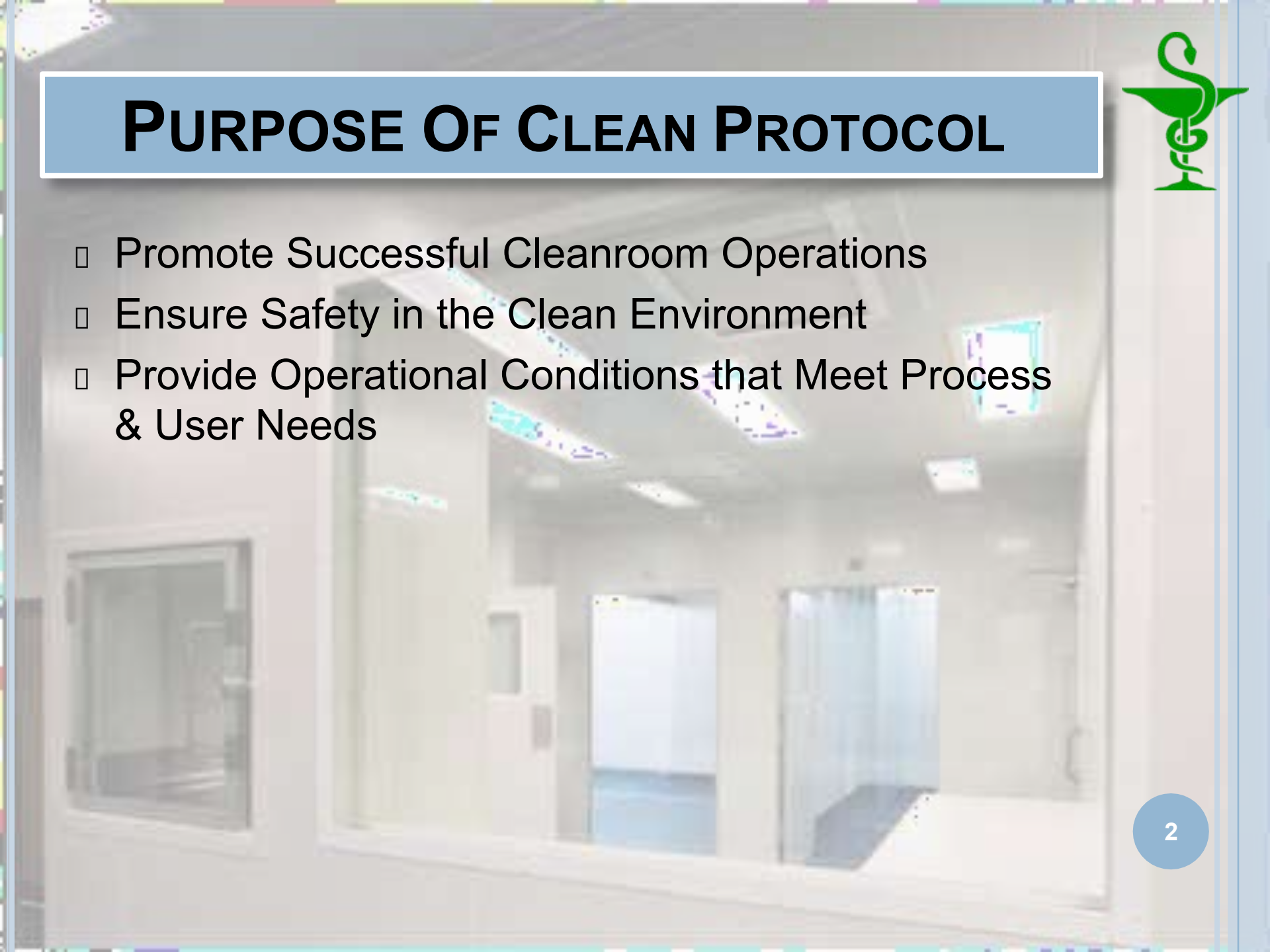
CLEAN AREA CLASSIFICATION

PURPOSE OF CLEAN PROTOCOL

- Promote Successful Cleanroom Operations
- Ensure Safety in the Clean Environment
- Provide Operational Conditions that Meet Process & User Needs



WHAT IS A CLEAN AREA?

- A clean environment designed to reduce the contamination of processes and materials. This is accomplished by removing or reducing contamination sources.
- "Federal Standard 209E" defines a clean area as a area in which the concentration of airborne particles is controlled to specified limits.
- "British Standard" defines a clean area as a area with control of particulate contamination, constructed and used in such a way as to minimize the introduction, generation and retention of particles in which inside the room and the temperature, humidity, airflow patterns and pressure are controlled.

Principles of the Clean Environment

- Air is highly (HEPA) filtered (99.97% @ 0.3µm)
- Layout should minimize particle sources in filtered air stream
- Air flow should remove most particles generated by process

Clean room

CLASSIFICATION OF CLEAN ROOM

Air Classifications by USFDA guideline on Sterile Drug Products

Clean Area Classification	<0.5 µm Particles/ft3	<0.5 µm Particles/mt3	Microbiological Limit	
			cfu/ft3	cfu/m3
100	100	3,500	<1	<3
1000	1000	35,000	<2	<7
10000	10000	350,000	<3	<18
100000	100000	3,500,000	<25	<88

ISO STANDARDS

Table 2 Selected ISO 14644-1 airborne particulate cleanliness classes for cleanrooms and clean zones

ISO Classification number	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below					
	≥0.1µm	≥0.2µm	≥0.3µm	≥0.5µm	≥1µm	≥5.0µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

CLEAN ROOM ENVIRONMENT MONITORING

Test	Frequency
I. Particle Monitoring in air	6 monthly
II. HEPA Filter Integrity Testing	Yearly
III. Air Changes Rate Calculation	6 Monthly
IV. Air Pressure Differentials	Daily
V. Temperature and Humidity	Daily
VI. Microbiological monitoring by settle plates and / or swabs in other aseptic areas	Daily, and at decreased frequency in other areas

CONCLUSION

- The main purpose of building a cleanroom suite is to provide a vital element in the assurance of product quality according to whole concept of good pharmaceutical manufacturing operation.
- The resultant facility should prevent contamination of the product.