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
(Microbiology & Immunology)

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 charge)

Date: / / 2008

Acknowledgement

Thanks to ***Allah most gracious, most merciful*** to whom I attribute any success in my life.

My profound gratitude and appreciation to ***Prof.Dr.Abdel Gawad Hashem;*** professor and Head of Microbiology and Immunology Department, Faculty of Pharmacy, Cairo University, for his generous assistance, encouragement and time spent supervising this work.

My deepest gratitude and thanks to ***Prof.Hesham Hassan Radwan;*** Professor and Head of Microbiology and Immunology Department, Faculty of Pharmacy, Helwan University.

I am sincerely thankful to ***Dr.Amal Emad El-Deen;*** Lecturer of Microbiology and Immunology, Department of Microbiology and Immunology Faculty of Pharmacy, Cairo University, who devoted great efforts and lots of her time and interest in supervising this work.

My great thanks to my mother and father for their help and support.

Table of contents

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