Formal Concept Analysis in Microbiology with Emphasis on Sterile Area from Design to Operation as Preventative Cost Of Quality

A thesis Submitted In Partial Fulfillment of The Requirement for the Degree of M.Sc. In Pharmaceutical Sciences

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By

Lamyaa Ahmad Fouad Gebreel

B.Sc. Pharmacy (2000)

Supervisors

Prof. Dr. Abd El-Gawad Hashem

Professor & Head of Microbiology & Immunology Department Faculty of Pharmacy, Cairo University

Prof.Dr.Hesham Hasan Radwan

Professor & Head of Microbiology & Immunology Department Faculty of Pharmacy, Helwan University

Dr.Amal Emad El-Deen Ali

Lecturer of Microbiology & Immunology Faculty of Pharmacy. Cairo University

Department of Microbiology and Immunology Faculty of Pharmacy Cairo University 2008

Approval Sheet

Name of student	Lamyaa Ahmad Fouaad Gebreel
Title of thesis	Formal Concept Analysis in Microbiology with Emphasis on Sterile Area from Design to Operation as Preventative Cost of Quality
Approved by:	
1.	
2.	
3.	
4.	
(committee in charg	ţe)
Date: / / 2	2008

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Table of contents

No.	Contents	Page
1	Introduction and aim of the work	1
2	Literature review.	5
2.1	Introduction to cleanrooms	5
2.2	Definitions and standards of cleanroom	6
2.3	History & applications of cleanrooms	7
2.3.1	Aerospace industry	7
2.3.2	Medical field	8
2.3.3	Pharmaceutical use	9
2.3.4	Other fields	11
2.4	Design of cleanrooms	11
2.4.1	Design objectives	12
2.4.2	Main features of design	13
2.4.3	Cleanroom parameters	19
2.4.3.1	Temperature and humidity control	19
2.4.3.2	Air born contamination control	21
2.4.3.3	Pressure deferential control	23
2.4.3.4	Constant airflow systems	25
2.4.3.5	Ventilation	26
2.4.4	Cleanroom classes	28
2.4.5	Types of cleanrooms	29

No.	Contents	Page
2.4.5.1	Conventionally ventilated cleanrooms	29
2.4.5.2	Unidirectional airflow cleanrooms	29
2.4.5.3	Mixed flow cleanrooms	30
2.4.5.4	Isolator or barrier technology	30
2.4.6	Cleanroom contamination	32
2.4.6.1	Sources of cleanroom contamination	32
2.4.6.2	Cleanroom contamination control	35
2.5	Aseptic practice in cleanroom	38
2.5.1	Personnel training and qualification	42
2.5.2	Personnel gowning	47
2.5.3	Cleaning and sanitation of work place	54
2.6	Validation of cleanroom and its operations	55
2.6.1	Process Validation (Media Fill)	56
2.7	Microbiological EM and cleanroom	63
2.7.1	Environmental Monitoring Sampling site	66
	selection and frequency	
2.7.2	EM Levels	70
2.7.3	Methods used in microbiological EM sampling	74
2.7.3.1	Air sampling	74
2.7.3.1.1	Passive air sampling	74
2.7.3.1.2	Active air sampling	76

No.	Contents	Page
2.7.3.2	Surface sampling	77
2.7.3.3	Personnel sampling	78
2.7.4.	Microbiological testing of EM samples	79
2.7.5	Characterization of isolates	79
2.7.6	Investigation of out of limits environmental monitoring data	81
2.7.7	Trend analysis of microbial monitoring results	82
2.8	Quality and cost in cleanroom	83
2.8.1	Quality costs starting from design	86
2.8.2	Cost consideration in cleanroom	88
2.8.3	Cleanroom components' cost	90
2.8.4	Example of costs	94
2.8.5	Recall of sterile products	95
3.	Materials and methods	99
3.1	Materials	99
3.1.1	Media	99
3.1.1.1	Solid media	99
3.1.1.2	Liquid media	99
3.1.2	Microorganisms	99
3.1.3	Chemicals	100
3.1.4	Equipment	100

No.	Contents	Page
3.2	Methods	102
3.2.1	Media preparation and handling	102
3.2.1.1	Solid media	102
3.2.1.2	Liquid media	103
3.2.2	Sampling method	104
3.2.2.1	Passive air monitoring using settling plates	104
3.2.2.2	Active air monitoring using STA air sampler	104
3.2.2.3	Surface / personnel sampling using RODAC	106
	plates	
3.2.3	Samples' QC testing	106
3.3	Fumigation validation	107
3.3.1	Preparation of the area for the fumigation	107
3.3.1.1	Cleaning tools	108
3.3.1.2	Cleaning agent used	108
3.3.1.3	Cleaning procedures	108
3.3.1.4	Disinfection procedures	110
3.3.2	Fumigation method	110
3.3.3	Sampling for the fumigation validation	112
3.3.3.1	Sampling process	112
3.4	Aseptic operator qualification	115
3.4.1	Selection criteria	115

No.	Contents	Page
3.4.2	Classroom/ orientation training	117
3.4.2.1	Orientation training	117
3.4.2.2	Gowning and entry to cleanroom training	118
3.4.2.3	Behavior in cleanroom	122
3.4.3	Gowning validation	126
3.4.4	On the job training	128
3.5	Aseptic process validation (media fill)	129
3.5.1	Procedures	129
3.5.2	Media inspection	133
3.5.3	Fill volume	134
3.5.4	Batch size	135
3.5.5	Incubation conditions	135
3.6	Environmental monitoring	135
3.6.1	Passive air monitoring	136
3.6.2	Active air monitoring	139
3.6.3	Surface monitoring	140
3.6.4	Personnel monitoring	143
3.7	Data handling	144
4.	Results	145
4.1	Design of facility X	146
4.2	Fumigation validation	149

No.	Contents	Page
4.3	Gowning validation	162
4.4	Media fill	166
4.4.1	Sterility	166
4.4.2	Growth promotion	166
4.4.3	Environmental monitoring during media fill	166
4.5	Environmental monitoring	167
4.5.1	Environmental monitoring during media fill	168
4.5.1.1	Passive air monitoring using settling plates	168
4.5.1.2	Active air monitoring using STA air sampler	172
4.5.1.3	Surface monitoring using RODAC plates	174
4.5.1.4	Personnel monitoring using RODAC plates	180
4.5.2.	Environmental monitoring during regular	182
	production	
4.5.2.1	Passive air monitoring using settling plates	182
4.5.2.2	Active air monitoring using STA air sampler	188
4.5.2.3	Surface monitoring using RODAC plates	190
4.5.2.4	Personnel monitoring using RODAC plates	193
4.6	Comparison of environmental monitoring results	197
	during media fill and regular production days	
4.6.1	Passive air monitoring	197
4.6.2	Active air monitoring	199

No.	Contents	Page
4.6.3	Surface monitoring	200
4.7	Statistical analysis of the results	201
4.7.1	STA air sampling	202
4.7.2	Surface monitoring	203
4.7.3	Settling plates	204
5.	Discussion	206
5.1	Design verification	206
5.2	Fumigation validation	208
5.2.1	Recommendations	211
5.3	Aseptic operator qualification	212
5.3.1	Recommendations	214
5.4	Media fill	214
5.4.1	Prerequisites	215
5.4.2	Acceptance limits	216
5.4.3	Frequency	216
5.4.4	Investigation and corrective actions in case of	217
	failed results	
5.4.5	Media fill conclusion	218
5.5	Environmental monitoring	218
5.5.1	Passive air monitoring	219
5.5.2	Active air monitoring	220

No.	Contents	Page
5.5.3	Surface monitoring	221
5.5.4	Personnel monitoring	222
5.5.5	Environmental monitoring recommendations	223
5.6	Final conclusion	225
6.	Summery	226
7.	Abstract	232
8.	References	234
9.	Arabic summary	

List of abbreviations

Abbreviation Meaning

AHU Air Handling Unit

APA Aseptic Processing Area

CDER Centre of Drug Evaluation and Research

cGMP Current Good Manufacturing Practice

CFR Code of Federal Regulations

Cfu colony forming unit.

CBER Centre for Biologics Evaluation and

Research

CIVAS Central Intravenous Additive Service

CIP Clean In Place

EC European Commission.

EM Environmental Monitoring

FDA Food Drug Administration

HEPA filters High Efficiency Particulate Air Filters.

HVAC system Heating, Ventilation and Air Conditioning

system

i.e. Which means

IEST Institute of Environmental Sciences and

Technology.

I.V product Intravenous product

Abbreviation Meaning

IQ Installation Qualification

GIT Gastro Intestinal Tract

kWh kilo watt

LAF Laminar Air Flow.

LI Life Islet.

MAL Material Air lock

NASA National Aeronautics and Space

Administration.

NA Not Applied

OR Operation Room

ORA Office of Regulatory Affairs

OQ Operational Qualification

Pa Pascal

PQ Performance Qualification

PDA Parenteral Drug Association

PAL Personnel Air Lock

PPM Parts Per Million.

RH Relative Humidity

RODAC plates Replicate Organism Detection And

Counting Plates.

SSI Surgical Site Infection

Abbreviation Meaning

STA air sampler Slit To Agar air sampler.

SIP Sterilize In Place

TPN Total Parenteral Nutrition.

TSB Trypticase Soy Broth

TSA Tryptic Soy Agar medium

US dollars United States dollars

WFI Water For Injection

List of Tables

No. 1.	ECGMP annex 1 recommended microbial levels	Page 71
2.	USP 28 guidelines	72
3.	FDA Guidance for Industry.(2004) recommendation for microbial levels of cleanroom	73
4.	Comparison between class 100 and class 10.000 costs	92
5.	XYZ cleanroom costs	94
6.	Description of passive air monitoring in facility X	136
7. 8.	Description of surface monitoring in facility X Fumigation validation results using settling plates with TSA medium	140 151
9.	Results of fumigation validation of the settling plates in the filling area class A	152
10.	Fumigation validation settling plates of the filling area in class B	153
11.	Fumigation Validation of the settling plates in the formulation area class A	153
12.	Fumigation validation settling plates in the formulation area class B	155