Evaluating Bacterial Contamination of Clean Room Clothing

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CLEANROOMS AND OPERATORS

Cleanroom function

- minimise particle introduction/production/retention[1]

Sterile medicinal products



- manufacture requires aseptic dispensing facilities[2]
- all individual components must be sterile[2]
- sources of contamination must be tightly controlled and continuously monitored to minimise particulate and microbial contamination of these products[1]

1. Winfried A.J., Rees J.A. and Smith I. Eds 2009. In: Pharmaceutical Practice, pp. 323-336. 4th Edition. Edinburgh Churchill Livingstone/Elsevier.
2. Jimenez L., 2004. In: Sterility Test and Procedures; Environmental Monitoring, pp. 77-132. New York, NY: Marcel Dekker.

CONTAMINATION SOURCES

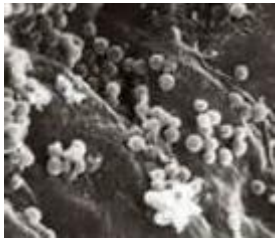
Sources of cleanroom contamination[3]

- operators, room surfaces, air and water



Cleanroom operator

- primary source of contamination[4]
- humans shed approx $1x10^9$ skin cells daily[4]
- 5-10% of shed skin scales carry microorganisms[5]
- >95% microorganisms are bacteria[6]



3. Sandle T., 2011. *PDA Journal of Pharmaceutical Science and Technology, 65(4)*, pp. 392-403.
4. Whyte W. and Hejab M., 2007. *European Journal of Parenteral and Pharmaceutical Sciences*, 12(2), pp. 39-46.
5. Scaltriti S. at al, 2007. *Journal of Hospital Infection, 66(4)*, pp. 320-326.
6. Whyte W. and Bailey, P.V., 1985. *PDA Journal of Pharmaceutical Science and Technology, 39(1),* pp. 51-61.

CLEANROOM SUITS



Fabric	Chemstat 909 extruded polyester
Air permeability	0.5 ml cm^{-2} sec^{-1}
Pore size	40µm
Physical features	Stud fastening at neck, cuffs & ankles

Clothing type	Bacterial dispersion per minute[6]
Underwear only	6
Tunic, trousers and underwear	487
Cleanroom suit ceramic polyester	1108

6. Whyte W. and Bailey, P.V., 1985. *PDA Journal of Pharmaceutical Science and Technology, 39(1),* pp. 51-61.

DIVERSITY OF HUMAN BACTERIAL FLORA

Men and Women

- differ in levels of sweat and sebum excreted[7]
- contrasting skin pH and microflora[7]

Consequently

- operator gender affects room contamination levels
- greater bacterial diversity on female skin[8]
- males disperse more microbe carrying particles[4]
- inter-gender differences exist[1]

1. Winfried A.J., Rees J.A. and Smith I. Eds 2009. In: Pharmaceutical Practice, pp. 323-336. 4th Edition. Edinburgh Churchill Livingstone/Elsevier.
4. Whyte W. and Hejab M., 2007. *European Journal of Parenteral and Pharmaceutical Sciences*, 12(2), pp. 39-46.
7. Giacomoni, P.U., Mammone, T., and Teri, M., 2009. *Journal of Dermatological Science, 55(3)*, 144-149.
8. Fierer N. at al., 2008. *Proceedings of the National Academy of Sciences, 105(46)*, pp. 17994-17999.

HUMAN BACTERIAL FLORA

Outermost layer of human skin

- carries ~ $1x10^6$ microorganisms per cm^2 [3]
- aerobic/anaerobic species inhabit hair follicles[9]
- more than 150 distinct bacterial phylotypes inhabit skin surface on palm of the hand[8]
- both hands exhibit similar bacterial diversity[8]

Gram-positive bacteria most commonly detected[3]

- *Micrococcus, Staphylococcus, Corynebacterium*

3. Sandle T., 2011. *PDA Journal of Pharmaceutical Science and Technology, 65(4)*, pp. 392-403.
8. Fierer N. at al., 2008. *Proceedings of the National Academy of Sciences, 105(46)*, pp. 17994-17999.
9. Reichel, M., Heisig, P. and Kampf G., 2011. *Journal of Hospital Infection, 78,* pp. 5-10.

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RESEARCH OBJECTIVES

- Assessment of bacterial contamination of cleanroom clothing at various time intervals
- Determination of most highly contaminated areas of cleanroom clothing
- Examination whether wearing gloves prior to donning garments impacts on the subsequent bacterial load of cleanroom clothing

METHODS

Bacterial detection assessment methods

- standardised swabbing procedure
- use of contact plates
- use of CleanTrace© ATP monitoring system

Assessment of limiting suit contamination through glove use

- no gloves
- non-sterile disposable gloves
- sterile disposable gloves

STUDY POPULATION

Assessment of suit contamination

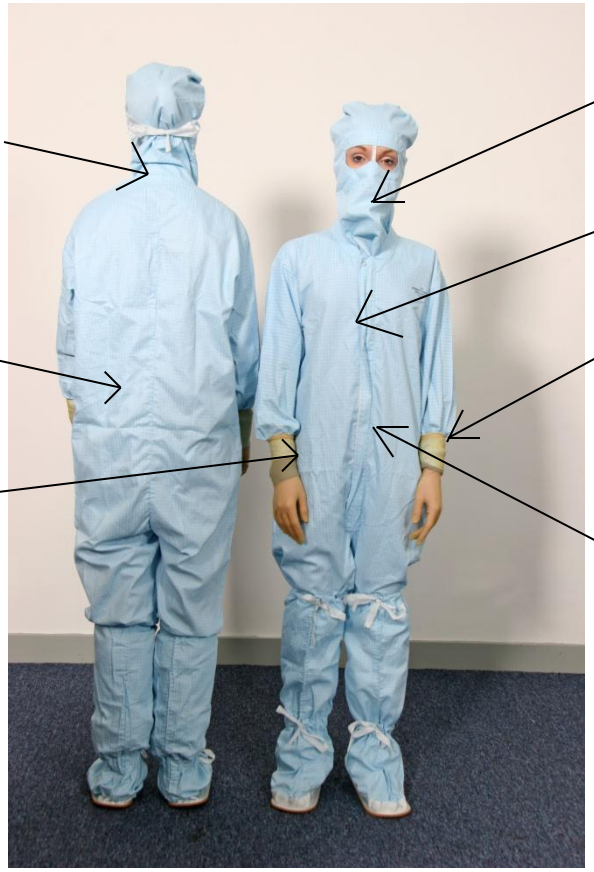
- 30 minute sampling
- 8 males and 27 females

- 60 minute sampling
- 18 males and 24 females

Limiting suit contamination through glove use

- 3 females

TEST SITES


Mouth
(over hood)
Nape of neck
Chest 5 cm from zip
Left wrist
Lower back
Right wrist
Umbilical region

SUIT CONTAMINATION AT 30 MINUTES

Sample site	Mean colony forming units recovered (*p* value < 0.001)	
	Male (n = 8)	**Female (n = 27)**
Nape of neck	1-9 x 7; 10-20 x 1	Zero x 8; 1-9 x 19
Lower back	Zero x 3; 1-9 x 5	Zero x 15; 1-9 x 12
Mouth (over hood)	Zero x 3; 1-9 x 2 > 20 x 3	Zero x 8; 1-9 x 12 10-20 x 7
Chest	Zero x 1; 1-9 x 7	Zero x 7; 1-9 x 20
Umbilical region	Zero x 1; 1-9 x 7	Zero x 13; 1-9 x 14
Inner right wrist	Zero x 1; 1-9 x 7	Zero x 13; 1-9 x 14
Inner left wrist	Zero x 3; 1-9 x 5	Zero x 12; 1-9 x 15

SUIT CONTAMINATION AT 60 MINUTES

Sample site	Mean colony forming units recovered (*p* value < 0.001)	
	Male (n = 18)	**Female (n = 24)**
Nape of neck	0 x 2; 1 - 9 x 12; 10 - 20 x 1; >20 x 3	0 x 15; 1 - 9 x 7; >20 x 2
Lower back	0 x 3; 1 - 9 x 10; >20 x 5	0 x 20; 1 - 9 x 4
Chest	0 x 3; 1- 9 x 7; 10 - 20 x 6; >20 x 2	0 x 16; 1 - 9 x 5; >20 x 3
Umbilical region	0 x 3; 1 - 9 x 9; 10 - 20 x 4; >20 x 2	0 x 18; 1 - 9 x 5; 10 - 20 x 1
Inner right wrist	0 x 4; 1 - 9 x 13; >20 x 1	0 x 21; 1 - 9 x 2; >20 x 1
Inner left wrist	0 x 5; 1 - 9 x 9; 10 - 20 x 1; >20 x 3	0 x 16; 1 - 9 x 6; >20 x 2

GENDER AND SUIT CONTAMINATION

Highest female bacterial contamination sites

- nape of neck
- chest area

Highest male bacterial contamination sites

- chest
- nape of neck
- lower back
- umbilical region

GLOVES AND SUIT CONTAMINATION

Sample Site	Bacterial suit contamination (colony forming units) (*p* value > 0.05)		
	No gloves	Non sterile gloves	Sterile gloves
Nape of neck	0 x 4; 1-9 x 3; 10-20 x 2	0 x 6; 1-9 x 3	0 x 6; 1-9 x 3
Lower back	0 x 7; 1-9 x 1; 10 -20 x 1	0 x 7; 1-9 x 2	0 x 7; 1-9 x 1; ; >20 x 1
Mouth (over hood)	0 x 1; 1-9 x 6; >20 x 2	0 x 1; 1-9 x 5; >20 x 3	0 x 4; 1-9 x 4; >20 x 1
Chest	0 x 4; 1-9 x 5	0 x 4; 1-9 x 5	0 x 5; 1-9 x 4
Umbilical region	0 x 5; 1-9 x 4	0 x 6; 1-9 x 2; 10-20 x 1	0 x 6; 1-9 x 3
Inner right wrist	0 x 6; 1-9 x 2; >20 x 1	0 x 7; 1-9 x 2	0 x 6; 1-9 x 2; >20 x 1
Inner left wrist	0 x 8; >20 x 1	0 x 5; 1-9 x 4	0 x 6; 1-9 x 3

CONCLUSIONS

- Reduction in bacterial suit contamination
  - no significant difference in suit contamination detected when operators wore no gloves, non-sterile gloves or sterile gloves when donning suits
- Suits worn by male operators
  - high levels of microbial contamination
- Highest level of bacterial contamination
  - nape of neck and chest common to males and females
  - plus lower back and umbilical regions in males

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