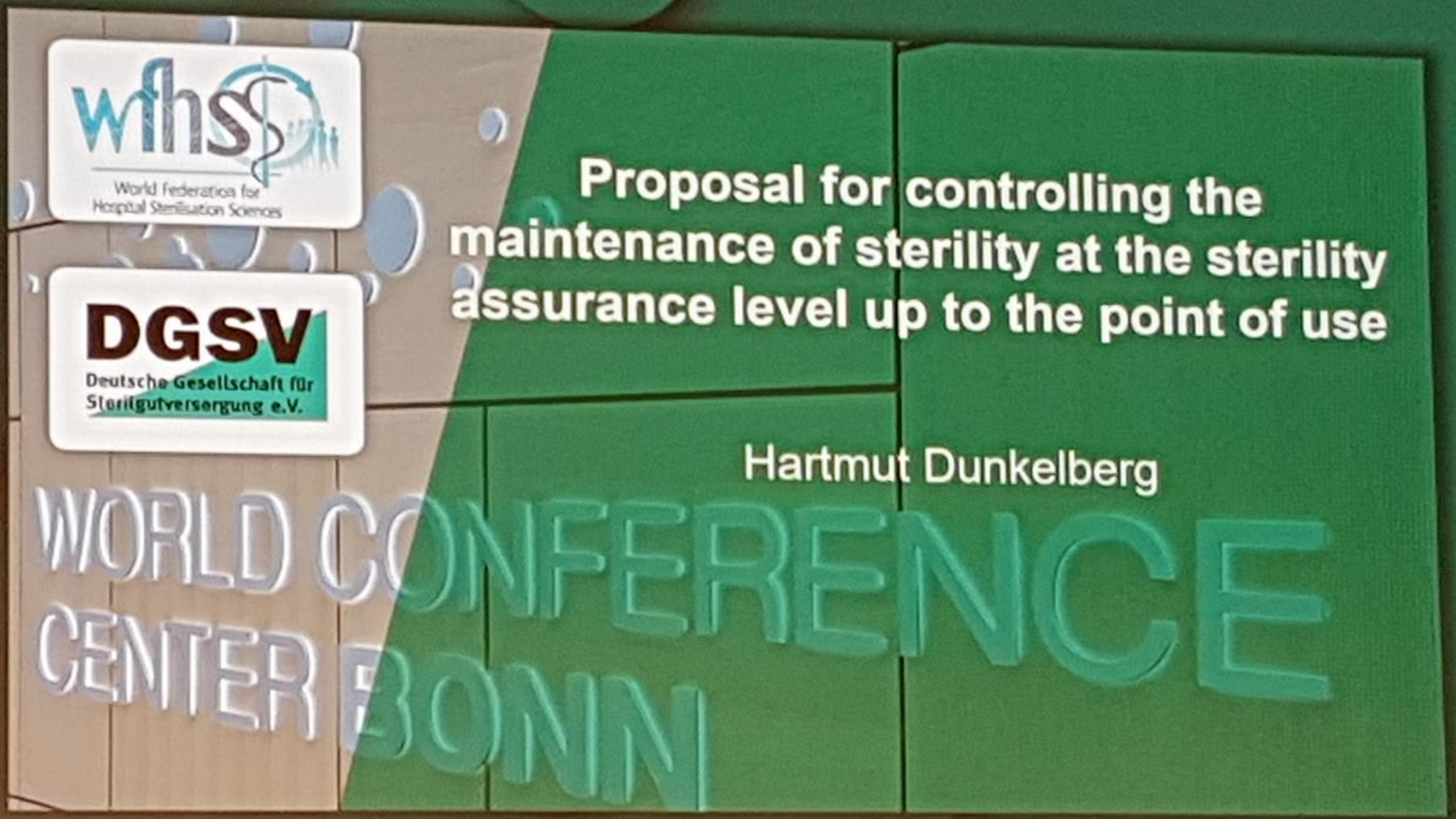

wfhss
World Federation for Hospital Sterilisation Sciences
DGSV
Deutsche Gesellschaft für Sterilgutversorgung e.V.
Proposal for controlling the maintenance of sterility at the sterility assurance level up to the point of use
Hartmut Dunkelberg
WORLD CONFERENCE
CENTER BONN

Topics

- Quality risk management of maintenance of sterility;
- Compatibility of the packaging filtration efficiency with the airborne microbial challenge during the post-sterilization period;
- Long-term recording of the airflow into the packages;
- Current concepts to control maintenance of sterility;
- Infection risks associated with exposure to terminally sterilized items which don't meet the sterility assurance level 1:1,000,000;
- Use of Cold Atmospheric Air Plasma Sterilization and continuous monitoring of the airborne microbial challenge for in-process control of maintenance of sterility;

Quality risk management of maintenance of sterility

Compatibility of the packaging filtration efficiency with the airborne microbial challenge during the post-sterilization period

Calculation of the compatibility of the packaging filtration efficiency with the airborne microbial challenge

Law of Boyle (1662) and Mariotte (1676):

P x V = const.

Charles law (1780): V ~ T

$$\frac{V_1}{T_1} = \frac{V_2}{T_2}$$

$$N_o \times \frac{100 - Filtration\ efficiency\ (\%)}{100} \leq 10^{-6}$$

Airborne microbial challenge:

$N_0 = \Delta V_{t+p}$ [m³] x n [CFU/m³]

where

$V_{1,2}$ = packaging volumes,

ΔV_{t+p} = volume of airflow into the package,

T = temperature of the gas (measured in Kelvin),

n = airborne microbial load

N_0 = airborne microbial challenge

Long-term recording of the airflow into the packages

Calculate

Expiration Date

Approximates the date at which microbial challenge will initially fall short of the declared security assurance level.

Parameters

Volume of package

Filtration efficiency

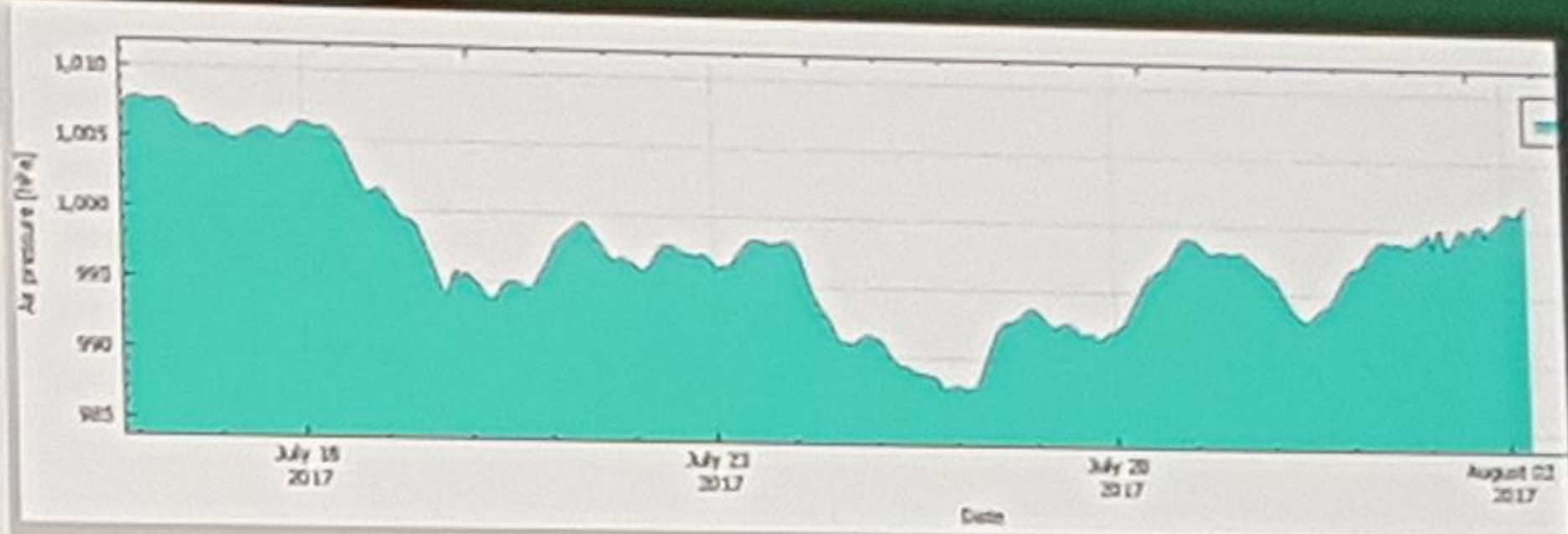
CFU/m³

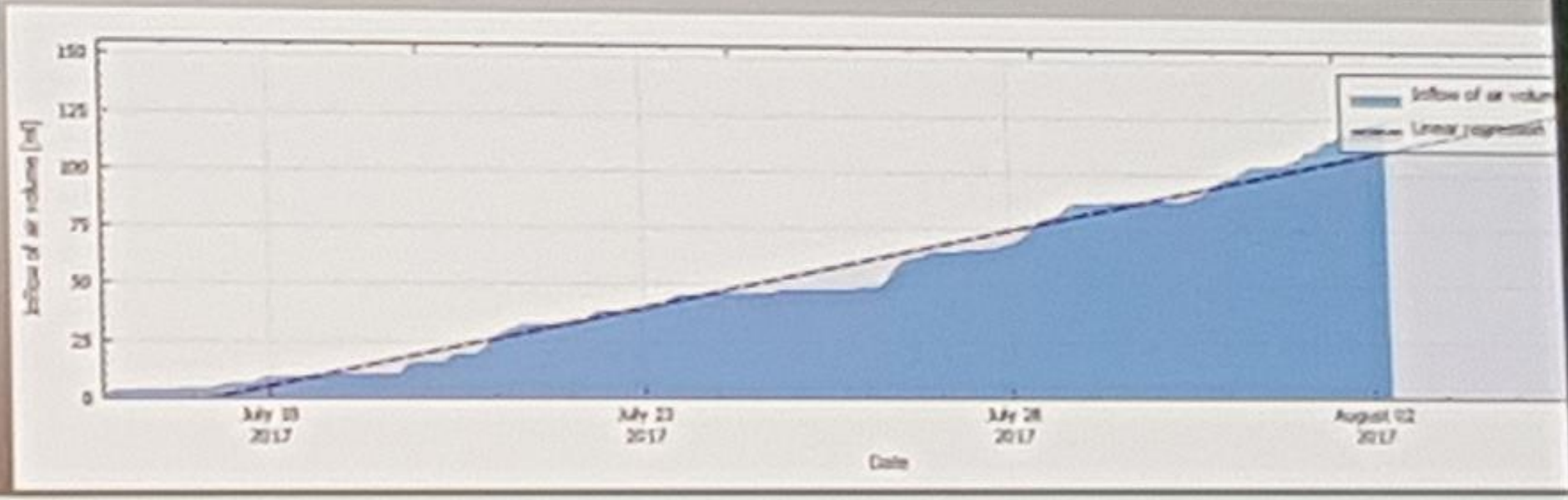
SAL

Result

Expiration Date

(expired) July 24 2017





Shelf life calculation for different packagings based on air pressure recordings from July 15 to August 2, 2017 and on an airborne microbial load of 200 CFU/m³

Packaging material	Volume [ml]	Filtration eff. (%)	Shelf life w = weeks, d = days
Paper/film pouches	150	98.40[2)]	3 d
Paper/film p. (double wrapped)	150	99.97[2)]	6 w
Tyvek® 1059B pouches	150	> 99.99[1)]	18 w
Baskets, double wrapped medical paper	2600	99.999[2)]	8 w
Baskets,Kimguard One-Step KC 400	2600	> 99.99[1)]	9 d

[1)] Data of filtration efficiency was taken from manufacturer's IFU; [2)] determined by exposure chamber method

Current concepts to control maintenance of sterility

CDC: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

„... many hospitals have switched to an **event-related shelf-life practice**. This latter practice recognizes that the product should remain sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging becomes wet, seal is broken)."

Assumed reasons why a data-based controlling the impact of the airborne microbial challenge was not introduced to protect sterility of sterilized items

- Electronic devices to register and to manage the cumulative airflow into the packages are missing;
- Manufacturers of packaging materials hesitate to present relevant test results that show the limitations of the barrier performance.

Infection risks associated with exposure to terminally sterilized items which don't meet the sterility assurance level (SAL)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Fungal Infections Associated with Contaminated Methylprednisolone in Tennessee

Marion A. Kainer, M.B., B.S., M.P.H., David R. Reagan, M.D., Ph.D., Duc B. Nguyen, M.D., Andrew D. Wiese, M.P.H., Matthew E. Wise, Ph.D., Jennifer Ward, M.S., Benjamin J. Park, M.D., Meredith L. Kanago, M.S.P.H., Jane Baumblatt, M.D., Melissa K. Schaefer, M.D., Brynn E. Berger, M.P.H., Ellyn P. Marder, M.P.H., Jea-Young Min, Pharm.D., M.P.H., John R. Dunn, D.V.M., Ph.D., Rachel M. Smith, M.D., John Dreyzehner, M.D., M.P.H., and Timothy F. Jones, M.D., for the Tennessee Fungal Meningitis Investigation Team*

N Engl J Med 2012;367:2194-203.

Spread of hospital acquired infection caused by recontamination of formerly sterile products

- Contamination of a large stock volume, that is used for thousands single-dose products;
- Storage for a prolonged period that growth to higher microbiological burden can occur;
- Application at high risk sites.

Sporadic device-associated infections caused by compromised packaging integrity are difficult to identify

- because the microbiological status of the unopened device can no longer be examined,
- because the cases occur isolated in time and location.

Use of Cold Atmospheric Air Plasma Sterilization and continuous air quality monitoring for in-process control of maintenance of sterility

Cold air plasmasterilization in a storage cabinet: results with the settle plate method

Inside the cabinet

Outside the cabinet

Efficiency of Cold Atmospheric Air Plasma Sterilization on the airborne microbial load (number of CFU/300 cm²)

Stage	I	II	III	IV	Mean
Outside	80	90.2	79.5	14.5	66.6
Inside	3	2	3	3	2.8

Reduction factor: 24

Shelf life calculation of wrapped sterilized products stored at estimated 10 CFU/m³: results are based on air pressure recordings from July 15 to August 2, 2017

Packaging	Volume (cm^3)	Filtration efficiency [%]	Shelf life w = weeks, y = years
Paper/film pouches, double wrapped	150	99.97	120 w
Tyvek® 1059B pouches	150	> 99.99	> 5 y
Baskets, double wrapped paper	2600	99.999	207 w
Baskets, Kimguard One-Step KC400	2600	> 99.99	21 w

Summary

- The compatibility of the barrier properties of the packaging with the airborne microbial challenge can be controlled by an automated long-term measurement system.

- A data based assessment of the maintenance of sterility at the sterility assurance level of 1:1,000,000 can help prevent hospital acquired infections.

Thanks

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Thank you for your attention