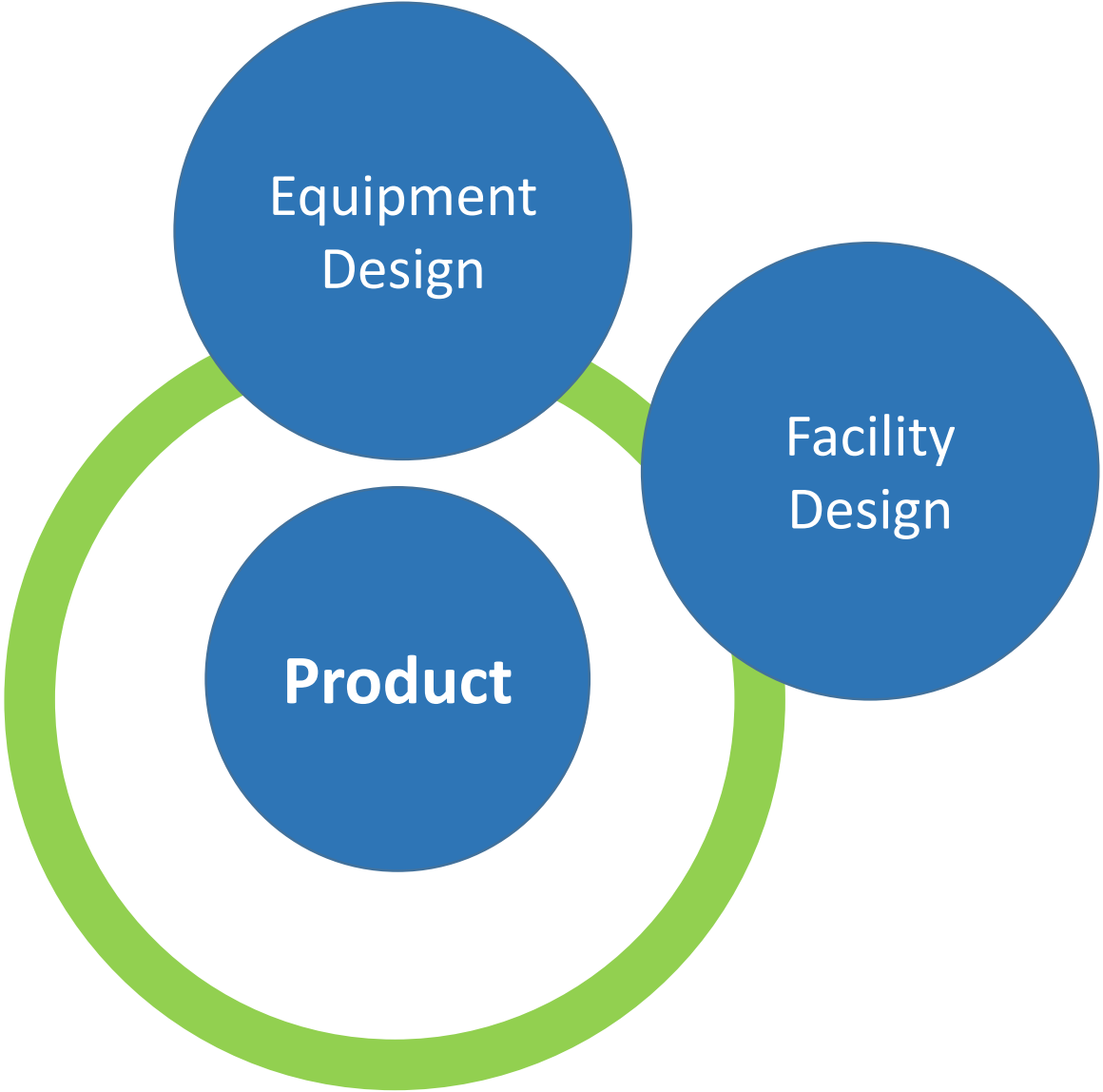
# Define Intended Uses & Risks

Risk Level	Intended Use and Products	Process Type	Customer
<b>High</b>	Injectable Drugs Infant Formula RTE Foods	Post Thermal Treatment	Infant Elderly Pregnant Immune Deficient
<b>Medium</b>	Low Acid Foods Fresh	Pre- Thermal Treatment	Healthy Children
<b>Low</b>	High Acid Foods Raw Foods to be Cooked	In package	Healthy Adults

# Key Cleanability Design Considerations

- Material of Constructions
- Surface Finishes
- Joint Design
- No Cracks or Crevices
- Free Draining
- No Dead Legs – Blind Spots - Hollows
- Accessibility to Clean
- Accessibility to Inspect

# Holistic Approach to Hygienic Design



# Facility Design

- Material of Construction
- No Niches
- Draining
- Process Isolation
- Temperature

# Holistic Approach to Hygienic Design





# Cleaning and Sanitizing

- Develop written SSOP
- Verify Procedures
  - Swab testing
  - ATP bioluminescent
  - Titration
- Training

# Holistic Approach to Hygienic Design



# Operational Design & GMP

- Isolate Raw and RTE
  - People
  - Product
  - Environment
- Maintain Safe Temperature
- Keep Plant Dry
- GMP
  - Clothing and Footwear
  - Hand Washing

# Holistic Approach to Hygienic Design



# Quality, Standards and Regulation

- Internal Quality Program
- Industry Standards
- Public Health Regulation

# Summary

- Holistic Approach
- Safe Food
- Quality Food
- Good for all stakeholders

