

„Basic Principles of GMP“

Tübingen 01st July 2019

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Contract Production and Analysis
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**„Good Manufacturing Practice for
Medicinal Products“**

or

**Rules governing human and
veterinary medicinal Products in the
European Union**

Legal Basis

- ☐ **Commision directive 2001/83/EC Article 47 ...medicinal products for human use...**
- ☐ **Commision directive 2001/82/EC Article 51 ...veterinary medicinal products...**
- ☐ **Commision directive 2003/94/EC ...medicinal.and investigational medicines for human use...**
- ☐ **Commision directive 91/412/EEC ...medicines for veterinary use...**
- ☐ **Commision directive 91/356/EEG ...basis for good manufacturing practice ...**
- ☐ **Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz, AMG)**
- ☐ **Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV)**
- ☐ **Apothekenbetriebsordnung (ApBetrO)**
- ☐ **BAK- and BÄK- Guidelines**
- ☐ **EU- GMP- Guidelines**
- ☐ **European Pharmacopoeiae (Ph. Eur.)**
- ☐ **PIC/S Recommendations (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme)**
- ☐ **ICH Recommendations (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for human use)**
- ☐ **DIN – German Standards / VDI- Engineering Guidelines (eg. DIN EN ISO 14644 / VDI 2083)**

EU- GMP- Guidelines (1)



Overview

**PART I – Basic Requirements for Medicinal Products
(For Human and Veterinary Use)**

**PART II – Basic Requirements for active Substances used as Starting Material
(API- Active Pharmaceutical Ingredient)**

PART III – GMP related Documents

- Explanatory Notes on the Preparation of a Site Master File
- Quality Risk Management System (ICH Q9)
- Pharmaceutical Quality System (ICH Q10)
- International harmonised Requirements for Batch Certification
- Template for the written Confirmation for Active Substances exported to EU
- Importation of Active Substances for Medicinal Products for Human Use

EU- GMP- Guidelines (2)



Part I: Basic Requirements for Medicinal Products

- ☐ Chapter 1 Pharmaceutical Quality System
- ☐ Chapter 2 Personnel
- ☐ Chapter 3 Premise and Equipment
- ☐ Chapter 4 Documentation
- ☐ Chapter 5 Production
- ☐ Chapter 6 Quality Control
- ☐ Chapter 7 Outsourced activities
- ☐ Chapter 8 Complaints and Product Recall
- ☐ Chapter 9 Self Inspection

EU- GMP-Guidelines (3)



Annexes

- Annex 1 Manufacture of Sterile Medicinal Products**
- Annex 2 Manufacture of Biological active substances and Medicinal Products for Human Use**
- Annex 3 Manufacture of Radiopharmaceuticals**
- Annex 4 Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products**
- Annex 5 Manufacture of Immunological Veterinary Medicinal Products**
- Annex 6 Manufacture of Medicinal Gases**
- Annex 7 Manufacture of Herbal Medicinal Products**
- Annex 8 Sampling of Starting and Packaging Materials**
- Annex 9 Manufacture of Liquids, Creams and Ointments**

EU-GMP- Guidelines (4)

Annexes

Annex 10 Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation

Annex 11 Computerised Systems

Annex 12 Use of Ionising Radiation in the Manufacture of Medicinal Products

Annex 13 Investigational Medicinal Products

Annex 14 Manufacture of Medicinal Products derived from Human Blood or Plasma

Annex 15 Qualification and validation

Annex 16 Certification by a Qualified person and Batch Release

Annex 17 Parametric Release

**Annex 18 Good manufacturing practice for active pharmaceutical ingredients
(covered under part II of EU-GMP-guidelines)**

Annex 19 Reference and Retention Samples

EU-GMP- Guidelines (5)



Part II

Part II Basic Requirements for Active Substances used as Starting Materials

API – Active pharmaceutical Ingredient

Chapter 1	Introduction	Chapter 14	Rejection and Reuse of Materials
Chapter 2	Quality Management	Chapter 15	Complaints and Recalls
Chapter 3	Personnel	Chapter 16	Contract Manufacturers (including Laboratories)
Chapter 4	Buildings and Facilities	Chapter 17	Agents, Brokers, Traders, Distributors, Repackers, and Relabellers
Chapter 5	Process Equipment	Chapter 18	Specific Guidance for APIs Manufactured by Cell Culture/Fermentation
Chapter 6	Documentation and Records	Chapter 19	APIs for Use in Clinical Trials
Chapter 7	Materials Management	Chapter 20	Glossary
Chapter 8	Production and In-Process Controls		
Chapter 9	Packaging and Identification Labelling of APIs and Intermediates		
Chapter 10	Storage and Distribution		
Chapter 11	Laboratory Controls		
Chapter 12	Validation		
Chapter 13	Change Control		

EU-GMP- Guidelines (6)



Part III

GMP- related documents (best praxis)

- ☐ **Explanatory Notes on the Preparation of a Site Master File**
- ☐ **Quality Risk Management System (ICH Q9)**
- ☐ **Pharmaceutical Quality System (ICH Q10)**
- ☐ **International harmonised requirements for Batch Certification**
- ☐ **Template for the “written confirmation” for active substances exported to the European Union for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC**
- ☐ **Importation of Active Substances for Medicinal Products for Human Use Questions and Answers**
- ☐ **Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared**
- ☐ **Guideline on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use**

Who needs GMP?



Pharmaceutical Companies which are:

- ☐ **Holder of a Manufacturing Authorization**
- ☐ **Medical Centers etc:**
 - ☐ **Stem cell units**
 - ☐ **Blood Transfusion Centers**
 - ☐ **Nuclear Pharmaceutical Institutes**
- ☐ **Outsourced Activities of Pharmaceutical Companies**
 - ☐ **Production of Active Pharmaceutical Ingredients**
 - ☐ **Production of Medicinal Products**
 - ☐ **Analytical Laboratories**
- ☐ **Medicinal Device Manufacturers
(close to GMP)**

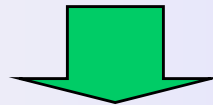
Why do we need GMP?



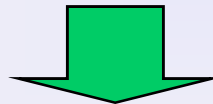
- ☐ **Legal basis: laws, regulations, guidelines, recommendations**
- ☐ **Requirement of a quality Management System**
- ☐ **Requirement for pharmaceutical manufacturing authorization**
- ☐ **Each Deviation during Manufacture can harm patients**

Quality relationships

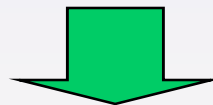
Quality Management



Quality Assurance



GMP



Quality Control

Pharmaceutical Quality System



Basic Requirements for Quality Control (1)

Resources:

- ☐ Adequate facilities
- ☐ Trained personnel
- ☐ Approved procedures (SOPs)

Basic Requirements for Quality Control (2)

Objects

- ☐ **Starting materials**
- ☐ **Packaging materials**
- ☐ **Intermediates**
- ☐ **Bulk products**
- ☐ **Finished products**
- ☐ **Control of Environmental conditions**

Basic Requirements for Quality Control (3)

1. **Sampling approved by QC department**
2. **Validated test methods**
3. **Records**
4. **Review and evaluation of production documentation**
5. **Failure investigations for all deviations**
6. **Ingredients comply with the marketing authorization**

Pharmaceutical Quality System



Basic Requirements for Quality Control (4)

- 7. Ingredients are of the required purity**
- 8. Proper containers**
- 9. Correct labelling**
- 10. Release of batches by the authorized person (QP)**
- 11. Retained samples of starting materials and products**
- 12. Controlled storage of medicinal products**

Other Duties of the Quality Control Department (5)

1. Establish QC procedures (SOPs)
2. Reference standards
3. Correct labelling
4. Stability testing
5. Complaint investigations
6. Environmental monitoring

Validation

Definition

- ☐ **Validation is the documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected result**

- ☐ **Types of Validation**
 - ☐ ***Prospective validation***
 - ☐ ***Concurrent validation***
 - ☐ ***Revalidation***
(Periodic revalidation)
(Revalidation after change)

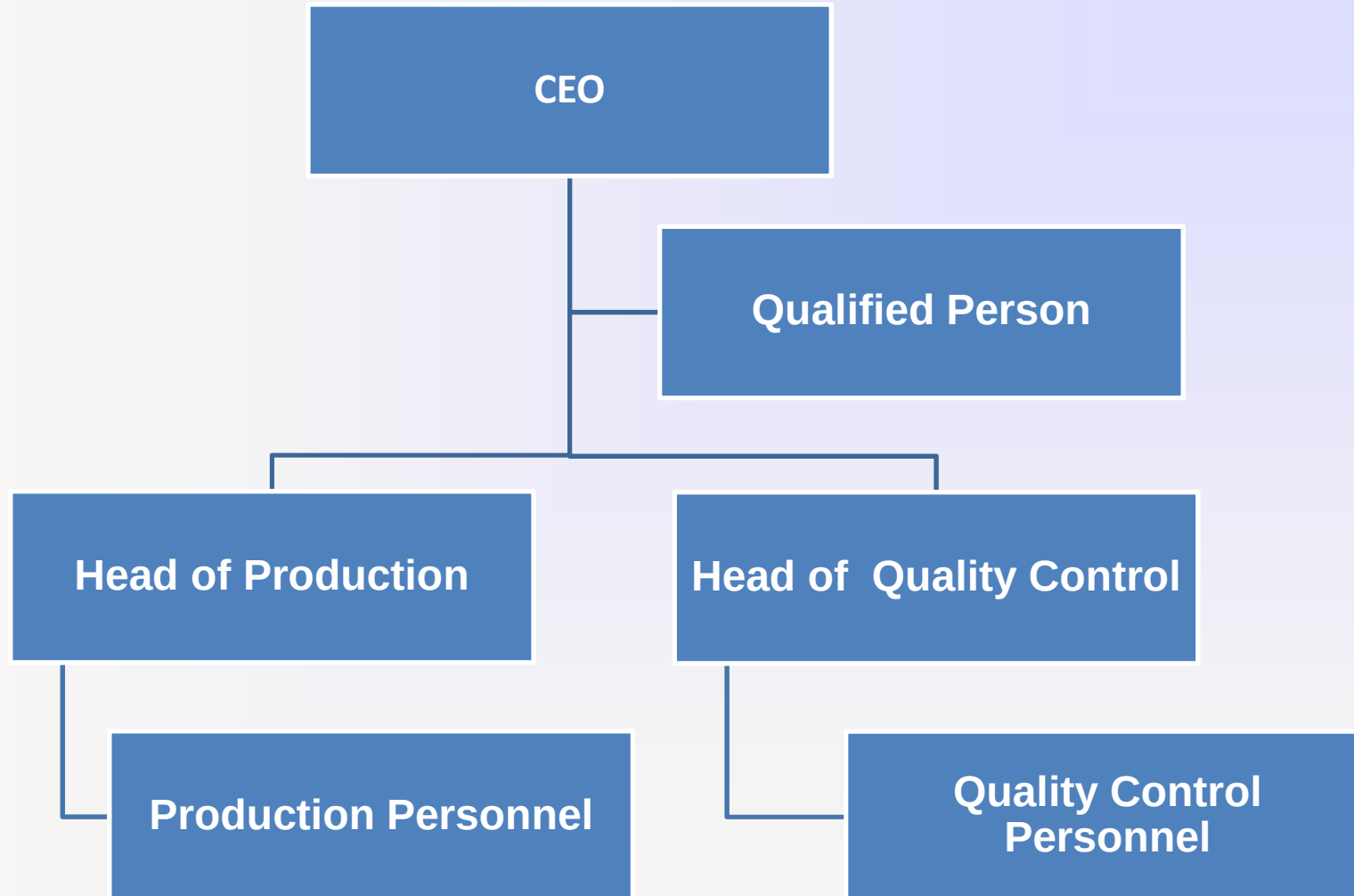
Quality Control



Stages of Validation

- ☐ **Design qualification (DQ)**
- ☐ **Installation qualification (IQ)**
- ☐ **Operational qualification (OQ)**
- ☐ **Performance qualification (PQ)**

Organigram



Personnel



Key Personnel (1)

Key personnel (which normally should be full-time) positions include:

- ☐ **Qualified Person**
- ☐ **Head of Production**
- ☐ **Head of Quality Control**
(Head of Production and Head of Quality
Head Control should be independent of each other)
- ☐ **Head of Sales and Distribution**

Personnel



Qualified Person Responsibilities (2)

- ☐ **Support writing Master Documents**
- ☐ **Control of batch records. Deviations?**
- ☐ **Evaluation of Analytical data. Do results match Specifications? Deviations? OOS? (Out of Specification)**
- ☐ **Ensure that all results are valid**
- ☐ **Control of Environment monitoring data during production. Deviations? OOS?**
- ☐ **Sign Certificate of Analysis (CoA)**
- ☐ **Final Release of finished medicinal products for sale**

Personnel

Head of Production Responsibilities (3)

- ☐ **Product production and storage according to appropriate documentation**
- ☐ **Evaluate production records; signed by designated person before passing to QC**
- ☐ **Maintenance of production department, premises and equipment**
- ☐ **Process validation and calibration performed, recorded and reports made available**
- ☐ **Training of production personnel; initial and continuing**

Personnel



Head of Quality Control Responsibilities (4)

- ☐ **Carrying out of necessary testing**
- ☐ **Evaluation of batch records**
- ☐ **Approval or rejection of materials, packing materials, intermediates, bulk and finished products**
- ☐ **Maintenance of quality department, premises and equipment**
- ☐ **Validation, including analytical procedure validation, and calibration of control equipment**
- ☐ **Initial and continuous training of QC personnel**

Technical Personnel



General (1)

- ☐ Adequate number of qualified people with practical experience
- ☐ An individual's responsibilities should not be so extensive as to present a risk to quality
- ☐ Individual written job description
- ☐ Organization Chart
- ☐ No gaps or unexplained overlaps
- ☐ Adequate authority to carry out responsibilities (supervisor)

Technical Personnel



General (2)

- ☐ **Individuals must receive training in GMP:**
 - ☐ **initial training**
 - ☐ **continuing training**
(including hygiene standards)

- ☐ **Motivated to**
 - ☐ **maintain high-quality standards**
 - ☐ **support the establishment**
 - ☐ **be compliant**

Premises (1)

Design Principles

- ☐ **Air circulation**
- ☐ **Material flow**
- ☐ **People flow**
- ☐ **Process flow**

Premises (2)

Principle

Premises must be located, designed, constructed, adapted and maintained for the operations:

- ☐ **Minimize risks of errors and cross-contamination**
- ☐ **Permit effective cleaning**
- ☐ **Permit effective maintenance**
- ☐ **Minimize build-up of dirt and dust**
- ☐ **Eliminate any adverse effects on quality**
- ☐ **Services availability**
- ☐ **Protection against entry of insects or other animals**

Premises (3)

Finish of Floors, Walls and Ceilings



- ☐ Windows should not open to the outside

Premises (4)

Finish of Floors, Walls and Ceilings



Not this



- Difficult but not impossible to get right, smooth, impervious, hard-wearing, easy to clean; but not bricks, tiles, wood or sliding doors!

Premises (5)

Finish of Floors, Walls and Ceilings



Much better



Premises (6)

Warehouse:

- ☐ **Clean, dry controlled and maintained within acceptable temperature limits**
- ☐ **Areas clearly marked and access limited for quarantine status good**
- ☐ **Separated area for released medicinal products**
- ☐ **Separated areas for rejected, recalled and returned materials**

Premises (7)

Weighing areas

- ☐ **Separated area**
- ☐ **Control systems**
- ☐ **Environmental controls, dust control**
- ☐ **Smooth, impervious, durable, easy to clean finishes**
- ☐ **Documentation**

Sanitation and Hygiene (1)



Scope

All aspects of manufacturing:

- ☐ **Personnel**
- ☐ **Premises**
- ☐ **Equipment**
- ☐ **Apparatus**
- ☐ **Production materials and container**
- ☐ **Products for cleaning and disinfection**
- ☐ **All potential sources of cross-contamination**

Sanitation and Hygiene (2)



Design of Premises

- ☐ **Design**
 - ☐ *Walls, floors, ceilings, ledges, drains, air supply, dust extraction*
- ☐ **Prevention of build-up of dirt and dust to avoid unnecessary risks of contamination**
 - ☐ *Cleaning programme, appropriate cleaning, cleaning records*
- ☐ **Effective cleaning and disinfection**
 - ☐ *choice of materials and chemicals, validation*
- ☐ **Drains**
- ☐ **Protection from insects, vermin and weather**
 - ☐ *from receipt of raw materials to despatch of released product*

Sanitation and Hygiene (3)



Avoidance of Cross-Contamination

- ☐ Segregated areas and/or separate facilities for campaign production
- ☐ Ventilation systems and airlocks
(incoming air filtered/pressure differentials/air extraction etc.)
- ☐ Clothing
(Protection of operator and product)
- ☐ Closed processing systems
(water processing system, clean in place (CIP))
- ☐ Cleaning and decontamination
(remove soil, dirt, cleaning chemicals, disinfected residues, microorganism etc.)

Sanitation and Hygiene (4)



Personnel Hygiene

- ☐ **Health examinations**
 - ☐ **On recruitment for direct operators , repeated on regular basis**
- ☐ **Training - check**
 - ☐ **induction training for new operators includes basic personal hygiene training**
 - ☐ **written procedures - to wash and disinfect hands before entering a manufacturing area**
 - ☐ **signs in changing rooms to reinforce hand washing**

Sanitation and Hygiene (5)



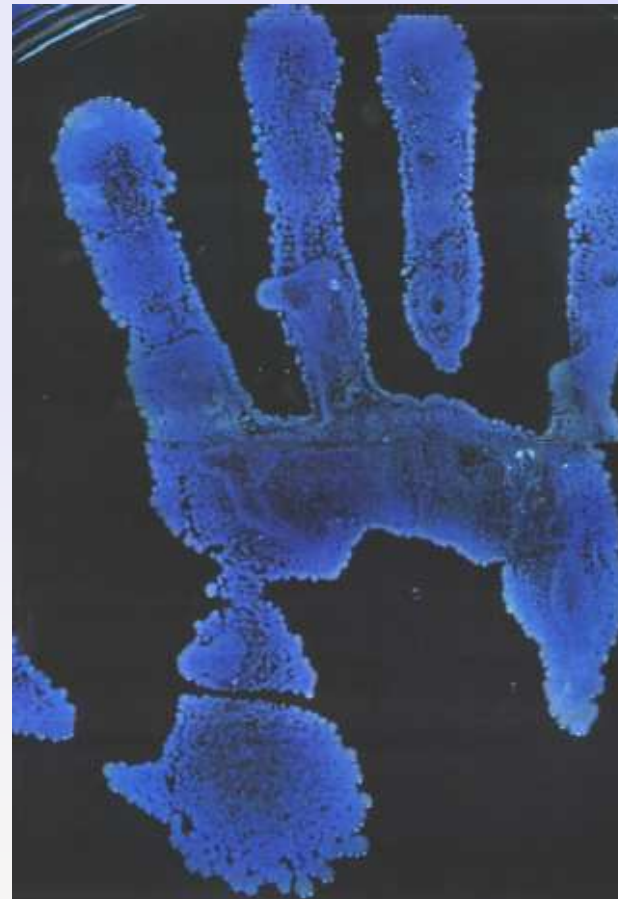
Personnel Hygiene

- ☐ **Smoking, eating and drinking should not be allowed in any manufacturing area, including laboratories and storage rooms.**
- ☐ **Chewing of gum should be banned.**
- ☐ **There should be no plants kept inside any factory areas.**
- ☐ **Rest and refreshment areas should be separate from manufacturing areas.**
- ☐ **Toilets should not open directly into production or storage areas.**

Sanitation und Hygiene (6)

Source of Contaminations

- ☐ *Micrococcus*
- ☐ *Staphylococcus*
- ☐ *Streptococcus*
- ☐ *Bacillus subtilis*
- ☐ *Escherichia coli*



Equipment

Principle

- ☐ **Equipment layout and design must aim:**
 - ☐ to minimize risks of error
 - ☐ to permit effective cleaning
 - ☐ to permit effective maintenance
- ☐ **And to avoid:**
 - ☐ cross-contamination
 - ☐ dust and dirt build-up
 - ☐ any adverse effect on the quality of products
- ☐ **Equipment must be installed to:**
 - ☐ minimize risks of error
 - ☐ minimize risks of contamination
- ☐ **Defective equipment**
 - ☐ removed
 - ☐ labelled

Materials (1)

General requirements for materials

- ☐ **Consignment with supplies**
- ☐ **All incoming materials and finished products:**
 - ☐ **quarantined after receipt,**
 - **until released for use**
 - **distribution**
- ☐ **stored**
 - ☐ **under appropriate conditions**
 - ☐ **orderly fashion (batch segregation)**
 - ☐ **materials management**
 - ☐ **stock rotation (FIFO)**
- ☐ **Starting material label**
- ☐ **Control primary, printed and packing materials**
- ☐ **Storage and transport:**
 - ☐ **Avoid mixed ups**

Materials (2)



Examples of Labelling of Starting Materials

Name of Material and/or internal code			
Control/ Batch No.			
Status	Quarantined/Released/Rejected (Colors may be used)		
Expiry date or retest date			
Date		Signature	

Sterile Production (1)



Types of sterile products

- ☐ **Terminally sterilized**
 - ☐ **prepared, filled and sterilised by autoklav**
- ☐ **Sterilised by filtration**
- ☐ **Aseptic preparation**

Sterile Production (2)

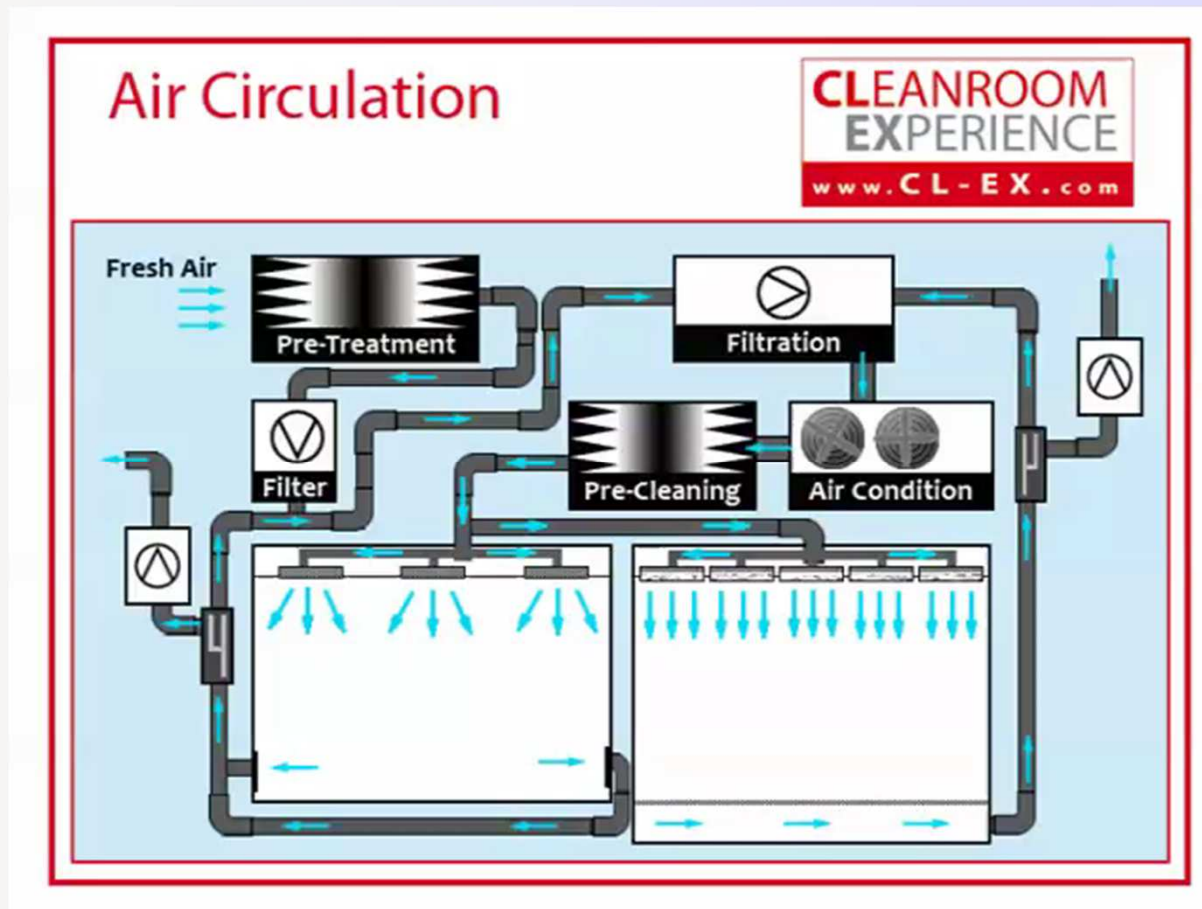


General Requirements

- ☐ **Production in clean areas**
- ☐ **Separate Airlocks for entry of**
 - ☐ *personnel*
 - ☐ *goods*
- ☐ **Separate areas for operations**
 - ☐ *component preparation*
 - ☐ *weighting*
 - ☐ *product preparation*
 - ☐ *filling*
- ☐ **Level of cleanliness (D,C,B,A)**
- ☐ **Filtered air**

Sterile Production (3)

Air Circulation



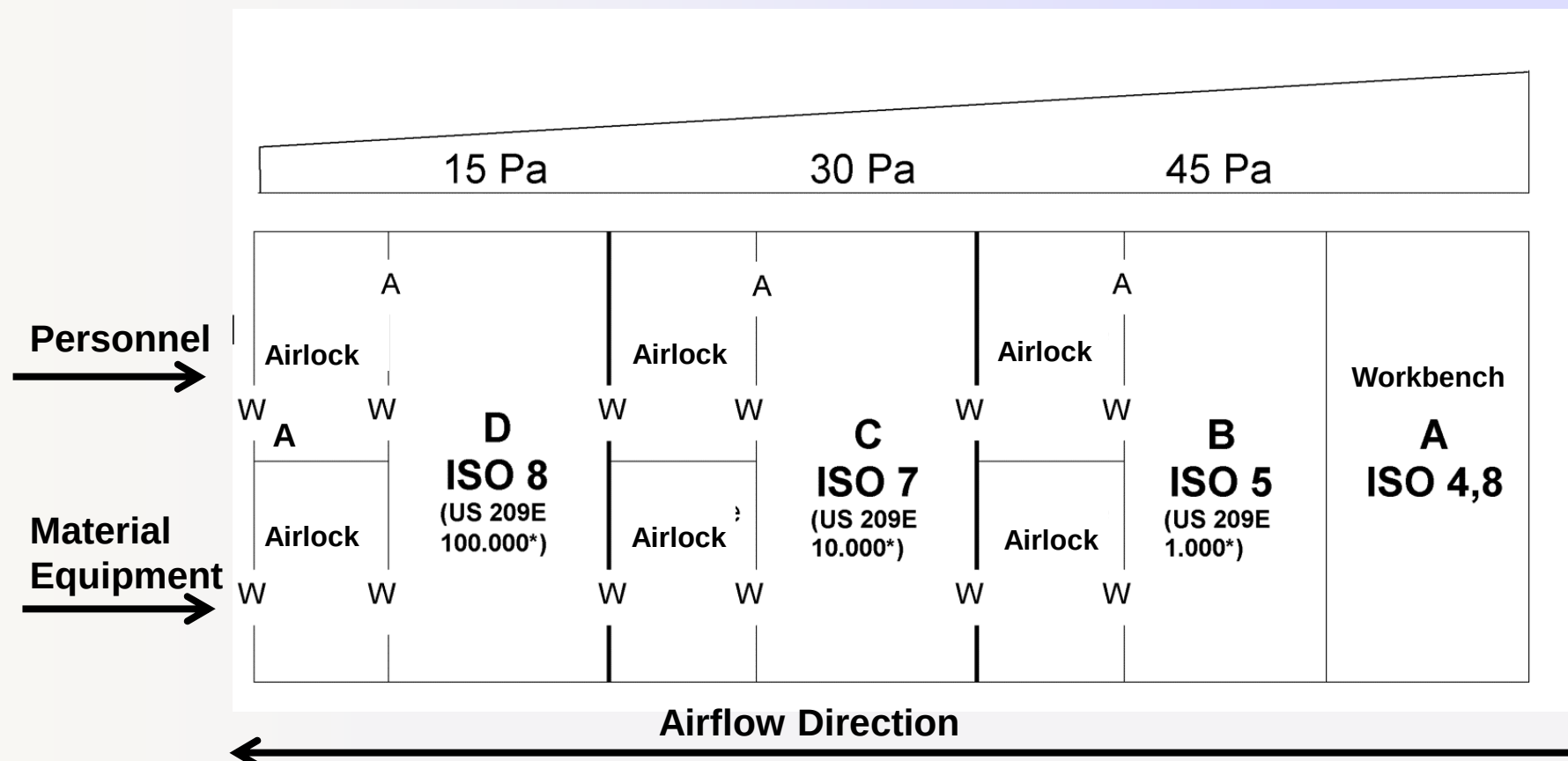
Sterile Production (4)



General Requirements

- ☐ **Air classification: Grade A, B, C and D,
Grade E for storage of consumable
supplies**
- ☐ **Laminar air flow:**
 - ☐ *air speed (horizontal versus vertical flow)*
 - ☐ *number of air changes*
 - ☐ *air samples*
- ☐ **Clean bench or isolator or barrier technology (Grade A)**

Cleanroom scheme



W - door openstop

A - alarmsystem

US 209E - 11/2001 withdrawn

Pa – difference pressure

Cleanroom layout



CC – Cleanroom Class

Sterile Production (5)

Air Classification System

	Maximum permitted number of particles per m ³ equal to or greater than the tabulated size			
	At rest		In Operation	
Grade	0.5 µm	5.0 µm	0.5 µm	5.0 µm
A	3 520	20	3 520	20
B	3 520	29	352 000	2 900
C	352 000	2 900	3 520 000	29 000
D	3 520 000	29 000	Not defined	Not defined

Sterile Production (6)

EU-GMP-Guidelines Annex 1

Recommended limits for microbiological monitoring of clean areas during operation:

	Recommended limits for microbial contamination			
Grade	air sample cfu /m ³	settle plates (diameter 90 mm) cfu /4 hours	contact plates (diameter 55 mm) cfu /plate	glove print 5 fingers cfu /glove
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

cfu – colony forming unit

Sterile Production (7)



Personnel clothing

- ☐ **Appropriate to air grade**
 - ☐ **Grade D**
 - *hair, beard and shoes*
 - ☐ **Grade C**
 - *hair and beard*
 - *suit covering wrists, neck*
 - *no fibres*
 - ☐ **Grade B**
 - *sterile masks, gloves*
 - *sterile clothing*
 - *sterile shoes*

Sterile Production (8)



Environmental Monitoring

Microbiological

- ☐ Air
- ☐ Surfaces
- ☐ Personnel

Sterile Production (9)



Environmental Monitoring (2)

Physical:

- ☐ **Particulates**
- ☐ **Differential pressures**
- ☐ **Filter integrity**
- ☐ **Air changes**
- ☐ **Temperature/humidity**

Contract Production and Analysis



Principle

Contract production and analysis must:

- ☐ **Be correctly defined, agreed, controlled in order to avoid misunderstandings that could result in inferior product**
- ☐ **Have a written contract clearly establishing each parties' duties**
- ☐ **Clearly state how the authorized person when exercising his or her full responsibility releases each batch or issues certificate of analysis**
- ☐ **Should allow audit of contract acceptor**

Complaints and Recalls (1)



Reasons for Recall

- ☐ **Customer complaint**
- ☐ **Detection of GMP failure after release**
- ☐ **Result from the ongoing stability testing**
- ☐ **Request by the national authorities**
- ☐ **Known counterfeiting or tampering**
- ☐ **Adverse reaction reporting**
- ☐ **Result of an inspection**

Complaints Handling Principle

All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures

- ☐ **Handled positively and carefully reviewed**
- ☐ **Must be seen as important work**
- ☐ **Managed by a senior staff member**
- ☐ **Thorough investigation of the cause is essential**
- ☐ **A major source of information and learning**
- ☐ **Enable possible production defects to be remedied before they lead to a recall**
- ☐ **Necessary actions taken -- even a recall decision --**

Classification of Defects

- ☐ If complaint is justified, then there has been a failure of the quality system
- ☐ Once defect has been identified, company should be dealing with it in an appropriate way, even recall.
- ☐ The following system has been found in some:
 - ☐ *Critical defects*
 - ☐ *Major defects*
 - ☐ *Other defects*

Critical Defects

- ☐ Those defects which can be life threatening and require the company to take immediate action by all reasonable means, whether in or out of business hours

Examples

- ☐ Product labelled with incorrect name or incorrect strength
- ☐ Counterfeit or deliberately tampered-with product
- ☐ Microbiological contamination of a sterile product

Self-Inspection

Scope of Self-Inspection Programme

- ☐ **Written instructions (SOP)**
- ☐ **Inspection Team:**
 - ☐ *team leader*
 - ☐ *local staff who are familiar with the area*
 - ☐ *experts in their own field*
- ☐ **Covering all aspects of GMP:**
 - ☐ *personnel*
 - ☐ *premises including personnel facilities*
 - ☐ *maintenance of buildings and equipment*
 - ☐ *storage of starting materials and finished products*
 - ☐ *equipment*
 - ☐ *production and in-process controls*
 - ☐ *quality control*

Status quo of DIN EN ISO 14644

“Cleanrooms and associated controlled environments”



Doc.- No.	Title	Status
DIN EN ISO 14644-1	Classification of air cleanliness by particle concentration	Standard 06-2016
DIN EN ISO 14644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Standard 05-2016
DIN EN ISO 14644-3	Test methods	Standard 03-2006
DIN EN ISO 14644-4	Design, construction and start up	Standard 06-2003
DIN EN ISO 14644-5	Operations	Standard 03-2005
DIN EN ISO 14644-7	Separate devices (clean air hoods, gloveboxes, isolators and mini- environments)	Standard 01-2005
DIN EN ISO 14644-8	Classification of air cleanliness by chemical concentration (ACC)	Standard 06-2013
DIN EN ISO 14644-9	Classification of surface cleanliness by particle concentration	Standard 12-2012
DIN EN ISO 14644-10	Classification of surface cleanliness by chemical concentration	Standard 06-2013
DIN EN ISO 14644-14	Assessment of suitability for use of equipment by airborne particle concentration	Standard 01-2017

Abbreviations



OOS	- Out of Specification
CoA	- Certificate of Analysis
FIFO	- <u>F</u> irst <u>i</u> n <u>F</u> irst <u>o</u> ut
GMP	- Good manufacturing Practice for Medicinal products
DIN	- German Institute for Standardisation
ICH	- International Conference on Harmonisation
PIC/S	- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
API	- Active pharmaceutical ingredient
QC	- Quality Control
DQ	- Design Qualification
IQ	- Installation Qualification
OQ	- Operational Qualification
PQ	- Performance Qualification
CEO	- Chief Executive officer
QP	- Qualified Person
CIP	- <u>c</u> lean <u>i</u> n <u>p</u> lace
ISO	- International Organisation for standardisation
EN	- european organisation for standardisation

Source

- ☐ **eudraLex volume 4: “EU-GMP-Guideline”**
- ☐ **WHO Educational Training: “Basic principles of GMP”**
- ☐ **Cleanroom Academy: “Cleanroom Experience”**

**In god we
trust,
everybody else
has to give
proof !**



Questions?

**Headquarters and
Management:**

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