How GMP and ICH Safeguard the Medicines We Rely On

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Overview

1. What are Good Manufacturing Practices (GMP)?
2. How does GMP relate to International Council on Harmonization?
3. Hidden aspects of drug quality

Overall objective: Provide knowledge you will remember to make you more effective in life sciences interviews and related jobs

What are Good Manufacturing Practices?

- What is GMP?
  - Regulations, procedures, and guidelines that ensure products like medicines, foods, and cosmetics are consistently produced and controlled to high-quality standards
  - Covers all aspects of production, from starting materials and premises to equipment and staff training
    - Goal: minimize risks and guarantee the safety, purity, and effectiveness of the final product
    - Current FDA terminology: “Current Good Manufacturing Practices” cGMP
    - GMP knowledge is needed if you will go into manufacturing related jobs, including mine

  - Interviewing:
    - Know the GLP/GMP philosophy:
    - If it wasn’t written down, it ***never*** happened
    - Effective scientific approaches help ensure drugs are safe and effective

What are Good Manufacturing Practices?

- Detailed written procedures and systems to provide ***documented proof*** that correct procedures are consistently followed at each step in the manufacturing process
  - every time a product is made.

- Countless rabbit holes
  - Weighing an item

- Product Quality Complaints example
  - Must record
  - Can't dispute – no proof the patient ever purchased the drug, can't disagree
  - FDA inspectors

Drug Quality
Basic terminology

Drug Substance = Active Pharmaceutical Ingredient (API)

API = essential for interviews

Drug Product = Finished dosage form

Excipients: “any inactive ingredients that are added intentionally to therapeutic or diagnostic products, but they are not intended to exert therapeutic effects at the intended dosage, although they may act to improve product delivery” (FDA, 2019)

GMP – Drug Quality
International Council for Harmonization (ICH)

ICH Mission: Achieve greater harmonization in the development, registration and manufacturing of medicines worldwide

Brings together regulatory authorities and the pharmaceutical industry regarding scientific and technical aspects of drug registration

https://www.ich.org/

Interviews:

- Knowing of ICH & its mission is likely helpful.
- ICH provides specific guidance on countless GMP requirements
- Most drug regulatory agencies follow & accept ICH

GMP – ICH Linkage example
ICH Q10 Pharmaceutical Quality System

ICH Q10:

- “augments GMPs by describing specific quality system elements and management responsibilities.
- provides a harmonized model for a pharmaceutical quality system throughout the lifecycle of a product and is intended to be used together with regional GMP requirements.”

FDA ICH Q10 Pharmaceutical Quality Systems, April 2009

ICH Examples
How pure is pure?

ICH Q3A - IMPURITIES IN NEW **DRUG SUBSTANCES**
ICH Q3B - IMPURITIES IN NEW **DRUG PRODUCTS**
ICH Q3C - IMPURITIES: GUIDELINE FOR RESIDUAL SOLVENTS
ICH Q3D - GUIDELINE FOR ELEMENTAL IMPURITIES

ICH M7 - Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk

ICH Guidelines:

- Usually simple, logical & easy-to-read
- Single sentences matter
- Re-read for important issues

Drug Quality
ICH Q3A & B

ICH Q3A - IMPURITIES IN NEW **DRUG SUBSTANCES**

Just 11 pages

ICH Q3B - IMPURITIES IN NEW **DRUG PRODUCTS**

Just 12 pages

Addresses:

impurities in new drug products classified as degradation products of the drug substance or reaction products of the drug substance with an excipient and/or immediate container closure system

Shelf-life limit example – 90%

Drug Quality
ICH Q3A

What level of impurity/degradant is acceptable?
Logical & scientific

ATTACHMENT 1
Thresholds

Maximum Daily Dose[1]	Reporting Threshold[2,3]	Identification Threshold[3]	Qualification Threshold[3]
≤ 2g/day	0.05%	0.10% or 1.0 mg per day intake (whichever is lower)	0.15% or 1.0 mg per day intake (whichever is lower)
> 2g/day	0.03%	0.05%	0.05%

Qualification = Show no risk to patients

Drug Quality
ICH Q3A – Logical & Scientific

What level of impurity/degradant is acceptable? How do you qualify a degradant?

- "The level of any impurity present in a new drug substance that has been adequately tested in safety and/or clinical studies"
  - GMP
- "Impurities that are also significant metabolites present in animal and/or human studies are generally considered qualified"
  - Oxidation
- Do toxicology studies on the degradant
  - Overall ICH Q3A: Intelligent, logical, scientific…

Summary

- When interviewing with a life sciences company
  - Learn the key terms from this talk
  - Keep in mind the GLP/GMP philosophy:
    - If it wasn't written down, it didn't happen
    - Effective scientific approaches help ensure drugs are safe and effective
- Being aware of ICH and its linkage with GMPs is valuable for many roles in pharma