



Clean Room Garments & Material Sterilization

GAURI BHATIA
TRAINER AND CONSULTANT
HEALTHCARE SERVICES

What is clean room ?

- ▶ Controlled level of contamination
(no. of particles per cubic metre at a specified particle size)
- ▶ Temperature , humidity , pressure and no. of air changes per hour
- ▶ Restricted entry
- ▶ Protective personnel attire
- ▶ Stringent operating protocols
- ▶ Standard cleaning and maintenance
- ▶ Periodic validation



Cleanroom classification

- ▶ FS209E
- ▶ ISO14644-1
- ▶ BSENISO14644-1
- ▶ Particle size and particle concentration charts

ISO 14644-1 Cleanroom Standards

Class	maximum particles/m ³						FED STD 209E equivalent
	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥1 μm	≥5 μm	
ISO 1	10	2.37	1.02	0.35	0.083	0.0029	
ISO 2	100	23.7	10.2	3.5	0.83	0.029	
ISO 3	1,000	237	102	35	8.3	0.29	Class 1
ISO 4	10,000	2,370	1,020	352	83	2.9	Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1.0×10 ⁶	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7	1.0×10 ⁷	2.37×10 ⁶	1,020,000	352,000	83,200	2,930	Class 10,000
ISO 8	1.0×10 ⁸	2.37×10 ⁷	1.02×10 ⁷	3,520,000	832,000	29,300	Class 100,000
ISO 9	1.0×10 ⁹	2.37×10 ⁸	1.02×10 ⁸	35,200,000	8,320,000	293,000	Room air

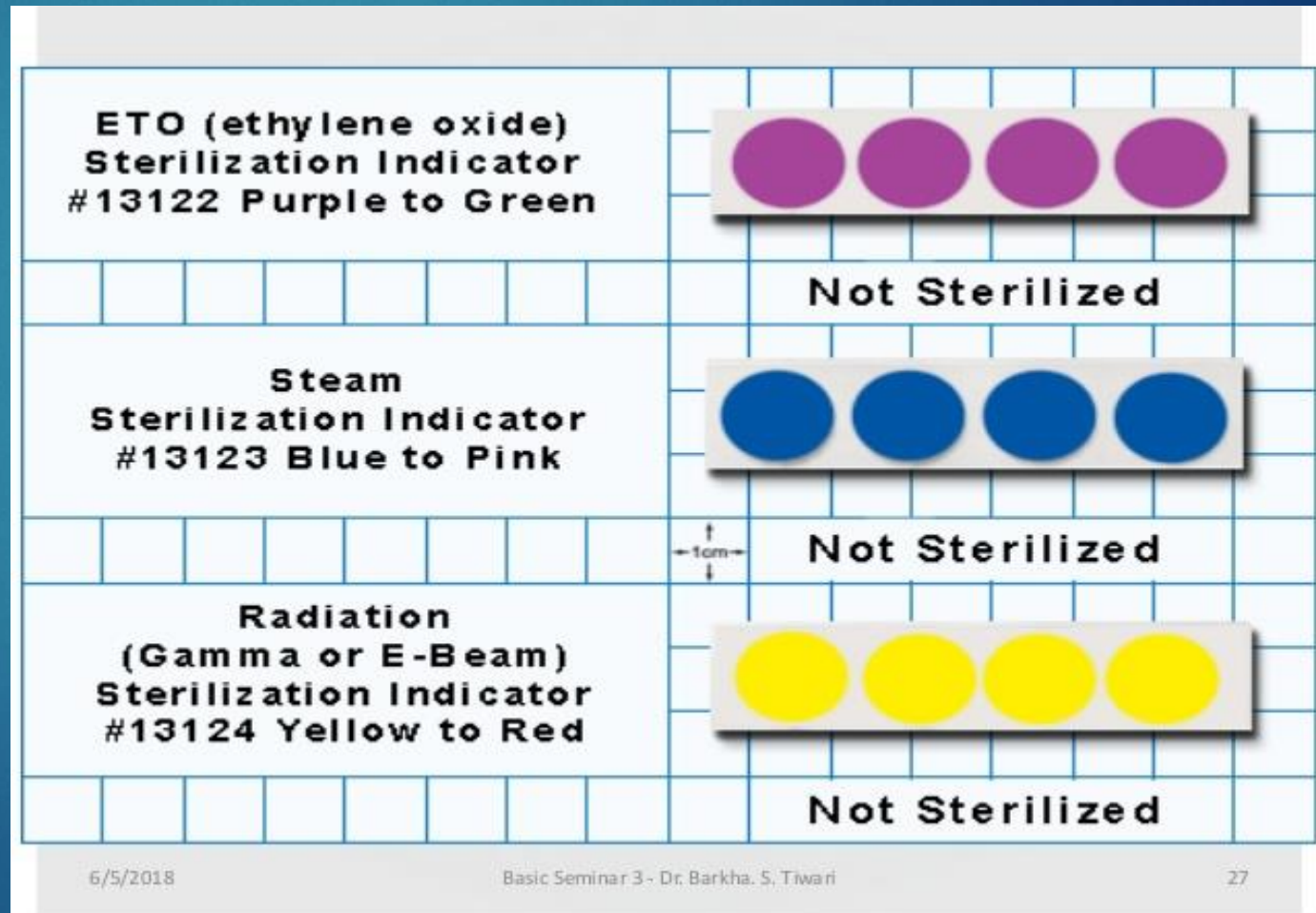
Cleanroom Maintenance

- ▶ Design
- ▶ Environment Control
- ▶ Personnel
(hygiene , movement , attire)



Sterilization of cleanroom material

- ▶ Steam(HPHV)
- ▶ ETO
- ▶ Ionizing radiation



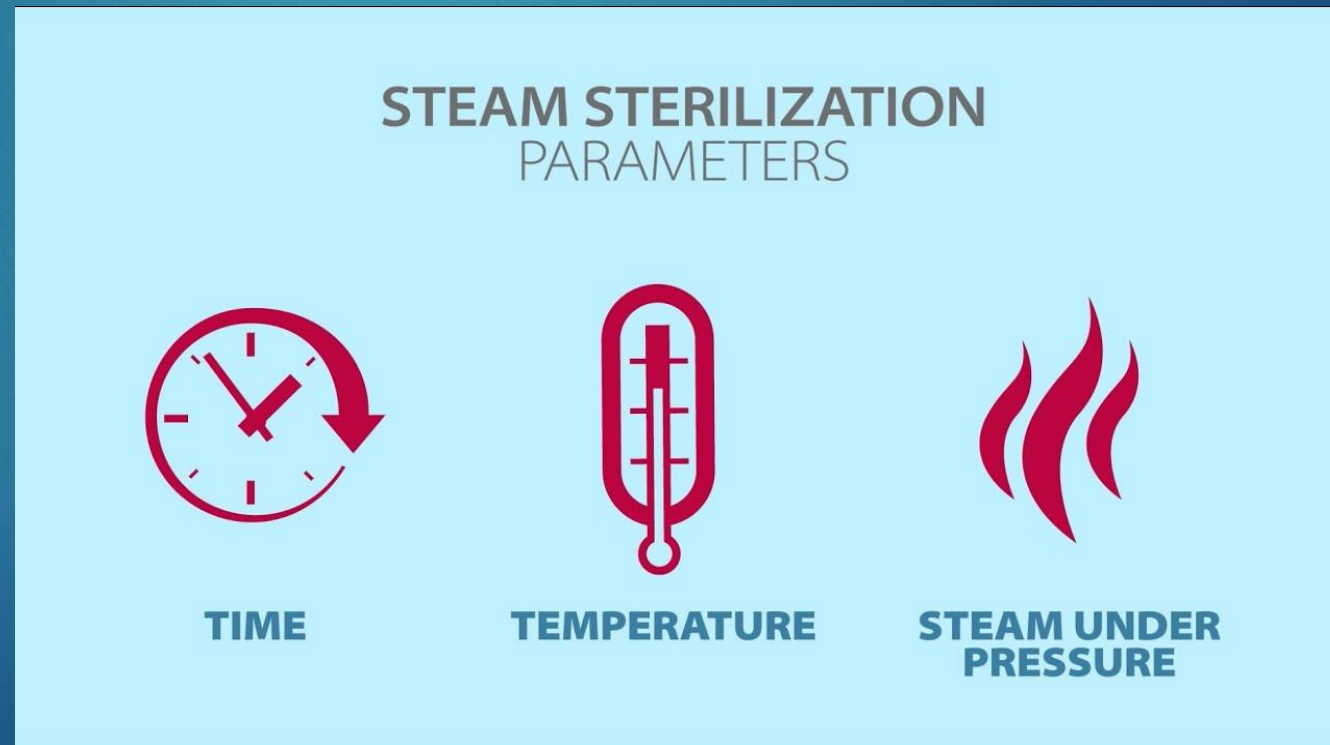
Steam Sterilization

- ▶ Wide compatibility
(except heat and moisture sensitive material)
- ▶ Cost effective
- ▶ Simple technology
- ▶ No toxic residues
- ▶ Easy understanding , operation & validation



Factors affecting steam sterilization

- ▶ Steam(water) quality
- ▶ Temperature
- ▶ Time



Underlying principle

- ▶ Air removal (vacuum)
- ▶ Dry saturated steam
- ▶ Sterilization hold time
- ▶ Drying of materials

Sterility Maintenance

- ▶ Barrier properties of packaging material
- ▶ Storage
- ▶ Sterile material handling
- ▶ Transportation
- ▶ Aseptic presentation
- ▶ User training

Quality Assurance

Batch Monitoring


Process Validation

Equipment Validation

Periodic Audits

Outsourcing sterilization

- ▶ Replicating current practices
- ▶ Service level agreement / MOU
- ▶ Role clarity
- ▶ Cost benefit analysis
- ▶ Pilot batch
- ▶ Turnaround time
- ▶ Process validation and quality assurance
- ▶ Documentation and record keeping
- ▶ Emergency backup



\$27.5 Bn Infection
Control Market -
Global Forecast to
2024: Increasing
Outsourcing of
Sterilization Services
Among
Pharmaceutical
Companies,
Hospitals, and
Medical Device
Manufacturers

Thank
you!

